

# ***Quality Management in FSL***

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# General:

- ▶ The forensic science laboratories shall establish, implement and maintain an effective quality management system appropriate to the type, range and volume of forensic science it undertakes.
- ▶ The quality system shall include policies and procedures addressing all the criteria detailed in these accreditation requirements.

# Documentation: Quality Manual

- ▶ All elements of the laboratory's quality system shall be documented. This will include all policies, systems, Programme, procedures, instructions etc. where the absence of documentation would adversely affect the test or examination results,
- ▶ Documentation of the quality system will be in a Quality Manual with cross-referencing to related operations documentation, where relevant.
- ▶ The Quality Manual and, where relevant, the associated operational documentation, shall be kept up-to-date under the authority and responsibility of the Quality Manager.
- ▶ Documentation of the laboratory's quality system must include, where appropriate, the protocol(s) permitting departures from the documented policies and procedures.

- ▶ Quality system documentation shall be readily available to all the personnel.
- ▶ Forensic science in administration of Criminal justice requires that intensive measures be undertaken to ensure the overall quality of scientific findings. To accomplish this, a quality system is required to provide laboratory management with continuing confidence that results and conclusions are accurate, impartial and relevant.
- ▶ The success of the quality system depends on the commitment of the management and active participation of each member of the laboratory staff.

# Document and Information Control

- ▶ The forensic science laboratory shall establish and maintain documented procedures to control all documents and information that relate to its quality system. (Documents include manuals, work books, work sheets, charts, posters, notices, memoranda, drawings, plans software, Standard Operating Procedures etc. It may also include documents of external origin such as standards, regulations, manufacturer's manuals etc. ).
- ▶ All documents shall be uniquely identified, such identification to include the date of issue and/or the revision number, the total number of pages or a mark to signify the end of the document and the authority for issue.

► All documents which form part of the quality management system shall be reviewed and approved for use by the authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents in the quality system shall be established and be easily available to preclude the use of obsolete documents. The procedures shall also ensure that:

- The authorized issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed.

- Documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

- Obsolete documents are deleted from the master list and promptly removed from all points of issue or use, or otherwise, assured against unintended use.

- Any obsolete document retained for legal and/or knowledge preservation purposes are suitably identified.

# Quality Control

Analytical performance must be monitored by using quality control procedures appropriate to the type and frequency of the testing undertaken. The range of quality control activities available to laboratories includes the use of:

- Reference collections
- Certified reference materials
- Internally generated reference materials
- Independent checks by other analysts/examiners
- Statistical tables
- Positive and negative controls
- Control charts
- Replicate testing
- Alternative methods
- Spiked samples, standard additions and internal standards



# RESPONSIBILITIES - QUALITY ASSURANCE; REPORTS TO THE PRESIDENT:

- **The Director of Quality & Improvement shall be responsible for the following:**
- ▶ Is appointed the Management Representative.
- ▶ Revision and control of this Quality System Program Manual.
- ▶ Performance of Internal Audits.
- ▶ Reporting regularly to management on the status and adequacy of the program.
- ▶ Oversees preparation of all certifications including review of request for changes to certifications.
- ▶ Delegates others to perform these responsibilities, provided they are independent of the activity or process but retains the overall responsibility for ensuring compliance with the requirements of the QA Program.
- ▶ Reports to the President on all 10CFR21 defects and non-compliances.
- ▶ **Ultimately responsible for the storage of Quality Assurance records.**

- ❑ **The Director of Quality & Improvement and the Quality Assurance Manager shall be responsible for the following:**
- ▶ Reviewing of customer purchase orders and contracts for defined requirements, capability to meet requirements and the availability of appropriate methods. This responsibility may be performed by Order Entry personnel, Managers / Supervisors, Customer Service Representatives, Technical Specialists, Coordinators, QA Personnel and the President.
- ▶ Review / approval and control of all quality, calibration and test procedures.
- ▶ Control of non-conforming materials, equipment and services.
- ▶ Performance of vendor audits and preparation and control of the Approved Vendors List.
- ▶ Control and documentation of calibration system.

# Internal audits

- ▶ This provides instructions for the periodic evaluation and audit of the LTI Quality Management system to assure its adequacy and implementation.
- ▶ The internal audit process also supports corrective action, risk management and continual improvement.
- ▶ Personnel (internal or external) conducting internal audits shall be appointed by the President and have no direct line of responsibility for the area or activity being audited.
- ▶ Internal auditors shall be qualified in accordance with the procedure.
- ▶ Audits of testing departments, calibration and specimen preparation, including the quality system, shall be performed at least once each year to a defined documented schedule in accordance with the Procedure .

- ▶ The internal audit is carried out to determine the adequacy, effectiveness and implementation of Quality Management System
- ▶ The risks and opportunities associated with the lab activities shall be taken into consideration 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 lab;
  - c) prevent or reduce undesired impacts and potential failures in lab activities;
  - d) achieve improvement.