**ISO/IEC 17020**

**MANAGEMENT REVIEW (OPTION A)**

**8.5.1 GENERAL**

**8.5.1.1** The Medical Examiner’s Office reviews its management system at yearly intervals to determine if it is suitable, adequate, and effective for meeting policies and objectives of the office. Reviews are performed jointly by the technical and quality managers.

**8.5.1.2** Management reviews will be conducted once yearly, beginning 6 months after the last NAME accreditation inspection and 6 months after the last ISO/IEC 17020 assessment. (NAME and ISO inspection are intentionally scheduled in the same month.) The reviews will utilize the NAME Accreditation Checklist, and the IEC/ISO 17020 International Standard.

**8.5.1.3** Records of Reviews shall be maintained as follows

1. The NAME Accreditation Checklist will be used to perform a self-inspection. Any phase I or II violations will be recorded and transmitted to the NAME assigned Inspection and Accreditation Committee Inspector. The year’s checklist will be signed, dated and saved in the corresponding year’s management review file, along with any correspondence from NAME I & A.
2. The IEC/ISO 17020 International Standard will be used as a basis for an internal audit along with any materials or checklist used by the company that performed the last 17020 assessment. Copies will be signed and dated and saved in the corresponding year’s management review file.

**8.5.2** Required Review inputs:

1. The internal review from the previous year, and the last NAME accreditation inspection results, as well as the last 17020 assessment result will be studied prior to the review. Any phase violations (NAME), and any 17020 nonconformities will be highlighted for emphasis in the internal review for follow-up.
2. Caseload statistics to include:
   1. autopsy number in the previous calendar year for each forensic pathologist
   2. turnaround times for toxicology and autopsy reports
   3. data from the annual statistical report from the previous year (required for NAME accreditation)
3. Summary reports for quarterly peer review from the previous calendar year, looking to identify any adverse trends
4. Any feedback from decedent families, law enforcement, attorneys, outside the complaints and appeals process.
5. The objectives listed in the annual county budget process for the previous 2 years, to determine fulfillment status
6. Documentation on the previous year’s preventive and corrective actions
7. The audit will include documentation about any changes in office staffing, procedures, or facility and how those changes might affect the management system.
8. All appeals and complaints from the previous year. These will be examined to search for any commonalities that might indicate need for change.
9. Review of the impartiality policy with identification of any risks to impartiality
10. Adequacy of current staff and equipment resources
11. Projected workloads
12. Training needs for new and existing staff
13. Effectiveness of systems established to ensure adequate competence of personnel
14. The results of all peer review, and the results of direct observation peer review for investigators, autopsy room staff, and forensic pathologists

**8.5.3** Required review outputs:

After the audit a report will be generated summarizing findings from the review and including:

1. Any identified needs for additional resources, material, facility or personnel.
2. Any actions or decisions from the audit to improve the effectiveness of the medical examiner processes or management system
3. Any actions or decisions from the audit that improve the medical examiner’s office conformity to ISO/IEC 17020

**8.6 INTERNAL AUDITS (OPTION A)**

**8.6.1** The medical examiner’s office has a policy with procedures regarding internal audits (see American Forensics Chapter 22 Internal Audits) and the described procedures effectively maintain the management system in accordance with the ISO 17020 standard.

**8.6.2-8.6.4** Internal audits are performed once per year, but will be performed more often when warranted based on results of previous audits, or instability in the management system from any cause. The content of the audit will be planned by the technical and quality managers using previous audits, and ensuring all areas and processes of the office are included. The agreed upon audit strategy will be written as a checklist with each part of the audit initialed and dated on completion.

**8.6.5** Required components of the Medical Examiner audit

a. The audit is conducted by the technical manager, with assistance of the quality manager, with either forensic pathologist as needed.

b. Auditors do not audit their own work, so when this conflict of interest exists, a different member of the audit group in “a” above performs the audit. For example, since the office manager serves as quality manager, one of the forensic pathologists will be assigned to complaint monitoring, and verification of quality management documents, etc.

c. After the audit, all staff members participate in a debriefing to provide all audit findings, and any identified non-conformities, or phase I/II deficiencies.

d. At debriefing all actions and any changes in office polices/practices required are identified and documented. Time expectations are developed for implementation.

e. The debriefing includes any areas identified for improvement, with deadlines, and agreed-upon methods for implementation.

f. The audit and debriefing results are documented and distributed to all staff members.

**8.7-8.8 CORRECTIVE ACTIONS and PREVENTIVE ACTIONS (OPTION A)**

**8.7.1, 8.7.2, 8.8.1**

a. At the conclusion of each internal review, or based on any non-conformity that emerges between reviews, the technical manager, quality manager, and forensic pathologists will meet to formalize identification and to document nonconformities. Prior to any action, investigation may be required to determine the cause of the nonconformity. In addition to identification of nonconformities, the group will develop an action plan for correction that includes a rating of the urgency of correction (minor 3, intermediate 2, major 1), and establish a timeline for correction based on the urgency rating.

b. The same group (as above), will check documentation of complaint management, and the results of the internal audit to form preventative actions, and will establish timelines for any preventative action proposed.

c. Any actions taken for correction or prevention of nonconformities will be chosen to eliminate the underlying cause of the nonconformity.

d. All actions identified for correction or prevention will be documented in writing by the quality manager.

e. The group described in (a.) above will include in the correction/prevention timeline a date for the completion of implementation, and will document on that date the completion of implementation or progress toward implementation.

f. The timeline will also establish future checkpoints after implementation. On the checkpoint dates the committee (technical manager, quality manager, forensic pathologists) will evaluate and document the effectiveness of the corrective or preventative action. If this action is ineffective, consensus will be reach regarding a substitute action that will be implemented and tracked as above.

g. All documentation of corrective/preventative actions will be saved with the year’s internal audit documentation.