MNPD Crime Laboratory

Quality Manual

Metropolitan Government of Nashville & Davidson County
Police Department

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1 Scope and Services

This Quality Manual describes and specifies the general requirements of the quality assurance program used in the Metropolitan Nashville Police Department Crime Laboratory (MNPD-CL) to ensure competent, impartial, and consistent operations. It sets forth the established requirements to competently and effectively achieve the program objectives of the laboratory. The MNPD-CL is committed to conformance with recognized standards of good laboratory practice, good quality practice, and implementation of policies and procedures to ensure continued quality output.

The MNPD-CL carries out its testing and examination activities in accordance with ISO/IEC 17025:2017, accreditation requirements from the accrediting body, and applicable FBI Quality Assurance Standards for DNA Testing Laboratories.

The MNPD-CL's management system, represented by the Quality Manual(s) and associated supporting documents (Technical Procedures Manuals, Technical Training Manuals, and associated addendums), provide a mechanism for identifying and implementing the practices that support high quality forensic examinations, and govern the operation of the MNPD-CL and the services provided.

This document is applicable to all Units within the MNPD-CL performing laboratory activities. In this document, notes are intended to provide clarification or examples of conformance and do not constitute additional requirements.

Where Unit Technical Procedure Manuals, Technical Training Manuals, associated addendums, or Quality Manuals do not specify, the policies and procedures set forth in this Quality Manual will be adhered to. Unit policies, procedures, and associated addendums may not be less stringent than those set forth in this Quality Manual.

MNPD-CL customers, regulatory authorities, organizations, and schemes using peer-assessment (such as internal audits), accreditation bodies, and others may use this document in confirming or recognizing the competence of the MNPD-CL.

1.1 Mission Statement

Provide reliable, accurate and unbiased forensic science laboratory services to the MNPD and associated criminal justice system customers in the Metropolitan Nashville area.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

1. ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)
2. ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM)1)
3. ISO/IEC 17000, Conformity assessment — Vocabulary and general principles
4. ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories (Geneva, Switzerland: ISO)

5. ISO/IEC 17034-General requirements for the competence and consistent operation of reference material producers
6. ISO /IEC 17043, Conformity assessment-General requirements for the competence of proficiency testing providers
7. Tennessee Code Annotated - www.lexisnexis.com/hottopics/tncode/layout.html
8. U.S. Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Quality Assurance Standards for Forensic DNA Testing Laboratories, most recent version.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

Table 1: Terms and definitions

Ref. #	Term	Definition
3.1.	(A)	Denotes an AR 3125 requirement
3.2.	(I)	Denotes an ISO requirement
3.3.	Accreditation cycle	The period of time between the date that accreditation is granted, and the date accreditation expires.
3.4.	Analysis/examination/test	Equivalent to a test as described in ISO/IEC 17025:2017. The procedure utilized by MNPD-CL technical personnel to obtain information from evidence in order to reach conclusions concerning the nature of and/or associations related to evidence received by the MNPD-CL.
3.5.	Analyst/Examiner /Forensic Scientist (however named)	An individual who is authorized to conduct and/or direct the analysis of forensic casework samples, interprets data, forms conclusions, issues test reports concerning conclusions, and testifies in court as to the results of the examinations performed. An analyst has successfully completed a documented training program to include a competency test.
3.6.	Annual	Once per calendar year with an acceptable variance of +/- 6 months.
3.7.	Association	A determination that a relationship exists between individuals and/or objects.
3.8.	Audit	Process for obtaining relevant information about the management system and evaluating it objectively to determine the extent to which specified requirements are fulfilled (ISO/IEC 17000:2020, modified)

Ref. #	Term	Definition
3.9.	Auditor	A person who conducts audits. In the MNPD-CL, all auditors must successfully complete Internal Auditor Training, Assessor Training, an MNPD-CL internal training course, or a training course related to the FBI Quality Assurance Standards, if applicable.
3.10.	Authorization	Process by which personnel and/or procedures are approved for the work (technical) of the MNPD-CL by suitably qualified personnel.
3.11.	Blank (instrument blank)	A volume of clean solvent that is analyzed on an instrument to ensure that the instrument is working properly and/or there are no contamination issues associated with the instrument.
3.12.	Blank (method blank)	An analytical control consisting of all reagents and solvents that is carried through the entire analytical procedure. The method blank is used to define the level of laboratory background contamination.
3.13.	Calibration	The adjusting or standardization of any instrument or equipment to ensure agreement with a reference standard, reference material or working standard of known value. It is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.
3.14.	Calibration check (performance check)	A check of calibration using known reference standards or materials (controls). This can be necessary when evaluating a procedure, after instrument shutdowns, following instrument maintenance, or any other situations determined to be necessary for good laboratory practices. A calibration check may also be called a performance check where applicable.
3.15.	Calibration laboratory	An external ISO compliant laboratory whose primary focus involves checking and recertifying the calibration of equipment and/or instruments. Their measurement standards and measuring instruments are traceable to the International System of Units (SI) (Example: Company or laboratory that recertifies the calibration of pipettes or balances).
3.16.	Can	Indicates a possibility or capability
3.17.	Case Identification Number (Lab number)	A unique alphanumeric identifier that is assigned to a MNPD-CL investigation for tracking purposes.
3.18.	Case records/case file	Administrative records, examination records, and any other applicable technical records (such as notes, notes on evidence/known standards in latent prints, reports, charts, analytical data, and correspondence whether electronic or hardcopy), generated or received by the MNPD-CL pertaining to testing

Ref. #	Term	Definition
		performed on a particular case. Case files may be electronic, hardcopy, or both.
3.19.	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 17034: 2016, modified). Note: The concept of value includes a nominal property of a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.
3.20.	Comparative examination	Physical and/or chemical testing performed on two or more items for the purpose of determining whether or not an association between the items exist (for example: the comparative microscopic examination of two bullets to determine if both bullets could have been fired through the barrel of the same firearm).
3.21.	Competence	Possessing the requisite knowledge, skills, and abilities to carry out a task correctly.
3.22.	Competency test	The evaluation of a person's knowledge, skills, and/or ability to perform a task.
3.23.	Complaint	Expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.
3.24.	Computer system	A working computer including all software and peripheral devices required to complete work.
3.25.	Condition adverse to quality	An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformity issues that affect the quality of a test.
3.26.	Control	A test performed to demonstrate that a test method and/or instrument works correctly and to ensure that data are valid. Positive and negative controls confirm that the procedure will produce the expected/reliable result.
3.27.	Controlled substance	A chemical compound listed in the Tennessee Drug Control Act of 1989 (TCA Title 39, Section 17, Part 4).
3.28.	Convenience seal/temporary seal	A seal used for internal MNPD-CL purposes only. This allows for ease in transferring evidence to ERU for corrections and to prevent loss of the item(s) while in the process of testing, while maintaining the integrity of the

Ref. #	Term	Definition
		evidence (e.g., a staple, a lid applied, tape). This type of seal does not require initials and may not be used for long term storage.
3.29.	Correction	Any action that is taken to amend the nonconformity. Corrections do not address root causes and do not eliminate the nonconformity.
3.30.	Corrective Action Report (CAR)	Document of a nonconformity which, at a minimum, includes root cause analysis, corrective action implementation, and monitoring of effectiveness.
3.31.	Crime laboratory/forensic laboratory	A laboratory (with at least one full-time scientist) which examines physical evidence in criminal matters, issues test reports, and provides opinion/interpretation testimony with respect to such physical evidence in a court of law.
3.32.	Crime scene	An area, object, or person, from which evidence may be identified, documented, collected, and preserved.
3.33.	Critical consumables, supplies and services	A consumable, supply, or service which must meet one or more crucial specifications to ensure the quality of the test result. In this context, "crucial" means significant or important.
3.34.	Critical finding	A decision about an association between items based on observable class and individual characteristics of the items.
3.35.	Custody	The care and control of an item implying responsibility for its protection and preservation.
3.36.	Customer	A person or organization that could or does receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external. The customer (or individual concerned) is considered to be members of the criminal justice community in the Metropolitan Government of Nashville and Davidson County (Metro) area. This may include • MNPD Officers, • personnel from the Medical Examiner's Office, • partner agencies such as FBI, TBI, and ATF, and • Court Officials who request MNPD-CL (supplier) testing services or receive reports or testimony about the service. As it applies to the MNPD-CL, the requirements of this document are written and implemented to address customers who

Ref. #	Term	Definition
		a) most commonly use MNPD-CL services, b) directly request services, and/or c) directly receive services (MNPD and District Attorney Office).
3.37.	Decision rule	Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement
3.38.	Deviation	The authorized variance from a documented policy, practice, or procedure.
3.39.	Director	The highest-ranking manager.
3.40.	Discipline	A major area of activity in forensic science.
3.41.	Document	Information in any medium including, but not limited to, paper copy, computer disk or tape, audio or video tape, electronic file, compact or digital video disc, photograph, overhead, or photographic slide that provides information or evidence or that serves as an official record.
3.42.	Document (controlled)	A document that is issued and distributed in a traceable manner and is required to undergo an approval process prior to distribution.
3.43.	Document control	The process of ensuring that controlled documents describing quality affecting activities or specifying quality requirements are reviewed for adequacy, approved for release by authorized personnel, and distributed for use to the personnel performing the applicable activities.
3.44.	Drug evidence	Illegal substances, drug paraphernalia, prescription, and non-prescription drugs.
3.45.	Environmental conditions	Any characteristic that could reasonably be expected to adversely impact the quality of the MNPD-CL's work (for example, lighting, heating, air conditioning, ventilation, plumbing, wiring, adequacy of exhaust hoods/bio-safety cabinets, etc.).
3.46.	ERU	Evidence Receiving Unit
3.47.	ESD	Evidence Storage Division
3.48.	Evidence	Equivalent to "item" as described in ISO/IEC 17025:2017, regardless of form, which is received by a the MNPD-CL for the purpose of testing using one or more test methods.
3.49.	Good Laboratory Practices	Operating practices and procedures for promoting quality and ensuring integrity of the work product.
3.50.	Impartiality	Presence of objectivity

Ref. #	Term	Definition
		Note 1: Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the laboratory. Note 2: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.
3.51.	Individual characteristic database	A computerized, searchable collection of features, generated from samples of known origin from which individual characteristic information originates (e.g., DNA profiles, friction ridge data, or firearm bullet/cartridge case images).
3.52.	Instructions	Document that details how to perform a specific task.
3.53.	Interested party	Person or group having an interest in the performance or success of an organization.
3.54.	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. Proficiency tests are a subset of interlaboratory comparison.
3.55.	Intralaboratory comparison	Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions. Internal proficiency tests are a type of intralaboratory comparison.
3.56.	Item identifier (Item number)	A unique alphanumeric designator assigned to an item submitted to the MNPD-CL for tracking purposes.
3.57.	Laboratory	Body that performs one or more of the following activities: • testing; • calibration; • sampling, associated with subsequent testing or calibration Note 1: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.
3.58.	Laboratory Information	A software system used in the MNPD-CL for management of evidence, samples, instrument data collection, workflow record keeping and official reporting writing.

Ref. #	Term	Definition
	Management System (LIMS)	
3.59.	Limited access	Access limited to personnel authorized by the Laboratory Director.
3.60.	Management system	The organizational structure, responsibilities, manuals, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly. Quality, administrative, and technical systems that govern the operations of a laboratory.
3.61.	Management Team	This team includes the Forensic Services Division Director, Laboratory Director, Assistant Director, Quality Manager, IT Manager, Business Manager, and Unit Supervisors/TLs.
3.62.	Manager	A person with the responsibility for directing and controlling an organizational Unit or program.
3.63.	May	Indicates a permission
3.64.	Measurement uncertainty	A parameter associated with the result of measurement that characterizes the dispersion of values that could reasonably be attributed to the particular quantity subject to measurement.
3.65.	Method	The course of action or technique followed in conducting a specific analysis or comparison.
3.66.	National measurement standards	Primary or secondary standards, such as SI units or other fundamental standards calibrated by a metrology institute such as the National Institute of Standards and Technology (NIST).
3.67.	Nonconformity/ Nonconformance	A deviation from the MNPD-CL's policies/procedures. This includes the quality management system as a whole.
3.68.	Nonconforming work	Nonconforming work is when any aspect of testing, including reporting and interpretation, and quality assurance does not conform to the MNPD-CL's policies/procedures, good laboratory practice, or good quality practice; or in the case of proficiency testing, when the expected/scientifically reasonable result is not obtained.
3.69.	Noncritical supplies and services	Services and supplies used in the laboratory that do not affect the quality of analysis.
3.70.	Notes	The documentation of procedures, standards, controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and

Ref. #	Term	Definition
		other documents generated which are used to support the examiner's conclusions and to assist in reproduction of the testing process under as similar conditions as possible.
3.71.	Objective	A measurable, definable accomplishment which furthers the goals of the organization.
3.72.	Performance check	A verification that the equipment, instrument, or process is working as expected. Analysis of a control may be used as a performance check.
3.73.	Policy	A guiding principle, operating practice, or plan of action governing decisions made on behalf of an organization.
3.74.	Practicable	If the laboratory is able to meet the requirement, it shall meet the requirement.
3.75.	Practices	A term used to describe division level quality affecting processes that are used in the laboratory.
3.76.	Primary standard	A standard designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quality.
3.77.	Procedure	A term used to describe Unit level processes.
3.78.	Proficiency testing	Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
3.79.	Prolonged absence	Absence lasting longer than 180 days.
3.80.	Proper seal	A seal that prevents loss, cross transfer, or contamination while ensuring that attempted entry into the container is detectable. A proper seal may include a heat seal, tape seal, self-adhering seals, tamper proof evidence tape, or a lock. The initials or other identification of the person creating the seal shall be placed on the seal or across the seal onto the container when possible.
3.81.	Qualified	A term used to identify personnel who successfully complete a Unit's training program or have documented records of training and experience, pass a competency test, participate in the laboratory proficiency testing program, and is authorized to perform casework testing independently.
3.82.	Quality assurance	The planned or systematic actions necessary to provide sufficient confidence that the MNPD-CL's product or service will satisfy given requirements for quality.

Ref. #	Term	Definition
3.83.	Quality control	Internal activities conducted according to established standards used to monitor the quality of analytical data and work performed and to ensure it satisfies specified criteria.
3.84.	Quality System Notification	Documentation of nonconforming work, nonconforming work product, deviations from MNPD-CL policies/procedures, or incident(s)/event(s) adverse to good laboratory/quality practices.
3.85.	Quality Management Software (QMS)	Software system that houses quality system documentation (i.e., technical procedure manuals, training manuals, workflows, Quality Manual, etc.) The current QMS for the MNPD-CL is Ideagen Quality Management.
3.86.	Quality Manager	An individual designated by the Laboratory Director who has the defined authority and obligation to design and ensure that the quality requirements of the management system are implemented and maintained.
3.87.	Quality system	The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. The system includes all activities which contribute to quality, directly and indirectly. The term is equivalent to "management system."
3.88.	Reagent	A substance used because of its known chemical or biological activity.
3.89.	Records (administrative records)	"Housekeeping" related Records that do not constitute data or information resulting from testing, including but not limited to: service requests, subpoenas, testing related communications, test item (evidence) receipts, item tracking (chain of custody) records, description of evidence packaging and seals, and reports not generated by MNPD-CL.
3.90.	Records (quality records)	Documentation of the activities related to the quality program including (but not limited to) such items as audit reports, management reviews, corrective and preventive actions, risk assessments, Quality System Notifications, document reviews, deviation requests, testimony evaluations, records of training, continuing education, competency, proficiency, and other quality-oriented records.
3.91.	Records (technical records and examination records)	Records, generated or received, used by the forensic professional to reach a conclusion; that provide evidence of a condition, observation, work performed, quality control, results and/or activities conducted; and can include (but not limited to) issued reports, case notes, instrument printouts, and technical and administrative review forms.

Ref. #	Term	Definition
		Technical records can also be quality records that do not support the test results such as reagent records, equipment logs, calibration check records, or other technically oriented records.
3.92.	Reference collection	Data or materials of known origin or property, which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, drug samples, firearms, bullets, cartridges, DNA profiles, laboratory developed population databases).
3.93.	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 17034:2016). A material or substance having known properties. These materials may be used for the identification of unknown substances, calibration of instruments, assessments of a measurement method or assigning value to materials. They should, where possible, be traceable to SI units of measurement or to certified reference materials (e.g., mass spectra, drug samples, bullets, cartridges, DNA profiles, frequency databases).
3.94.	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).
3.95.	Reference standard	A measurement standard designated for the calibration/performance check of other measurement standards for quantities of a given kind in a given organization or at a given location (JCGM 200:2012). Note: Working measurement standard – measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems (JCGM 200:2012). They must be traceable to the International System of Units (SI). Reference standards are calibrated by a body that can provide traceability to the International System of Units (SI). Such reference standards of measurement held by the laboratory shall be used for measurement calibration/performance check only and for no other purpose unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment. Also see definition in the Forensic Biology Quality Manual.
3.96.	Request date	Date that request was created in LIMS.

Ref. #	Term	Definition
3.97.	Review (administrative)	Review of case records for consistency with MNPD-CL policy and for editorial correctness.
3.98.	Review (technical)	Review of technical records (notes, data, and other supporting documentation), test reports and testimony to ensure the validity of test results, opinions, and interpretations. The review consists of determining whether the appropriate examinations have been performed, the conclusions are consistent with the documented data and are within the scope of the discipline or sub-discipline.
3.99.	Sample	Portion drawn from a whole or population for the purpose of examination/testing, not necessarily representative of the whole (ISO 21043-1:2018).
3.100.	Sample selection	A practice of selecting items to test, or portions of items to test, based on training, experience, and competence. In sample selection, there is no assumption about homogeneity.
3.101.	Sampling	Selection and/or collection of material or data (ISO/IEC 17000:2020, modified) Note 1 to entry: Selection can be on the basis of a procedure, an automated system, professional judgement, etc. Note 2 to entry: Selection and collection can be performed by the same or different organizations. Note 3 to entry: The approach to sampling can be either non-statistical or statistical.
3.102.	Sampling method/procedure	The method used to collect a sample or samples from the larger whole, to ensure that the result obtained in the analysis is representative of the whole.
3.103.	Sampling plan	A statistically valid approach to determine the number of sub-items that must be tested in order to make an inference about the whole population.
3.104.	Secondary evidence	Material derived from an item of evidence.
3.105.	Secondary standard	A laboratory produced sample or casework sample that has been compared to a primary standard. A secondary standard must be compared to a primary standard by utilizing GC/MS, LC/MS, GC/FTIR or FTIR. The resulting documentation of this comparison will be maintained in the appropriate record. Standards calibrated by another national metrology institute.
3.106.	Secured area	Locked or otherwise limited access space under MNPD-CL control that has access restricted to personnel authorized by the Laboratory Director.

Ref. #	Term	Definition
3.107.	Shall (must)	Indicates a requirement
3.108.	Should	Indicates a recommendation
3.109.	Solvent	A liquid used to dissolve or dilute another substance.
3.110.	Standard procedure	A method that specifies the steps necessary to perform a test, contains documented performance characteristics and is published by a standards producing organization such as ASTM International (American Society for Testing and Materials) or is published and has been peer reviewed.
3.111.	Subcontractor/Out sourcing vendor	A non-MNPD-CL entity that independently performs a service for the MNPD-CL that the Laboratory is accredited to provide. The subcontractor must act within the scope of the MNPD-CL's accreditation.
3.112.	Sub-divided or sub-itemed evidence	Multiple items of evidence that were originally inventoried as a single item and have subsequently been assigned a unique identifier, such as initially receiving a bag of clothing as evidence and later sub-dividing its contents.
3.113.	Supervisor	A person directly responsible for overseeing the work of an individual or an organizational Unit.
3.114.	Technical Management	The person(s) who has technical responsibility for a discipline that may or may not supervise any persons and may or may not have "manager" or "supervisor" in a job title or job description. At the MNPD-CL, Technical Management comprises of the Lab Director, Quality Manager, and Unit Supervisors/Technical Leaders.
3.115.	Technical procedure (manual)	A document that specifies the steps, methods, equipment, and materials necessary to perform a task properly. TPMs are written to provide instruction and standardization for activities affecting the quality/validity of testing.
3.116.	Technician	An employee who is qualified by the MNPD-CL and who works in support of Unit operations.
3.117.	Testing	From ISO 17000:2004, includes analytical and physical examinations to determine one or more characteristics of a test item, according to a procedure in order to reach conclusions concerning the nature of and/or associations related to the item.
3.118.	Traceability	Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.
3.119.	Validation	verification, where the specified requirements are adequate for an intended use

Ref. #	Term	Definition
3.120.	Verification	Provision of objective evidence that a given item fulfils specified requirements. An independent check on a critical finding. The procedure used to evaluate the validity of a test result/opinion reached by re-performing the comparison between the unknown and the known or an unknown to another unknown. EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg. EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved. EXAMPLE 3 Confirmation that a target measurement uncertainty can be met. EXAMPLE 4 Confirmation of a test result/opinion by performance of the comparison between the unknown and the known by a different person. Note 1: When applicable, measurement uncertainty should be taken into consideration. Note 2: The item may be, for example, a process, measurement procedure, material, compound, or measuring system. Note 3: The specified requirements may be, for example, that a manufacturer's specifications are met. Note 4: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system. Note 5: Verification should not be confused with calibration. Not every verification is a validation. Note 6: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

4 General requirements

4.1 Impartiality

4.1.1(I) MNPD-CL activities are undertaken impartially and structured and managed so as to safeguard impartiality.

The MNPD-CL achieves this by following the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel.

There is a separation of duties such that MNPD-CL personnel do not partake in the investigation of cases, other than in testing and reporting activities as defined in the MNPD-CL manuals. The active investigation of cases is conducted by MNPD sworn Officers/Investigators. This ensures impartiality is safeguarded.

Activities are performed as defined in the Unit Technical Procedure Manuals (TPMs), Technical Training Manuals (TTMs), associated addendums, and related Quality Manuals (QMs) to ensure consistency in carrying out administrative, technical, and quality-related activities. This ensures that activities are structured to safeguard impartiality.

Forensic Scientists and Forensic Technicians report directly to their respective Unit Supervisor, who may also function as the Unit's Technical Leaders. The MNPD-CL Organization Chart illustrates the hierarchy of the management system. This ensures that the activities undertaken by all MNPD-CL personnel are managed to safeguard impartiality.

4.1.2(I) The MNPD-CL management are committed to impartiality.

The MNPD-CL management begins their commitment to impartiality with appropriate and strict hiring practices which are overseen and managed by the MNPD Human Resources Department. Only individuals who qualify for the position and who pass rigorous background checks and tests can be hired. Impartiality is then further emphasized throughout the individual's training and day-to-day activities. The MNPD Department Manual also contains policies on ensuring impartiality.

It is the MNPD's policy that all personnel undergo performance evaluations annually (at minimum), which includes a background check.

Management and personnel commitment to impartiality is also documented through annual acknowledgement and acceptance as well as continuous adherence to the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel (see QMS Test Reports).

4.1.3(I) The MNPD-CL is responsible for the impartiality of its laboratory activities and does not allow commercial, financial or other pressures to compromise impartiality.

All MNPD-CL personnel are responsible for ensuring the integrity of the examination process.

If, at any time, personnel feel that someone could influence laboratory activities, they will immediately inform the Unit Supervisor/TL. This will be communicated through the chain of command. Testing will be halted until there is reasonable confidence that testing will not be affected. If concerns exist where laboratory activities conducted by personnel or a Unit or the MNPD-CL may not be free from undue

pressure/influence or where impartiality, judgment, or operational integrity could be affected, the laboratory activities will either be assigned to another competent individual unaffected by the pressure/influence or to another accredited laboratory.

In addition, the MNPD has policies that MNPD-CL personnel must also adhere to so that commercial, financial, or other pressures do not compromise the impartiality of the individual.

4.1.3.1(A) The management system shall:

a) **have a code of ethics as part of the management's commitment to good professional practice;**
   - The MNPD-CL incorporates the current, published version of PR 3150 Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel, as part of the management's commitment to good professional practice.

b) **ensure annual review of the code of ethics by all personnel and retain a record of the review; and**
   - Annual review of the document is performed by all personnel. A record of the review is retained in QMS Test Reports.

c) **ensures appropriate actions are taken when necessary.**

In addition, the Quality Policy Statement (Section 8.2.2) is reviewed annually by MNPD-CL personnel. Records of these reviews are maintained in QMS through the **Testing** and **Report Modules**, where MNPD-CL personnel document the acknowledgement of the reviews.

