New Mexico Environment Department Surface Water Quality Bureau

Standard Operating Procedure

for

CREATION AND MAINTENANCE of STANDARD OPERATING PROCEDURES (SOPs)

Approval Signatures :

Acting Quality Assurance Officer

11/14/2017

Kris Barrios, Subject Matter Expert/ Program Manager, MASS

Date

Date

11.14.17

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 2 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

1.0 Purpose and Scope

This Standard Operating Procedure (SOP) describes the process for creating, reviewing, and maintaining SOPs for the Surface Water Quality Bureau (SWQB). Its purpose is to assure consistency and uniformity in the development of the procedures for collecting environmental data and all field activities that are conducted by the SWQB.

2.0 Responsibilities

2.1 Program Manager

- Provides input on the scope and intent of the SOP as it pertains to the program's goals and objectives
- Responsible for ensuring Subject Matter Expert (SME) is coordinating and providing updates to the Quality Assurance Officer (QAO)
- Reviews existing SOPs every 2 years and provides input to revising the SOP, as applicable
- Provides revisions to the QAO

2.2 Project Manager

- Provides input on the scope and intent of the SOP as it pertains to the program's goals and objectives
- Provides revisions to the QAO and SME

2.3 Quality Assurance Officer (QAO)

- Ensures SOPs meet the requirements of the Surface Water Quality Bureau's Quality Assurance Project Plan (QAPP)
- Refers to technical resources to ensure process is defensible with peer reviewed science
- Notifies SME when SOP is within 6 months of the two (2) year review period
- Requests input from SWQB personnel or other individuals with expertise in the subject matter.
- Approves the SOP following review and consensus of the document.
- Maintains electronic and hard copies of the document along with acknowledgement forms of staff working under the SOP.
- The QAO ensures the SOP is accessible through the SWQB's website.
- The QAO ensures that the current SOPs are available at available on the SWQB's internal server.

2.4 Subject Matter Expert (SME)

- Responsible for coordinating and providing updates to the QAO
- The SME uses applicable references in order to prepare or revise the SOP
- Reviews existing SOPs every two (2) years and updates the SOP as the procedure or equipment changes

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 3 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

- Provides revisions to the QAO
- 2.5 <u>Other Personnel and Staff</u>—Other personnel and staff working under a particular SOP are required to sign an acknowledgment that they are familiar with the SOP and follow the procedure outlined in the SOP.

3.0 Background and Precautions (Procedural and Safety)

- 3.1 <u>Background</u>—This SOP was created to ensure SOPs developed by the SWQB are prepared, reviewed, and implemented in a consistent manner.
- **3.2** <u>Procedural Precautions—This</u> SOP is intended to be used for the administrative development of SOPs for the SWQB and has not identified specific precautions in regard to its procedure beyond those found in a typical office environment.
- 3.3 <u>Safety Precautions</u>—This SOP does not cover actions or procedures that may pose specific safety issues beyond those found in a typical office environment.

4.0 Definitions

- **4.1** <u>Program Manager</u>An individual within the SWQB that manages a program such as the Watershed Protection Section (WPS), the Point Source Regulation Section (PSRS) or the Monitoring, Assessment and Standards Section (MASS). The Program Manager and Project Manager are not necessarily synonymous.
- **4.2** <u>Project Manager—An individual responsible for a specific project.</u> This individual, in most cases, holds a different title within the organization. The Program Manager and Project Manager are not necessarily synonymous. The Project Manager may be the same individual as the Subject Matter Expert.
- **4.3** <u>**Quality Assurance Officer (QAO)**</u> Is the individual within the MASS that is responsible for overseeing the development and implementation of all quality assurance procedures and processes within the SWQB including those projects that receive support or funding from the SWQB. The QAO is also responsible for validating and verifying data sets for potential use in assessment of surface waters.
- **4.4** <u>**Quality Assurance Project Plan (QAPP)**</u>—A formal planning document for environmental data collection activities that describes the data collection procedures and the necessary quality assurance and quality control activities that

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 4 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

must be implemented to ensure that the results are sufficient and adequate to satisfy the stated performance criteria.

