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8 Management System Requirements

8.1 Options

The Forensic Science Division selects Option A of ISO/IEC 17025:2017 as its management system criteria.

8.1.1 General

The management of the Michigan State Police Forensic Science Division is dedicated to enhancing public safety by providing the highest standard of forensic science services and investigative support to the criminal justice community. The quality system of the Michigan State Police Forensic Science Division ensures that functions are performed as intended and conform to the requirements of the ISO/IEC 17025:2017 standards and the ANAB AR 3125 supplemental requirements. Objectives are listed within the MSP Forensic Science Division Strategic Plan.

The quality management system is documented by policies and procedures found in the FSD Quality Manual, Laboratory Operations Manual, discipline specific procedure manuals, Safety Manual, Department Official Orders and local laboratory policies. Other documents such as instrumentation manuals and technical training manuals are available.

8.1.2

The Forensic Science Division of the Michigan Department of State Police strives to ensure the quality and reliability of the laboratory data produced at its eight regional forensic laboratories. This is achieved through a Quality Management System that incorporates the use of the Quality Manual (QM), the Laboratory Operations Manual (LOM), Discipline Training Manuals, Discipline Procedures manuals, Department Official Orders, Safety Manual and Local Laboratory Policies. These policies and procedures are located on the Internet at <https://msp.qualtrax.com> or on the Department's intranet.

Additional quality system documents such as equipment and instrument manuals and records are located at each laboratory.

The management system documents provide document control of the management system records and case records ([LOM 1.3 Records Retention](#) and [LOM 2.12 Document Revision and Control](#)). It also addresses risks and opportunities, improvement that may be needed ([LOM 2.2 Risks and Opportunities](#)), corrective actions ([LOM 2.11 Corrective Action](#)) that have occurred, internal audits ([LOM 2.3 Laboratory Audits](#)) and management reviews.

8.2 Management System Documentation

8.2.1

Michigan State Police Forensic Science Division employees are responsible for understanding and applying all aspects of the Quality Management System to meet management objectives. Compliance

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with the Quality Management System by staff ensures that analyses are performed in accordance with standards of good laboratory practice, are scientifically sound, and are defensible.

All quality system documents are reviewed annually and updated as necessary to continuously improve the effectiveness of the Quality Management System. If conditions or situations having an adverse impact on the quality system are identified, appropriate changes will be made, and/or corrective actions will be implemented.

The Quality Management System incorporates the use of the Quality Manual (QM), Laboratory Operations Manual (LOM), discipline training manuals, discipline procedures manuals, Department Official Orders, Safety Manual and Local Laboratory Policies. All Quality Management System policies and procedures are available to laboratory members at all levels through access online. All members are notified of changes through automated emails from the document management system or by policy to review documents routinely.

8.2.1.1

The following words (to include the forms of the same word) used in ISO/IEC 17025:2017 or in ANAB AR 3125 require addressing the requirements in writing:

- Agreed
- Appoint
- Authorize
- Define
- Instructions
- Method
- Plan
- Procedure
- Program
- Record
- Schedule
- Specify

8.2.2

The competency of laboratory staff members is accomplished through discipline specific training manuals and the onboarding process (LOM 6.0 Onboarding). Impartiality is a component of the onboarding and training programs, as well as reinforced annually through the review of the *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel*. Standardization of laboratory practices is accomplished by consistent application of analytical procedures, adherence to the Laboratory Operations Manual and the Quality Assurance program. The documents of the Quality Management System are reviewed and updated as necessary to improve the effectiveness of the program. All personnel are required to familiarize themselves with the manuals specific to the scope of their responsibility.

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8.2.3

Evidence of the Michigan State Police Forensic Science Division commitment to the development and implementation of the management system may be included within the policies, procedures, activities and documentation stored on the document management system. The management system is continually evaluated, and steps taken to improve it as evidenced by the annual auditing and management system review. Key Management commitment to the development, implementation, and continual improvement of the effectiveness of the program may also be evidenced through discussions at regular supervisor meetings, laboratory meetings, discipline meetings and Division command meetings.

8.2.4

All documents, processes, systems, and records related to the fulfillment of the ISO/IEC 17025:2017 standards are maintained on the document management site and referenced as part of the management system.

8.2.5

The document management site utilized by the Michigan State Police Forensic Science Division is available with an internet connection and user profile with login credentials. All members of the Forensic Science Division, regardless of roles or responsibilities, have access to relevant portions of the site to carry out their duties.

8.3 Control of Management System Documents

8.3.1

The Forensic Science Division manages all the documents that comprise its quality system. Internally generated documents are controlled according to [LOM 2.12 Document Revision and Control](#). All documents posted on the FSD Documentation Management System site shall be the official version of the document. Hard copies of documents are uncontrolled.