4.1.4(I) The MNPD-CL identifies risks to its impartiality on an on-going basis. This includes 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.

The MNPD-CL identifies risks to its impartiality on an on-going basis in several ways.

Table 2: Types of risks

Type of Risk	Identification method
Risks that arise from activities	The MNPD-CL has in place several points for checks and balances to ensure that on-going laboratory activities are undertaken impartially. These include, but are not limited to, documentation of laboratory activities, technical review, administrative review, testimony review, quality control, and audits. MNPD-CL personnel also receive training in ethics and are required to adhere to MNPD policies and procedures to ensure impartiality.
Risks that arise from relationships	The command structure of the MNPD is aware and supportive of the MNPD-CL management system. The responsibilities of personnel are clearly defined in the Organizational Charts to illustrate the relationships between relevant personnel, and in the ***Functional Job Descriptions*** stored in the **Document Module** in QMS. Cases where MNPD-CL personnel may have an association with or know the individual(s) related to the case (e.g., as a victim or subject, etc.) may not be

Type of Risk	Identification method
	processed by that/those MNPD-CL personnel. Such cases will be assigned to another analyst or sent to another agency for processing. Personnel are required to notify their Unit Supervisor/TL if they are assigned a case in which they are aware of having a personal association with any parties associated with the case.
Risks that arise from relationships between MNPD personnel	In all circumstances, it is the responsibility of MNPD-CL personnel to notify their immediate Unit Supervisor of any relationship(s) that may have potential to compromise impartiality in decision making. Those circumstances would include, but not be limited to, casework as well as other decisions, such as purchasing of equipment, services, and consumables. Unit Supervisors will determine on a case-by-case basis if any decision-making roles need to be re-assigned due to any possible conflict.

4.1.5(I) If a risk to impartiality is identified, the MNPD-CL will be able to demonstrate how it eliminates or minimizes such risk.

If a risk to impartiality is identified, demonstration of eliminating or minimizing such risk will be dependent on the circumstances surrounding the risk factor. This may include following Human Resources procedures or MNPD-CL procedures, whichever is most appropriate.

4.2 Confidentiality

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

There is a reasonable expectation that due to the nature of the work conducted at the MNPD-CL, information pertaining to work performed may be placed in the public domain during the course of the judicial process. This is generally understood by the customer for doing business with the MNPD-CL.

It is the MNPD-CL's policy to ensure that customers' confidential information and proprietary rights are protected through:

- Abiding by the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel and
- Using secure information systems for documents, records, and reports. This includes information obtained or created during the performance of laboratory activities.

Such information systems include, but are not limited to, Laboratory Information Management System (LIMS), Digital Information Management Software (Foray), Quality Management System (QMS), instrument software, and storage locations all hosted on MNPD secure servers.

4.2.2(I) When the MNPD-CL is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned will, unless prohibited by law, be notified of the information provided.

When the MNPD-CL is required by law to release confidential information, the requesting party is typically an MNPD-CL customer and/or an involved (approved) member of the criminal justice system.

When the MNPD-CL is authorized by contractual arrangements to release confidential information (this is typically related to toxicology results), the requesting party is required to complete a Form 280 (Crime Lab Release of Toxicology Report Request Form) that acknowledges that the requesting party is operating on the behalf of the concerned individual. The customer or individual concerned will, unless prohibited by law, be notified of the information provided when the MNPD-CL completes the execution of the request. This may be in the form of email communications, a signed receipt of the information, or other form of acknowledgement.

There is a reasonable expectation that due to the nature of the work conducted at the MNPD-CL, information pertaining to work performed may be required to release confidential information during the course of the judicial process. This is generally understood by the customer for doing business with the MNPD-CL.

4.2.3(I) Information about the customer obtained from sources other than the customer (e.g., complainant, regulators) is confidential between the customer and the MNPD-CL. The provider (source) of this information is confidential to the laboratory and will not be shared with the customer, unless agreed by the source.

The MNPD-CL receives items for testing from the customer and the final product (test report) is initially released to the same customer. If the original customer becomes unavailable or is no longer responsible for the case being tested, the test report may be released to the customer responsible for the case at the time or to a member of the customer's chain of command.

It is uncommon that the MNPD-CL would acquire or need to acquire information about the customer.

4.2.4(I) Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the MNPD-CL's behalf, will keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

Maintaining confidentiality is part of adhering to the MNPD Manual and the MNPD-CL's Quality Manual.

When required by law, documentation from court officials will be required to support the release of confidential information.

The MNPD-CL does not have committee members, contractors, personnel of external bodies, or other individuals acting on its behalf other than MNPD-CL personnel.

Receiving records requests

Requests for the release of records contained in the MNPD-CL may be received from involved criminal justice system attorneys and other individuals. Requests for release of records are most frequently

obtained by or through Discovery Motions, Court Orders, the Freedom of Information Act, or similar requests.

All court orders (subpoena duces tecum) and discovery requests received by the MNPD-CL must be reported to the Laboratory Director and/or Quality Manager.

All requests for the release of records from the MNPD-CL must be in writing or documented in a Memorandum of Record with any attached motions or orders. The requests must be specific as to the information desired. When requests are received, the Laboratory Director and/or Quality Manager may request that they be reviewed by Metropolitan Government Legal Department. In these instances, the Metropolitan Government Legal Department must approve before action is taken by the MNPD-CL (e.g., ex parte orders).

Table 3: Documentation required for records request

Type of record requested	Type of documentation required
Information pertaining to proficiency test results, corrective actions, Quality System Notifications, preventive actions, risk assessments, authorizations, testimony logs, deviation requests, audits, assessments, maintenance logs, QAQC records, equipment records, validation records, raw data, meta data, and/or training records (including continuing education)	Court order
Information pertaining to the case file, chain of custody, report, and information required to reach the reported findings and conclusions **Toxicology Reports***	Discovery request or Email or Request on official business letterhead or Documentation indicating both prosecuting and defense attorneys are aware of the request
Information pertaining to the case file and/or reports, and information required to reach the reported findings and conclusions where the records requested contain confidential/personal information (e.g., SSN, DOB, medical information, etc.)	Discovery request Court order

*For requests for Toxicology Reports from agencies other than the MNPD or District Attorney's Office, Form 280 must be completed by the requesting and processing parties.

After review, only the MNPD-CL Laboratory Director, Quality Manager, or Unit Supervisor/TL is authorized to direct the release of information. In most instances the MNPD-CL employee(s) affected by the request will gather the required records for release. Quality records will be assembled by the Quality Manager.

Discovery packet

If requested, the below information will be provided to the requesting party for the forensic discipline listed on the written request:

1) Case file records to include:

- Technical records (examination/analysis notes) used in arriving to the reported results and conclusions
- Instrument data used in arriving to the reported results and conclusions
- Photographic notes related to the examined/analyzed evidence
- Chain of custody records related to the evidence examined/analyzed
- Correspondence records related to the service request
- Official Laboratory Report

2) Laboratory policies and procedures effective during the examination/analysis of the evidence to include:
   - Discipline-Specific Technical Manuals
   - Quality Manual
   - Evidence Receiving Unit Standard Operating Procedures
3) *Quality assurance and quality control summary logs generated internally, covering 3 months prior and up to the completion of this case, for instrument(s) used in the examination/analysis of the evidence for this case
4) *Performance maintenance (performed by contracted service providers) summary logs, covering 3 months prior and up to the completion of this case, for instrument(s) used in the examination/analysis of the evidence for this case
5) *Contamination summary log covering 3 months prior and up to the completion of this case
6) *Work authorization summary log for Forensic Technicians and Forensic Scientists associated with this case
7) *CV and/or resume of Forensic Technicians and Forensic Scientists associated with this case
8) *Proficiency test summary log for Forensic Technicians and Forensic Scientists associated with this case
9) *Corrective action summary log, covering 3 months prior and up to the completion of this case, for Forensic Technicians and Forensic Scientists associated with this case

*Many records are stored and maintained electronically within data management systems. As such, requesting party(ies) may be invited to schedule an appointment to view individual data files at the MNPD-CL with a designated member of Crime Laboratory personnel.

Note: In instances where an agency is unable to obtain the above forms of documentation, the Laboratory Director and/or Quality Manager will determine how to proceed.

Verbal release of results

Verbal release of any laboratory results to customers is strongly discouraged but permitted under limited justifiable circumstances (such as urgent investigative lead, trial information, court order). Verbal results may be given prior to finalization of a report; however, the results/data must at a minimum, be verified (if applicable) and/or technically reviewed. For disciplines which perform verifications, a technical review is not required to verbally release results. Unit Supervisors/TLs have the authority to release verbal reports or parts of a report and are encouraged to communicate that while the verbal report has been verified or technically reviewed, the written report will be forthcoming and final. The Laboratory Director should be informed of the verbal release of any laboratory results as soon as possible.

Records may be released in the following formats:

1) Email

- Emails to agencies other than the MNPD, District Attorney's Office, Public Defender's Office, and/or law enforcement agencies partnering with the MNPD or MNPD-CL must be encrypted.

2) In person
   - Form 281 is to be completed when records are relinquished to the requesting party in person, whether in the form of paper or CD or other medium.
3) Shipping
   - The shipping receipt with tracking number or record containing similar information must be retained when records are relinquished to the requesting party through the mailing system.

Transaction emails, Form 281 for records, and/or shipping receipts must be retained in QMS in the respective Discovery Request workflow.

5 Structural requirements

5.1(I) The MNPD-CL is a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

The MNPD-CL falls under the Metropolitan Government of Nashville and Davidson County (Metro), an organization which can be held legally responsible.

5.2(I) The MNPD-CL has identified management that has overall responsibility for the laboratory.

See Organizational Charts and ***Functional Job Descriptions*** stored in the **Document Module** in QMS for descriptions of overall responsibilities.

The Laboratory Director and the Quality Manager, have laboratory-wide responsibility for the laboratory's quality/management system.

Unit Supervisors and Technical Leaders, who work together with the Laboratory Director and Quality Manager, have responsibility for their Unit's quality/management system.

5.2.1(A) There is a director, whose duties are defined.

The Laboratory Director possesses sufficient authority to make and enforce decisions (see ***Functional Job Descriptions*** stored in the **Document Module** in QMS for definition of duties). The organizational structure of the MNPD-CL is a visual depiction of the levels of authority (See Organizational Charts).

5.3(I) The MNPD-CL has defined and documented the range of laboratory activities for which it conforms with this document. The MNPD-CL only claims conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

The MNPD-CL provides examinations in the following forensic disciplines:

Table 4: Services offered

Discipline	Service
Biology	Body fluid identification Nuclear DNA analysis
Friction Ridge	Latent print comparison Tenprint comparison
Firearms/Toolmarks	Distance determination Firearms examination Serial number restoration Toolmark examination
Seized Drugs	Controlled substances identification General chemical testing THC Quants
Toxicology	Blood alcohol concentration analysis

The definitions and documentation of the range of laboratory activities that conform to this document are found in the Unit TPMs, associated addendums, and related Quality Manuals.

The MNPD-CL provides certain services on emergency or exigent circumstance cases, which may include the need to provide those services outside of normal business hours. Requests for emergency services must come through the MNPD chain of command to the FSD Director and/or Laboratory Director.

- The Director will contact the affected Unit Supervisor(s)/TL(s) and ensure the necessary personnel are called to assist.
- The MNPD-CL Administrative Assistant will maintain and update a MNPD-CL phone contact list for the Management Team.
- Unit Supervisors/TLs will maintain a call list for their Unit in the event additional emergency response services are required. The list should include contact information and be accessible to the FSD Director and Laboratory Director.

5.4(I) MNPD-CL activities are carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities, and organizations providing recognition. This includes 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.

NOTE Examples of regulatory authorities are the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS) and state forensic science commissions providing accreditation.

The MNPD-CL carries out its laboratory activities in such a way as to meet the requirements of

a. ISO/IEC 17025:2017,
b. The accrediting body's policies and requirements,
c. The customers provided that it is within the scope of accredited services,
d. Other regulatory authorities and organizations providing recognition, such as the FBI Quality Assurance Standards, MNPD-CL quality and management system documents, and applicable Tennessee State Statutes

The MNPD-CL accomplishes this by having established and implemented QMs, discipline specific TPMs, TTMs, associated addendums, and additional forms and documents. The MNPD-CL continues to maintain all of these documents.

The management system (QMs, TPMs, and associated addendums) covers work carried out in the MNPD-CL's permanent facility, which is located on the 2nd floor of the Madison Precinct at 400 Myatt Drive, Madison, TN 37115.

The management system also covers work carried out by MNPD-CL personnel at sites away from the permanent facility (e.g., home office), or in associated temporary or mobile facilities provided that the work is within the scope of accredited services. In these situations, measures will be taken to maintain the integrity of the evidence and the quality of the work product (test reports). Policies and procedures established in the QMs, TPMs, associated addendums, and Safety Plan will be followed as much as practicable.

The management system does not cover work carried out at a customer's facility.

5.4.1(A) The MNPD-CL conforms to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

In addition, if results of subcontracted tests are included in a test report that makes reference to accreditation, the accreditation symbol of the subcontractor will not be used on the report if the subcontractor is not accredited by ANAB.

5.4.2(A) 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.

NOTE See MA 3033 Section 4.6.

The MNPD-CL Forensic Biology Unit (FBU) is required to perform testing on 100% of sexual assault kits submitted. This requirement may be found under Tennessee House Bill 1239 (TN HB 1239) and under the Tennessee Code Annotated, Title 29, Chapter 13, Part 1; Title 38, Chapter 6, Part 1; and Title 39, Chapter 13, Part 5.

Victims can sign a waiver to request that their sexual assault kit not be tested. In these instances, the sexual assault kits will be retained at ESD.

5.5(I) The MNPD-CL has:

a) **defined the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;**
   - See Organizational Charts

b) **specified the responsibility, authority and interrelationship of all personnel who manage, perform, or verify work affecting the results of laboratory activities;**
   - See ***Functional Job Descriptions*** stored in the **Document Module** in QMS for the responsibilities and authority of all personnel who manage, perform, or verify work affecting the results of laboratory activities
   - See Organizational Charts for the interrelationship of all personnel who manage, perform, or verify work affecting the results of laboratory activities

c) **documented its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.**
   - The MNPD-CL has established and implemented a management system appropriate to the scope of its activities.
   - The management system is comprised of Unit QMs, TPMs, TTMs, and associated addendums. All of these documents are stored and maintained in the **Document Module** in QMS and are available to all MNPD-CL personnel.
   - The system's documentation is communicated to, understood by, available to, and implemented by the appropriate personnel. Personnel acknowledge understanding of the management system through the QMS **Testing Module**. The MNPD-CL continues to maintain the management system.

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

5.6(I) The MNPD-CL has 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;

Unit Supervisors/TLs, Forensic Scientists, and Forensic Technicians have the authority to carry out their duties as documented in their authorizations. The Technical Leader, Lab Director, and Quality Manager comprise the technical support for authorized Forensic Scientists and Forensic Technicians with the implementation, maintenance, and improvement of the management system (see Organizational Charts and ***Functional Job Descriptions*** stored in the **Document Module** in QMS).

The budget (resources) pertaining to the MNPD-CL is obtained through the parent agency.

b) identification of deviations from the management system or from the procedures for performing laboratory activities;

When deviations from the management system, from procedures for performing laboratory activities, or from good laboratory/quality practice are identified, MNPD-CL employees have the responsibility, authority, and capability to initiate actions to correct, prevent and/or minimize such deviations and any conditions adversely affecting the quality system.

c) initiation of actions to prevent or minimize such deviations;

Actions to prevent or minimize such deviations as stated in 5.6.b starts by first notifying Technical Leaders or management and documenting deviation requests and/or corrective actions (see **Report Module** in QMS).

d) reporting to laboratory management on the performance of the management system and any need for improvement;

All MNPD-CL personnel have the responsibility, authority, and capability to report to laboratory management on the performance of the management system and any need for improvement.

e) ensuring the effectiveness of laboratory activities.

Management ensures that the quality system's effectiveness, including all laboratory activities, is continuously monitored. This may be achieved through technical and administrative reviews, court testimony evaluations, proficiency tests, performance evaluations, and regular audits.

5.7(I) MNPD-CL management ensures that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

- Management ensures that appropriate communication processes are established within the MNPD-CL.

- QMs, TPMs, associated addendums, and directives are used as written communication tools. MNPD-CL meetings, Unit meetings, management meetings, memos, conversations and/or electronic means support the written documents and allow feedback regarding the effectiveness of the management system.
- MNPD-CL personnel are responsible for keeping up to date on all forms of communication issued by Management.
- If added to the most current revision, new directives issued in between document revisions will expire upon the publication of the next revision of the respective document.
    - *Example: if the current publication is revision 3 and directives were issued afterwards, the directives issued between revision 3 and revision 4's publication dates should be incorporated into revision 4. If the directive is not incorporated into the newest revision, it is still valid.*

b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

- This may be accomplished by management review of proposed revisions to the MNPD-CL quality system and management system documents. A record of these reviews can be found in the document's ***Properties*** in the **Document Module** in QMS.

6 Resource requirements

6.1 General

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

- Personnel
  - See Organization Charts and ***Functional Job Descriptions*** stored in the **Document Module** in QMS
- Facilities
  - 400 Myatt Drive, Suite 200, Madison, TN 37115
- Equipment
  - Typically located within each Unit
- Systems
  - Electronic and hardcopy information systems
- Support services
  - MNPD IT, HR, and Fiscal

6.2 Personnel

6.2.1(I) All personnel of the MNPD-CL, either internal or external, that could influence the laboratory activities will act impartially, be competent and work in accordance with the laboratory's management system.

The MNPD-CL uses personnel who are employed by, or (occasionally) under contract to, the MNPD-CL through the Metropolitan Government of Nashville and Davidson County. The MNPD-CL will, to the best of its ability, ensure that all such personnel will act impartially, be competent and work in accordance with the MNPD-CL's management system.

Impartiality is affirmed annually through review and acknowledgement of the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel (see **Testing** and **Report Modules** in QMS).

Competency is established through successful completion of competency tests (see **Personnel** and **Training Modules** in QMS). Competency tests are issued and taken at the end of training modules, training programs and/or as needed when competence needs to be re-established.

Appropriate supervision and management are in place to ensure that work is performed in accordance with MNPD-CL's policies and procedures (see Organization Charts).

Re-establishing competency

After a prolonged absence from the discipline, an individual's knowledge, skills, and abilities (KSA) may be reassessed upon return to duty at the discretion of the Unit Supervisor/TL The reassessment will preferably be through a practical exercise but need not be as extensive as the end of training tests as long as it is sufficient to provide the appropriate assessment.

During an individual's absence (regardless of the length) from the discipline, should there be events that may affect an individual's KSA, a reassessment of KSA will be performed.

At the discretion of the Unit Supervisor/TL, reassessment of an individual's KSA may also occur sooner than the prolonged absence.

At a minimum, Unit Supervisors/TLs will consider the cause and length of absence, events that occurred during the absence, procedural and policy changes that were implemented during the absence, and the individual's level of experience when determining the extensiveness of the reassessment.

6.2.2(I) The MNPD-CL documents the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, and experience.

Table 5: Functions that influence results of laboratory activities

Functions that influence the results of the laboratory activities	Personnel
Development, modification, verification, and validation of methods	Personnel assigned by Unit Supervisor/TL
Performs laboratory activities (performs testing or sampling)	Forensic Technicians/Forensic Scientists/Unit Supervisors/TLs
Analysis of results	Forensic Technicians/Forensic Scientists/Unit Supervisors/TLs
Review of results	Individual drafting and/or signing the report
Authorize results	Individual drafting the report
Verification of a result	Forensic Scientists/Unit Supervisors/TLs; cannot be the same individual reviewing/authorizing the results
Technical review	Forensic Technicians/Forensic Scientists/Unit Supervisors/TLs (can be the same individual who verifies the results but cannot be the same individual who reviews/authorizes the results)
Express opinion or interpretation	Forensic Technicians/Forensic Scientists/Unit Supervisors/TLs
Report results	First individual who signs the report
Authorizes reports	Last individual who signs the report

Table 6: Required elements for qualification

	REQUIRED ELEMENTS				
Tasks	Authorization	Training	Education requirements	Competency tested	Monitoring competence
Development, modification, verification, and validation of methods	X	X	X		

	REQUIRED ELEMENTS				
Tasks	Authorization	Training	Education requirements	Competency tested	Monitoring competence
Performs laboratory activities (testing, sampling)	X	X	X	X	X
Analysis of results	X	X	X	X	X
Review of results	X	X	X	X	X
Authorize results	X	X	X	X	X
Verification of results	X	X	X	X	X
Technical review	X	X		X	
Express opinion or interpretation	X	X	X	X	
Report results Authorize reports	X	X		X	X

See Unit TTMs and ***Functional Job Descriptions*** stored in the **Document Module** in QMS for competence requirements.

See **Personnel Module** in QMS for records of competence. Additional documentation of qualification is retained with the HR Department.

6.2.2.1(A) Personnel who authorize results, express opinions, and/or interpretations in the following disciplines meets the minimum educational requirements below.

Table 7: Education requirements

Discipline	Minimum Education Requirements
Biology Seized Drugs Toxicology	A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.
Firearms/Toolmarks Friction Ridge	Meet the educational requirement(s) specified for competence (see ISO/IEC 17025:2017 6.2.2).

NOTE Minimum educational requirements apply to personnel working in any discipline for which training begins after November 13, 2018 to ISO/IEC 17025 in that discipline.

Personnel who were previously authorized to authorize results, opinions, and/or interpretations, but do not meet current educational requirements may be authorized to perform such functions at the discretion of Management. Records to support competence and authorized functions must be available.

6.2.2.2(A) The training program, for each function influencing the results of the MNPD-CL activities, to the extent necessary based on job function, includes:

a) The knowledge, skills, and abilities needed to perform work;
- Incorporated into discipline training programs.

b) General knowledge of forensic science;

- Training modules with associated tests are automatically distributed to all new employees through the **Training** and **Testing Modules** in QMS.
- New employees enter into a rotation through the MNPD-CL forensic units.

c) The application of ethical practices in forensic science;

- Training modules with associated tests are automatically distributed to all new employees through the **Training** and **Testing Modules** in QMS.

d) Criminal law, civil law, and testimony;

- Training modules with associated tests are automatically distributed to all new employees through the **Training** and **Testing Modules** in QMS.

e) Provisions for retraining;

- Remedial training will be specific to a recognized need to re-train. This will be coordinated by the Unit Supervisor/TL and may include use of internal or external training tools.
- Documentation of retraining will be retained in the **Training Module** in QMS.

f) Provisions for maintenance of skills and expertise; and

- Ongoing training in-house or at external meetings or seminars etc. will be coordinated by Management, with the Unit Supervisor/TL communicating and coordinating training activities for their Unit.
- The MNPD-CL maintains or provides access to literature resources such as relevant books, journals and other literature related to each discipline. These resources may be hardcopy or electronic.
- Review of appropriate new literature by MNPD-CL personnel is documented through the **Workflow Module** in QMS.

g) Criteria for acceptable performance.

- Incorporated into discipline training programs.

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.

The MNPD-CL has documented training programs in each discipline (see Unit TTMs).

New employees of the MNPD-CL should complete the required Metro training as soon as practicable. These include:

- New hire orientation and training and
- DDC (Defensive Driving) – mandatory refresher every 3 years

Court testimony training

Where applicable, training programs will also include training in the presentation of evidence in court (courtroom testimony). Personnel new to the MNPD-CL that have previous/recent courtroom testimony experience may not be required to undergo a full training program for the presentation of evidence in court. The Unit Supervisor/TL will determine the extent of training needed for each member of the Unit based on recent courtroom experience and the methods used in testing.

Experienced personnel

When hiring experienced personnel, the Unit Supervisor/TL will assess previous training and ensure that it is adequate and documented. Modification to a discipline specific training program may be appropriate and will be documented by the Unit Supervisor/TL based on their assessment of previous training and experience. Also see Note 1.

Training substitution

Validation work performed for the Unit may be substituted for training and competency testing for the method/work performed; however, a formal practical competency test is recommended.