- **4.5** <u>**Quality Management Plan (QMP)**</u>establishes the principles, requirements, and practices necessary to implement the quality system for the SWQB's environmental data operations.
- **4.6** <u>Standard Operating Procedure (SOP)</u>—A document that lists the steps that should be completed when doing a task.
- **4.7** <u>Subject Matter Expert (SME)</u>—A person who is familiar with the purpose and procedure for accomplishing a task. The SME may be the same individual as the Project Manager.
- **4.8** <u>Surface Water Quality Bureau (SWQB)</u> A Bureau under the Water Protection Division of the New Mexico Environment Department. The SWQB's mission is to preserve, protect, and improve New Mexico's surface water quality for present and future generations.

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 5 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

5.0 Equipment and Tools

Not applicable for this SOP

6.0 Step-by-step Process

6.1 Development, Reviewing or Revising an SOP

6.1.1 Creating a New SOP

- The Program Manager, Project Manager, SME or QAO proposes that a new procedure is needed.
- A draft SOP is prepared by the SME following the outline identified under SOP 1.1 Creation and Maintenance of SOPs (this document).
- The QAO ensures that the SOP is aligned with the SWQB's objectives and established quality assurance processes as described in the SWQB's QMP and QAPP.
- The QAO coordinates with the SME, Project Manager and Program Manager to develop an SOP that outlines the process and procedure in a clear, concise and defensible manner.
- The Program Manager, QAO, and SME document their approval by signing the front page of the SOP.
- The QAO ensures the SOP is accessible through the SWQB's website.

6.1.2 Revising an existing SOP

- The Program Manager, Project Manager or SME will identify when a revision to a specific procedure is needed; for example, when a new instrument is purchased or a new procedure is adopted.
- Periodically, the QAO may contact SMEs and/or Project Managers to inquire about any changes which have been made to a specific procedure.
- Proposed revisions to the SOP are prepared by the SME following the outline identified under this SOP (SOP 1.1 Creation and Maintenance of SOPs).
- The QAO coordinates with the SME, Project Manager and Program Manager to incorporate clear, concise and defensible revisions.
- The QAO, upon satisfaction of the SOP, approves revisions.
- The Program Manager, QAO, and SME document their approval by signing the front page of the SOP.
- The QAO ensures the latest version of the SOP is accessible through the SWQB's website.
- If substantive changes are proposed, then a statement of basis (rationale) for the changes should be summarized in the revision history in each SOP for the historical reference.

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 6 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

6.1.3 <u>Undergoing the two (2) year review of and SOP</u>

- The QAO keeps track of SOPs and the review dates, and will contact the SME 6 months before the SOP's 2-year review date.
- The SME and Program Manager are responsible for reviewing the SOP and ensuring that the methods are still valid and up to date.
- Proposed revisions to the SOP are prepared by the SME following the outline identified under this SOP (SOP 1.1 Creation and Maintenance of SOPs).
- The QAO coordinates with the SME, Project Manager, and Program Manager to incorporate clear, concise and defensible revisions.
- The QAO approves revisions.
- The Program Manager, QAO, and SME document their approval by signing the front page of the SOP. Standard Operating
- The QAO ensures the latest version of the SOP is accessible through the SWQB's website.

6.2 Drafting the SOP

6.2.1 General Organization of the Document

- Margins should be set as "Normal Margins" which by default includes 1" margins on all sides
- Typeset should be "Times New Roman"
- Font Size should be 12 pt. font (excepting sub- and superscripts or footnotes/endnotes)
- Format should be in outline structure using a decimal outline format as used in this SOP
- Alignment should be left with no justification.
- Paragraphs should be single spaced.
- Headers should be on every page and contain the following:
 - title (should be descriptive and brief);
 - the SOP identification number (for example, SOP 1.1);
 - the Revision number (use 0 as original and numerically increase one whole number for each signed and approved revision);
 - the page number (number all pages) and how many total pages in the document;
- the effective date (the last date of the signatories); and
- and the next revision date (no more than two (2) years after the effective date).
- References, including primary literature shall be cited using the Council of Science Editors (CSE) format.

6.2.1 Components of the SOP

An SOP explains how to accomplish a specific task and does not contain extraneous information. Staff are required to follow the SOP as written and without deviation. If there are any significant changes to the process,

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 7 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

procedure, or equipment which inhibit staff from conducting the work as written in the SOP, the SOP is required to be updated in accordance with this SOP prior to working under any new changes.

The SWQB's SOPs, in general, will include:

6.2.1.1 Title Page

Should Include the following language:

<u>Title</u> New Mexico Environment Department Surface Water Quality Bureau Standard Operating Procedure For TITLE OF SOP

Approval Signatures

The approval should include signatures from the following:

- Program Manager
- Subject Matter Expert (can in some instances also be the Program Manager or Project Manager)
- Quality Assurance Officer.

6.2.1.1 Table of Contents

Generally, do not include a table of contents because the document should be organized stepwise so that a table of contents is not necessary.

If a Table of Contents is incorporated, include the sections described below in most SOPs. If a section does not apply, indicate "NONE" below the section heading. Include additional sections as necessary.

6.2.1.2 Sections of the SOP

Section One (1.0). "Purpose and Scope"

State the purpose of the SOP. Indicate the scope of the work or tasks that it covers (for example, the collection of water samples for chemical analysis). The scope may be used to expand on the brief title.

Section Two (2.0). "Responsibilities"

List by title or group the persons who are responsible for implementing the SOP. This should include staff involved in the development, implementation or oversight of the SOP. This

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 8 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

should include each individual title and their responsibilities as well as qualifications to carry out those responsibilities.

Section Three (3.0). "Background and Precautions (Procedural and Safety)"

Provide any background that will make the SOP more useful. Do not include "background information," which, although perhaps interesting, does not contribute to the usefulness of the SOP.

Procedural Precautions—any interferences or reasoning on process that needs to be considered, cautions on equipment use, or implementation that could cause data invalidation (holding a flow meter at an unlevel angle).

Safety Precautions—should include any personal health or safety warnings or precautions to be aware of when implementing the SOP

Unless expressly stated in the specific SOP or unless the person doing the procedure has approval from their supervisor, all other SOPs must be followed for the procedures that they cover.

Section Four (4.0). "Definitions"

Include definitions that make the SOP more useful; particularly define terms that may be easily or commonly confused.

- Surface Water Quality Bureau (SWQB)
- Quality Management Plan (QMP)
- Quality Assurance Project Plan (QAPP)
- Project Manager
- Program Manager (may be the same as the project manager)
- Subject Matter Expert (SME, may be the same as Project Manager or Program Manager)
- Quality Assurance Officer (QAO)
- Standard Operating Procedure (SOP)

Section Five (5.0). "Equipment and Tools"

List the equipment and tools that are needed to accomplish the task described by the SOP. Include any periodic maintenance notes and common trouble shooting procedures (if brief) or citations to documents addressing these equipment and tool procedures.

<u>Section Six (6.0). "Step-by-step Process Description</u>" List the steps that are required to accomplish the task. Write this section as a series of stepwise instructions using the following guidelines in structure and content: Use simple imperative

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 9 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

sentences. For example, say "Calibrate the sensors in the lab," and not "The sensors shall be calibrated in the lab." Make the instructions clear and complete so that most personnel could take the instructions and complete the task in accordance with the SOP. If a flow chart would make the SOP more useful, prepare one.

- Describe preparation. Include how equipment is cleaned and calibrated, or if there is a specific SOP on equipment calibration, then reference that SOP
- Provide complete sampling procedures
- Specify the person who is responsible for doing each step
- Describe when and how data collection forms or other forms should be completed and where to find them. Include forms in Section 7 of the SOP.
- If applicable state the specific standard method that will be followed. It may be an EPA approved method or other standard method. Explain any deviations or modifications to the standard method and the circumstances under which a deviation may or may not be acceptable
- State how samples will be preserved, processed, handled and stored to ensure integrity
- Provide directions for operation and maintenance of field equipment
- Describe sample tracking method/ chain of custody information if submitting samples to an analytical laboratory
- Describe post collection/processing procedures
- Explain the process for data verification and validation
- Include any other QA processes or applicable references to the QAPP or other SOPs.

