Laboratory Quality Systems Homework # 1 – Identifying Documents and Records for ISO Accreditation/ Writing SOPs
Due by Midnight on Monday, February 10, 2025

Background

Part I: Identifying Documents and Records for ISO Accreditation
The ISO/IEC 17025:2017 standard considers the operations in laboratory as processes. To ensure that the laboratory processes are working and the outcomes should be as expected. During an audit, the assessor will be reviewing the laboratory system to ensure the following:

- Consistent understanding of the laboratory processes;
- Consistent application of laboratory processes; and
- Outcomes as expected

The standard requires that all laboratories maintain two types of items:

1. Documents: Outline or describe procedures, documented processes, programs, and plans.

2. Records: Provide proof of and document laboratory activities (eg. data files, deviations, complaints, corrective action), and define criteria and requirements for lab activities.

Directions for Completing Part I of the Assignment:

1) Review ISO/IEC 17025: 2017 (Sections 4 – 8)

2) Complete the Table in the following document ("Table identifying records and documents required per ISO/IEC 17025:2017"). For each section (listed in Excel Sheet) of the ISO/IEC 17025:2017 Standard (link above):

   - Provide a brief description of the section , and

   - Determine if the statement requires a document or record or neither and indicate in Column C. Documents outline or describe procedures, documented processes, programs, and plans. Records are used to provide proof of and document laboratory activities (eg. data files, deviations, complaints, corrective action), and define criteria and requirements for lab activities.

   Example is provided in table.

Part II: Writing SOPs

All laboratories develop a Standard Operating Procedure (SOP) to outline or describe procedures, documented processes, programs, and plans. SOP is a set of written instructions that document a routine or repetitive activity conducted by an organization. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of a product or end-result.

The purpose of SOPs is to:

- detail the regularly recurring work processes that are to be conducted or followed within an organization; and
- outline the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality.

SOPs are usually specific to an organization or facility. The description of SOP activities assists the organization to maintain quality control and quality assurance processes and ensure compliance with governmental regulations.

SOPs should be written in a concise, step-by-step, and easy-to-read format. The information presented should be unambiguous and not overly complicated. The use of active voice and present verb tense is recommended. The term "you" should not be used, but implied. The document should not be wordy, redundant, or overly lengthy. Keep instructions simple and short. Information should be conveyed clearly and explicitly to indicate exactly what is required.

Directions for Completing Part II of the Assignment:

1) For one of the documents identified in the table from Part I of the assignment, develop a SOP using the attached SOP template and "General SOP Guidelines/Checklist" (Note: you may want to select a document that is related to a process you are familiar with) Please follow the guidelines/checklist listed below.

Resources for completing Homework

- Guidance for Preparing Standard Operating Procedures (SOPs) by EPA
- SOP Template (On Course Website)
- General SOP Guidelines/Checklist (On Course Website)
- Table identifying records and documents required per ISO 17025:2017 (On Course Website – Excel Sheet)

GRADING

Part I: Identifying Documents and Records for ISO Accreditation	
Most required documents and records identified with brief descriptions	4 pts
Part II: Writing SOPs	
All relevant sections included in the SOP	1 pt

Language in the SOP is clear and consistent	2 pts
All steps in the SOP are included and listed in appropriate order	2 pts
Mechanics/ Grammar/ Formatting	1 pt