6.2.3(I) The MNPD-CL will ensure that personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

Personnel performing the functions in Table 5 will be qualified on the basis of the Required Elements in Table 6 as well as technical knowledge, skills, experience, and/or demonstrated skills (see **Personnel Module** in QMS). Education documentation is only accessible by Management.

The minimum education and experience requirements that must be met as part of ensuring competence of personnel are documented in the ***Functional Job Descriptions*** stored in the **Document Module** in QMS.

The MNPD-CL management also ensures the competence of personnel who:

- Operate specific equipment
- Perform tests

Competency is established through successful completion of competency tests (see **Personnel** and **Training Modules** in QMS).

The significance of deviations from the TPMs will ultimately be evaluated by the Unit Supervisor/TL and significance of deviations from the quality system will ultimately be evaluated by the Quality Manager (see **Report Module** in QMS). Where appropriate, the significance of deviations may be evaluated by both the Unit Supervisor/TL and the Quality Manager.

6.2.3.1(A) All personnel who perform testing will be competency tested. Testing includes the review and authorization of results and expressing an opinion or an interpretation. The competency test includes practical examination(s) that cover the spectrum of anticipated tasks related to the test. The competency test intended results must be achieved prior to performing the tasks on a test item.

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

Competency test(s) are also required for personnel that perform specific tasks that create items that could be used for testing.

If applicable, the competency test(s) will include issuing a test report and providing testimony.

For any MNPD-CL personnel whose job responsibility includes test report writing, a competency test will include, at a minimum:

- Examination of sufficient unknown samples to cover the anticipated spectrum of assigned duties and evaluate the individual's ability to perform proper testing methods;
- A written test report to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of those results/conclusions; and
- A written or oral examination to assess the individual's knowledge of the discipline, category of testing, or task being performed.

Items for competency tests can be obtained or created in several different ways:

Table 8: Competency test samples

Unit/Type	Methods for Obtaining or Creating Competency Test Samples
Drug Identification	samples may be obtained from adjudicated cases with the approval of the District Attorney's Office or from available suppliers
Firearms and Toolmarks	samples may be obtained or created using the Unit's reference collection or from evidence that has already been examined
Forensic Biology	samples may be obtained or created using donated specimens of known origin
Latent Print	samples may be obtained from evidence that has already been examined
Tenprint	samples may be obtained from evidence that has already been examined
Toxicology	samples may be obtained from evidence that has already been analyzed

Note: Proficiency test samples may not be a fair representation of the types of items routinely received and should only be used as competency tests if other alternatives are not legally or logistically available.

For competency tests using already examined evidence or previously generated data, the competency test must not be performed on the originals. Competency tests may not be performed on official casework or on samples/cases where the intended results are not yet known to the test distributor at the time of distribution.

Intended result(s) is defined as result(s) obtained that are scientifically justifiable based on the quality of the test item and/or the experience of the individual. These results are either known to the distributor (such as trainer or Unit Supervisor/TL or test provider) and/or can be compared to a qualified source (such as qualified analyst or test provider).

Example: In Toxicology, competency test items could be obtained from past proficiency tests or past evidence that have exceeded the MNPD-CL's retention policy. Due to the length of time elapsed, retesting of these items may not achieve the exact concentrations obtained from the initial tests.

Competency test records are retained in the **Personnel** and **Training Modules** in QMS.

Also see section on Re-establishing competency.

6.2.3.2(A) Personnel who perform technical review of results or testimony, will meet the competency requirements as specified in 6.2.3.1 for the testing tasks being reviewed.

Technical reviewer: a person who is authorized by MNPD-CL management to conduct technical reviews of casework based on expertise gained through training and casework experience in the specific task, and who is competent and qualified in the task being reviewed. In addition, the reviewer shall have knowledge

of the MNPD-CL's technical procedures. A technical reviewer need not be an active analyst, currently proficiency tested in the discipline, or an employee of the MNPD-CL.

Administrative reviewer: An individual who conducts an administrative review. An administrative reviewer need not be competent in the tasks being reviewed.

Competency test records are retained in the **Personnel** and **Training Modules** in QMS.

6.2.4(I) The management of the MNPD-CL communicates to personnel their duties, responsibilities, and authorities.

The MNPD-CL maintains current job descriptions for managerial, technical, and key support personnel involved in tests (see ***Functional Job Descriptions*** stored in the **Document Module** in QMS).

Duties, responsibilities, and authorities are communicated to personnel through the job description, throughout the hiring process, and throughout the training program. Duties, responsibilities, and authorities of personnel may also be communicated during performance evaluations.

6.2.5(I) The MNPD-CL has procedure(s) and retains records for:

Requirement	Procedure	Retention of records
a) determining the competence requirements;	Competence requirements are determined by the Unit Supervisor/TL and are, at a minimum, relevant to the present and anticipated tasks/services provided by the MNPD-CL. This is documented in each Unit's TTM. The effectiveness of the training actions taken will be evaluated by the Unit Supervisor/TL.	Records of competence are retained in the **Personnel** and **Training Modules** in QMS. Effectiveness of training is documented in the **Personnel** and **Workflow Modules** in QMS.
b) selection of personnel;	Generally, the procedure for the selection of personnel starts with candidates meeting requirements described in the ***General Job Descriptions*** (see ***Position Descriptions*** stored in the **Document Module** in QMS). These requirements assist the HR Department in providing a list of candidates for the Unit Supervisor/TL to evaluate. Final selection of personnel could be based on the application, phone interview(s), testing, and/or in-person interview(s) or any combination of these. The Unit Supervisor/TL uses their experience in combination with the available information to select the most appropriate candidate for the function.	Records for personnel selection are retained by the HR Department. Additional records may be retained by the Unit Supervisor/TL if they were used in the selection process (e.g., tests).
c) training of personnel;	The procedures for training of personnel are documented in each Unit's TTM. In addition, the Unit Supervisor/TL can identify training needs for their staff on an annual basis.	Training records are maintained for all personnel in the **Personnel**, **Training**,

Requirement	Procedure	Retention of records
	Training may involve participation in professional organizations, attendance of technical and/or professional development courses, conferences, seminars, review of current literature, preparation, and submittal of journal articles for publication, presentation of papers/posters at technical meetings, vendor provided classes, etc.*	and **Report Modules** in QMS. Documentation of training needs may be in the form of budget requests (retained by the Business Manager) and/or recorded at annual management reviews (see **Report Module** in QMS).
d) supervision of personnel;	Personnel are supervised by the Unit Supervisor/TL or designee.	Supervision of personnel is as documented in the Organizational Chart and/or training records (see **Personnel** and **Training Modules** in QMS).
e) authorization of personnel;	Personnel may be authorized by module/task or by program. The Unit Supervisor/TL will initiate the authorization process by reviewing and signing off on the relevant module(s)/task(s). An Authorization Workflow is processed and submitted to the Quality Manager for finalization. Once finalized, the authorized individual will receive notification that authorized task(s) may be performed independently. Subsequent authorizations may be issued as necessary to reflect accurate authorized statuses. Examples of when these are issued may include, but are not exclusive to: • A lapse in proficiency test to include test evaluation and feedback • Transfer to another discipline • Prolonged absence from a discipline • A need for re-training	All authorizations are supported by records of appropriate training and competency test(s). Records of authorizations are maintained in the **Report Module** in QMS.
f) monitoring competence of personnel.	Competence of personnel is continually monitored through the usage of verifications, technical reviews, administrative reviews, testimony monitoring, proficiency tests, internal audits, management reviews, supervision, and/or annual performance evaluations to name a few.	Records of verifications, technical reviews, and administrative reviews are retained in the case file. Records of testimony monitoring, proficiency tests, internal audits, and management reviews are retained in QMS. Records of supervision and annual performance evaluations are retained by

Requirement	Procedure	Retention of records
		HR and/or the Unit Supervisor/TL.

*Training needs that require financial resources will be submitted to the Business Manager for processing. Approval from the Unit Supervisor/TL is required. The individual who intends to attend training must gather and provide applicable documentation including:

- Information about the training,
- Training registration confirmation/invoice,
- Travel information (flight, vehicle, etc.),
- Accommodation confirmation,
- Per diem rates, and
- A complete Metro form 445

The MNPD-CL Personnel Records contain all or part of the following information (as appropriate) for each member of the MNPD-CL technical personnel:

- Current Curriculum Vitae or resume (not required if Statement of Qualifications available)
- Statement of Qualification (not required if CV available)
- Educational Records, including continuing education
- Training Record Checklists if applicable (linked to full training records)
- Competency Testing Record and Certificate(s)
- Other (*Example: Recognition letters*)

Each employee is responsible to gather and update their information in the above categories and make it available to their Unit Supervisor/TL, Quality Manager, Assistant Director, or Laboratory Director. Unit Supervisors/TLs may maintain additional records for staff in their Unit. Management will keep these personnel records secured.

6.2.6(I) The MNPD-CL will authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification, and validation of methods;
- Authorization to perform development, modification, verification, and validation of methods is documented upon the assignment of the responsibility.

b) analysis of results, including statements of conformity or opinions and interpretations;

c) report, review, and authorization of results.

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

The Unit Supervisor/TL will also authorize specific personnel to:

- Operate specific equipment
- Perform tests

The Unit Supervisor/TL will ensure that all necessary documentation to support the authorization is complete and available. Personnel who were previously authorized to perform tasks, but do not meet

current educational requirements may be authorized to perform such functions at the discretion of Management. Records to support competence and authorized functions must be available.

The Quality Manager and/or Laboratory Director will authorize Unit Supervisors/TLs who are actively working cases to perform work on the basis of appropriate education, training, experience, demonstrated skills and competency tests in their assigned discipline (see **Personnel** and **Training Modules** in QMS).

6.3 Facilities and environmental conditions

6.3.1(I) The facilities and environmental conditions are suitable for the MNPD-CL activities and do not adversely affect the validity of results.

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 MNPD-CL is located on the 2nd floor of the Madison Precinct of the Metropolitan Nashville Police Department, 400 Myatt Drive, Madison, TN 37115.

All areas of the MNPD-CL are under appropriate conditions (typically ambient conditions) so that activities can occur without adversely affecting the validity of the results.

Where ambient conditions are not suitable, appropriate equipment is available to meet those requirements.

Where activities must be spatially separated to not adversely affect the validity of results, the facility has created appropriate separation.

If environmental conditions become unsuitable or could adversely affect the validity of results, relevant MNPD-CL activities will be halted until the environment returns to suitable conditions.

6.3.2(I) The requirements for facilities and environmental conditions necessary for the performance of the MNPD-CL activities will be documented.

Unless noted in Unit QMs and/or TPMs, all activities require normal (typically ambient conditions) laboratory environmental conditions.

6.3.3(I) The MNPD-CL monitors, controls, and records environmental conditions in accordance with relevant specifications, methods, or procedures or where they influence the validity of the results.

Environmental conditions (such as storage temperatures) are controlled and monitored in accordance with Unit QMs and/or TPMs. These records are retained in the **Report Module** in QMS.

Relevant activities will be stopped if the conditions could influence/jeopardize the validity of the results of the tests.

6.3.4(I) Measures to control facilities are implemented, monitored and periodically reviewed and include, but not be limited to:

a) **access to and use of areas affecting MNPD-CL activities;**

Access to and use of areas affecting MNPD-CL activities will be controlled by Management and is determined based on particular circumstances. Typically, only personnel who perform laboratory activities in an area will have access to that area. Exceptions are to the Management Team and Administrative Assistant where access to MNPD-CL office areas is essential to facilitate daily operations. Access to laboratory areas is monitored throughout the regular course of business by members of the Unit.

Access is implemented upon hire when the individual receives a unique electronic key card that provides access to needed areas of the MNPD-CL. Monitoring of electronic key card access is performed throughout the regular course of business where unauthorized access is reported to a member of the Management Team.

Review of access to areas is performed by the Unit Supervisor/TL at least annually. Records of reviews are in the **Reports Module** in QMS. Any adjustments will be brought to the attention of the IT Manager through an IT Request Workflow.

b) prevention of contamination, interference, or adverse influences on MNPD-CL activities;

In general, office areas are separated from laboratory areas and, as much as possible, personnel have their own laboratory and office workspaces to prevent contamination, interference, or adverse influences on laboratory activities. Workspaces are sufficiently spaced out, have adequate areas for performance of MNPD-CL activities, and are also routinely sanitized and decontaminated to prevent cross-contamination.

c) effective separation between areas with incompatible MNPD-CL activities.

In addition to items addressed in 6.3.4.b above, measures will be taken to prevent cross-contamination and are addressed in Unit TPMs, associated addendums, or Forensic Biology Quality Manual.

In particular, in the Forensic Biology Unit, laboratory areas where serological screening, pre-amplification, and post-amplification activities occur are separated. This was implemented when the MNPD-CL was architecturally designed. Monitoring is performed throughout the regular course of business to ensure appropriate activities are performed in designated areas.

6.3.4.1(A) There is a procedure that addresses security and access to areas where testing occur.

NOTE Topics to consider may include, but are 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.

Security to areas where testing occur is enforced by electronic key cards and personnel. Control of access is designated by the Laboratory Director.

- Lobby outside the MNPD-CL and Tenprint Unit is secured 24/7.
- Crime Laboratory:
    - Tier 1 – Internal operational areas such as the administrative office area, hallways, break room, internal elevators, bathrooms, training room and lobby area
    - Tier 2 – Forensic Unit laboratory testing areas, Evidence Receiving Unit (ERU), and miscellaneous mechanical room and IT closets
    - Tier 3 – Evidence storage vaults in the Units, ERU Vaults, and FTIU gun reference collection

a) Access to the MNPD-CL is typically gained during the normal operational hours described below:
   - Monday through Friday 0730-1600: Administration and Evidence Receiving
   - Monday through Friday 0500-1800: Forensic Units

   Public access: North side

   MNPD personnel access: South side. The entrance/exit is located within the secure parking facility and requires a proximity key card to access. Authorized MNPD personnel have key card access.

   Public access for deliveries: West side. Entrance/exit to the area is through a back entrance/exit and requires a proximity key card to access the freight elevator.

   All entrance and exit points and the outer perimeter to the MNPD-CL have electronic locks, proximity card access, and video camera monitoring. All other exterior doors and vehicle bays have proximity key card access only to authorized MNPD personnel, but do not allow access to the MNPD-CL.

   Assigned personnel should use the north or south entrance unless bringing supplies to the west side.

   Public access to the first floor Precinct entrance is secured and locked at 1630 hours, except for community events scheduled through the Precinct.

   The second floor is secured 24/7, except for community events/tours scheduled through the MNPD-CL. The securing of the MNPD-CL includes blocked access to stairs and key card control of the elevator and main MNPD-CL door entrance.

b) Access by personnel:

   - Administration and hallways: all FSD personnel
   - Evidence storage locations: limited to personnel involved in casework in that Unit, the Lab Director, and the FSD Director
   - Forensic Units: limited to personnel assigned to that Unit, Administrative Assistantand the Management Team

   Unit personnel should escort other MNPD-CL personnel into their laboratory testing areas. An escort is not required for MNPD-CL personnel if there is a predetermined tour, business activity or an urgent reason for a member of the Management Team to proceed into the laboratory testing areas.

c) Access by visitors:

   Metro Nashville General Services contractors, who have been background checked and assigned to maintain or service the facility, are allowed access to the internal operational areas of the laboratory. These individuals must be accompanied by MNPD-CL personnel if entering any Tier 2 area within the MNPD-CL. Identifying information must be visible at all times.

Any visitors (individuals other than MNPD or authorized Metro Nashville personnel) must sign into the MNPD-CL in the Administration Lobby or ERU if visiting ERU only. Visitors coming through the Administration Lobby will be given a "Visitor's Tag" and will be escorted into the Tier 1 or Tier 2 areas for the purpose of the visit.

Persons doing business with administrative offices need not sign in if they do not enter the laboratory testing or office areas. In general, no member of the public is permitted to enter the MNPD-CL operational or restricted areas unless accompanied by MNPD-CL personnel.

d) Security during (non)operational hours:

The MNPD-CL is monitored during vacant hours by an intrusion alarm which sounds if forced entry is made. In addition, Madison Police Precinct is located on the first floor of the MNPD-CL building and Precinct personnel work 24/7 shift assignments.

Cameras are set up to monitor the interior and exterior of the MNPD-CL at all times. During vacant hours, the cameras will alert MNPD-CL management of an intrusion.

Appendix A Alert Notification Procedures

e) Devices that grant access:

The MNPD-CL restricts physical access to the interior of the MNPD-CL through the use of proximity card readers. Hard keys can be used to manually open locks on doors without proximity card readers. Doors with proximity card readers may be opened with a hard key only in emergency situations. Proximity key card restricted areas will alarm when accessed by using a hard key. Assignments of hard keys are determined by the Laboratory Director and are used to facilitate the opening of rooms with key access only. Proximity key cards are to be used in all other situations.

A secure, password-protected, card key controlled key box with access to emergency master keys is located in the central hallway in the MNPD-CL. As authorized by the Laboratory Director and/or the FSD Director , MNPD-CL management has access to the secured key box and specific hard keys.

Proximity cards are issued through MNPD-Facility Security.

Hard keys are issued by Metro General Services. All hard keys are numerically stamped or engraved and may describe the doors or evidence lockers/cabinets they open and to whom they are assigned.

The Quality Manager has a locked box containing labeled Unit lock box keys or codes and administration area keys. Unit Supervisors/TLs have a locked box containing labeled copies of hard keys assigned to individuals as well as to evidence lockers/cabinets in their Unit.

When an MNPD-CL employee's assignment is terminated, his/her exterior and interior keys/cards will be returned to their Supervisor before the end of the last day of assignment.

In the event that an MNPD-CL staff member loses his/her key card, the lost key card will be reported immediately to an MNPD-CL Unit Supervisor/TL. The Unit Supervisor/TL will inform

the Laboratory Director and the lost key card will be removed from the computer system as soon possible. A report of the lost key card's access log for the period since it was last in the staff member's possession to deactivation will be generated to determine whether or not any unauthorized access was gained using the lost key card.

If a hard key is lost or found, it must be reported immediately to an MNPD-CL Unit Supervisor/TL. The area(s) to be re-keyed will be at the discretion of Management. Any other lost interior keys such as evidence storage cabinets must be reported to an MNPD-CL Unit Supervisor/TL without delay, and a decision on re-keying will be made. In addition, an MNPD Incident Report will be completed reporting the lost key/card key and the employee will be responsible for the cost of the new key. Any key card replacement or deactivations will be coordinated through the Facility Security Section at Headquarters.

6.3.5(I) When the MNPD-CL performs laboratory activities at sites or facilities outside its permanent control, it will ensure that the requirements related to facilities and environmental conditions of this document are met.

The MNPD-CL does not routinely perform laboratory activities at sites or facilities outside its permanent control. In situations where this may occur, such as in situations where personnel work from home, particular care will be taken to ensure that the requirements related to standards as stated in this document are met where applicable. Evidence and equipment will not be permitted to be removed from the permanent facility to perform laboratory activities.

6.4 Equipment

6.4.1(I) The MNPD-CL has 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.

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.

6.4.2(I) When the MNPD-CL uses equipment outside its permanent control, it will ensure that the requirements for equipment of this document are met.

The MNPD-CL has not and currently does not use equipment outside its permanent control.

6.4.3(I) The MNPD-CL has a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

Handling: Equipment will be handled according to manufacturer's recommendation and/or according to scientific literature, whichever is deemed more appropriate by the Unit Supervisor/TL.

Transport: The MNPD-CL does not transport equipment unless it is related to sending equipment out for calibration services or for repair. In rare instances, equipment may be transported to other locations for training purposes and/or demos. In the event that equipment will need to be transported, appropriate packaging and shipping instructions will be carried out according to vendor/manufacturer's recommendations/specifications. Collaboration with the vendor will be important as it may be necessary for the vendor to package and ship the equipment.

NOTE Equipment that is transported for training purposes and/or demos will be decontaminated prior to and after transport back into the lab. A performance check will be performed and documented prior to being used in any casework related activities.

Storage: Equipment will be stored according to manufacturer's recommendations and/or according to scientific literature, whichever is deemed more appropriate by the Unit Supervisor/TL.

Use and Planned maintenance: References and instructions for the use and planned maintenance of equipment may be found in Unit QMs, TPMs, associated addendums, TTMs, or kept in the Unit ***Equipment*** folder in QMS. Technical support services, manufacturers' websites, and online Help menus may also be utilized.

The MNPD-CL has a procedure for routinely checking the reliability of its equipment (see Unit QMs, TPMs, and/or associated addendums). The reliability testing occurs before use or, if appropriate, concurrent with testing. Such checks will be recorded. The routine recorded use of appropriate controls, in accordance with an approved procedure, is a suitable method to ensure the continued reliability of the equipment.

The procedures for conducting equipment checks and how to record these checks are identified in Unit QMs, TPMs, and/or associated addendums.

6.4.3.1(A) 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.

Records are maintained by the Unit in which the reagent is used.

If the container is too small to be labeled with all of the above elements, then the individual container must, at minimum, be labeled with the identity of the reagent and the proximal container will be labeled with the remainder of the elements.

Reagents normally stored in proximal containers must be labeled according to this standard if it is isolated from the proximal container overnight.

6.4.3.2(A) Reference collections will have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest.

Records of reference collections are fully documented, uniquely identified and properly controlled by each Unit. Control of reference collections may be in the form of limited access to the database, computers, and work and/or storage areas pertaining to the Unit.

6.4.4(I) The MNPD-CL verifies that equipment conforms to specified requirements before being placed or returned into service.

This can be verified through performance checks and/or validations (see **Report Module** in QMS).

6.4.5(I) The equipment used for measurement will be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

This can be checked through performance checks and/or regular calibrations performed by a calibration service provider.

6.4.6(I) Measuring equipment will be calibrated when:

- **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.*

The MNPD-CL will ensure that this requirement apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.

In situations where the calibration of equipment does not have a significant effect on sampling, the test result, or the total uncertainty of the test result, the MNPD-CL has objective evidence to demonstrate the insignificant contribution.

Objective evidence to demonstrate the insignificant contribution may be in uncertainty of measurement data/budget, and/or Unit QMs or TPMs.

6.4.7(I) The MNPD-CL has established a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

The MNPD-CL has a program for the calibration of its reference standards and measuring equipment (see Unit QMs and/or TPMs). Reference standards of measurement held by the MNPD-CL will be used for calibration/performance checks only and for no other purpose. Reference standards and measuring equipment will be calibrated before and after any adjustment.

Calibration of measuring equipment and reference standards will be performed by calibration service providers that can provide traceability.

Review of the individual calibration programs are performed by the Unit Supervisor/TL during document review and are adjusted as necessary in order to maintain confidence in the status of calibration.

Records of calibrations are maintained in the **Documents/Report Module** in QMS.

6.4.7.1(A) The program for the calibration of equipment includes

a) **A list of the equipment requiring calibration;**
   - See **Report Module** in QMS.

b) **Specifications for the calibration laboratory;**
   - Every effort will be made to utilize providers accredited to ISO/IEC 17025, when needed or required, to calibrate MNPD-CL equipment. The MNPD-CL will obtain chemicals and standard solutions utilized for calibration from suppliers with implemented quality systems wherever possible.

c) **Specified requirements for the calibration; and**
   - Specified requirements for calibration of equipment/instrumentation are defined in Unit QMs and/or TPMs.
   - Where Unit QMs or TPMs do not define, the service provider's requirements for the calibration will be met.

d) **The interval of calibration.**
   - In general, calibration check intervals will not be less stringent than manufacturers' recommendations. The interval of calibration is defined in Unit QMs and/or TPMs.

6.4.8(I) All equipment requiring calibration, or which has a defined period of validity will be labelled, coded, or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

This may be achieved through the application of labels on equipment by the vendor or the Unit.

6.4.9(I) Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, will be taken out of service. It will 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 MNPD-CL will examine the effect of the defect or deviation from specified requirements and will initiate the management of nonconforming work procedure (see 7.10).

Verification of correct performance may be done through performance checks.

Examination of the effect of the defect or deviation from specified requirements will be performed and documented in a Quality System Notification report.

6.4.10(I) When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks will be carried out according to a procedure.

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.

Intermediate checks needed to maintain confidence in the performance/calibration status of equipment will be carried out according to procedures (see Unit QMs, TPMs, and/or associated addendums).

Procedures to check calibration of equipment/instrumentation will be established depending on the specific requirements of the testing or analytical work being carried out. It will normally be necessary to check calibration after any shut down, whether deliberate or otherwise, and following service or other substantial maintenance.

If the MNPD-CL Forensic Unit determines that intermediate checks of the calibration status are needed, the procedure will define the frequency of the checks (see Unit QMs, TPMs, and/or associated addendums).

6.4.11(I) When calibration and reference material data include reference values or correction factors, the MNPD-CL ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

Reference values and correction factors are updated and implemented as soon as possible. Specified requirements are described in Unit TPMs.

6.4.12(I) The MNPD-CL will take practicable measures to prevent unintended adjustments of equipment from invalidating results.

Measures may include, but are not limited to, restricted access to the laboratory areas, password protection, prohibiting movement of equipment where such movements could invalidate the calibration, and differentiating administrator permissions from user permissions.

6.4.13(I) Records are retained for equipment which can influence laboratory activities. The records 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;**
  - Unique identification can be in the form of a serial number, an MNPD barcode number, or a name assigned by the Unit.
- **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.**

See the **Report Module** in QMS.

6.5 Metrological traceability

6.5.1(I) The MNPD-CL will 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.

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 ISO/IEC 17025:2017 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. See also ISO/IEC 17025:2017 6.4.6.

The Drug Identification and Toxicology Units alter the traceable measurement value of certified reference materials in the process of creating controls and calibration curves. The equipment used to perform the alterations are evaluated annually by accredited calibration service providers and incorporated in the Unit's uncertainty of measurement evaluation.

This is achieved by using equipment that has been calibrated by calibration service providers that meet the requirements of 6.5.1.1.

The MNPD-CL will obtain chemicals and standard solutions utilized for calibration from suppliers with implemented quality systems wherever possible.

6.5.1.1(A) The MNPD-CL has established and maintained metrological traceability of its measurement results by utilizing products and services from suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials that are:

- **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 purchased 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 purchased 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 be purchased.**

Records of approved suppliers/vendors are maintained in the **Report Module** in QMS.

Records of traceability are maintained in the **Documents/Report Module** in QMS.

6.5.1.2(A) 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 will be confirmed. Objective evidence of the confirmation will be available for review.

Records of objective evidence are maintained in QMS.

6.5.1.3(A) 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 of the related requirements in ISO/IEC 17025 and this document are met:

- **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.**

The MNPD-CL does not perform its own calibrations.

The MNPD-CL does perform checks on the calibration status of measuring equipment where the calibration of the equipment has a significant effect on the accuracy or validity of sampling or a test result, or the total uncertainty of the test result. Personnel performing checks on the calibration are trained, competency tested, and authorized to perform the checks through their training program.

6.5.2(I) The MNPD-CL ensures that measurement results are traceable to the International System of Units (SI) through:

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

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

Every effort will be made to utilize providers accredited to ISO/IEC 17025, when needed or required, to calibrate MNPD-CL equipment.

- **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.

Every effort will be made to utilize providers accredited to ISO/IEC 17025 (or 34), when needed or required, to ensure the validity of the test results and/or performance check.

- **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.

Calibration certificates issued by calibration service providers will contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

6.5.3(I) When metrological traceability to the SI units is not technically possible, the MNPD-CL will demonstrate metrological traceability to an appropriate reference, e.g.:

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 above requirements will be requested from the calibration service provider to give a reliable physical or chemical characterization of a material.

When a CRM is used in conjunction with a measuring system for establishing measurement traceability, the measuring system itself will not be subject to the requirements for measurement traceability.

6.6 Externally provided products and services

6.6.1(I) The MNPD-CL ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

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

To the best of the MNPD-CL's ability, the following will be ensured:

- Measurement standards and equipment to be provided by vendors that can demonstrate traceability to the SI Units.
- Consumable materials to be purchased from vendors that can demonstrate an acceptable quality of product for the MNPD-CL's intended usage.
- Reference materials to be purchased from vendors accredited to ISO/IEC 34 or 17034.
    - This is only required if the reference material will be used for quantitative purposes.
- Calibration services to be provided by laboratories accredited to ISO/IEC 17025 with a scope of accreditation that covers the services being requested.
- Testing services to be provided by laboratories accredited to ISO/IEC 17025 with a scope of accreditation that covers the services being requested and approved by the Unit Supervisor/TL. For DNA testing services, the laboratory must also be accredited to the FBI QAS. The MNPD-CL is responsible to the customer for the testing services subcontracted by the MNPD-CL, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.
- Facility maintenance to be provided by MNPD General Services.

- Equipment maintenance to be provided by the original vendor/manufacturer or another vendor that can provide the same or better level of service.
- Proficiency testing to be provided by organizations accredited to ISO/IEC 17043.
- Assessment and auditing services to be provided by organizations that are a signatory of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) multilateral recognition arrangements.

If the above cannot be met by the MNPD-CL and/or the product/service provider, the MNPD-CL will evaluate the available provider for suitability and acceptability.

6.6.2(I) The MNPD-CL has a procedure and retains records for:

a) defining, reviewing, and approving the laboratory's requirements for externally provided products and services;

Requirements for externally provided products/services that affect the quality of the tests are defined in Unit QMs and/or TPMs.

Purchases will be coordinated through the MNPD-CL Business Manager to ensure that MNPD and Metro procurement policies and regulations are followed.

Purchasing documents for items that affect the quality of the tests will contain information describing the product/service ordered. Purchases are reviewed and approved by the Unit Supervisor/TL prior to ordering. Records of meeting these requirements are retained in the **Report Module** in QMS.

Upon receipt, each Unit will review the received product/service to ensure that the requirements are met.

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

Criteria for evaluation: to the best of the MNPD-CL's ability, the MNPD-CL will use external providers of products/services that affect the quality of the tests that, at a minimum, meet the requirements defined in 6.6.1 above.

Criteria for selection: providers of products/services that affect the quality of the tests must be able to meet the technical and quality requirements of the Unit.

Criteria for monitoring of performance: ability to meet the MNPD-CL's requirements for quality, ability to deliver the product/service within an acceptable time frame, and access to technical support. This will be monitored through the regular course of business as these products/services are being utilized. Any deviations from acceptable quality/technical requirements will be brought to the attention of the Unit Supervisor/TL.

Criteria for re-evaluation: where applicable, relevant members of the Management Team will (re)evaluate external providers by reviewing their accreditation or certification status, ability to meet the MNPD-CL's requirements for quality, ability to deliver the product/service within an acceptable time frame, and access to technical support.

A list of the approved vendors is maintained in the **Report Module** in QMS.

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;

This is achieved by not using products/services until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests concerned.

When products/services that affect the quality of tests are received, the Unit will check the product/service to verify compliance with the Unit's specifications defined in the Unit QM and/or TPM. The receiver may initial and date the packing slip as a record of acknowledgement that the product/service was received.

Records of inspection/verification/quality checks/performance checks may be documented on the packing slip and/or Unit specific performance maintenance record. The MNPD-CL Business Manager will maintain the packing slip.

The MNPD-CL will maintain a register of all subcontractors that it uses for tests and a record of the evidence of compliance with ISO/IEC 17025 for the work in question. The register is maintained by the Business Manager and required records pertaining to the subcontractor will be stored in the **Report Module** in QMS.

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

If an issue arises, the MNPD-CL will contact the product/service provider to work on a resolution.

6.6.3(I) The MNPD-CL will communicate its requirements to external providers for:

a) the products and services to be provided;
- This is achieved by completion of Purchase Orders (PO), Invitation to Bid (ITB), or Requests for Proposals (RFP).

b) the acceptance criteria;
- This is achieved by completion of Purchase Orders (PO), Invitation to Bid (ITB), or Requests for Proposals (RFP).

c) competence, including any required qualification of personnel;
- When acquiring products/services through a PO, the Unit Supervisor/TL evaluates the provider to ensure ISO requirements are met as outlined in 6.6.1 above.
- When acquiring products/services through an ITB or RFP, the Unit Supervisor/TL will request vendors to include documents in their proposal to verify they meet ISO requirements.
    - *Note: Verification documents can include, but not limited to, personnel CVs, personnel training records, ISO certificates, examples of prior contracts that were similar in scope and service.*

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.
- This is not applicable to the MNPD-CL.

7 Process requirements

7.1 Review of requests, tenders, and contracts

Request: the process utilized by a customer when seeking testing services from the MNPD-CL.

Tender: the MNPD-CL's response to the customer regarding their request.

Contract: the agreement between the MNPD-CL and the customer.

7.1.1(I) The MNPD-CL has a procedure for the review of requests, tenders, and contracts. The procedure ensures that:

a) the requirements are adequately defined, documented, and understood;
- Information pertaining to the Scope and Services of the MNPD-CL is supplied to customers as requested.
- Roll Call Trainings for MNPD and MNPD-CL provided trainings to customers facilitate in communicating these policies and procedures to ensure understanding.

b) the laboratory has the capability and resources to meet the requirements;
- Items to be considered during review, if appropriate, will include whether or not the MNPD-CL has the capability and resources to meet the requirements, the clarity and/or completeness of the request, and the appropriateness of the request (i.e., appropriate test requested, appropriate evidence item(s) for the request, or appropriate party making the request).

c) where external providers are used, the requirements of 6.6 are applied and the MNPD-CL will advise the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;
- The MNPD-CL will advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.
- This will be accomplished by the Unit Supervisor/TL who has made the arrangement for the subcontracted work.

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.*

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.
- The assigned MNPD-CL analyst will assess the submitted item and use training and experience to choose the appropriate process/method(s) for analysis and use validated and/or approved methods of analysis, as defined in the Unit TPMs. If an item needs analyses by different Units in the MNPD-CL, the involved Unit Supervisors/TLs will evaluate and choose the appropriate course for multi-discipline examinations.

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

General Procedure

Requests for forensic laboratory services are typically submitted to the MNPD-CL through the MNPD form 282 and MPD Form 110. Tenprint service requests are submitted via email through MNPD Form 133. When evidence is collected, it is recorded in the Records Management System (RMS) on MPD form 110 by officers (see ERU SOP).

The MPD form 110 (Property/Evidence Report) is a request for service (by proxy) for latent prints AFIS processing, toxicology, and NIBIN evidence. This initiates the MNPD Evidence Storage Division (ESD) to transport these items to the MNPD-CL.

The MNPD form 282 (Forensic Services Request) is a request for service for Drug Identification, Forensic Biology, and Firearm/Toolmark and Latent Print cases that require direct comparisons. This form is available to all MNPD officers. Approval of service request through the MNPD form 282 initiates ESD to transport these items to the MNPD-CL.

Service requests are reviewed for appropriateness and completeness by the MNPD-CL ERU Supervisor (or designee)prior o approval.

The MNPD-CL will also review any requests that are subcontracted.

Unit Supervisors/TLs may also review the requests for their Unit before assigning cases for processing. Alternatively, designated persons may request cases from the ERU and review at receipt as appropriate.

Urgent service requests

Urgent service requests, requiring MNPD-CL personnel to take immediate action, must be communicated through the FSD and MNPD chain of command with the request and case information documented in the LIMS. Upon approval for rush processing, MNPD-CL procedures will be followed but may require on-call personnel from ESD and the MNPD-CL to facilitate.

Service requests from non-MNPD agencies

Service requests from agencies other than the MNPD must have a proven connection to an MNPD incident. MNPD-CL services for agencies other than MNPD must be approved by the Laboratory Director or FSD Director before submission, with the exception of Tenprint requests which are submitted on an MNPD Form 133. Once approved, an MNPD Officer/Investigator involved with the case will be identified as the liaison and will follow the same process as MNPD requests for MNPD-CL services. An MNPD incident number associated with the case must be used on the MPD form 110 and/or the MNPD form 282 completed by the liaison officer. ESD facilitates requests from these agencies by receiving the evidence and transporting them to the MNPD-CL. For database search requests for latent prints and/or Tenprints, the evidence is generally received digitally via secure email and/or link to shared filed software due to size and/or image quality.

NOTE: Exceptions to this procedure and the requirement for chain of command approval:

- Latent print comparison service requests from law enforcement agencies within Davidson County who were accessing MNPD Latent Print Unit services prior to the incorporation of the Latent Print Unit into the MNPD-CL.
- Tenprint comparison service requests from law enforcement agencies within Davidson County (i.e., Medical Examiner's Office, Davidson County Sheriff's Office) who were accessing MNPD Tenprint Unit services prior to the incorporation of the Tenprint Unit into the MNPD-CL.

The MNPD-CL generally receives and accepts all requests for service as long as the requested service is within the scope of accredited services. However, requests may be rejected if the information on the evidence containers, barcodes, form 110s, and/or form 282s are incomplete or incorrect or the evidence is improperly packaged/sealed. In these situations, the customer will be contacted to correct the submission. Once corrected, the Forensic Unit can then take custody of the items for testing.

Exceptions apply. See ERU SOP.

Procedure for the request to re-examine evidence

Requests to re-examine or re-analyze evidence must be received in writing from the requestor to the MNPD-CL and/or the affected Unit Supervisor/TL. Each request will be evaluated/reviewed by the Unit Supervisor.

In cases where the original analyst is no longer employed at the MNPD-CL and testimony is required, the Unit Supervisor/TL should consider whether the original analyst is available for testimony and whether re-examination/analysis would be appropriate for the case.

If sufficient sample is available and re-examining/analysis does not pose an undue hardship to the MNPD-CL Unit, the request can be accepted, and the procedures and methods approved by the MNPD-CL will be used.

The Unit Supervisor/TL will determine whether re-examination/analysis will cause an undue hardship on the Unit on a case-by-case scenario and may, at minimum, take into account the feasibility, reasonableness, resources, staffing, and caseload status of the MNPD-CL Unit. The affected Unit Supervisor/TL will communicate with the requesting customer regarding the MNPD-CL response to the request to re-examine evidence.

7.1.2(I) The MNPD-CL will inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

The record will be retained as part of the case file.

7.1.3(I) The MNPD-CL does not issue statements of conformity.

7.1.4(I) Any differences between the request or tender and the contract will be resolved before laboratory activities commence. Each contract will be acceptable both to the laboratory and the customer. Deviations requested by the customer will not impact the integrity of the laboratory or the validity of the results.

If a request for service is received by the MNPD-CL in an area outside the scope of forensic examinations, the MNPD-CL will assist in finding appropriate and high-quality forensic services and may assist in arranging for analysis. Some of these areas include: microanalysis (hair, fiber, glass, and paint), shoe and tire track analysis, arson analysis, etc.

If a request for service is received by the MNPD-CL where the request is inconsistent with the evidence submitted, the service selected, or in conflict with the policies and procedures of the MNPD-CL, then the inconsistency must be resolved before laboratory activities commence. The resolution will be documented and filed in LIMS.

The MNPD-CL will select the most appropriate method for analysis. The MNPD-CL retains the right to limit or expand the final scope of analysis to determine which items are tested and which are not. In rare instances where the MNPD-CL has to use a subcontractor as needed, the requesting individual will be notified prior to testing.

Deviations requested by the customer will be evaluated by the MNPD-CL and the impact on the integrity of the laboratory and the validity of the results will be taken into consideration in making a final decision on whether to implement the deviation. The final decision will be agreed upon by the customer before work commences on the evidence. This will be documented in the case file and a formal Deviation Request in QMS.

7.1.5(I) The customer will be informed of any deviation from the contract.

The majority of the MNPD-CL's customers concerns are related to the execution of the contract to obtain testing results. As such, technical deviations may not warrant informing the customer (e.g., extending the run time on an instrument).

The customer will be informed of deviations that may affect the validity/quality/interpretation of the results.

If the request (as stated in the submitted Form 282) is being modified/cancelled, the customer will be notified (if the modification/cancellation was not at the request of the customer) and the reason documented in the Notes section in LIMS. Records of the communication will be retained in the case file.

7.1.6(I) If a contract is amended after work has commenced, the contract review will be repeated, and any amendments will be communicated to all affected personnel.

Amendment of a contract that would require a repeat of the contract review process would include amending the service requested, amending the related individuals, or amending the requested evidence. The original contract will be retained in LIMS. This does not apply to the Tenprint Unit.

After work has commenced, all case related communication and correspondence records pertaining to subsequent reviews of service requests are maintained as part of the case file in LIMS/Foray. Communication records may include the date the communication occurred, the individuals involved in the correspondence, and a narrative summarizing the nature of the communication and can be in the form of emails or phone conversations.

7.1.7(I) The MNPD-CL will 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.

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.

General questions about MNPD-CL services, service requests from outside of the MNPD, and other enquiries are typically answered through an email address, crimelab@nashville.gov. This e-mail address

is communicated to customers through the MNPD. A log of the enquiries is maintained by the FSD Administrative Assistant or designee.

When evidence has been received for testing, communication may be necessary. If a customer's service request is not clear or there are questions about the evidence received, the Unit Supervisor/TL or assigned analyst will contact the customer or the appropriate representative to clarify the customer's request and communicate the MNPD-CL's abilities and limitations (scope and validated methods).

Monitoring of work by individuals not assigned to the MNPD-CL is not permitted except by court order, at which time the MNPD-CL will communicate with the requestor to make reasonable accommodations.

7.1.8(I) Records of reviews, including any significant changes, will be retained. Records will also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

Records of reviews of the request, pertinent discussions with a customer related to the request, and results of the testing will be retained in LIMS/Foray.

Approvals of service requests indicate that the reviews have been completed. This is typically done by including a date of approval in the name of the file. Approved requests are placed in a folder on the server to signify to the Forensic Units that a service request was approved. Approved service requests will then be entered into LIMS.

7.1.9(A) The extent of database (e.g., DNA profiles, friction ridge, ballistics, biometrics) searches will be communicated to customers and updated as needed.

NOTE 1 "extent" will be specific to the database but may include aspects of the scope or range of the search (e.g., local, state, national, international), the frequency of the search or if the customer is required to make a request to elevate the scope of the search or to have a search performed.

NOTE 2 This may be communicated on a case-by-case basis, in the report, or in a general customer communication.

Table 9: Database searches

Database	Method of communication
CODIS	Official Forensic Biology Reports and/or Official Forensic Biology CODIS Reports via LIMS
AFIS	Preliminary Latent Status ARMS weblink and Official Latent Examination Reports where applicable AFIS leads are communicated via AFIS Notification Reports via LIMS
NIBIN	NIBIN leads are communicated via email
All	Roll Call Trainings for MNPD Other communication methods as necessary

7.2 Selection, verification, and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1(I) The MNPD-CL uses 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.

NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

Appropriate methods and procedures are those that are valid, generally acceptable and practiced by the forensic science community, validated, performance checked, and/or peer reviewed.

Methods and procedures are addressed in Unit TPMs and associated addendums. These may include procedures for sampling, handling, transport, storage, and preparation of items to be tested, data interpretation, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data.

7.2.1.1.1(A) The MNPD-CL uses appropriate methods and procedures for all associated data analysis and interpretation.

See Unit TPMs and associated addendums.

7.2.1.1.2(A) 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).

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

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

Methods are addressed in Unit TPMs and associated addendums.

7.2.1.1.3(A) The MNPD-CL does not perform calibrations.

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

The MNPD-CL has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, where the absence of such instructions could jeopardize the results of tests. These instructions are stored in the **Document Module** in QMS and/or at/near the area of operation where a computer terminal is not readily available.

Reference data relevant to the laboratory activities are also readily available to personnel and kept up to date by the respective providers. These include, but are not limited to NIST Mass Spectral library, Sciex Spectral library, SWGDRUG Mass Spectral library, SWGDRUG IR library, Cayman Chemical Spectral library, Wiley Mass Spectral library, MNPD-CL library, and TBI library.

7.2.1.3(I) The MNPD-CL ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method will be supplemented with additional details to ensure consistent application.

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.

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

Reputable technical organizations: IAI, AFTE, SWGDAM, etc.

By submitting the MNPD form 282, the customer acknowledges the following:

> The Metropolitan Nashville Police Department - Crime Lab (MNPD-CL) will select the most appropriate method for analysis using the MNPD-CL technical procedure manuals. The MNPD-CL retains the right to limit or expand the final scope of analysis to determine which items are tested and which are not. In rare instances where the MNPD-CL has to use a subcontractor as needed, the requesting individual will be notified prior to testing.

The MNPD-CL uses test methods, including methods for sampling, which meet the needs of the customer, and which are appropriate for the tests it undertakes.

Laboratory-developed methods or methods adopted by the MNPD-CL may also be used if they are appropriate for the intended use and if they are validated.

7.2.1.5(I) The MNPD-CL verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification will be repeated to the extent necessary.

New methods used on new equipment will follow a method validation process.

Records are retained in the **Report** and **Document Modules** in QMS.

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

Modifications to the development plan will be approved and authorized by the Unit Supervisor/TL in collaboration with the Quality Manager. Records of laboratory-developed methods are maintained in the **Document** or **Report Module**s in QMS.

7.2.1.7(I) Deviations from methods for all laboratory activities will occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

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

Deviation requests should be filed before the deviation from the method/procedure, whether technical or administrative, is performed. It is understandable that there are certain deviations from methods/procedures where the decision must be made immediately due to the time sensitive nature of the process. Approval must then be acquired from the Unit Supervisor/TL prior to proceeding. In best case scenarios, approval should be acquired from both the Unit Supervisor/TL and the Quality Manager in order for the deviation to be sustained.

Except in instances of a time sensitive nature, if approval from the Unit Supervisor/TL is not obtained prior to the execution of a deviation, it will result in a Quality System Notification.

The majority of the MNPD-CL's customers concerns are related to the execution of the contract to obtain testing results. As such, some technical deviations may not warrant informing the customer (e.g., extending the run time on an instrument).

The MNPD form 282 also contains the following statement or similar language:

> "By submitting the MNPD form 282, I acknowledge the following:
> The Metropolitan Nashville Police Department - Crime Lab (MNPD-CL) will select the most appropriate method for analysis using the MNPD-CL technical procedure manuals. The MNPD-CL retains the right to limit or expand the final scope of analysis to determine which items are tested and which are not. In rare instances where the MNPD-CL has to use a subcontractor as needed, the requesting individual will be notified prior to testing. Please e-mail crimelab@nashville.gov or call 615-880-1200 for further information."

7.2.2 Validation of methods

7.2.2.1(I) The MNPD-CL will validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation will be as extensive as is necessary to meet the needs of the given application or field of application.

NOTE 1 Validation can include procedures for sampling, handling, and transportation of test 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.

7.2.2.1.1(A) Method validation 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.

Procedures for method validations are created and retained in the **Report** and **Document Modules** in QMS.

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

Modifications to a validated method require evaluation to confirm that the changes do not have an adverse effect on the method's performance. The decision regarding which performance characteristics require additional validation is based on logical consideration of the specific parameters likely to be affected by the change(s).

This will be determined by the Unit Supervisor/TL in collaboration with Quality Manager prior to starting the method validation.

NOTE Changes to associated data analysis and interpretation are considered changes to a validated method.

7.2.2.3(I) The performance characteristics of validated methods, as assessed for the intended use, will be relevant to the customers' needs and consistent with specified requirements.

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.

7.2.2.4(I) The MNPD-CL retains the following records of validation:

a) the validation procedure used;
b) specification of the requirements;
c) determination of the performance characteristics (parameter evaluation) of the method;
d) results obtained;
e) a statement on the validity of the method (parameter acceptance), detailing its fitness for the intended use.

See **Document** and **Report Modules** in QMS.

7.3 Sampling

7.3.1(I) The MNPD-CL has a sampling plan and method when it carries out sampling of substances, materials, or products for subsequent testing. The sampling method addresses the factors to be controlled to ensure the validity of subsequent testing results. The sampling plan and method are available at the site where sampling is undertaken. Sampling plans are, whenever reasonable, based on appropriate statistical methods.

See Drug Identification Unit TPM

Every effort will be made to conserve evidence during the analytical process. However, it may be necessary to consume the entire evidence item in order to perform a complete analysis. If an item is consumed/altered/destroyed in analysis, notation will be made in the case file to indicate that no sample remains for additional analysis. The process of sampling of forensic items submitted to the MNPD-CL is unique for each Forensic Unit (see appropriate Unit TPMs or Forensic Biology Quality Manual for further policy and procedure).

7.3.2(I) The sampling method describes:

- **a) the selection of samples or sites;**
- **b) the sampling plan;**
  1) Statistical sampling at a stated level of confidence is used if an inference will be made to report on the whole population.
- **c) the preparation and treatment of sample(s) from a substance, material, or product to yield the required item for subsequent testing.**

NOTE 1 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.

See Drug Identification Unit TPM

7.3.3(I) The MNPD-CL retains records of sampling data that forms part of the testing that is undertaken. These records 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.**
  - The Unit Supervisor/TL must be notified prior to testing and approve any deviations.
  - These will be recorded in detail with the appropriate sampling data and will be included in all documents/reports containing test results and will be communicated to the appropriate personnel.

Records of sampling data that forms part of the testing (a – g) undertaken are retained in the case file. The statistics that the sampling procedures are based upon will be included, where appropriate.

Records of deviation requests are retained in the **Report Module** in QMS.

7.4 Handling of test items

7.4.1(I) The MNPD-CL has a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test items, including all provisions necessary to protect the integrity of the test item, and to protect the interests of the laboratory and the customer. Precautions are taken to avoid deterioration, contamination, loss, or damage to the item during handling, transporting, storing/waiting, and preparation for testing. Handling instructions provided with the item will be followed.

Transport

Evidence items are transported to and from the MNPD-CL and ESD by ESD personnel.

MNPD-CL personnel do not normally transport evidence to and from court except for latent lifts. In the rare instance that evidence is required to be removed from the laboratory by MNPD-CL staff, the following procedure will be followed:

- A request from the case analyst will be sent through the Crime Laboratory Chain of command including the case information, reason for removal, final destination, and approximate time the evidence will be outside the laboratory. The Quality Manager will also be notified.
- If approved, the evidence will be scanned to the analyst prior to removal from the laboratory. A note will be made in the case record to document the purpose of the evidence removal. The request approval will also be uploaded into the case record.
- Unit safety procedures will be followed while the evidence is outside of the laboratory.
    - If drug evidence is being removed, the analysts will bring required PPE to include gloves, NARCAN, and face respirator(s) at a minimum.

NOTE A sworn escort should be considered when transporting drug evidence.

- The evidence will remain in the analyst's possession at all times while it is outside of the laboratory.
- When the evidence is returned to the laboratory, it will be inspected by the analyst and ERU staff to ensure that it is properly sealed, and the integrity has been maintained.
- The evidence will then be scanned back to the appropriate storage location.

In the event that evidence needs to be shipped, it will be packaged in a manner that safeguards the integrity and quality of the evidence. The shipping method will include tracking. Records will be stored in LIMS.

Receipt

See the ERU SOP for detailed procedures on receipt of test items. Generally, test items are received from ESD. Exceptions to this may include: rush cases, officer involved shootings, evidence from a partnering

law enforcement agency, etc. In these instances, evidence may be submitted to the ERU directly via a hand-to-hand transaction or submitted via the evidence lockers outside ERU. (See ERU SOP and relevant Unit Manuals).

Items received by the ERU must be appropriately packaged and properly sealed. Exceptions may apply to items that are shipped.

Where packaging and sealing of test items do not comply with this document, the test items will be returned for remediation where possible. In incidents where returning the test item for remediation is not possible, documentation of the condition of the test item will be made in LIMS and the case file.

Security

Evidence storage areas are secured to prevent theft or interference and there is limited, controlled access. The storage conditions will be such as to prevent loss, deterioration, and contamination and to maintain the integrity and identity of the evidence. This applies both before and after examination/analysis has been performed.

Proper security can be achieved by storing the evidence in locked areas such as cabinets, refrigerators, vaults, or rooms. Evidence storage space may be shared by MNPD-CL personnel. Refrigerators and freezers do not have to be locked if they are maintained in rooms and/or areas which are secure and restricted.

Evidence storage areas in the Evidence Receiving area and each of the Forensic Units have floor to ceiling concrete block construction with proximity card access limited to the individuals assigned to the Unit. Each evidence vault is designed with storage systems, refrigeration, and/or appropriate climate control to prevent loss, deterioration, or contamination and to maintain the integrity and identity of the evidence.

The MNPD-CL is a secure facility where video surveillance, electronic key cards, and hard keys are used to provide limited access to areas of the MNPD-CL. The MNPD-CL also provides different conditions for evidence storage which are utilized on an as needed basis. All evidence storage areas are secured to protect the integrity of the item.

If motion is detected in evidence storage areas during the active times listed in **Table 18**, an e-mail alert is generated to the Laboratory Director and the relevant Unit Supervisor (see Alert Notification Procedures).

See Unit QMs and/or TPMs for details on handling, protection, storage, retention, and disposal or return of test items. Generally, test items are to be handled with care to ensure that the integrity and quality of the test item is not affected.

7.4.1.1(A) For all test items received except known origin individual characteristic database samples, the procedure:

- **a) addresses requirements for storage, packaging, and sealing of items to:**
  - **1) protect the integrity of all items; and**
    - The MNPD-CL generally does not permanently store or retain evidence at its facility (unless in the Latent Print Unit or Tenprint Unit). Evidence waiting for testing is initially stored in the ERU evidence vaults. Temporary storage locations are available in each Unit for storage of evidence that is in the process of being tested. Evidence

where testing has been completed will be returned to ESD (exceptions are in the Latent Print, Tenprint, and Toxicology Unit; see Unit TPMs). Special storage, retention and/or disposal procedures specific to the Units are written in Unit QMs and/or TPMs. Secure evidence storage rooms/vaults are present in each Unit for evidence which has been checked out of the ERU. Secure ERU vaults are in a central area in the laboratory.

- Items are packaged in appropriate containers to protect the integrity of the items and to prevent loss/deterioration/contamination/damage. These may be in the original containers received upon submission to ERU, proximal containers to contain overflowing items, plastic/paper/cardboard containers, etc. Selection of the type of packaging material is at the discretion of personnel handling the items and is determined on a case-by-case basis.
- The MNPD-CL will ensure that evidence accepted and stored in the MNPD-CL is properly sealed. The initial observation is done on receipt at the ERU (See ERU SOP). Evidence in the ERU will remain sealed at all times.
- All evidence not in the process of examination/analysis will be maintained in a secured, limited-access storage area, properly sealed.
  - *Exception: when the evidence seal is not conducive to marking, where the markings may be difficult to detect, the area directly above/below the seal will contain the date and initials of the individual applying the seal.*
  - *Exception: items fully sealed with either tamper proof evidence tape or packing tape, where unauthorized access to the contents of the container would be noticeable, may be accepted when received through the mail.*
  - *Exception: items in the process of being tested may not be properly sealed or fully sealed (sealed without date/initials on or across the seal) as long as the integrity of the evidence is maintained using measures such as temporary/convenience seals and/or increased secured/limited access to the evidence (e.g., locked screening room).*

2) require items to be re-sealed as soon as practicable;

- Items will be re-sealed with tamper proof evidence tape and/or packing tape as soon as practicable, with the initials of the person applying the seal to be placed over the seal, after the requested testing is completed.
- Evidence such as fingerprints and projectiles in unsolved cases that are subject to frequent requests for comparison may be treated as "evidence in the process of examination/analysis" and may be stored unsealed or with a temporary/convenience seal in a secure limited access area for up to one year.

b) addresses measures to be taken to secure unattended items;

- When items are unattended, they must be in a secure environment. Items may remain in an individual's custody for a period of time, as stated in the Unit QMs and/or TPM, while in the process of examination/analysis and are considered under the individual's care and control. The time period for when evidence is under the care and control of an individual is based upon a justifiable expectation of frequent examination/analysis (see Unit QMs and/or TPMs and ERU SOP).
- In general, laboratory work areas have locking cabinets or drawers, individually keyed, for storage of evidence which is in process. Each Unit's evidence storage room/vault also has lockable areas within (see Unit QMs and/or TPMs for discipline specific procedures).
- All evidence in the process of examination/analysis is stored appropriately in the respective Unit's temporary storage locations, however named, prior to the end of business day each

day. Once examination/analysis is complete, the evidence is returned to a more permanent storage location.

c) requires chain-of-custody for:

1) all items received; and

- The MNPD-CL chain of custody will begin at the time the evidence is received into the laboratory at the ERU and will be maintained to the eventual disposition of the evidence (either destroyed or relocated from the MNPD-CL). The exception to this is the Tenprint Unit, which does not receive evidence from ERU but via secure email.
- Forensic Biology, Firearms/Toolmarks and Drug Identification Unit's evidence will be tracked through return to the main MNPD evidence facility (ESD).
- Toxicology Unit evidence (blood tubes) will be tracked and securely maintained in sealed condition until destruction (See Toxicology TPM).
- Tenprint Unit evidence will be tracked using secured email and DIMS (Foray) and stored on the L Drive. If hardcopies are submitted, they will be returned to the requesting officer and/or Records Center.
- Latent Print Unit evidence will be tracked and securely maintained in temporary sealed or properly sealed condition in the long-term Latent Print vault. Older archived evidence may be stored in a secured off-site storage facility (See Latent Print TPM - Administrative Processing and Storage of Latent Evidence).
  - Exemplars submitted as evidence with 282 requests are returned upon completion of examination.

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

- Test fires are tracked in LIMS
- The Latent Print Unit does not create items
- DNA extracts are tracked in LIMS
- When evidence is subdivided in the laboratory, sub-items will be tracked through a documented chain of custody record to the same extent that original items of evidence are tracked.

d) requires chain-of-custody to securely and accurately identify:

1) the individual(s) or location(s) receiving or transferring the item(s); and

2) the item(s) being transferred; and

3) the chronological order of all transfers, including the date;

- Chain of custody records are maintained in the LIMS with the exception of the Tenprint Unit, which will be maintained in DIMS (Foray). The MNPD-CL uses the chain of custody as documentation to show that the evidence examined and reported on was that which was submitted to the MNPD-CL.

e) requires communication to the customer regarding the disposition of all items received; and

- Disposition of items received by the MNPD-CL may be communicated through test reports and/or notifications.

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

- Items created and preserved for future testing by the MNPD-CL may be communicated to the customer through test reports and/or notifications.

NOTE 1 c) An item being tracked could contain multiple components and be tracked as one item.

NOTE 2 d)1) Documentation of internal transfers does not need to include use of personal storage locations.

7.4.2(I) The MNPD-CL has a system for the unambiguous identification of test items. The identification will be retained while the item is under the responsibility of the laboratory. The system ensures that items will not be confused physically or when referred to in records or other documents. The system will, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

Each item of evidence is marked for identification in such a manner as to ensure that it is uniquely identifiable and traceable to the unique case number. If the evidence does not lend itself to marking, its proximal container or identifying tag will be marked.

The system accommodates all sub-divided items or groups of items including transfer of items.

7.4.2.1(A) The system used to identify items covers all items received.

The MNPD-CL uses JusticeTrax as its LIMS provider. Tenprint uses Foray as its DIMS provider and the L Drive as its document repository.

7.4.3(I) Upon receipt of the test item, deviations from specified conditions will be recorded. When there is doubt about the suitability of an item for test, or when an item does not conform to the description provided, the MNPD-CL will consult the customer for further instructions before proceeding and will record the results of this consultation. When the customer requires the item to be tested acknowledging a deviation from specified conditions, the laboratory will include a disclaimer in the report indicating which results may be affected by the deviation.

If an analyst receives an item that is different than what is described in the request, the description of the received evidence will be documented in the technical records. Communication to clarify the discrepancy will be initiated if there is substantial difference between the submitted and received item. Work will not commence on this item until the discrepancy has been resolved. If there are additional items of evidence in the case, the processing of the remainder of the case may proceed as the discrepancy is being clarified. Communications will be retained in the case file.

If an analyst determines that a submitted item of evidence may need additional processing or testing from another MNPD-CL Forensic Unit, the examiner will notify their Unit Supervisor/TL that a multi-discipline examination or process may be required. The affected Unit Supervisors/TLs will evaluate and choose the appropriate course such that all aspects of the chain of custody are recorded for the evidence, and the applicable technical procedures for processing or testing of the evidence are followed and documented. Communication between disciplines and/or with the customer related to multi-discipline examinations will be documented in the case record.

If the **submission contains more than one item** as described by the evidence description (e.g., evidence description indicates “victim’s clothing” and the container contains a shirt, socks, and pants), each item will be sub-itemized as child items of the parent, repackaged/resealed after analysis, and returned in the original packaging. The report will identify the sub-items.

If the **submission contains money (any amount), jewelry/valuables, or narcotics** (inadvertently packaged with non-narcotic evidence), the analyst will sub-item, package, and return the evidence separately to ERU. The analyst will also notify ESD personnel and the requesting customer.

7.4.4(I) When items need to be stored or conditioned under specified environmental conditions, these conditions will be maintained, monitored and recorded.

Special environmental conditions specific to the Units are written in the Unit TPMs or Forensic Biology Quality Manual. Records of monitoring of special conditions are maintained in the **Reports Module** in QMS.

7.5 Technical records

7.5.1(I) The MNPD-CL ensures 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. The technical records will include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations will be recorded at the time they are made and will be identifiable with the specific task.

NOTE Options for recording observations include, but are not limited to: written notes, photography, drawing, photocopying, or scanning.

Technical records will be traceable to a unique test record identifier.

If electronically recorded examination documentation is printed, the unique identifier for that case must be on each page of the printed documentation. If the documentation is maintained in electronic form only, the unique identifier must appear visibly on a screen related to the document.

The unique identifier for each case for which data was generated will be appropriately recorded on the printout when data from multiple cases is recorded on a single printout.

When examination records are prepared by an individual(s) other than the analyst (however named) who interprets the findings, prepares the test report, and/or testifies concerning the records, the handwritten initials (or secure electronic equivalent of initials or signature) of that individual(s) will be on the page(s) of examination records representing his/her work. The case records are to be clear as to who performed all stages of the examination/analysis.

> *Exception: Initials or signatures may not be on each page of examination records as long as they are traceable to the task performed and observations on those pages.*

The electronic equivalent of handwritten initials or signature is acceptable when the Unit can demonstrate that the electronic signature is secure and can only be applied by the individual whom the electronic initials or signature represent.

When examination records (handwritten or electronic) are recorded on both sides of a page, each side will be treated (identified and initialed) as a separate page.

When examination records consist of multiple pages, a page numbering system indicating total number of pages is used (e.g., page X of Y) or a method of identifying a series of pages and the last page may be employed.

7.5.1.1(A) Define the technical record(s) to be retained if all related technical records are not retained.

All technical records generated prior to and during testing are maintained in the related case file. Technical records that also constitute quality records are maintained in QMS.

7.5.1.2(A) Where abbreviations or symbols specific to the MNPD-CL are used, the meaning of the abbreviations or symbols will be defined.

See Unit QMs, TPMs, or associated addendums.

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

Example of ways to record the basis for conclusions derived from evidence examination/analysis, include, but are not limited to: a narrative description of the examination/analysis process and observations made, photographs, photocopies, diagrams, drawings, and/or worksheets.

7.5.1.4(A) Records will be created or maintained in a permanent manner.

NOTE For example, technical records originally captured in pencil (e.g., a rough sketch) can be maintained in a permanent manner by photocopying, scanning, or taking a photo.

Handwritten notes and observations are made in ink.

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

The record of the rejection, reason, date, and individual rejecting the observation, data, or test result can be recorded in LIMS, within the case file, and/or on the technical/administrative review forms.

7.5.1.6(A) 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)

This is not applicable to the MNPD-CL.

7.5.2(I) The MNPD-CL ensures that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files will be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

NOTE Contemporaneous revisions are not considered amendments.

When mistakes occur in records, each mistake will be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations (i.e., corrections of mistakes and changes made to existing hardcopy examination records) to records will be signed or initialed (or electronic equivalent) by the person making the correction or change. In the case of records stored electronically, equivalent measures will be taken to avoid loss or change of original data. Handwritten records will be scanned into the case file.

All changes made to technical records as a result of verification or technical review are tracked to the extent where sufficient information to determine who made the changes, when, and what was changed.

7.6 Evaluation of measurement uncertainty

7.6.1(I) The MNPD-CL will identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, will be taken into account using appropriate methods of analysis.

7.6.1.1(A) The method of analysis for evaluation of measurement uncertainty:

a) **requires 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) **includes the process of rounding the expanded uncertainty;**
c) **requires the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and**
d) **Specifies the schedule to review and/or recalculate the measurement uncertainty.**

See Unit QMs and/or TPMs.

7.6.2(I) The MNPD-CL does not perform calibrations.

7.6.3(I) The MNPD-CL performs testing and will evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation will 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 Unit QMs and/or TPMs.

Units whose reports include measurements of uncertainty will attempt to identify all the components of uncertainty and make a reasonable estimation and will ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation will also be based on the measurement scope and will make use of, for example, previous experience and validation data.

7.6.3.1(A) Measurement uncertainty will 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 Unit QMs and/or TPMs.

7.6.4(A) 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 **Document Module** in QMS and Unit QMs and/or TPMs.

7.7 Ensuring the validity of results

7.7.1(I) The MNPD-CL has a procedure for monitoring the validity of results. The resulting data will be recorded in such a way that trends are detectable and, where practicable, statistical techniques will be applied to review the results. This monitoring will be planned and reviewed and will include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;
- Where applicable, the MNPD-CL performs testing on positive and/or negative controls prior to or concurrently with evidence to ensure the validity of the tests undertaken. Reference materials are also used in creating calibration curves etc. (see Unit QMs and/or TPMs)

b) use of alternative instrumentation that has been calibrated to provide traceable results;
- This method is not utilized.

c) functional check(s) of measuring and testing equipment;
- See Unit QMs and/or TPMs
- *Example: running positive/negative controls and blanks; balance checks; AFIS performance checks; instrument tuning*
- Records will be retained in the case file and/or QMS.

d) use of check or working standards with control charts, where applicable;
- See Unit QMs and/or TPMs
- *Example: calibration/standard curves*
- Records will be retained in the case file and/or QMS.

e) intermediate checks on measuring equipment;
- See Unit QMs and/or TPMs
- *Example: regular maintenance/performance checks (balances, calipers, micrometers, etc.)*
- Records will be retained in QMS.

f) replicate tests using the same or different methods;
- Replicate tests are performed using the same or different methods in the Drug Identification Unit, Toxicology Unit, and the Forensic Biology Unit where applicable (see Unit QMs and/or TPMs).
- *Example: AP test and p30 test; (2) alcohol extractions; combination of category A/B/C techniques*

- Records of replicate tests are retained in the case file.

g) retesting of retained items;

- Due to the limited quantity of evidence, retesting of retained items is typically not practiced.

1. (A) 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 will be made and the record will identify who performed the verification, when it was performed, and the result of the verification;

- Records of verification are retained in the case file.

c) the resolution of any discrepancy will be recorded.

- Resolutions of discrepancy are recorded and retained in the case file.

h) correlation of results for different characteristics of an item;

- Correlation of results for different characteristics of an item can be practiced in the Drug Identification Unit and the Forensic Biology Unit where applicable (see Unit QMs and/or TPMs).
- *Example: AP test and p30 test; combination of category A/B/C techniques*
- Records of correlations are retained in the case file.

i) review of reported results;

- Results reported by the MNPD-CL are reviewed. See 7.7.1.(l).3 below.

j) intralaboratory comparisons;

- Intralaboratory comparisons are conducted when proficiency tests are created and taken internally for functions such as test firing or when proficiency tests are not submitted to the test provider.
- Records of intralaboratory comparisons are retained in QMS. See **Report Module**.

k) testing of blind sample(s); and

- The MNPD-CL does not test blind samples.

l) there is a procedure for the technical review of technical records, including reports, and testimony. The procedure:

1. requires the individual performing the technical review to have been competency tested to perform the testing work that is being reviewed;

- Technical reviewers are competency tested and authorized by appropriate MNPD-CL management based on expertise gained through training and casework experience in the tasks being reviewed. In addition, the reviewer will have knowledge of the MNPD-CL's technical procedures.

2. precludes an individual from technically reviewing their own work;

- This is ensured through the LIMS system where the author cannot set the Technical Review milestone.

3. defines the process to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;

- 100% of case files (technical records and test reports) undergo technical review in Drug Identification, Forensic Biology, and Toxicology.
- 100% of Official Tenprint reports, Official Latent Print Examination Reports, and AFIS Notifications undergo technical review.
- A minimum of 10% of Admin Processing requests with no associated AFIS Notifications undergo technical review. *
- 100% of Official Firearms Reports and NIBIN Notifications with leads undergo technical review.
- 100% of NIBIN Notifications without leads undergo technical review.

- **Annual internal audits check to ensure that the minimum percentage has been reviewed.*

4. **defines the process to be used to ensure testimony in each discipline is reviewed;**
   - Testimony in each discipline will be reviewed by a technically competent reviewer at least once per calendar year.
   - It is the responsibility of Unit Supervisor/TL to ensure that testimony has been observed and reviewed in their Unit, provided that personnel in the Unit have testified.
   - As time and personnel availability permit, the first discipline testimony of the calendar year should be technically reviewed.
5. **defines the process to be used to conduct and record the review;**
   - Technical reviews of technical records and test reports are conducted in accordance with the Unit QMs and/or TPMs. Records of technical review are retained in the case file.
   - Another qualified or previously qualified analyst, Management, or attorney who was present for the testimony may perform the review. However, only reviews performed by technically competent personnel may count towards meeting this requirement. It is encouraged that reviews conducted by non-technically competent personnel continue for good practice and to monitor for impartiality.
   - Technical reviews of testimony are typically conducted in-person. The observation and review should be documented using the Court Testimony Observation Form (MPD Form 283) if evaluated by a non-MNPD-CL employee or in QMS if evaluated by a MNPD-CL employee (see **Report Module**). It is acceptable for Management to contact an attorney by telephone to document the review.
   - The analyst must be given feedback regarding his/her testimony, both positive and in any area needing improvement.
   - If a problem is noted with an analyst's testimony, the Unit Supervisor/TL will take appropriate action and notify the Quality Manager and Director.
6. **ensures that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record;**
   - This is achieved during verification/technical review.
7. **ensures conformance with methods and applicable management system documents; and**
   - This is achieved during technical review.
8. **describes a course of action to be taken if a discrepancy is found.**
   - Discrepancy is defined as a lack of agreement between the forensic scientist/technician and the technical reviewer or verifier regarding the scientific conclusions reached, analytical methods used, requirements of the MNPD-CL management system, accrediting body's accreditation program, or applicable DNA Quality Assurance Standards. The forensic scientist/technician and technical reviewer or verifier bears the responsibility to resolve any instances where there is lack of agreement to the satisfaction of both individuals.
   - If a discrepancy or needed correction is identified, the reviewer will select the option to 'Reject Findings' in LIMS and describe the discrepancy or needed correction citing the reference to policy (if applicable) in the 'Reviewer Notes' for the request.

