D2 The Living Quality Manual: An Essential For Every Forensic Laboratory

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The goal of this presentation is to describe one laboratory's approach to the development of a quality manual that incorporates all essential accreditation requirements and still has room for future growth.

The focus of today's business environment is towards one of increasing quality, certification, and accreditation. The forensic com- munity has also felt the impact of this trend, mainly through the changing and growing requirements put forth by ASCLD-LAB as it looks to adopt recommendations from ISO (International Organization for Standardization) and various scientific and technical working groups. The problem many laboratories face today is how to incorporate require- ments and recommendations from so many different sources in order to maintain necessary accreditations. Laboratories have had policies and procedures for many years, but often those manuals were written in such a way as to make adaptation to today's standards nearly impossible. How to write a quality manual that can change with the times is not an insignificant task.

Ideas for how to structure the new quality manual were researched. The quality manuals from other forensic laboratories and the quality systems implemented by non-forensic ISO certified organizations were reviewed. The system ultimately devised was structured by sectioning off all the different areas of laboratory operations into a table of contents. This consisted of the following nineteen areas:

1. Introduction
2. Personnel
3. Physical Plant
4. Document and Information Management
5. Safety
6. Customer Service
7. Subpoenas and Court
8. Purchasing
9. Laboratory Audits and Inspections
10. Chemicals, Standards, and Reagents
11. Evidence Control
12. Processing and Analyzing Controlled Substances
13. Processing and Analyzing Suspected Ignitable Liquid Submissions
14. Processing and Analyzing "Other" Evidence
15. Instruments and Equipment
16. Validation and Verification of Analytical Methods
17. Proficiency and Competency Testing
18. Corrective and Preventive Action
19. Other Professional Services.

Each section was further subdivided as necessary. The subsections were numbered at increments of five or ten to allow room for additions and changes. The development of each subsection was assigned to different personnel under the direction of the laboratory director. Each subsection contained only one policy supported by multiple methods, forms, documents, and logbooks as appropriate. A unique identifier was given to each document created. This identifier included the subsection number and a letter designation of "P" for policy, "M" for method, "F" for form, "L" for logbook, and "D" for document.

A standard layout was established under which each policy and method was created. Every policy and method had the same header of the laboratory name, section number and title. The information that appeared next was whether it was a policy or method followed by the subsection title. For example: 1535P Equipment Maintenance. Lines indicating revision, effective date, affected personnel, and approval signatures appeared next on each policy or method. The body of each policy and method included: scope, references, definitions, policy, or method as appropriate, and records. References included any other related sections of the quality manual, internally created documents, and external literature references. Definitions were created for consistency and clarity and were compiled into a glossary created for the quality manual. Records included any related forms or logbooks that were created during execution of the policy or method. Lastly, each policy had an area that was titled "compliance." Here the laboratory tracked the ASCLD-LAB, SWG, and TWG sections covered by the policy.

Analytical methods were structured a little differently to include additional sections titled "validation and verification" and "reagents and chemicals." The validation and verification section listed references for the method as well as in-house testing that was done to further validate or verify the use of the method. In-house testing documentation required for the quality manual is specified in the quality manual under a section titled "validation and verification." This format allowed a tie between the investigation and implementation phases of a method.

One of the biggest challenges a laboratory faces Under ISO is document control. This challenge is

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largely overcome by electronic maintenance of the quality manual. The electronic version is cross-referenced by hyperlinks to make it very user friendly. Only one hard copy of the quality manual exists in the laboratory and is maintained by the quality manager. This is the controlled copy of the quality manual. Laboratory personnel affected by a policy or method are required to sign each document signifying they were trained and cognizant of the method or policy content. As new revisions go into effect, they are presented at the monthly staff meeting and affected personnel are required to sign the new revision. All personnel have access to the quality manual electron- ically and sections of the quality manual may be printed. It is the users responsibility to ensure that they are not referring to outdated versions. A spreadsheet is maintained to track the implementation dates and revisions while old revisions are archived. Another spreadsheet is main- tained to track on-going work to the quality manual including personnel responsibilities and target deadlines.

While starting a new quality manual from scratch can be an overwhelming task, structuring the documentation system in such a manageable format is well worth the time. By gaining input from as many people as possible the task not only becomes easier, but even more important, buy-in to the new system is achieved. Adding pieces to older documentation to meet the new accreditation requirements only results in an awkward and difficult to use quality manual. A new quality manual that is electronically based will allow for easy, unlimited future growth.

Quality Assurance, Accreditation, Quality Manual

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