Developing and maintaining a functioning quality management system (QMS) is fundamental to the success and quality of laboratory calibration services. Managing the quality management process establishes the infrastructure for all laboratory operations. It’s important to note that the quality manual is never finished, it is always being improved…by you!

Use this analysis tool to evaluate essential QMS elements to determine the functionality of your system. These elements are considered when reviewing QMS during the annual recognition cycle. An active QMS program can assure the laboratory is in a constant state of readiness, prepared for an external assessment.

1: **Quality Policy.** Describe the laboratory quality policy. Cite the location where is it published? How does the policy provide assurances that the laboratory top management has designated mission, objectives, roles (including quality manager, technical manager, deputies) to laboratory personnel?

2: **Personnel.** Describe the current laboratory personnel and organizational hierarchy. Compare the related documents to ensure they are current, up-to-date and aligned with what is submitted to OWM in the recognition package (e.g., Appendix B-D).

Describe the status and location of these documents and information: laboratory organization chart, personnel list and authorized signatories, job descriptions, personnel competencies, training and qualification process. Describe how lines of authority and responsibility are clearly defined for all laboratory staff.

Identify the QMS policy and Standard Administrative Procedure (SAP) that address training, professional development, continuing education, and OJT in-house education and how they are currently implemented and documented (recorded). Describe how you identify and authorize staff who have requisite knowledge and skills to train others in the laboratory. Identify specific opportunities for improvement that facilitate and guarantee succession planning (i.e., minimum 3 examples).

3: **Document Control.** Observe and describe the functionality of your document control process. What challenges have been observed or documented in internal audits or external evaluations?

List the name and location of your Standard Administrative Procedure (SAP) for Document Control. Does the Document Control SAP contain a flowchart? If yes, analyze the process and flowchart for gaps and improvements. If no, sketch a flowchart that matches the current document control process and then analyze the process for gaps and improvements. Identify specific opportunities for improvement that facilitate document control (i.e., minimum 3 examples).

Describe the status of these QMS components:

**Master List** – Identify and provide a list of all locations where documents, references, and procedures are incorporated into your QMS. Are there ways to simplify these lists to minimize the effort required to maintain them as up to date? Evaluate the status of each publication (e.g., current or out of date) on the master list. Are there publications listed that are outside the current laboratory measurement scope? What publications are missing or should be added? Describe the objective evidence that confirms periodic review has occurred.

**Version Control** – Briefly describe the process used for version control. List an example of the current version structure. Examine document page headers, footers, formatting. Are they consistently applied over all QMS documents? Note corrective, preventive, or improvement actions that you identify during your review. [Review the *Electronic File Organization Tips* handout for simple version control best practices.]

**File Naming and Structure** – Examine and describe the electronic file and/or archive structure used to organize QMS documents. Are they intuitive and easily retrievable by multiple personnel? Do file names contain the issuing authority (e.g., the lab name/abbreviation; AK, MD, VA)? Do the file names include the title of the document? Is there a Table of Contents or Index? Test your answer by having a team member find a document within the file structure (i.e., they provide their observations to you). Record and evaluate their feedback to identify improvements. Would new laboratory staff or external auditor be able to follow your file structure to locate a desired controlled document or record? [Review the *Electronic File Organization Tips* handout for best practices.]

**Note**: Verify QMS uses the current name for the Office of Weights of Measures (OWM), not Weights and Measures Division (WMD). Identify all instances using the outdated name and develop corrective action to implement the updated reference.

4: **QMS Organization and Functionality.** What is the current official version of the Quality Manual? Is it regularly reviewed and updated. Is the QMS written in clear, easily understood language? Describe improvements that you recommend.

**Document Structure.** Is your QM maintained as a multiple individual document files or in one (1) combined file, containing all chapters with one revision date representing the version (one complete unit is the preferred structure, uniform headers, footers, page numbering, version control)? Are your SAPs maintained as individual files or in one (1) combined document file, containing all SAPs with one revision date representing the version (one complete unit is the preferred structure, uniform headers, footers, page numbering, version control)? [QM and SAP structured as individual files with multiple revision dates is inefficient and increases likelihood of document control nonconformities.] Describe improvements that you recommend.

Describe the Standard Administrative Procedure (SAP) used by the laboratory to ensure the QMS is read, understood, and used by all laboratory staff. Cite the process or procedure and describe where objective evidence of QMS training and ongoing updated training is located. Describe the objective evidence that demonstrates that each laboratory personnel understand the QMS.

**Quality Management System (QMS) Activity.** Illustrate (or trace) the relationships between QMS components, including the links (or references) from the appropriate sections of the quality manual to the standard administrative procedures (SAPs), work instructions, appendices, forms, and other supporting documents. Follow one (1) *Topic Thread*, such as Personnel Training, Document Control, or Internal Quality Auditing. Use the space below or attach the analysis. Identify gaps, where connections between QMS components don’t exist and develop appropriate corrective actions.

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|  | **Management Review – QMS Relationships**   * QM 5 Management Review 🡪 SAP 19 * QM 5 🡪 Master List Reference (APLAC TC003: 2010) * SAP 19 🡪 Conducting a Management Review * SAP 19 🡪 SAP 12 Corrective Action Process * SAP 19 🡪 Appendix F Organizational Chart (identify staff attending meetings) * SAP 19 🡪 Management Review Template (Form – document meeting) * SAP 12 🡪Action Item Log, Action Item (Form for RCA & Action Plan) * SAP 12 🡪 QM 12 Records Retention Policy (Retaining action item documentation) * **MISSING:** SAP 19 does not connect to 🡪 QM 12 Records Retention Policy (Retaining Management Review reports and other associated records) * **C.A.:** Add link/reference to QM 12 in SAP 19; implement in updated QMS (Due: 5/1/2016). |

5: **Internal Audit Process.** Assessment is critical to monitoring the effectiveness of the laboratory QMS. Identify the documented procedure used in your laboratory to conduct an internal audit and identify the roles and responsibilities performed by each laboratory personnel. Provide a list of the forms and tools used to conduct the audit and record the objective evidence you identify. Describe how your laboratory ensures a FRESH assessment, each year, avoiding complacency, when using the same template audit forms and process.

Does the internal audit process (SAP) contain a flowchart? If yes, analyze the process and flowchart for gaps and improvements. If no, sketch a flowchart that matches the current documented process and then analyze the process for gaps and improvements. Identify specific opportunities for improvement that will facilitate the internal auditing process (i.e., minimum 3 examples).

Describe a trend or common nonconformity observed during the last two internal audits. Describe the process used to identify the root cause (e.g., RCA) of problems and the resulting actions taken and how the actions were monitored. Describe the CAPA forms and logs used to document and track your findings. Describe the follow-up assessment and monitoring process that was used to ensure that actions were effective.

6: **Management Review Process.**

Describe the short term goals identified in the last management review. If missing, describe three (3) short term goals for the laboratory.

Describe the long term goals identified in the last management review. If missing, describe three (3) long term goals for the laboratory.

Describe three (3) laboratory strengths identified during the last management review process. If missing, read the management review records (e.g., report and PPT) and describe three (3) strengths you identified.

Describe 3 laboratory weaknesses identified during the last management review process. If missing, read the management review records (e.g., report and PPT) and describe three (3) weaknesses you identified.