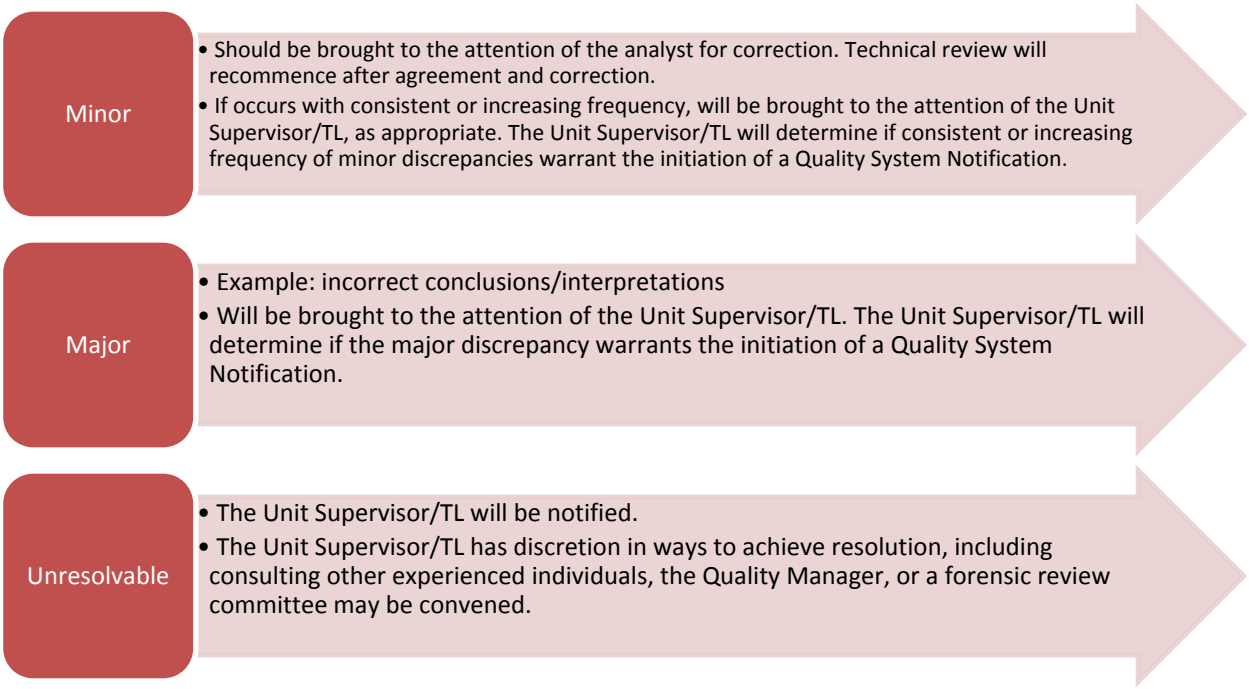

Figure 1: Types of discrepancies

- Should the Unit Supervisor/TL be an involved party, the Quality Manager, and/or the Laboratory Director will be involved in seeking to achieve resolution.
- Records of discrepancies are retained in the case file and/or QMS.
- Forensic Review Committee (FRC):*
    - Should the parties be unable to resolve the discrepancy, the Laboratory Director may authorize the formation of an FRC. The formation of a FRC may be requested by the concerned forensic scientist/technician, the reviewer, or Unit Supervisor/TL. The Laboratory Director will make a final decision after consideration of the Quality Manager ,Unit Supervisor/TL, and Committee's recommendations.
    - The FRC will be established by the Quality Manager. Other members may be included depending on the particulars of the case circumstances and will be selected by the Director and Quality Manager. All records related to the resolution of the discrepancy will be maintained, including those of the FRC.
    - **Exceptions may apply in the Forensic Biology Unit where the authority of the DNA Technical Leader is as documented in the FBI QAS.*

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 1a) See requirements of 6.2.6 in ISO/IEC 17025:2017.

NOTE 2 An individual who performs a verification can also perform a technical review.

NOTE 2b) Verification may be recorded for each result verified or as a summary for all results verified.

NOTE 3 The frequency may vary for different disciplines.

7.7.2(I) The MNPD-CL monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned and reviewed and includes, but not be limited to, either or both of the following:

a) **participation in proficiency testing;**

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.

The MNPD-CL participates in several proficiency testing programs throughout the year.

b) **participation in interlaboratory comparisons other than proficiency testing.**
   - The MNPD-CL participates in interlaboratory comparisons through submitting results to the proficiency test provider.

7.7.2.1(A) The MNPD-CL'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**
   - This was achieved in March of 2015 when accreditation was granted for the first time.

b) **demonstrate successful performance in at least one proficiency test or an approved alternative means of interlaboratory comparison for each accredited discipline per calendar year at each location.**
   - The MNPD-CL is not part of a laboratory system where there are multiple locations.

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 the calendar year, evaluation of successful performance can occur in the subsequent calendar year.

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

Records of the review of quality control data will be documented and maintained in the case file or QMS, where appropriate.

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

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 be testing and are subject to these requirements.

NOTE 3 For performance monitoring conducted at the end of one calendar year, evaluation of successful performance can occur in the subsequent calendar year.

Internal proficiency tests may include internally created practical tests, previously worked or older unworked commercially provided practical tests, testing reanalysis, or observation-based tests.

The MNPD-CL performs observation-based monitoring in the Firearms/Toolmarks and Latent Print Units as it relates to Test firing/NIBIN and Admin processing/AFIS respectively.

Individuals who solely perform testing but do not issue reports or solely acting as a report author must also be proficiency tested to this capacity.

The MNPD-CL may also participate in pre-distribution testing with the proficiency test provider. Personnel participating in pre-distribution testing may choose not to participate in the actual test provided that they are the same test.

If an individual misses a required proficiency test due to prolonged absence, temporary reassignment, or other management approved circumstance, that individual must successfully complete a proficiency test or another approved qualifying test to demonstrate competency prior to resuming independent casework.

Table 10: Proficiency test schedule/plan

<table>
<tr><th>Forensic Unit Component</th><th>Personnel</th><th>Proficiency test frequency and minimum requirements</th></tr>
<tr><td>Drug ID
Qualitative Determination,
Quantitative Analysis,
Weight measurement</td><td>Supervisor/TL
Scientists</td><td>
<table>
<tr><th></th><th>Test type</th><th>Test takers</th></tr>
<tr><td>1st half</td><td>Controlled substance</td><td>~Half staff</td></tr>
<tr><td>2nd half</td><td>Controlled substance</td><td>~Half staff</td></tr>
<tr><td>Q3</td><td>THC quantitation</td><td>All staff</td></tr>
</table>
• Minimum: 1 test/year/person
• At least 1 test for the discipline will be submitted externally; the rest can be internal
</td></tr>
<tr><td>Forensic Biology
DNA STR</td><td>Supervisor/TL
Scientists
Technicians</td><td>
<table>
<tr><th></th><th>Test type</th><th>Test takers</th></tr>
<tr><td>1st half</td><td>Serology-DNA</td><td>All staff</td></tr>
<tr><td>2nd half</td><td>DNA-Semen</td><td>All staff</td></tr>
</table>
• Minimum: 2 tests/year/person for staff with DNA authorization
• Minimum: 1 test/year/person for staff with ONLY serology authorization
• All tests are submitted externally
*Technicians do not perform DNA interpretation
</td></tr>
<tr><td>Forensic Biology
CODIS</td><td>Supervisor/TL
Scientists</td><td>• 1 test/year/person
• Part of Annual NDIS Eligibility through FBI</td></tr>
<tr><td>Forensic Biology
Body Fluid ID</td><td>Scientists
Technicians</td><td>
<table>
<tr><th></th><th>Test type</th><th>Test takers</th></tr>
<tr><td>1st half</td><td>BFI</td><td>Relevant staff</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Forensic Unit Component</th><th>Personnel</th><th>Proficiency test frequency and minimum requirements</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td>2nd half</td><td>BFI</td><td>Relevant staff</td></tr>
</table>
• Minimum: 1 test/year/person
• All tests are submitted externally
</td></tr>
<tr><td>Firearms/Toolmarks
Firearms examination, SNR, Distance Determination, NIBIN, Collection, Determination of Functionality, Length Measurement, Product Determination</td><td>Supervisor/TL
Scientists</td><td>
<table>
<tr><th>Year</th><th>Qtr</th><th>Test type</th><th>Test takers</th></tr>
<tr><td rowspan="4">Odd</td><td>Q1</td><td>Observation*</td><td>All staff</td></tr>
<tr><td>Q2</td><td>Firearms examination</td><td>~Half staff</td></tr>
<tr><td>Q4</td><td>Firearms examination</td><td>~Half staff</td></tr>
<tr><td>Q4</td><td>Toolmark examination</td><td>All staff</td></tr>
<tr><td rowspan="4">Even</td><td>Q2</td><td>Distance</td><td>All staff</td></tr>
<tr><td>Q2</td><td>Firearms examination</td><td>~Half staff</td></tr>
<tr><td>Q3</td><td>Serial # restoration</td><td>All staff</td></tr>
<tr><td>Q4</td><td>Firearms examination</td><td>~Half staff</td></tr>
</table>
• Minimum: 1 test/year/person
• At least 1 test for the discipline will be submitted externally; the rest can be internal
Observation-based evaluation to include NIBIN, Collection, Determination of Functionality, Length Measurement, and Product Determination
</td></tr>
<tr><td>Firearms/Toolmarks
NIBIN</td><td>Technicians</td><td>• 1st half of the year
• 1 test/year/person
*Observation-based evaluation</td></tr>
<tr><td>Latent Print
Enhancement, Physical Comparison</td><td>Supervisor/TL
Scientists</td><td>
<table>
<tr><th></th><th>Test type</th><th>Test takers</th></tr>
<tr><td>1st half</td><td>Latent Print Examination</td><td>~Half staff</td></tr>
<tr><td>2nd half</td><td>Latent Print Examination</td><td>~Half staff</td></tr>
</table>
• 1 test/year/person
• At least 1 test for the discipline will be submitted externally; the rest can be internal
</td></tr>
<tr><td>Latent Print
AFIS</td><td>Supervisor/TL
Scientists</td><td>• 2nd half of the year
• 1 test/person
• Odd years
*Observation-based evaluation</td></tr>
<tr><td>Latent Print
AFIS</td><td>Technicians</td><td>• 2nd half of the year
• 1 test/year/person
*Observation-based evaluation
**Enhancement and Physical Comparison incorporated in Observation-based evaluation</td></tr>
<tr><td>Tenprint</td><td>Supervisor
Technicians</td><td>• 1 test/year/person
• At least 1 test for the discipline will be submitted externally; the rest can be internal</td></tr>
<tr><td>Toxicology
Qualitative Determination, Quantitative Determination</td><td>Supervisor/TL
Scientists</td><td>
<table>
<tr><th>Qtr</th><th>Test type</th><th>Test takers</th></tr>
<tr><td>Q1</td><td>Blood alcohol</td><td>All staff</td></tr>
</table>
• Minimum: 1 test/year/person
• At least 1 test for the discipline will be submitted externally; the rest can be internal
</td></tr>
</table>

7.7.5(A) The process for monitoring the performance of the laboratory and personnel shall:

a) ensure that results are not known or readily available to the participant being monitored;
- Tests are created by individual(s) other than the test taker.
- Test results obtained after the results have been made readily available will be disqualified. The test taker will need to take another proficiency test to meet the standard.

b) ensure use of approved methods by the individual(s) whose performance is being monitored;
- See Unit TPMs.

c) establish criteria for successful performance prior to the monitoring activity being conducted;

Table 11: Proficiency test evaluation criteria

Type of test	Evaluation criteria
Commercially provided	Based on manufacturer's information and/or consensus summary reports to account for the potential for sample degradation
Internally generated	Based on ground truth established by the test creator
Observation-based evaluations	Based on the appropriate application of the Forensic Unit's policies and procedures

- Evaluation criteria/results are documented through the **Workflow Module** in QMS that also includes evaluating whether conclusions of inclusion (identification), exclusion, and/or inconclusion are appropriate and supported.

d) require a mechanism to ensure the quality of the monitoring activity prior to personnel performance being monitored;
- Internally created/previously used proficiency tests are created/issued by the Unit Supervisor/TL or designee who is responsible for ensuring the quality of the test created.
- Tests that are conducted via the Observation-based method will be chosen at random and assessed on a case-by-case basis. Evaluators will be qualified and competent in the tasks being evaluated and are either a Forensic Scientist or a Unit Supervisor/TL who is authorized to perform Technical Reviews.

e) The MNPD-CL does not perform calibrations.

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 result 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.

7.7.6(A) The laboratory shall have a performance monitoring plan that:

a) demonstrates conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4; and

See Table 10

b) ensures inclusion of a portion of the components/parameters and equipment/technologies within each accredited discipline.

Where applicable, DNA analysts and technical support personnel (technicians) performing DNA analysis will comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories.

Note: Proficiency tests may test a specific job-related skill or skills but does not have to test all aspects of an employee's job function. The MNPD-CL varies the design/distribution of proficiency tests so that over one accreditation cycle an employee is tested on all aspects of the assigned job functions. See Table 10.

7.7.7(A) To satisfy the proficiency test or interlaboratory comparison requirements in clauses 7.7.2.1.a) and b), the MNPD-CL 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 on its scope of accreditation; 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 an alternative means of interlaboratory comparison** (FM 3041 Alternative Proficiency Test Request Form)

NOTE d) 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.

7.7.8(A) The following records shall be retained for all performance monitoring of the laboratory and its personnel:

- **a) discipline(s) monitored;**
- **b) design of the monitoring activity (how test was obtained or created);**
- **c) expected results;**
- **d) location, when more than one location is associated with a single accreditation certificate;**
  - The MNPD-CL is not part of a laboratory system where there are multiple locations.
- **e) records submitted to a proficiency test provider, if applicable;**
- **f) appropriate technical records;**
- **g) evaluation of results and action taken for unexpected results; and**
  - Depending on the unexpected results obtained, an investigation into the nonconformity may be initiated.
  - Evaluation of results and actions taken for unexpected results should occur no later than one month from when the test results are released by the Quality Manager. In the case of observation-based evaluations, the evaluation should occur no later than one month from when the test was conducted.
- **h) feedback on individual performance provided to the participant.**
  - Feedback is provided to the test participant by the Unit Supervisor/TL. This is recorded through the **Workflow Module** in QMS.
  - Feedback should be provided to the test taker no later than two weeks from when the Unit Supervisor/TL receives the test results from the Quality Manager.

7.8 Reporting of results

7.8.1 General

7.8.1.1(I) The results will be reviewed and authorized prior to release.

Results are reviewed and authorized by the report author (individual signing the report).

7.8.1.1.1(A) The authorizer of results will review the technical record and document the review.

This may be in the form of verification/technical review forms, indication on each page of technical record reviewed, milestones set in LIMS, or other similar formats.

7.8.1.2(I) The results will be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g., a test report or report of sampling), and will include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports will be retained as technical records.

NOTE 1 For the purposes of this document, test reports are sometimes referred to as test certificates.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.8.1.2.1(A) The results will be provided in a written report or through electronic access.

Electronic access of a written report may be through I-Results, RMS, or through secure email.

Official reports are normally disseminated to the customer via the iResults system with the exception of Tenprint which sends reports through encrypted email. If the iResults system is not available for use, or when reports or other case records are requested by telephone, facsimile, or other electronic means, the individual providing the documentation will adhere to the following:

- Ensure that the requesting party is an appropriate party to make the request
- Ensure that the report and case file has been technically and administratively reviewed
- Ensure that the documentation will be going to the proper destination (i.e., verify fax number, e-mail address, etc.)
- Ensure that the documentation is encrypted if sending via e-mail (to agencies other than MNPD, DA's Office, Public Defender, partnering Law Enforcement Agencies)
- Ensure the report is being released to an authorized customer

The MNPD-CL ensures these measures are in place when using LIMS to directly send reports through the iResults system. LIMS starts the process by e-mailing the authorized customer that a report is ready to be viewed. E-mail addresses for customers are from the MNPD active directory or manually entered by the LIMS Administrator. Customers must log into iResults to view the report.

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

7.8.1.2.2(A) There is 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 partial work performed;

Type of item	What will be reported
Items received and tested	Test results obtained
Items received by ERU but not Forensic Unit	Not reported
Items received by Forensic Unit but not tested	Reported as not processed/analyzed or similar phrasing
Items collected/created and preserved for future testing	Reported as collected/created and preserved or similar phrasing
Partial work performed	Test results obtained In the event that reporting a result where only partial testing was able to be completed, and the report could be misleading to the customer, the reporting author will indicate in the report the reason for not reporting a test result (e.g., insufficient quality or quantity of sample, data not meeting quality requirements, etc.) A result of "inconclusion" or similar phrasing may also be used.

All analytical work must have a corresponding test report generated unless one of the following applies:

- If a case is adjudicated before the work or report is completed
- If a customer cancels a request before work is completed
- Or similar situation

Documentation in the case file will record the reason test results were not reported. Data from analytical testing that do not meet MNPD-CL quality standards, where testing cannot be redone, will not be used to draw a scientific conclusion and will be identified in the final report. A result of "inconclusion" or similar phrasing may also be used.

b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement;
- See Unit QMs or TPMs.

c) requires communicating the reason(s) in the report when the reported results are inconclusive; and
- See Unit QMs or TPMs.

d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics).
- CODIS: reported through Official Forensic Biology Reports and/or Official Forensic Biology CODIS Reports.
- AFIS: reported using MNPD weblink and/or Official Latent Examination Reports.
- NIBIN: reported using NIBIN Notifications.

NOTE 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.

7.8.1.2.3(A) The MNPD-CL does not perform calibrations.

7.8.1.3(I) 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 will be readily available.

Simplified reporting exists in the following:

- MNPD Preliminary Latent Status: searchable results issued through the MNPD weblink, which is a mechanism used to securely release information pertaining to database searches to internal customers.
- Official Firearms Examination Reports
- Official Forensic Biology Reports
- Official Drug ID Reports

7.8.1.3.1(A) When results are reported in a simplified way, the agreement with the customer will specify which information in 7.8.2 through 7.8.7 of ISO/IEC 17025:2017 will not be included in a written report or through electronic access. The requirements 7.8.2 through 7.8.7 in this document are applicable even if the MNPD-CL reports results in a simplified way.

See **Document Module** in QMS for a copy of the effective customer agreement.

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

7.8.2.1(I) Each report includes at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

a) a title (e.g., "Test Report" 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 (such as a serial number or case identifier) that all its components are recognized as a portion of a complete report and a clear identification of the end (i.e., analyst only signs the last page, page x of y, etc.);
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;
- If evidence is received in a manner that compromises its integrity (i.e., unsealed, leaking, cross contamination with other evidence items, etc.) then a notation of its condition will be placed on the final report.

h) the date of receipt of the test item(s), and the date of sampling, where this is critical to the validity and application of the results;
- the date of receipt of test item(s) is not critical to the validity and application of results.

i) the date(s) of performance of the laboratory activity;
- The date range will be from the examination start date to when the report is administratively reviewed.

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 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;
- The person authorizing the report is the last individual signing the report.

p) clear identification when results are from external providers.
- When the test report contains results of tests performed by subcontractors, these results will be clearly identified. The subcontractor will report the results in writing or electronically directly to the MNPD-CL. The MNPD-CL will issue a copy of the report, if applicable, to the customer.
- Approval will be obtained from the subcontractor's report or certificate.

NOTE 1 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 test.

NOTE 4 o) Authorization of the report does not have to be performed by the same person(s) who authorized the results.

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

The MNPD-CL is responsible for all of the data generated, results, and conclusions reported. All items are provided to the MNPD-CL by the customer along with information necessary to perform testing; but information supplied by the customer will not be used in arriving at results/conclusions. Results and conclusions are independent of and are not affected by the information provided by the customer.

7.8.3 Specific requirements for test reports

7.8.3.1(I) In addition to the requirements listed in 7.8.2, test reports will, where necessary for the interpretation of the test results, include the following:

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);
- The MNPD-CL does not issue statements of conformity.

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;**

1. **(A) 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;**
      - Uncertainty may be reported as a fraction if the measurement is expressed as a fraction
   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.**
      - Examples:
        - 2.3 ng/mL ± 0.35 becomes 0.4 ng/mL
        - 425 ng/ml ± 42.7 becomes 43 ng/mL
        - 850 ng/mL ± 125.2 becomes 125 ng/mL

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.

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.

7.8.3.1.1(A) 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 MNPD-CL shall:

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.

The format for reporting of a result is not specified by a regulatory body, statute, case law or other legal requirement.

7.8.3.2(I) Where the MNPD-CL is responsible for the sampling activity, test reports will meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

The MNPD-CL is not responsible for the sampling activity that occurs outside of its permanent facility.

7.8.4 Specific requirements for calibration certificates

The MNPD-CL does not perform calibrations.

The MNPD-CL may use this standard to assess calibration service providers to ensure compliance to these standards.

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 will include the following, where necessary for the interpretation of results:

- **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;**
  1. **(A) If statistical sampling is used, the report will contain the confidence level and corresponding inference 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.**

7.8.6 Reporting statements of conformity

The MNPD-CL does not issue statements of conformity.

7.8.7 Reporting opinions and interpretations

7.8.7.1(I) When opinions and interpretations are expressed, the MNPD-CL ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory will document the basis upon which the opinions and interpretations have been made.

See **Report Module** in QMS for personnel authorizations.

The basis upon which opinions and interpretations are made are documented in the case files.

7.8.7.2(I) The opinions and interpretations expressed in reports will be based on the results obtained from the tested item and will be clearly identified as such.

These are clearly marked as such in test reports.

7.8.7.3(I) When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue will be retained.

If a justifiable request is received to release verbal results prior to full case review, the requesting party must be informed that any results, conclusions and opinions are not final and may be revised following all final reviews. This communication must be documented in the case file.

When opinions and interpretations are communicated during testimony, the courtroom transcript will serve as the record of the communication to the customer.

When opinions and interpretations are communicated by telephone, a summary will be documented in the casefile.

Information communicated that can be found in the case file and/or report does not need to be documented in this manner as this information is readily accessible.

7.8.8 Amendments to reports

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

Identification of changes to issued reports are included in the report under the "Amended Notes" section.

Issued reports will not be amended if the original report author is no longer an employee of the MNPD-CL. If necessary to provide the customer with accurate technical information, a new report will be issued by a new author following all reporting policies and procedures of this standard.

7.8.8.2(I) Amendments to a report after issue will 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 will meet all the requirements of this document.

When amending test reports, the following task is completed when using LIMS:

1. The original administratively reviewed test report must be saved and imaged into LIMS to preserve the original test report. The nomenclature for naming the file is: DATE ORIGINAL REQUEST TYPE REQ # (e.g., 2018-07-18 Original Toxicology Request 0005) or similar.
2. Right click on the request in question and select "Cancel Report Releasable," which returns the report to the review stage in LIMS.
3. Click on "Set Milestones" and uncheck one milestone at a time to get back to "Findings Entered."
4. Amend the test report.
5. In the "Additional Data" field, set the Amended Report flag, including the "Original Report Date," and describe the reason for the amendment in the "Additional amend statement" field.

The amended report is released when milestones are reset by technical and administrative reviewers.

Note: Unless unique and justifiable circumstances arise, amending of test reports must be performed by the original author, and the technical and administrative reviews must be performed by the original reviewers. Actions performed by individuals other than the original set of individuals who took part in releasing the original report must have an accompanying memorandum of record to explain the variance, and verification/technical review/administrative review will need to be re-performed.

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

Amended reports will be identified with red markings and reference the original in the following manner:

"This report reflects amendments to the report previously released on DATE OF ORIGINAL REPORT."

7.9 Complaints

7.9.1(I) The MNPD-CL has a documented process to receive, evaluate and make decisions on complaints.

The MNPD has a documented process to receive, evaluate and make decisions on complaints that allege infractions of MNPD policy. That process is described in the MNPD Manual (located on PDWeb). In addition, the MNPD-CL has a documented process to receive, evaluate, and make decisions on complaints that are specific to MNPD-CL laboratory activities (i.e., Quality System Notifications).

7.9.2(I) A description of the handling process for complaints will be available to any interested party on request. Upon receipt of a complaint, the MNPD-CL will confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, will deal with it. The MNPD-CL will be responsible for all decisions at all levels of the handling process for complaints.

The process for handling complaints is available on the MNPD's website. Upon receipt of a complaint, the MNPD-CL will confirm whether the complaint relates to laboratory activities and/or MNPD policy. MNPD-CL management will determine if the complaint is addressed by either or both processes.

7.9.3(I) The process for handling complaints that are specific to MNPD-CL activities includes at least the following elements and methods:

a) **description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;**
   - When a customer or other party has a complaint (including quality related issues by the MNPD-CL employees), the complainant will be asked to submit the complaint in written form. Complaints may be received from various avenues, for example, customer surveys, court testimony reviews, telephonic or electronic message, inter-laboratory communication, etc. If a complaint is received by voice communication only, the person who received the complaint will make a written record of the complaint.
   - The process for the validation of the complaint involves research into the incident, starting with interviews with related individuals and the process, if applicable.
   - The investigation of the complaint will be managed/conducted by Management and an appropriate course of action planned and executed.
   - If the investigation reveals that a founded complaint is related to quality/operations, a Quality System Notification will be initiated, and procedures followed to remediate the cause of the complaint.

b) **tracking and recording complaints, including actions undertaken to resolve them;**
   - Complaints will be tracked through the **Workflow Module** in QMS and/or through the process outlined in the MNPD Manual, whichever is more appropriate.
   - Records of complaints involving the quality system, results of the investigations and any corrective actions taken will be maintained by the Quality Manager in QMS (see **Report Module**). Records of complaints involving infractions of MNPD policy will be maintained in accordance with the MNPD Manual.

c) **ensuring that any appropriate action is taken.**
   - Management will ensure that appropriate actions are taken.