Section Seven (7.0). "Data and Records Management" Describe where the data will be stored or managed after obtaining it from field work or the laboratory. Records, including field notes, should be described here with information as to length of time they will be retained. Be sure to ensure management and retention of records are in accordance with the State's General Government Administration, Public Records regulations (1.13 NMAC).

<u>Section Eight (8.0). "Quality Control and Quality Assurance"</u> Describe the preparation of appropriate QC procedures (selfchecks, such as calibrations, recounting, reidentification) and QC material (such as blanks (trip, field, or method); replicates; splits;

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 10 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

fortifications; spikes; and performance evaluation samples) that are required to demonstrate successful performance of the
method. Specific criteria for each should be included. Describe
the frequency of required calibration and QC checks and discuss
the rationale for decisions. Describe the limits/criteria for QC
data/results and actions required when QC data exceed normal
range. Describe the data verification or validation process or
reference the SOP for data verification and validation.

Section Nine (9.0). "Related Forms"

List the forms or supporting documents that are needed to complete the task. Ensure that the forms are available at SWQB/PUBLIC/MAS Core Documents/Field Sheets and Forms.

Section Ten (10.0). "Revision History"

Describe the changes to the current revision, the date and whether the revision was technical or editorial. Format should be as follows:

- Revision 0. Effective YYYY.MM.DD. Original SOP. NAME OF QAO, QAO; NAME OF SME, SME
- Revision 1. Effective YYYY.MM.DD. Brief summary of necessary revisions.
 NAME OF QAO, QAO; NAME OF SME, SME
- Revision 2. Effective YYYY.MM.DD. Breif summary of necessary revisions.
 NAME OF QAO, QAO; NAME OF SME, SME

Section Eleven (11.0). "References"

Include all references used to establish the technical merits of the procedure. Format should be in a name-year scientific style citation format. This section should always include the QA/QC Guidance for SOPs.

7.0 Data and Records Management

The QAO ensures that SOPs are available at available on the Bureau's internal server and on the SWQB website.

Approved and signed SOPs are converted to a PDF format for protection against inadvertent and unauthorized changes. Nomenclature for all SOPs is designed for

Title: Creation and Maintenance of SOPs	No: SOP 1.1	Page 11 of 11
	Revision 1	
Effective Date: November 14, 2017	Next Revision Date: November 14, 2019	

version control and ease of determination of most current and editable document. Nomenclature of an SOP shall be in the following format:

SOP [NUMERICAL TITLE] [TITLE OF SOP] [YYYYMMDD] [INITIALS OF REVIEWER]

Example: SOP 1.1 Creation and Maintenance of SOPs 20171001 KB

The QAO also ensures that SOPs that are not current have been removed from the website. The QAO retains both electronic and hard copies of all SOPs for historical reference along with the acknowledgement pages for each. These records shall be maintained in a manner to which they are accessible by staff but are secured from being destroyed or manipulated by unauthorized personnel. Electronic versions shall be protected from editing and backed up regularly. Hard copies shall be kept in a secure location.

8.0 Quality Control and Quality Assurance

Quality Control and Quality Assurance of the creation and maintenance of the Department's SOPs is done through adherence to the process outlined in this SOP and oversight of the process by the QAO. If at any time, the QAO determines this process, is not being adhered to, the QAO has the authority to withhold approval of an SOP thereby ceasing activities specific to that SOP until such a time in which the issue can be resolved. The QAO does not have the authority to cease activities or withdraw approval on an SOP that has already been approved and implemented without prior support and approval by the Bureau Chief and Program Manager.

9.0 Related Forms

Template for SOPs

10.0 Revision History

- Revision 0. March 21, 2011. Original. Jodey Kougioulis, QAO; James Hogan, SME/Program Manager
- Revision 2. November 14, 2017. Major updates and structural organization to entire SOP.

Jennifer Fullam, Acting QAO; Kris Barrios, SME/Program Manager MASS

11.0 References

Environmental Protection Agency (EPA). April 2007. Guidance for Preparing Standard Operating Procedures (SOPs) QA/G-6.