**ISO/IEC 17020 MANAGEMENT SYSTEM DOCUMENTATION AND CONTROL OF DOCUMENTS**

**8.2 Management system documentation (Option A)**

**8.2.1** The Medical Examiner’s Office maintains a quality improvement manual specific to ISO/IEC 17020, using the numbering system and sections from the international standard. This quality manual is separate from the general office policies and procedures, but compliments them, and cross references the policies and procedures where there is overlap. The quality manual is reviewed in its entirety by all staff members every 2 years, in conjunction with the policy and procedures review. Specific sections of the quality manual are distributed to all staff when any change to the section is made. Objectives developed from internal audits are discussed with all staff members at the first monthly staff meeting after the audit is completed. Progress on objectives is a standing meeting agenda item for each monthly all-staff meeting.

**8.2.2** The office forensic pathologists/medical examiners are invested in the management system and in fulfilling the objectives and requirements of ISO/IEC 17020.

**8.2.3** The Medical Examiner’s Office Manager is the appointed Quality Manager. The Quality Manager ensures that the processes and procedures are maintained after implementation. The Quality Manager reports to the Chief Medical Examiner when a need for improvement is recognized.

**8.2.4** Records, processes, and documents to fulfill the International Standard are linked or referenced in the quality manual.

**8.2.5** All Medical Examiner Personnel have access to management system documentation and related information, applicable to their duties. (Almost all documents are shared on the M-drive, accessible to all staff.) A few documents, such as personnel performance documents are provided to specific individuals, and are not universally available.

**8.3 Control of documents (Option A)**

**8.3.1** The Medical Examiner’s Office has procedures to control documents pertinent to ISO/IEC 17020. See also Medical Examiner’s Office Policy: Enactment of New Policies and Use of Policy and Procedure Manual

* 1. All sections in the Quality Improvement Manual are approved by the Forensic Pathologists, who sign and date the section at approval. The document is distributed (typically by email) 2 weeks before implementation.
	2. The Quality Improvement Manual is reviewed and updated in its entirety every two years. The revision date is added to each section, and the document is re-approved by signature. Changes to any section made in the interim, are similarly given a revision date, and require signature approval. Any revised document is distributed 2 weeks before it becomes effective.
	3. Changes to any section are noted/highlighted at distribution. Each policy and procedure and ISO/IEC section has the printed revision history of the document. Previous versions are saved in archive. Only the current version of “forms” are saved for computer access on the M-drive.
	4. Hard copy documents of the Quality Manual and all policies and procedures are maintained in 2 notebooks, one located in the administrative area, and one in autopsy area. All these documents are scanned and are available on the employee M-drive, and are indexed by category such as “safety”.
	5. All policies and procedures are labeled “Medical Examiner’s Office Statement of Policy, Procedure, and Practice”, followed by the policy title, and a policy summary. All Quality Improvement Manual items have the corresponding ISO/IEC 10720 title, numerical designation and title.
	6. Documents of external origin are stamped with the date received, and placed in the specific case file, or quality management file.
	7. Obsolete documents are pulled from circulation (hard copies and computer available) and archived. Only current forms are available on the M-drive. Aside from the archive, obsolete documents are not retained.