7.9.4(I) The MNPD-CL will be responsible for gathering and verifying all necessary information to validate the complaint.

This will be conducted by Management.

7.9.5(I) Whenever possible, the MNPD-CL will acknowledge receipt of the complaint and provide the complainant with progress reports and the outcome.

This will be accomplished through written communication and MNPD Manual procedures will be adhered to.

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

NOTE This can be performed by external personnel.

Outcomes will generally be communicated by the Laboratory Director unless the complaint is related to the Laboratory Director. In that case, individual(s) not involved in the complaint will communicate the outcome to the complainant.

7.9.7(I) Whenever possible, the MNPD-CL will give formal notice of the end of the complaint handling to the complainant.

This will be accomplished through written communication and MNPD Manual procedures will be adhered to.

7.10 Nonconforming work

7.10.1(I) The MNPD-CL has a procedure that will 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). The procedure ensures that:

a) **the responsibilities and authorities for the management of nonconforming work are defined;**
   - All MNPD-CL employees have the responsibility and authority to submit a report of nonconforming work through the **Workflow Module** in QMS.
   - The Quality Manager has the responsibility and authority to manage nonconforming work (see ***Functional Job Descriptions*** stored in the **Document Module** in QMS).

b) **actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;**
   - Once identified, appropriate corrective action is taken immediately to remedy the nonconforming work.
   - The Unit Supervisor/TL is responsible for ensuring that correction to the nonconforming work is taken without delay.
   - Actions taken in response to nonconformity will vary depending on the nonconforming work.
     - *Examples: general discussion of all nonconformities in a laboratory-wide quality meeting, documented verbal and/or written counsel, email reminders/notifications, halting of work for all or some procedures or some individuals*.
   - Halting or repeating of work and withholding of reports is the decision of the affected Unit Supervisor/TL in conjunction with the Quality Manager, and/or Laboratory Director.

    - The Forensic Biology TL has the authority to initiate, suspend and resume DNA analytical operations for the Forensic Biology Unit or an individual in the Forensic Biology Unit.
  - If casework is suspended due to nonconforming work, the Unit Supervisor/TL, Quality Manager, and Laboratory Director will be notified immediately.

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

- An evaluation of the significance of the nonconforming work is made for each case by the Unit Supervisor/TL in collaboration with the Quality Manager and/or appropriate level of management.
- Nonconforming work (Quality System Notifications) may be categorized as any of the below three types. Certain incidents may involve more than one category.
    1. Technical nonconformance
    2. Administrative nonconformance
    3. SKA (skills, knowledge, abilities) nonconformance
    4. Quality System nonconformance
    5. Other
- The corrective action process will be initiated when
    - a Quality System Notification demonstrates that there is a fundamental impact on the quality of the work product or integrity of the evidence,
    - the incident raises an immediate concern regarding the quality/reliability of the MNPD-CL's or analyst's work, and/or
    - there is a concern that continuation of the nonconforming work for an extended period of time may negatively affect the work product or integrity of the evidence.
    - Systemic incidents and incidents that continue to recur may also undergo the corrective action process.

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

- This will be documented in written form and retained in the **Report Module** in QMS.

f) the responsibility for authorizing the resumption of work is defined.

- The Unit Supervisor/TL in conjunction with the Quality Manager has the responsibility for authorizing the resumption of work.
- In the Forensic Biology Unit, only the Forensic Biology TL can authorize resumption of DNA casework, although s/he must still keep the Director and Quality Manager informed.

7.10.2(I) The MNPD-CL retains records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

See **Report Module** in QMS.

7.10.3(I) Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the MNPD-CL's operations with its own management system, the MNPD-CL will implement corrective action.

Through evaluation of a nonconformance, it can be determined that the source of the nonconforming work may be related to a procedure, protocol, individual, equipment or material, identifying a need for reviews and/or modifications.

Nonconformances are assessed by the Unit Supervisor/TL and/or Quality Manager with the process being managed by the Quality Manager.

Identification

Nonconformances may be identified in a variety of ways, including, but not limited to, self-reporting Quality System Notifications,quality assurance controls, technical or administrative review, proficiency testing, audits (internal or external), management reviews, case file reviews, observation, courtroom testimony monitoring, complaints, and any other quality assurance programs the MNPD-CL employs.

On a daily basis, ways to determine if an event must be documented in QMS include but are not limited to the following:

- Anything that results in an amended report (technical or administrative)
    - E.g., findings/conclusions were reported and released that contain incorrect information
        - *Note: Correction of notes and reports prior to being released will generally not be considered Quality System Notifications if caught prior to or during technical/administrative review*
        - *Note: Amended reports which result from circumstances outside of the Crime Laboratory's control (e.g., incorrect agency/complaint numbers) will be documented in the Matter of Record workflow in QMS and will not rise to a Quality System Notification.*
- Any violation of written policies and procedures that cannot be corrected administratively
    - E.g., deviation from procedure without prior documented approval via Deviation Request Workflow
    - E.g., missing performance check dates (acceptable length of time elapsed will be instrument/equipment dependent based on the potential impact, which are Unit dependent)
- Incidents that result in or are related to sample switching
    - E.g., mislabeling/reporting incorrect description of evidence or samples, incorrect entry into LIMS – description, barcode, etc.
- Evidence related and/or Chain of custody issues when the integrity of the evidence may be affected
    - E.g., missing transfers or documentation of transfers that were not detected until the report has been released
    - E.g., improper sealing/storage/handling/preservation of evidence
- For the purposes of tracking repetitive events
    - E.g., persistent errors in identifications/associations/eliminations/exclusions
    - E.g., missing errors/mistakes during reviews
- Actions resulting in unnecessary consumption of additional evidence
    - E.g., using expired reagents where the reagents are no longer effective
    - E.g., proceeding with failed controls

In cases where nonconforming work is identified, management's emphasis will be on correcting the issue and improving and alleviating the issue as efficiently and effectively as possible.

It is important to note that the above are just some common examples and is not an exhaustive list of incidents that would result in a Quality System Notification. One of the core objectives of the quality management system is to provide quality forensic science services to the people of Metropolitan Nashville and Davidson County. As such, incidents that do not conform to good laboratory practice, good

quality practice, or good forensic science practice may also be considered as Quality System Notifications. These incidents will be evaluated on a case-by-case basis between the relevant Unit Supervisor/TL and the Quality Manager.

Review

The Quality System Notification will be reviewed for effectiveness, if applicable.

This entire process will be documented in QMS through the **Workflow Modules**.

Reporting

All identified nonconforming incidents must be reported and submitted to the Quality Manager for review and evaluation through the **Workflow Module** in QMS.

7.11 Control of data and information management

7.11.1(I) The MNPD-CL has access to the data and information needed to perform laboratory activities.

The MNPD-CL has and issues updated Unit QMs, TPMs, and/or associated addendums that are needed to perform laboratory activities.

Additional data and information are also available in journal subscriptions and literature library housed in each Unit.

Data and information needed to support testing may also be provided by the customer on an as needed basis.

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

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.

The MNPD-CL has not and currently does not utilize information management systems outside of its designed application range.

Changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are authorized by the IT Manager. These changes are documented in the **Workflow Module** in QMS.

The following are electronic laboratory information management systems used for collection, processing, recording, reporting, storage, and retrieval of data.

- Pdlabedpr03 (L:)
- Pdlabrppr01 (JusticeTrax LIMS)
- Pdlabwbpr01 (JusticeTrax iResults)
- Pdappqtpr01 (QMS Prod)
- Pdappqtts01 (QMS Test)
- Pdappdmpr01 (Adams Foray)

7.11.2.1(A) There will be a plan for validation of computer software developed by the user and records of the validation shall be retained.

The MNPD-CL does not develop its own computer software.

7.11.3(I) The laboratory information management system(s) will:

a) be protected from unauthorized access;
- Access to LIMS is only available to MNPD-CL personnel and MNPD IT and requires password entry for access. Personnel only have access to information relevant to their function.
- Access to work areas where data may be accessed are limited and controlled through IT related permissions, usernames and/or passwords

b) be safeguarded against tampering and loss;
- All systems have tiered permission levels managed by System Administrators to safeguard 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;
- Information systems in the MNPD-CL are in suitable environments. These are typically maintained by the Unit in collaboration with the IT Manager where applicable

d) be maintained in a manner that ensures the integrity of the data and information;
- Information systems are maintained by System Administrators and MNPD IT, where modifications and changes to data and information are strictly controlled through tiered permission levels and are password protected. In addition, certain information systems contain audit trails to track alterations.

e) include recording system failures and the appropriate immediate and corrective actions.
- These are reported to the IT Manager who records them in the **Workflow Module** in QMS.

7.11.4(I) When a laboratory information management system is managed and maintained off-site or through an external provider, the MNPD-CL ensures that the provider or operator of the system complies with all applicable requirements of this document.

Servers are managed and maintained off-site by MNPD IT, who have been advised of these requirements.

The MNPD-CL does not have systems maintained through an external provider.

7.11.5(I) The MNPD-CL ensures that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

See the **Document Module** in QMS or instructions at/near the area of operation where a computer terminal is not readily available.

7.11.6(I) Calculations and data transfers will be checked in an appropriate and systematic manner.

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

This is accomplished and documented during the technical review process.

7.11.6.1(A) 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.

NOTE This check may be part of a technical review.

8 Management system requirements

8.1 Options

8.1.1 General

The MNPD-CL has established, documented, implemented and maintains 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 MNPD-CL implements a management system in accordance with Option A or Option B.

NOTE See Annex B for more information.

See Unit QMs, TPMs, TTMs, and associated addendums.

The MNPD-CL implements a management system in accordance with Option A.

8.1.2 Option A

As a minimum, the management system of the MNPD-CL addresses the following:

- **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).**

8.1.3 Option B

Option B is not applicable to the MNPD-CL.

8.2 Management system documentation (Option A)

8.2.1(I) MNPD-CL management has established, documented, and maintains policies and objectives for the fulfilment of the purposes of this document and ensures that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

See Unit TPMs, associated addendums, and Quality Manuals.

The MNPD-CL requires that all personnel involved with the quality system and laboratory activities within the MNPD-CL familiarize themselves with the quality documentation and implement the policies and procedures in their work.

Acknowledgment of policies and objectives are documented through completion of tests issued through the **Test Module** in QMS. Except for extenuating circumstances, this should be completed within 1 month of when the policy/procedure is published.

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

8.2.2(I) The policies and objectives address the competence, impartiality and consistent operation of the MNPD-CL.

The MNPD-CL's management system policies related to quality, including a quality policy statement (below), is defined in this manual. The overall objectives are established and are reviewed during management review. The quality policy statement is issued under the authority of the Laboratory Director and Quality Manager.

The Management Team and personnel of the MNPD-CL are committed to:

- competent, good professional laboratory practices, and adherence to the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel, and to the quality of its testing in servicing its customers;
- management's statement of the MNPD-CL's standard of service (MNPD-CL Mission);
- ensuring that the output of the MNPD-CL is consistent and of superior quality.

The main objectives of the management system are as follows:

- To provide quality forensic science services to the people of Metropolitan Nashville and Davidson County through
    - Ensuring that laboratory results provided to customers are reliable and scientifically sound.
    - Establishing formal methods of quality assurance within the MNPD-CL through the implementation of recognized standards for good laboratory and professional practice.
    - Using procedures that are valid, dependable, reproducible, and adequate for the intended purpose.
    - Employing good laboratory, quality, and forensic service practice.
    - Ensuring continued competence of personnel through appropriate continuing education and/or proficiency testing and provide the necessary training for personnel to carry out the provisions of the quality system.
    - Preserving the integrity of evidence.
    - Appropriately maintaining and controlling management system documents and records.
    - Maintaining quality, excellence, and integrity in the activities of the MNPD-CL.
    - Conforming to the requirements of the accrediting body's accreditation program.

8.2.3(I) MNPD-CL management provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

This may be accomplished through discussion at regular management meetings, internal audits, the annual management review, and feedback from ongoing review of quality documents.

All Management Team members are responsible for overseeing, monitoring and ensuring compliance to the Management System in their assigned area, and providing the proper attention and encouragement to all MNPD-CL personnel to continuously improve quality in every area of forensic endeavor. The Management Team is committed to a supportive work environment that fosters open communication, creativity, individual initiative and personal achievement as part of the quality system.

The MNPD-CL is also committed to compliance with ISO/IEC 17025, requirements from the accrediting body, and any applicable FBI Quality Assurance Standards and to continually improve the effectiveness of the management system.

8.2.4(I) All documentation, processes, systems, records, related to the fulfilment of the requirements of this document will be included in, referenced from, or linked to the management system.

The quality manual also outlines the general overall policies and procedures of the management system.

Table 12: Discipline specific manuals

Technical Procedure Manuals (TPM)	Technical Training Manuals (TTM)
Drug Identification	Drug Identification
Drug Identification Instrument and Equipment Procedures Manual	
Latent Print	Latent Prep Team, Latent Print
Firearms and Toolmarks	Firearms and Toolmarks
Firearms and Toolmarks Quality Manual	NIBIN Entry Team
Forensic Biology	Forensic Biology
Forensic Biology Quality Manual	
Tenprint	Tenprint
Toxicology	Toxicology
Toxicology Laboratory Procedures Manual	
Evidence Receiving Unit (SOP)	Evidence Receiving

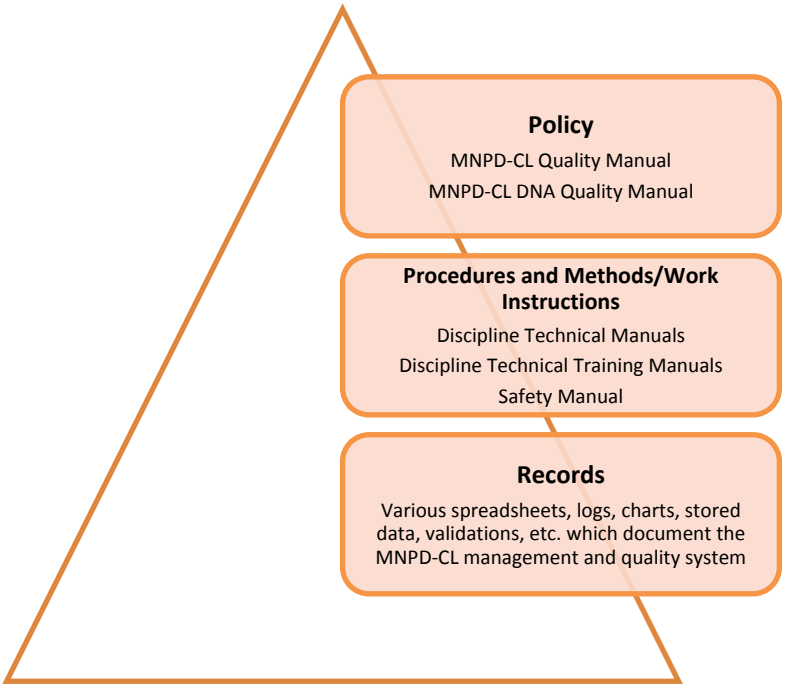

Figure 2: Hierarchy of quality system

Records are retained in LIMS, Foray, QMS, and in MNPD storage servers.

8.2.5(I) All personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

QMs, TPMs, associated addendums, TTMs, and ERU manuals are accessible to every member of MNPD-CL personnel in a "read only" format in the **Document Module** in QMS. This application/software is accessible only to authorized MNPD-CL employees. These are the "controlled" versions and are the official, up-to-date documents for use in the MNPD-CL. Each Unit may use additional documents in its daily operations such as forms or worksheets. These documents also comply to requirements of the management system.

8.3 Control of management system documents (Option A)

8.3.1(I) The MNPD-CL controls the documents (internal and external) that relate to the fulfilment of this document.

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

The document manager in QMS is responsible for ensuring that documents are kept updated on an ongoing basis in order to ensure that the policies and procedures are current and accurate.

Management system documents may include but are not limited to quality manual(s), safety manuals, evidence receiving manuals, TPMs, TTMs, laboratory-wide forms, worksheets, regulations, and equipment manuals, if applicable. Management system documents may be internally generated or from external sources.

Control of Software and Corresponding Documents

If software is used to instruct personnel on how to perform processes, it must be controlled. Three areas where this may occur are with equipment calibration, maintenance and performance checks.

Software is normally used in three ways:

a. to control an instrument,
b. to instruct users on performance of processes, and
c. to analyze data.

Software that only operates an instrument will not to be controlled but will be validated along with the instrument validation.

External software manuals will not be marked with the information that is required for other controlled documents, such as approvals, page numbers, date of issue, etc. This requirement only applies to internally generated controlled documents, which would include internally generated software but not macros developed for off the shelf applications such as Excel, Access, etc.

There is no need to keep copies of externally controlled software in the document control system.

Software will be controlled when Unit QMs, TPMs, or associated addendums contain instructions mandating personnel to follow instructions in the software. When this occurs, the Unit QMs, TPMs,

and/or associated addendums will, at a minimum, specify the current version of the software which users must follow in the SOP for the method. This may require updating with each new version. It is also recommended that instructions that users must follow are written into an approved procedure which is kept updated as a controlled document.

Equipment and software manuals maintained only for general reference purposes are not subject to document control requirements. In this context, "general reference purposes" means that personnel are not required to follow specific procedures or instructions contained in the equipment or software manual.

The MNPD-CL uses the QMS software to provide document control, critical process automation, audit and reporting capabilities to list and maintain controlled documents. This software resides on a secured MNPD server, with regular maintenance and daily back-up.

8.3.2(I) The MNPD-CL ensures that:

a) documents are approved for adequacy prior to issue by authorized personnel;

- QMS facilitates revisions, reviews, approvals and issuing of all operational documents periodically, and as needed to ensure continuing suitability and compliance with applicable requirements.
- Authorities are assigned within QMS which allow certain levels of access to individuals who need to edit, review, approve and/or publish documents. Authorization is given by the Laboratory Director or Quality Manager and is documented in each of the document's properties.
    1. When a controlled document needs to be revised, Editors or Document Managers can follow the below procedure:
        a. Click on the "Edit" option in the gray ribbon and enter in the reason for the edit.
        b. "Check out" the document either manually or using the Auto File Transfer client tool.
        c. If the Auto File Transfer client tool has not been installed, the document can be checked out manually.
    2. The document will now be stored in the user's QMS working folder for the user to access for edits.
    3. Upon completing the revision of the document, users can follow the below procedure:
        a. Go to the document in QMS and click on the "Check in" option in the gray ribbon. The same rules apply for using the Auto File Transfer client tool or manual transfer.
        b. Click on "Release for Approval" if a reviewer is not needed.
        c. Ensure the list of changes that were made to the document are in the available field.
        d. To complete the edit process, click on the blue "Release and approve" button to initiate the chain of approvals for publication.
            i. Option: Select "Release for Review" instead of "Release for Approval" to send the document to a reviewer first. Once the review process has been completed, the user can proceed to either make more amendments or release for approval.

Notes:

- *Do not save the document out as a PDF and then convert to a word document. Doing so will eliminate all built-in formats and macros.*
- *The document name or file extension may not be changed as that would interfere with the checking in process and built-in macros.*
- *The "Replace" function in the gray ribbon is designed to be used seldomly. By not checking out the document when a revision is needed, the user may not be editing the most current revision.*

- A Master Document List is maintained within the **Report Module** in QMS. The list identifies the title of the document, the document identification number, revision number, last published date and other pertinent information.
- Controlled document distribution is accomplished by publishing documents in the **Document Module** in QMS and maintaining a document tree with access control or permissions which allow users access to view pertinent management system documents. Users must use a unique login to perform functions other than viewing documents.
- Documents in the **Document Module** in QMS are the official version of the document. Hard copies printed from QMS are uncontrolled. Printed copies of management documents are designated and labeled as not controlled when printed.

b) documents are periodically reviewed, and updated as necessary;

- Documents are reviewed and updated as necessary for suitability, at minimum, on an annual basis.

c) changes and the current revision status of documents are identified;

- Changes are identified by entering the new or altered text/content in the "changes made" field of the **Document Module** in QMS after editing and prior to release of documents for review and approval. Altered text/content may also be formatted in the document for ease of identification.
- Revisions of quality/management system documents have the new revision number and date displayed and affected MNPD-CL personnel will be notified of the changes in the new revision.

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

- All documents in QMS are readily available in the **Document Module**. Authorized editions of appropriate documents are available on networked computers at all locations where operations essential to the effective functioning of the MNPD-CL are performed. Where networked computers are not available at locations where operations take place, hardcopies of appropriate documents are available.
- The footer of the QMs, TPMs, TTMs, and associated addendums also contain the below statement or similar verbiage:

> *"Printouts of this document may be out of date and considered uncontrolled. To accomplish work, the published version of the document should be viewed online."*

e) documents are uniquely identified;

- Such identification includes the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority.
- The date of issue is the most recent date of approval, which is the date the document becomes effective when published in the **Document Module** in QMS. This occurs after all required approvals are obtained.
- This information is present on the footer.

- Additional unique identifications include the MNPD-CL name and title of the document in the header and a unique Document ID that is assigned to each document by QMS.
- Documents in PDF or Excel format may not have the above statement in (d) but will have equivalent information in the footer.
- Externally generated controlled documents are not required to be marked with the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority. Externally generated controlled documents may be controlled in three different ways:
    1. Externally generated controlled documents uploaded to the **Document Module** in QMS. These are not required to be marked with all of the information required for internally generated controlled documents.
    2. As an inclusion in an internally generated controlled document.
    3. In an appendix/reference listing the externally generated controlled documents used by a discipline, MNPD-CL, or other group. The appendix will be approved as an internally generated controlled document and uploaded to the **Document Module** in QMS. The appendix will reference the document revision for each document or refer to "the latest revision" or similar language.

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

- Invalid and/or obsolete documents are archived or retired so that they are removed from circulation. QMS automatically archives superseded or obsolete documents. Permissions to view retired/archived documents are also controlled.
- The document user who prints or saves copies of controlled documents from the **Document Module** in QMS is responsible for removing them from all points of access when they are superseded by a new revision. Unit Supervisors/TLs should monitor this in their areas of responsibility.
- Retired/archived documents are suitably marked.

8.4 Control of records (Option A)

8.4.1(I) The MNPD-CL has established and retain legible records to demonstrate fulfilment of the requirements in this document.

8.4.2(I) The MNPD-CL has implemented the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory retains records for a period consistent with its contractual obligations. Access to these records will be consistent with the confidentiality commitments, and records will be readily available.

NOTE 1 Additional requirements regarding technical records are given in 7.5.

NOTE 2 Contractual obligations for records retention include legal requirements and customer expectations.

Identification and Indexing

All technical records within the case file are identified with the unique case (or batch) identifier, analyst's initials and page number. The unique case identifier and the identification of the case analyst and other involved analysts must be apparent on each page of the record.

- *Exception: Identification of the case analyst and other involved analysts may not be on each page of technical records if they are traceable to the task performed and observations on those pages (e.g., audit trails).*

The unique case identifier used is the Case number designated in LIMS, except for records in Foray where the unique case identifier is the Agency incident number designated in LIMS under the "Agency" tab.

Quality records are identified by their association to a unique QMS ID. Each document, workflow, field, test, training, report, and person is assigned a unique ID.

Records, whether digital or paper, are designed to be equivalent in the information they contain. Paper records may serve as a contingency or back-up should a digital storage system be temporarily unavailable. When practicable, paper records are scanned into digital form once the issue is resolved.

Collection

Case files are assembled in an electronic format by the analyst assigned to analyze the evidence for their specific discipline. Any handwritten technical records associated with the case will be scanned and included with the case file if practicable. When the analyst has completed testing, LIMS is used to mark the case "draft complete." The case is then sent for technical and administrative review.

Quality records are collected using QMS predominantly through the use of workflows.

Hardcopy case files should only be used when an electronic case file is not possible. Hardcopy case files will be converted into electronic format and stored in LIMS, the L drive, or Foray for the Latent Print Unit, as soon as practicable.

Access and Retrieval

Following technical and administrative review of the case file, the laboratory report is completed and available for dissemination to the customer. The final report is made available electronically to authorized customers. LIMS will notify the customer that test results are available. Customers may log into the iResults system (part of the MNPD-CL LIMS) to view the report. If the iResults system is temporarily unavailable, authorized customers may request and receive encrypted PDF reports sent by Unit Supervisors/TLs or analysts. Unless authorized, MNPD-CL personnel can only access LIMS for reports pertaining to their own discipline. Completed reports are also uploaded into RMS for internal MNPD customers.

