July 15, 2025

Subject: Guidance on 2025 Annual Submission Special Technical Assessment

Title: Special Technical Assessment (STA) of Standard Administrative Procedure (SAP) Topic Area: Training (w/ Audit of Reporting and Software recommended)

This is guidance for the 2025 Annual Submission STA evaluating QMS documents pertaining to:

- Training (required to complete with SAP Worksheet)
- Reporting (recommended to complete with SAP Worksheet but not required)
- Software (recommended to complete with SAP Worksheet but not required)

This is a technical audit with a focus on evaluating how the topic area is addressed within the QMS; it provides an opportunity for removing redundancy and simplifying QMS documents through referencing and citing (webbing) primary documents (e.g., SAP). It involves the evaluation of all QMS documents, including but not limited to, the QM and associated appendices, SAPs, Forms, and the latest ISO/IEC 17025 internal audit form. A template SAP audit form was provided to participants June 26, 2025 and at the CRMAP training. An updated version of this SAP worksheet with more guidance is attached.

OBJECTIVE: To improve the efficiency of procedural documents.

- Ensure QMS is functioning as intended.
    - The procedures are current with ISO/IEC 17025 requirements and operating within the framework of the QMS.
    - The lab process is complete/sufficient
- Highlight where topic area is addressed in QMS documents and how items are linked, helping to minimize redundancy.
- Identify continuous improvement opportunities for QMS documents for topic area.

SUBMISSION REQUIREMENT: There are three required submittal items

- SAP tool for assessment Worksheet
- Reference documents
- Objective evidence

and two optional items.

- Cross-reference table
- Visual mapping

EVALUATION: Required submittal items and identified improvements

- The audit is complete and all required items are submitted.
- The objective evidence demonstrates conformity and execution of the SAP and how it satisfies lab requirements (e.g., marked up calibration certificate).
- If gaps are identified, then action items are created according to lab procedures.

WEBINAR: Microsoft Teams Special Technical Assessment Q&A webinar will be held on Wednesday, July 23 at 1 pm Eastern Time. Teams link: **Join the meeting now**

Additional Details for STA submission: The following probing questions are intended to assist with the audit; addressing these as you work through the STA will help ensure completeness.

1) The SAP Worksheet Assessment Tool should be used for the assessment (See Attached). *One Worksheet required per SAP.* A lab may have more than one SAP for the topic. The worksheet has columns that should be filled out while considering the below questions (it is possible that all columns will not be filled out for each requirement):
   - Worksheet: What SAP is dedicated to the topic area?
     - Where is this SAP referenced in the latest ISO/IEC 17025 Internal Audit (section numbers)?
     - Where in the Quality Manual is this ISO/IEC 17025 requirement addressed?
     - What SAP sections address this requirement? Is it adequate? If not, add to gaps.
     - What associated QMS documents (appendices, forms, other SAPs, templates, etc.) support conforming with this requirement?
     - What objective evidence is available to support fulfillment of the requirement?
     - Gaps and Action Items
       - Does SAP adequately address the requirements of ISO/IEC 17025, Quality Manual, and NIST Handbook requirements (HB 143 and 105s have training and reporting requirements, respectively)?
       - Is the SAP cross-referenced to QMS? Is it referenced properly?
     - Observations provided at bottom of table in SAP worksheet
       - Are there areas in your QMS that addresses other requirements of the topic area not addressed in the SAP? If so, are they only addressed in the QM?
         - The cross-referencing exercise discussed in optional #4 would help with locating requirements not addressed in SAP. And where the topic area in question is addressed in other QMS documents.
       - Are there opportunities to simplify or clarify the QMS documents with references to the SAP to minimize redundancy?
       - Is additional detail needed for consistent application?
       - Are the records for the SAP easily accessible and discoverable to required staff?
       - Are templates, forms, and other docs referenced properly in the SAP?
2) The corresponding reference documents, such as SAP, QM, associated appendices, and forms used in the SAP Worksheet Assessment Tool.
3) Associated Objective evidence and any action items identified in the SAP Worksheet Assessment Tool.
4) *Optional*: Cross-Reference Exercise. This supports the identifying of other sections of the QMS and ISO/IEC 17025 that has requirements for the given topic area not addressed in the SAP. No template form is provided. An example of word search cross-referencing the topic area in ISO/IEC 17025, Quality Manual, and other SAPs and assessing if the primary SAP covers all lab requirements will be provided on Wednesday, July 23 at 1 pm eastern time at the STA Q&A webinar.
5) *Optional*: Map or Web. This represents the cross-reference exercise graphically.

SAP	**#**	*Title (Paraphrase)* **□Training □Reporting □Software □Other**				
ITEM	**Internal Audit References** *(one section per row)*	**Quality Manual References** *(appropriate sections)*	**SAP References** *(appropriate sections)*	**Other References** *(templates, forms, and other SAPs as applicable)*	**Objective Evidence** *(short description and file name as applicable)*	**Gaps and Action Items if Applicable** *(conformity with documentary standards (i.e., ISO/IEC 17025, NIST Handbooks, SOPs, etc.) and lab practices; add short description as applicable)*
1						
2						
3						
4						
5						
6						

*Add or remove rows as needed

Observations *(Are other requirements not addressed in this SAP? Any Opportunities to simplify? Records organized?)*: