STANDARD OPERATING PROCEDURE (SOP) – REVIEW CHECKLIST

Agency:	
SOP Title:	
Revision Number:	Revision Date:

SOP SECTION	YES	NO	N/A	COMMENTS
Title Page				
Document Control (on each page following the Title Page)				
Short Title or ID Number				
Revision Number				
Date				
Page Number				
Table of Contents				
Introduction/Scope and Applicability				
Summary of Method				
Definitions of Terms/Acronyms				
Interferences				
Personnel Qualifications				
Health, Safety and Cautions				
Equipment and Supplies				
Procedures				
Instrument Siting Requirements				
Instrument Set-Up				

STANDARD OPERATING PROCEDURE (SOP) – REVIEW CHECKLIST

SOP SECTION	YES	NO	N/A	COMMENTS
Operation				
Calibrations				
Sample Collection and Handling				
Routine Service Checks				
Preventative Maintenance and Repairs				
Troubleshooting				
Data Management and Record				
Data Acquisition				
Calculations				
Data Storage/Transmittal				
Quality Control and Quality Assurance				
Reference Section				

ADDITIONAL ITEMS	YES	NO	COMMENTS
Is the SOP updated to reflect current instrument model or process being used?			
Has SOP been reviewed/revised within required frequency?			
Have items in addendum been added to new version?			

Recommendation:	☐ Approve as is	☐ Request amendment
Reviewer Signature:		Date:
Peer Reviewer Signature:		Date:
Management Signature:		Date:

Title Page-The title page or cover page of each SOP should contain the following information:

- Title that clearly identifies the activity or procedure
- SOP identification (ID) number (only if a MLD SOP)
- Date of issue and revision number
- Name of the applicable agency, division, and/or branch to which this SOP applies
- Signatures and signature dates of those individuals who approved the SOP. Electronic signatures are acceptable for SOPs maintained in a computerized database. (A separate signature page is acceptable.)

Document Control-Document control should be on each page following the title page and should contain the following information:

- Short title (abbreviated version of the actual title) or SOP ID number
- Revision number (the number of times the SOP has been revised)
- Date of issue
- Page number and total number of pages (Page X of Y)

Table of Contents-A quick reference for locating specific information. The Table of Contents should include a section number, title, and the page number in which the section begins.

Introduction/Scope and Applicability-Describes the purpose of the SOP, regulatory requirements and limits to the use of the SOP.

Summary of Method-Briefly summarizes the procedure.

Definition of Terms/Acronyms-Defines any uncommon terms and acronyms used throughout the SOP. These can additionally be summarized in a list in the beginning of the document.

Interferences-Describes any component of the process that may interfere with the accuracy of the final product.

Personnel Qualifications-States the minimum experience the user of the SOP should have in order to complete the tasks satisfactorily, including any applicable requirements (i.e. certifications, training).

Health, Safety and Cautions-Listed in this section and at critical steps in the procedure are operations that could result in personal injury or loss of life if the procedure is not followed or is followed incorrectly. Additionally, critical steps in the procedure should be identified that could result in equipment damage, degradation of sample, or invalidation of results.

Equipment and Supplies-Describes essential equipment, materials, reagents, chemical standards, and biological specimens needed for the procedure.

Procedures-Identifies all pertinent steps, in the order they should be performed, including all materials needed to accomplish the method. Instrument SOPs should include the following

- Instrument siting requirements - How to site the instrument
- Instrument set-up – How to set up the instrument for use
- Operation – How to operate the instrument
- Calibrations – Step by step instructions
- Sample collection and handling – Step by step instructions
- Routine service checks – Step by step instructions, including frequency
- Preventative maintenance and repairs – Summary of maintenance checks and repairs, including frequency
- Troubleshooting – Common problems and how to resolve them

Data Management and Records-Includes methods of data acquisition and reduction, calculations performed, forms used, reports written and data and record storage information.

Quality Control and Quality Assurance-This section describes quality control (QC) materials and procedures that are required to demonstrate successful performance of the method. It should include frequency of QC checks, limits/criteria for QC results, actions required if QC results are not within limits/criteria (corrective action process), and procedures for reporting QC data and results.

Reference Section-Documents or procedures (such as related SOPs, published literature or other manuals) that interface with the SOP should be fully referenced, version included. Citations cannot substitute for the description of method being followed by the organization.

Is SOP updated to reflect current instrument model being used? -Indicate if the SOP matches the current instrument model being used.

Has SOP been reviewed/revised within required frequency? -Indicate if the SOP has been reviewed/revised within the required time period. SOPs are required to be revised at least every 5 years.

Have items in addendum been added to new version?- If there is an addendum to the previous version, indicate if all items have been incorporated into the new version.