**ISO/IEC 17020**

**8.6**

**8.6 Internal audits**

**8.6.1 Definition -** Audits are a planned and documented investigative evaluation of all functions of the Medical Examiner Office against established requirements, standards, policies, and procedures. Medical Examiner Offices shall conduct systematic internal audits 1) to monitor and determine compliance with the requirements of the quality system and ISO standards and 2) to evaluate the technical activities and work products of employees.The role of internal audit is to provide independent assurance that an organization’s management, governance, and quality control processes are operating effectively. The inspection body shall establish procedures for internal audits to verify that if fulfils the requirements of the international standard ISO/IEC 17020, and that the management system is effectively implemented and maintained.

**8.6.2 Planning and Aims -** The audit program shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits. What is being audited during the yearly audits is if the office is conforming to ISO 17020, and that the management system is effectively implemented and maintained.

The internal audit’s role is to enhance and protect organizational value by providing risk-based and objective assurance, advice, and insight. This should be the mission statement of any internal audit clearly summarized in the introduction and final report. Aims of internal audits are to evaluate and improve the effectiveness of governance and quality control processes.

The planning process for audits will include these steps:

1. The audit results from the previous 2 years will be reviewed.
2. Any issues or non-conformities from the previous two years of audit data will be listed and categorized.

**Information and notification** - Each section of the Medical Examiner Office shall be notified in advance of audit dates to minimize disruption of operations and to ensure the presence of necessary personnel. Customer satisfaction as a quality improvement tool should be also considered: families, turnaround time, law enforcement, prosecutors, funeral homes, organ procurement.

**8.6.3** **Effectiveness** - The inspection body shall conduct periodic internal audits covering all procedures in a planned and systematic manner, to verify that the management system is implemented and is effective. ISO 19011 provides guidelines for conducting internal audits. To be effective, internal auditors should be qualified, skilled and experienced people who can work according to International Standards and the Code of Ethics. They should evaluate and report to the highest level of Medical Examiner Offices. Usually internal auditors must look at areas outside their own so that audits can be more objective to identify the risks facing the Medical Examiner Office and to understand how risks can impact its mission and reputation

**8.6.4** **Frequency and** **the Quality Manager** - According to ISO 17020 standards, internal audits shall be performed at least once every 12 months. The frequency of internal audits may be adjusted depending on the demonstrable effectiveness of the management system and its proven stability. A quality manager (QM) or designee shall be responsible for planning and coordinating all internal audits. The QM shall ensure that internal audits are performed annually by independent trained and qualified personnel and encompass all aspects of the quality system. Multi-year planning with defined and measurable goals could be scheduled in order to individualize quality improvement to the practice setting.

**8.6.5 Contents -** The inspection body shall ensure that:

a) internal audits are conducted by qualified personnel knowledgeable in the forensic process, in inspection and auditing, and in the requirements of the International Standard ISO/IEC 17020;

b) auditors do not audit their own work;

c) personnel responsible for the area audited are informed of the outcome of the audit;

d) any actions resulting from internal audits are taken in a timely and appropriate manner;

e) any opportunities for improvement are identified;

f) the results of the audit are documented.

The auditor shall go through all the standards provided in ISO 17020. (In this regard, most companies that perform ISO inspections have sheets for audits that include all of the items in 17020, and in more detail.

The evaluation of the implementation of the forensic unit’s procedures shall include direct observations of the examinations and testing undertaken on-site or in the laboratory. “Implementation” implies that when a procedure is first introduced, it must be evaluated by direct observation, and this would be a function of the internal audit to see if direct observation occured and was documented. The inspection body might also consider including the NAME accreditation checklist as part of the audit.

**Audit form and Traceability** – The scopes, dates and detailed scheduling of audits shall be planned and conducted in accordance with a documented procedure. Documents of internal audits shall be maintained. An audit form shall include a revision of case data (name, reference, date of post-mortem, originating pathologist, reviewing pathologist, date reviewed) including administrative items (history provided, summary and opinion provided, cause of death completed) and technical items (if autopsy descriptions and photographs are satisfactory, if appropriate ancillary testing has been performed, if opinion and conclusion are internally consistent, if report is free of major language errors, if cause of death appears reasonable).

**8.7 Non-conformity –** The forensic unit shall establish procedures for identification and management of nonconformities in its operations. The procedures shall define requirements for the following:

1. identifying nonconformities,
2. determining the causes of nonconformity,
3. correcting nonconformities,
4. evaluating the need for actions to ensure that nonconformities do not recur,
5. determining the actions needed and implementing them in a timely manner,
6. recording the results of actions taken,
7. reviewing the effectiveness of corrective actions

The forensic unit shall also, where necessary, take actions to eliminate the causes of nonconformities to prevent recurrence. If a non-conformity is observed and can be corrected immediately, on-the-spot corrective action may be taken. If the non-conformity cannot be corrected immediately, the Medical Examiner Manager or Section Supervisor shall conduct corrective and/or preventive action(s), if warranted, as provided in the Procedure for Corrective Action and/or Procedure for Preventive Action. The QM will also retain the management reviews and audit reports.

In case of the autopsy report’s review, a major discrepancy must represent a significant change between the original diagnosis and the one rendered upon review, and the discrepancy must potentially have a serious impact. Serious impact is defined as requiring a change in the death certificate or in court testimony. Minor discrepancy includes when small changes in diagnosis are found, but have minimal relevance or impact.