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The Master List--A Great Tool for Document Management

By Elizabeth Gentry

I am often asked, "What documents make up our management system" and "Is there a simple and efficient way to maintain and keep track of these publications?" Management system documents are comprised of the laboratory quality manual, appendices, standard administrative procedures (SAPs), good measurement practices (GMPs), good laboratory practices (GLPs), standard operating procedures (SOPs), checklists, and forms, but also include regulations, standards, normative documents, drawings, software, specifications, instructions, and manuals. The management system includes documents from both external and internal sources. External sources may include organizations like NIST, NVLAP, ASTM, OIML, and ISO/IEC to name a few.

ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories, notes that the term "document" can be broadly applied and includes "policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. . ." This broad definition essentially means that laboratories are faced with the task of managing huge numbers of documents in both hard copy and electronic formats.

Not to worry, ISO/IEC 17025:2005 provides an effective tool to keep track of them all...the Master List. The Master List is used to list all of management system documents in one place. All laboratory personnel can go to this list to make sure they are using the correct version of any management document. The Master List specifies the current revision and distribution of each document. Not only does the Master List help prevent invalid or obsolete documents from being used, but helps avoid time-consuming corrective actions.

The Master List may be a stand-alone document or it may be included in a document control procedure (Section 4.3.2.1 b). Laboratories that based their system on the quality manual template (NISTIR 5802, compliant to ISO/IEC Guide 25:1990) will find Master List components located in QM 2 (References and Definitions), Appendix H (Procedures List), and Appendix N (Document Control). Note: numbers in parenthesis represent section numbers in ISO/IEC 17025 or NIST Handbook 143.

They say spring is the season to clear out the clutter and streamline our lives. We often apply this idea in our home closets or garages. Since laboratories are required to periodically review management system documents to ensure continuing suitability and compliance with requirements (Section 4.3.2.2), they should apply the house cleaning principle to the Master List as well. Laboratories with large numbers of documents often develop a review schedule to spread their review work throughout the year, making it easier to fit into their busy calibration schedules. Management system document review activities can be summarized and the Master List updated during the annual quality audit.

Laboratories are also guided to use the latest valid edition of standards and methods published in international, regional, or national standards when possible (Section 5.4.2). Current versions of technical, quality, and proficiency testing publications are on the WMD website (<http://www.nist.gov/labmetrology>). What happens when a new standard or method is issued mid-year? If it is permitted by the laboratory's document control procedure, an authorized individual can review and adopt the procedure, followed by a hand-marked change (with date and signature) on the controlled copy of the Master List, thus designating the new version until the next time the quality manual is updated.

It is important to evaluate whether all Master List documents are necessary and appropriate to the laboratory's current scope and calibration activities. Why maintain procedures for calibrations that are not even performed? Removing unnecessary documents can make an instant impact and streamline document control efforts.

What about obsolete documents or those needed for either legal or historical purposes? These documents are not included in the Master List, but should be suitably marked so laboratory personnel do not mistake them for active documents. Some laboratories have found it useful to designate a well marked storage location for their obsolete and historic documents to help ensure they are not unintentionally used.

New Master List Resource Available Online

WMD has developed a new resource of externally generated metrology publications to assist in developing and reviewing Master Lists. Laboratories should only include documents that are appropriate to the current WMD Recognition or NVLAP Accreditation Scope. Remember, the template Master List is not an all inclusive list, but simply a snapshot in time. Organizations are constantly revising and updating their publications. This list is posted online at the WMD website (<http://www.nist.gov/labmetrology>).