Documents from external sources are also used to form the management system. All controlled documents from external sources are referenced within a controlled space on the FSD Documentation Management System. The description of all controlled documents shall include an issue date, version number, or other indicator to clearly identify the approved document.

Equipment and software manuals that are maintained at the laboratory only for general reference purposes are not required to be controlled. If the equipment or software manual must be referenced to complete casework, it must be controlled and properly included within a controlled space.

Approvals of the documents posted within each space on the FSD Documentation Management System are performed according to [LOM 2.12 Document Revision and Control](#).

8.3.2

Prior to implementation, all FSD laboratory quality system documents shall be thoroughly reviewed and approved for release by the Quality Assurance Manager (QAM) and/or Laboratory Operations Manager (LOM). Policy [LOM 2.12 Document Revision and Control](#) contains provisions for identifying the current

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version of documents, for distributing quality system documents, and to preclude the use of invalid and/or obsolete documents.

Policy [LOM 2.12 Document Revision and Control](#) ensures that:

- Current revisions of appropriate practices, procedures and instrumentation manuals shall be available where critical operations are performed;
- Quality system documents are periodically reviewed and revised as necessary to comply with applicable requirements;
- Changes and the current revision status of documents are identified;
- Invalid or obsolete documents are promptly removed or identified as such to prevent their unintended use;
- Archived quality system documents are marked as such to preclude their use;
- Quality system documents are uniquely identified

8.4 Control of Records

8.4.1

All records (Quality and Technical) shall be legible in form and retained according to the Department's records retention policies ([LOM 1.3 Records Retention](#)). Quality records include reports from internal audits, management reviews, corrective actions and preventive actions. Technical records include all case analysis records and those records that support the case records.

8.4.2

Records shall be properly identified, stored, protected, backed-up and archived to allow for proper retrieval and disclosure ([LOM 1.3 Records Retention](#)). Records are controlled by limited access via user login credentials and facility security. Electronic records are maintained on servers that are routinely backed up, archived and verified that the records can be retrieved. The Forensic Science Division abides by the State of Michigan data retention and security requirements.

8.5 Actions to Address Risks and Opportunities

8.5.1

The Michigan State Police Forensic Science Division has a policy that assesses risks and opportunities that may impact laboratory activities ([LOM 2.2 Risks and Opportunities](#)) in order to:

- Give assurance that the management system achieves the intended results by considering the management system review inputs listed in QM 8.9.2;
- To find opportunities for improvement that will enhance the objectives of the Division including preventive actions;
- Prevent or at least reduce any undesired impacts or failures in the laboratory activities ([LOM 2.2 Risks and Opportunities](#));
- To achieve overall improvement in the quality and timeliness of services to our customers.

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8.5.1.1

Risks and opportunities related to health and safety shall be considered. This may be accomplished through annual health and safety audits or updates throughout the year.

8.5.2

[LOM 2.2 Risks and Opportunities](#) outlines the required steps to identify and address potential risks and opportunities. The annual management system review shall incorporate a review of documentation prepared as a result of addressing potential risks and opportunities.

[LOM 2.2 Risks and Opportunities](#) shall incorporate an effectiveness review of any actions as part of the policy.

8.5.3

Any actions taken as a result of [LOM 2.2 Risks and Opportunities](#) shall be proportional to the potential impact on the validity of laboratory results generated for the customer.

8.6 Improvement

8.6.1

The Michigan State Police Forensic Science Division routinely identifies areas for improvement through an annual review of procedures and management system review that includes the overall laboratory objectives, audit results, corrective actions, suggestions, risk assessment and proficiency testing results. When identified, action plans will be developed, implemented, and monitored. Documentation will be maintained on the document management site. [LOM 2.2 Risks and Opportunities](#).

8.6.2

The Michigan State Police Forensic Science Division receives feedback from its customers through numerous methods that may include localized “chiefs” meetings, surveys and through direct submission to the laboratory. The survey invitation may be posted at each laboratory evidence reception counter or included in the automated email notification of laboratory results. Feedback provided to laboratories is analyzed during annual audits and necessary changes are made to the management system.

8.7 Corrective Actions

8.7.1

The FSD has established a policy ([LOM 2.11 Discrepancies and Corrective Actions](#)) that designates appropriate authorities for implementing corrective action when discrepancies, nonconforming work, or departures from the policies and procedures in the management system or technical operations have been identified. Any FSD employee may identify conditions or situations where corrective actions are required.

[LOM 2.11 Discrepancies and Corrective Actions](#) includes initiating an investigation to determine the root cause(s) of the nonconformity.

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[LOM 2.11 Discrepancies and Corrective Actions](#) provides guidance for determining the level of the nonconformity. Once the level is determined, the appropriate personnel will select, document and implement the action(s) most likely to eliminate the nonconformity and to prevent recurrence.

The Quality Assurance Manager will monitor and verify the results of corrective actions to ensure that they have been effectively resolved.

Where conditions or situations require a corrective action, the Quality Assurance Manager will determine if an additional audit is necessary to assess the effectiveness of the corrective action. If an audit is required, the audit will be conducted in a timely manner.

Updates to risks and opportunities shall be completed once the outcome of corrective actions are determined.

Changes to the management system shall be completed if results of any corrective actions necessitate such changes.

8.7.2

Corrective actions will be appropriate to the magnitude and risk of the nonconformity.

8.7.3

Corrective Action records shall be maintained on the Forensic Science Division document management system site.

8.8 Internal Audits

8.8.1

The completion of Internal Audits shall be satisfied by the completion of the following annual audits: Technical Discipline Audits, Health and Safety Audits, Property Audit, Laboratory Internal Audit, and Professional Standards Audit. [LOM 2.3 Laboratory Inspections and Audits](#) policy shall be followed when conducting scheduled audits to verify that each laboratory conforms to the requirements of the Forensic Science Division's management system and the ANAB-International accreditation program.

The audits shall include all pertinent areas of the ANAB supplemental requirements, ISO/IEC 17025:2017, the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories, FSD Laboratory Operations Manual, FSD Quality Manual, Discipline Specific Procedure Manual and Training Manual.

Internal audits shall be conducted in accordance with the schedule in [LOM 2.3 Audit Schedule](#).

All audits except the Property audits shall be conducted as to cover the time period of the previous 12 months or the period since the last audit of that type, whichever is longer. The Property audit is intended to be a current assessment of the location and disposition of all evidence at the time the audit is performed.

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8.8.1.a).1

[LOM 2.3 Audit Schedule](#) provides information on whether the management system conforms to the requirements of ISO/IEC 17025:2017 and ANAB AR 3125.

8.8.1.1

Internal audits will be performed annually to ensure all requirements are met. Additionally, internal audits will be performed prior to the initial accreditation of new standards.

8.8.2

Internal audits are performed on the management, quality and technical operations of the laboratory annually to ensure all policies and procedures are being followed. Internal audit records shall be retained for a minimum of at least one accreditation cycle, or 5 years, whichever is longer.

When an audit identifies a deficiency that affects the validity of test results or effectiveness of the discipline operations, the deficiency shall be communicated to the respective laboratory director prior to the closeout of the on-site audit activity. A corrective action report shall be opened, without undue delay, to document the findings ([LOM 2.11 Discrepancies and Corrective Actions](#)). When necessary, the laboratory shall notify contributors, in writing, if the results of any testing have been affected. This notification may be in the form of a corrected report.

A report shall be issued for every internal audit report and shall contain the area of activity audited, the audit findings and all corrective actions taken.

Documentation of all audits comprising the Internal Audit will be reviewed during the annual Management Review conducted by the Assistant Division Director-Quality Assurance Manager. This review shall be the final verification and record of the implementation and effectiveness of the remediation and/or corrective action taken.

8.8.2.b).1

Internal audits will include direct observation of at least a portion of the testing activities conducted in each discipline included in the laboratory's scope of accreditation. The audit team will select the activity for observation unless otherwise selected by the Quality Assurance Manager.

8.9 Management Reviews

8.9.1

An annual Management Review shall be conducted according to the schedule outlined in the [LOM 2.3 Laboratory Inspections and Audits](#). The objective of the Management Review is to ensure the management system's continued suitability, adequacy and effectiveness. The Management Review shall also incorporate future planning for the laboratory.

8.9.1.1

The Management Review shall be conducted at least annually and before an initial accreditation assessment.

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8.9.2

The annual Management Review shall include a review of the following:

- Changes in relevant internal and external issues
- Fulfillment of laboratory objectives
- Suitability of the policies and procedures utilized by the laboratory
- Status of any actions undertaken from previous management reviews
- Outcomes of any internal audits
- Corrective actions
- Outcomes of any external assessments
- Changes in the type or volume of work requested of the laboratory or in the range of activities
- Feedback from customers and/or personnel
- Complaints
- Effectiveness of any improvements that were implemented
- Adequacy of resources available to the laboratory
- Results of risks that were identified
- Outcomes of the assurance of the validity of results
- Suitability of training programs and continuing education

8.9.3

The Quality Assurance Manager, in cooperation with the Laboratory Operations Manager and the Division Director, will document the annual review of the management system and/or actions that arise from the review. The management review shall include:

- The effectiveness of the management system and its processes;
- Improvement of the laboratory activities related to the fulfillment of the requirements;
- Provisions of required resources;
- Any need for change.