The Tenprint Unit uses the L-Drive to store casefiles and records and sends reports through encrypted email.

Access to quality records is restricted based on the needs, permissions, and assigned Unit that the individual belongs to. Quality records are accessed through QMS, and permissions are approved by the Quality Manager.

Filing

Case file records:

Table 13: Records filing system

Unit	File location	Filed by
Drug ID	LIMS (JusticeTrax)	MNPD Incident number before March 1, 2016; LIMS Case file number since March 1, 2016
Firearms/Toolmarks	LIMS (JusticeTrax)	MNPD Incident number before March 1, 2016; LIMS Case file number since March 1, 2016
Forensic Biology	L drive G drive LIMS (JusticeTrax)	Completion date > LIMS Case file number Batch number Since March 1, 2016
Latent Print	DIMS (Foray) or LIMS (JusticeTrax)	MNPD Incident number
Tenprint	DIMS (Foray) L drive	Agency Incident Number
Toxicology	LIMS (JusticeTrax)	MNPD Incident number before March 1, 2016; LIMS Case file number since March 1, 2016

Technical records within each discipline are generally located in close association to their purpose, within the laboratory area, on hardcopy or electronic forms, logs or spreadsheets. Technical records are generally kept in chronological order on the forms, logs or spreadsheets. Hardcopy forms, logs or spreadsheets will be stored electronically when completed or as per the Unit QMs and/or TPM.

Quality records are filed in QMS.

Storage

All records will be legible and are stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. All records are stored and retained on secure and backed up servers.

Technical records are stored on servers located in the MNPD Data Center with many stored or organized in LIMS, L drive, Foray for the Latent Print Unit, or QMS software.

Administrative records are stored in LIMS, L drive, or Foray for the Latent Print Unit.

Quality records are stored in QMS on a secured MNPD server.

Electronic records are stored on secured servers located in the MNPD Data Center. These servers are backed up daily and strict access control procedures are followed.

Maintenance, Protect, Back-up and Archive

Case files are maintained in electronic format, available on a secured server, and identified with the same unique case identifier.

Quality, technical, and administrative records maintained on computers are saved and archived, as appropriate. Passwords and other protective measures may be used if deemed necessary as part of archival processes.

All records are held secure on backed up servers and in confidence. The MNPD-CL has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

Records are protected on secure servers that are backed up daily and strict access control procedures are followed. Access to backed-up records is restricted based on user permissions setup by the MNPD-CL IT Manager and/or MNPD-IT.

All desktop workstation computers will remain connected to the secure MNPD network while processing controlled data. Laptop computers and other portable devices capable of communicating wirelessly do so only over an encrypted connection. When processing MNPD data from remote locations, all portable devices connect directly to the MNPD network through an encrypted Virtual Private Network (VPN) tunnel.

All policies and procedures governed by the MNPD Information Security Policy will be followed by the MNPD-CL.

Retention and Disposal

After five years, **case files** may be transferred (electronically or physically) to another approved, secured server or location where they will be stored for fifty years or until deemed no longer necessary by the Davidson County District Attorney.

After five years, **technical records** may be transferred (electronically or physically) to another approved, secured server or location where they will be stored until deemed no longer necessary by the Davidson County District Attorney.

Quality records are retained for at least one cycle of accreditation. Records are maintained in the **Report Module** in QMS.

8.5 Actions to address risks and opportunities (Option A)

8.5.1(I) The MNPD-CL considers the risks and opportunities associated with the laboratory activities in order to:

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.**

8.5.1.1(A) Risks and opportunities related to health and safety are considered.

The MNPD-CL has designated a Health and Safety Manager who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that a health and safety program is implemented and followed at all times (see Safety Plan).

Unit specific safety issues are documented in the Unit QMs and/or TPMs and are part of the training for each Unit.

8.5.2(I) The MNPD-CL will plan:

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.

Generally, when risks and/or opportunities are identified, Management will develop action plans to include integration and implementation into the management system. An evaluation of the effectiveness of these actions will be performed. Plans, actions, and evaluations will be documented in the **Workflow Module** in QMS.

8.5.3(I) Actions taken to address risks and opportunities will be proportional to the potential impact on the validity of laboratory results.

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.

The following matrices may be used to assess the level of risk for risks identified.

Table 14: Risk likelihood matrix

Risk Matrix					
Impact/Likelihood of occurrence	**Highly unlikely**	**Unlikely**	**Possible**	**Likely**	**Very likely**
Severe	Moderate	High	High	Very high	Very high
Major	Moderate	Moderate	High	High	Very high
Moderate	Low	Moderate	Moderate	High	High
Minor	Low	Low	Moderate	Moderate	High
Insignificant	Low	Low	Low	Moderate	Moderate

Table 15: Failure mode and effects analysis

Process step	Potential failure mode	Potential failure effect	Potential causes	Current process controls	Action recommended
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	What causes the step to go wrong (i.e., how could the failure mode occur?)	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.

Severity (SEV): Severity of impact of the failure. How severe is the effect on the customer?

Occurrence (OCC): Frequency of occurrence of failure. How frequently is the cause likely to occur?

Detection (DET): Ability of process control to detect the occurrence of failure: How probable is the detection of the failure mode or its cause?

Table 16: Risk rating scale

1	2	3	4	5	6	7	8	9
Extremely low	Moderately low	Low	Somewhat low	Moderate	Somewhat high	High	Moderately high	Extremely high

Table 17: Risk priority number (RPN)

RPN	High risk	Moderate risk	Low risk
Risk priority number	Requires immediate attention and action	Requires attention and action but with less urgency	Does not require immediate attention but personnel will be made aware of the risk

Risks will also be evaluated on their severity should the risk not be mitigated, the probability of occurrence, and the probability of detection. The combined scores will be taken into consideration when determining if actions need to be taken to mitigate the risk.

Actions for reducing the occurrence of the cause or for improving the detection of the failure event will be developed for moderate and high-risk events and for events with a high impact should the failure event occur.

8.6 Improvement (Option A)

8.6.1(I) The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

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.

8.6.2(I) The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.

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

8.7 Corrective actions (Option A)

Policy

The purpose of corrective action is to bring about continuous improvement. Corrective actions specify steps, practices, and requirements that will ensure that nonconformity is corrected, that the effect(s) on prior work products or records is remediated (where practicable) and minimizes recurrence.

Corrective actions are potential solutions that address nonconformity and eliminate or minimize the risk of repeating the nonconforming work or departure from policies and procedures.

The MNPD-CL will initiate a corrective action when management determines that an instance of nonconformance has occurred within the MNPD-CL that rises to the level of a corrective action, that it is likely to recur, or is a significant departure from the policies/procedures of the quality management system or technical operations (e.g., nonconformities detected in casework analysis, proficiency tests, testimony, and audits).

A problem with the management system or with the technical operations of the MNPD-CL may be identified through a variety of activities, such as control of nonconforming work, methods used in ensuring the validity of results, internal/external audits, management reviews, feedback from customers, and from staff observations.

Procedure

All MNPD-CL employees have the responsibility and authority to submit a report of nonconforming work through the **Workflow Module** in QMS. The Quality Manager, Unit Supervisor/TL, and/or appropriate level of management will review the report of nonconformance and implement the corrective action procedure, if applicable.

Where appropriate, other cases that may also have been affected by an identical or similar nonconformity will be included in the corrective action and a retrospective analysis of the affected cases will be performed if possible.

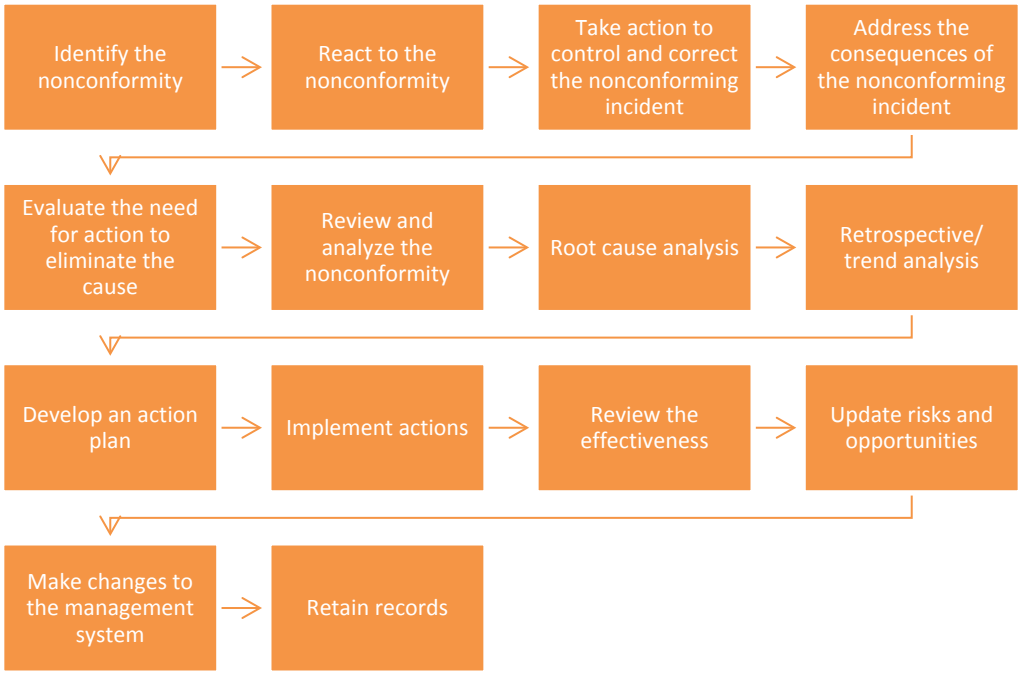

Figure 3: Corrective action process

8.7.1(I) When a nonconformity occurs, the MNPD-CL will:

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 analyzing the nonconformity;**
- **determining the causes of the nonconformity;**
- **determining if similar nonconformities exist, or could potentially occur;**

Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, personnel skills and training, consumables, or equipment and its calibration.

Root cause analysis policy and procedure

Root cause analysis should be conducted on all nonconformities/Quality System Notifications.

Personnel who have had internal auditor training, assessor training provided by the accrediting body, or quality assurance training provided by the MNPD-CL Quality Manager may participate in root cause analysis as designated by the Quality Manager or Laboratory Director. Typically root cause analysis will be performed by the Unit Supervisor/TL in collaboration with the Quality Manager.

Root cause analysis may include investigating:

- Human factors (e.g., skills, knowledge, abilities)
- Accommodation and environmental conditions
- Test methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test items
- Quality assurance measures
- Safety measures

General investigation process:

1. Detailed review of the event
2. Identify the problem
   2.1. What went wrong?
   2.2. Is this a one-time nonconformity or a recurring error?
   2.3. What objective data is available or could be obtained?
   2.4. Are there any identifiable patterns and trends?
3. Identify the root causes/contributing factors
   3.1. Why it went wrong?
4. Prioritize the factors that contributed to the nonconformity, evaluating both the severity and the probability that these factors may cause nonconformity again in the future

c) implement any action needed;

- Where corrective action is needed, the Quality Manager, Unit Supervisor/TL and/or appropriate level of management will identify potential corrective actions. Once potential corrective actions have been identified, the MNPD-CL will select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.
- Where applicable, actions to correct the nonconformance will be taken prior to the resumption of casework.
- The MNPD-CL will document and implement any required changes resulting from corrective action investigations. These changes will be communicated to the appropriate personnel.
- The effectiveness of the corrective action plan is approved by the Unit Supervisor/TL and Quality Manager.
- The Unit Supervisor/TL and the Quality Manager will work as a team, as applicable.

d) review the effectiveness of any corrective action taken;

- The Unit Supervisor/TL and the Quality Manager will work together to monitor the results to ensure that the corrective actions taken have been effective.
- If it is found that the corrective action has not been effective, the Quality Manager in collaboration with the Unit Supervisor/TL will investigate the situation and coordinate a new corrective action plan.
- Where the identification of nonconformities or departures casts doubts on the MNPD-CL's compliance with its own policies and procedures or on its compliance with accreditation requirements, the Quality Manager will ensure that the appropriate areas of activity are audited. These additional audits often follow the implementation of the corrective actions to confirm their effectiveness.
- The final review and close-out of a corrective action requires the approval of the Unit Supervisor/TL, the Quality Manager, and the Laboratory Director.

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

g) (A) The process for corrective action establishes a reasonable timeframe for completion for each corrective action.

- The timeframe is determined by the affected Unit Supervisor/TL and the Quality Manager. The initial timeframe that is determined may be modified should circumstances arise that interfere with meeting the original timeframe (e.g., evolution of the corrective action that requires a change in the approach/direction of the research; scheduling of/between personnel, management, vendors, etc.).

8.7.2(I) Corrective actions will be appropriate to the effects of the nonconformities encountered.

8.7.3(I) The MNPD-CL will retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

All corrective actions will be documented through the **Workflow Module** in QMS. The workflow includes steps for cause analysis and corrective action plan development, where the description of the initial remediation and the plan to prevent recurrence is documented. All the records pertaining to the corrective action are retained electronically and accessible by the Management Team.

See **Report Module** in QMS.

8.8 Internal audits (Option A)

8.8.1(I) The MNPD-CL conducts internal audits at planned intervals to provide information on whether the management system:

a) conforms to:
- **the laboratory's own requirements for its management system, including the laboratory activities;**
- **the requirements of this document;**

1. **(A) Internal audits will provide information on whether the management system conforms to the requirements of this document.**

b) is effectively implemented and maintained.
- The Quality Manager will plan and organize audits every calendar year. Additional focused audits may also be conducted at the Quality Manager's discretion.
- The Quality Manager will also select and train members of the audit team or choose members who have been trained to assist with internal audits or assessments, and who are, wherever resources permit, independent of the activity to be audited
- Audits of the Forensic Biology Unit to the FBI QAS will be carried out by individuals who meet the requirements of the FBI QAS document.

8.8.1.1(A) Internal audits will be conducted at least annually, as well as prior to the initial accreditation assessment.

8.8.2(I) The MNPD-CL will:

a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which will take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
- Frequency: at minimum, once per calendar year
  - Internal audits of applicable evidence storage locations will be performed when personnel with access to those locations ends their employment with the MNPD-CL.
- Method: combination of vertical and horizontal auditing of the management system and select requirements
- Responsibilities: Quality Manager will initiate, schedule, and plan the internal audit as well as select the requirements to be audited. The Quality Manager will also form an audit team and manage the internal audit. Audit team members will be responsible for auditing the requirements and Units that they are assigned to.
- Requirements: Management will be notified of when internal audits are planned. Unit Supervisors/TLs responsible for resolving nonconformances resulting from the internal audit will not take part in performing an internal audit on their own Unit.
- Reporting: a final report containing audit results will be issued.

b) define the audit criteria and scope for each audit;
- Audit criteria and the scope of each audit will be defined when internal audits are planned by the Quality Manager or at the request of Management.

1. **(A) Internal audits will 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;
- A final report will be assembled and issued by the Quality Manager.

d) implement appropriate correction and corrective actions without undue delay;
- Any nonconformances discovered during the internal audit will be documented as a Quality System Notification or corrective action and issued to the relevant Unit Supervisor/TL for processing.
- Corrective actions resulting from internal audits should be resolved within 60 calendar days from when the affected Unit Supervisor/TL is notified of the finding.

e) retain records as evidence of the implementation of the audit program and the audit results.
- Records of internal audits will be retained in the **Report Module** in QMS

8.9 Management reviews (Option A)

8.9.1(I) The MNPD-CL management will 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.

Review of the management system will take place at least once per calendar year.

8.9.1.1(A) Management reviews will be conducted at least annually, as well as prior to the initial accreditation assessment.

8.9.2(I) The inputs to management review will be recorded and will include information related to the following:

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.

8.9.3(I) The outputs from the management review will record all decisions and actions related to at least:

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.

Appendix A Alert Notification Procedures

1 General Security System

The security system of the MNPD-CL is managed by MNPD-IT Security. The MNPD-CL is on the second floor above the MNPD Madison Precinct.

Access for the public and staff through the front entry is open from 0700 to 1630 Monday through Friday, excluding holidays.

Any other exterior entries to the facility are controlled access. MNPD officers do not have access to the non-public areas on the second floor where the MNPD-CL is located.

2 MNPD-CL Facility Alert

2.1 Purpose

These procedures are to be followed when the MNPD-CL Management Team is alerted by General Services of an emergency in the MNPD-CL facility. For the purposes of this procedure, “facility emergencies” would involve problems with infrastructure of the facility which might damage equipment or compromise testing. Examples may be water leaks, failure of heating or cooling systems, prolonged power outage, proximity card read failure, etc.

Emergencies that involve fire, natural disaster, chemical or biological hazard, etc. adhere to emergency procedures common to those incidents.

2.2 Specific security plan for General Services and Metro/MNPD-IT

Metro General Service and Metro/MNPD-IT assigned personnel have access to the Madison Precinct and Crime Laboratory Lobby, but not the secured area of the Crime Laboratory. Metro General Service and Metro/MNPD IT may gain access to the Crime Laboratory main halls and community areas by being escorted into the secured area by Crime Laboratory personnel.

Once escorted into the secured hall, authorized General Services or Metro/MNPD-IT have access to maintenance and IT rooms (approved through Metro security) within the secured hall area of the Crime Laboratory. An escort is not required following sign-in and access granted to the inside hall areas.

If an emergency key is required to get into a maintenance or IT room, it may be obtained by authorized use of the secured key box (blue box) outside of the entrance to the secured hall into the Crime Laboratory. This door is located down the hall of the Crime Laboratory lobby.

Use of the keys in the secured key box may also be used if the proximity key system is not working, and it is necessary to gain entrance to secured areas of the laboratory.

General Services or Metro/MNPD-IT does not have access to the Forensic Laboratory Units or areas where evidence is stored. If access is needed to a laboratory area after hours, it is necessary to notify Crime Laboratory Management.

2.3 Procedure for General Service Emergency Notification:

In the event that General Services monitoring equipment detects a facility emergency in the MNPD Crime Laboratory, a member of the Laboratory Management Team must be notified. Calls should be made until someone is alerted. General Services is provided with numbers for members of the MNPD-CL General Service Alert Team for facility emergencies:

- Laboratory Director
- FSD Director

2.3.1 Actions when Alerted:

The MNPD-CL person receiving the facility emergency notification shall:

- Determine the nature of the emergency
- Determine the location of the emergency
- Call the Unit Supervisor, and Director to decide about actions
- Arrange for MNPD-CL Management Team member to respond and assist the General Services emergency team into the affected laboratory as soon as possible
- Notify the FSD Director or appropriate chain of command

2.4 Responding to the Emergency call

The MNPD-CL Management Team member who is available to respond shall:

- Arrive at the MNPD-CL to meet the General Services emergency team
- Access emergency keys to the Laboratory Units at the secured key box outside of the entrance to the secured hall into the Crime Laboratory
- Accompany General Services to the area where the service is needed
- Update the chain of command as needed or when the repair is completed
- Assure the facility is secured when leaving

3 MNPD-CL Motion Sensor/Camera Security System Alert

3.1 Purpose

These procedures are to be followed when the MNPD-CL Management Team is alerted by the motion sensor/camera security system of the MNPD-CL. These procedures are intended to allow the quickest possible response in determining the validity of the alert and the action that follow.

3.2 Procedure for Security Alert Notification:

Each Unit evidence storage area and the Evidence Receiving Unit vaults are monitored by motion detectors and cameras. The motion control alerts are set in coordination between the Unit Supervisor and MNPD – IT Security for pre-set times when there is approved activity in laboratory Units. If motion is detected after approved hours, alerts are sent.

Table 18: Motion sensor times

Unit	Day	Time
Drug Identification	Monday – Friday Saturday-Sunday	1800-0500 All day
Evidence Receiving (all vaults)	Monday – Friday Saturday – Sunday	1800 – 0500 All day
Forensic Biology	Monday-Friday Saturday-Sunday	1800-0500 2100-0600
Firearms/Toolmarks	Monday – Friday Saturday – Sunday	1800-0500 1900 – 1100
Latent Print	Monday – Friday Saturday – Sunday	1800 – 0500 All day
Toxicology	Monday – Friday Saturday – Sunday	1800 – 0500 All day

3.2.1 Alert Chain

When motion is detected in laboratory Units after hours, alerts will be sent to:

- FSD Director
- Unit Supervisor where the motion detected
- Laboratory Director
- MNPD IT

As quickly as possible, this group of people will work together to determine the validity of the alert based on video records and knowledge of who should or should not be in a laboratory area. This group of people is hereafter referred to as the "Alert Team."

When an alert is sent to the Alert Team, the order of responsibility starts with the Unit Supervisor, and proceeds to the next team member, in the absence of immediate response to the alert chain.

3.2.2 Alert Team Actions when Alerted:

The Unit Supervisor Alert Team member and/or other Alert team members (as required) should observe the recorded video or photographs as soon as possible.

Using information from other Alert Team members, the responsible Alert Team member shall make a determination of validity, and as appropriate, respond to everyone copied on the alert as soon as possible.

If a breach of security is determined, call for assistance.

3.2.2.1 MNPD IT- Security Manager for MNPD-CL

Assists and participates in communication concerning the alert and videos.

Views the video if possible and communicates with the team.

3.2.3 Determination of Validity

3.2.3.1 Circumstances where an alert may be determined invalid

Personnel assigned to the Unit and working late or weekends with Supervisor approval.

Emergency circumstance where personnel assigned to the Unit respond to call out.

Other unforeseen, but determined to be legitimate circumstances, such as a facility related problem.

The Alert Team determines the incident was a failure to communicate with Unit Supervisor but the person's presence is not improper otherwise.

3.2.3.2 After hours work procedures (to avoid false alerts)

Unit Supervisors shall notify the chain of command of approved after hours work for Unit staff.

The chain of command shall let Unit Supervisors know if an emergency circumstance requires Laboratory or General Service personnel to respond to their Unit.

3.2.3.3 Circumstances where an alert may be determined valid

Video observation shows a person unknown to the MNPD-CL Alert Team in the monitored area, after hours.

Video observation shows a person known to the MNPD-CL Alert Team, but the Team has no knowledge of anyone approved to be in the functional area of the Unit and/or the person cannot be reached. In this case, the Alert Team can't make a determination the alert is invalid, so it is determined to be valid.

3.2.4 Call for Assistance

When an alert is determined to be valid, the responsible Alert Team member will:

Assure that a reply is sent to other Alert Team members to summarize the situation.

Call Emergency Number: 911

Identify themselves

Alert dispatch to the location and circumstance

Advise Control to call the CSI Lieutenant

3.2.5 Response to Call

In addition to officers who may be responding to a dispatched call, the CSI Lieutenant will notify appropriate commissioned CSI Supervisors or Officers to respond to the call. CSI officers have proximity card key access to the halls of the Crime Laboratory and can assist and also facilitate access to responding officers.

The Laboratory Director or responsible Alert Team member will arrange for a Unit Supervisor to respond to access the emergency key to the Forensic Unit areas, thus giving access to the Forensic Unit/s for the responding officers.

The CSI Lieutenant will advise the FSD Director and Alert Team of the situation and outcome.

Appendix B Administrative review

The MNPD-CL has established a procedure which requires administrative review of the case record prior to the release of each test report. MNPD-CL policy has defined the scope of the review, and how the administrative review is documented. Administrative reviews will be conducted by someone other than the author(s) of the test report.

At a minimum, the administrative review will include:

- A review of the test report for spelling and grammatical accuracy;
- A review of all administrative and examination records to ensure that the records are uniquely identified according to laboratory policy and/or procedure;
- A review of the test report to ensure that all key information is included;
- A review of the corrections made by the analyst, if any, are properly remediated;
- A review of all technical documentation within the case file are appropriately page numbered and initialed or electronic equivalent;
- Documentation of chain of custody;
- Technical review appropriately documented.

The reviewer must have sufficient knowledge to verify compliance with the MNPD-CL management system relative to the minimum requirements of administrative review.

It is preferable, but not required, that the technical reviewer and administrative reviewer be different individuals.

Checking the LIMS milestone for administrative review is equivalent to having checked all the requirements of the Unit administrative review checklist or TPM for administrative review requirements. Administrative review checklist records (forms), if used, will be included in the case file.