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New Mexico Environment Department (NMED) Surface Water Quality Bureau (SWQB)

Standard Operating Procedure (SOP) for

CREATION AND MAINTENANCE OF STANDARD OPERATING PROCEDURES

Approval Signatures:

Miguel Montaya

Miguel Montoya Subject Matter Expert

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Miguel Montoya Quality Assurance Officer

Kristopher Barrios Program Manager - Monitoring, Assessment and Standards Section

2/26/2020

2/26/2020

2/26/2020 Date

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1.0 Purpose and Scope

This Standard Operating Procedure (SOP) describes the process requirements 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 Personnel Responsibilities

The Program Manager will provide input on the scope and intent of the SOP as it pertains to the program's goals and objectives. The Program Manager coordinates with Project Manager as applicable, when determining the Subject Matter Expert for a specific SOP and ensuring the SME is coordinating and providing updates to the Quality Assurance Officer for SOP revisions. The Program Manager will review updated SOPs every 2 years and provide necessary revision to SOPs to ensure procedures are current.

Project Manager will provide input on the scope and intent of the SOP as it pertains to the program's goals and objectives and has the authority to suggest revisions to the Quality Assurance Officer and SME.

The Quality Assurance Officer (QAO) ensures SOPs meet the requirements of the SWQB's Quality Assurance Project Plan (QAPP) and requirements of this SOP. The QAO refers to technical resources to ensure process is defensible with peer reviewed science. The QAO notifies SME when SOP is within (3) three months of the two (2) year review period and can request input from SWQB personnel or other individuals with expertise in the subject matter. Following review and consensus of the SOP the QAO will approve. The QAO will maintain electronic and hard copies of the document along with acknowledgement forms of staff working under the SOP and ensures the latest version of the SOP is accessible through the SWQB's secured server and the NMED publicly accessible website.

The Subject Matter Expert (SME) must possess the skills, experience and knowledge which enables them to perform the duties of a SME. The SME is responsible for coordinating and providing updates to the QAO for SOPs in which they are considered the SME. The SME will use applicable references in order to prepare or revise the SOP. The SME also reviews existing SOPs every two (2) years and updates the SOP as the procedure or equipment changes in coordination with the QAO and Program Manager.

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 Background

This SOP was created to ensure SOPs developed by the SWQB are prepared, reviewed, and implemented in a consistent manner.

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3.2 Procedural Precautions

This 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 Safety Precautions

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

Program Manager – 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.

Project Manager — An individual responsible for a specific project. 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.

Quality Assurance Officer (QAO) — 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.

Quality Assurance Project Plan (QAPP) — 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 must be implemented to ensure that the results are sufficient and adequate to satisfy the stated performance criteria.

Quality Management Plan (QMP) — A formal planning document which establishes the principles, requirements, and practices necessary to implement the quality system for the SWQB's environmental data operations.

Standard Operating Procedure (SOP) — A document that lists the steps that should be completed when doing a task.

Subject Matter Expert (SME) — 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.

Surface Water Quality Bureau (SWQB) — 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.

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5.0 Equipment and Tools

A computer with Microsoft Office or equivalent.

6.0 Step-by-step Process

An SOP explains how to accomplish a specific task in a step-by step process description. Staff are required to follow the SOP as written and without deviation. If there are any significant changes to the process, procedure, or equipment which inhibit staff from conducting the work as written, the SOP is required to be updated in accordance with this SOP prior to working under any new changes.

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).
- An SOP explains how to accomplish a specific task in a step-by step process description and does not contain extraneous information.
- 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 QAO ensures SOPs meet the requirements of the SWQB's QAPP and requirements of this SOP.
- The Program Manager, QAO, and SME document their approval by signing the approval page of the SOP.

6.1.2 Revising an existing SOP

- The Program Manager, Project Manager, SME, or QAO 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 SME 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 Program Manager, Project Manager, SME, or QAO 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.

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- 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.
- The Program Manager, QAO, and SME document their approval by signing the approval page of the SOP. The revisions to SOP are not final nor can they be implemented until all individuals with signature authority have signed SOP.

6.1.3 Undergoing the two (2) year review of an SOP

- The QAO keeps track of SOPs and the review dates, and will contact the SME (3) three 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 and requirements 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 approval page of the SOP. The revisions to SOP are not final nor can they be implemented until all individuals with signature authority have signed SOP.

6.2 Drafting the SOP

6.2.1 General Organization of the Document

- Margins set as "Normal Margins" which by default includes 1" margins on all sides
- Typeset "Calibri"
- Title of SOP should be 14pt font. Section headings and subsection headings should be 12pt. font. Body font size should be 11 pt. font (excluding sub- and superscripts or footnotes/endnotes)
- Format in outline structure using a decimal outline format. Decimal format shall only go to the 3rd degree and thereafter will be in bullet format as seen in this section of the SOP.
- Alignment left with no justification.
- Paragraphs single spaced.
- Headers on every page that 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)
 - 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.

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6.2.2 Components of the SOP

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

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

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.

Sections of the SOP

Section One (1.0). "Purpose and Scope"

State the purpose of the SOP and applicability to the SWQB by indicating 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). "Personnel 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 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)" Section 3.1 Background –

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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.

Section 3.2 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).

Section 3.3 Safety Precautions -

Should include any personal health or safety warnings or precautions to be aware of when implementing the SOP

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.

Section Six (6.0). "Step-by-step Process Description"

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 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.

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- 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 9 (Related Forms) 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) and the New Mexico's General Government Administration, Functional Records Retention and Disposition Schedules, Retention and Disposition of Public Records (1.21.2 NMAC).

Section Eight (8.0). "Quality Control and Quality Assurance"

Describe the preparation of appropriate QC procedures (self-checks, such as calibrations, recounting, reidentification) and QC material (such as blanks (trip, field, or method); replicates; splits; 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.

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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 through the SWQB's secured server and the NMED publicly accessible website.

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. Brief 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

Approved and signed SOPs are converted to a PDF format and certified with "no changes allowed" by the OAO for protection against inadvertent and unauthorized changes. The QAO than ensures latest version of a SOP is accessible through the SWQB's secured server and the NMED publicly accessible website. 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.

Nomenclature for all SOPs is designed for 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] [Revision #] [YYYYMMDD] [INITIALS OF REVIEWER]

Example: SOP 1.1 Revision 3 20191224 MM

8.0 Quality Control and Quality Assurance

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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.

Any deviations from procedures identified in a SWQB SOP must be approved by the Program Manager and QAO in coordination with the SME. All other processes in SWQB SOPs must be adhered to for the procedures that they cover.

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 1. November 14, 2017. Major updates and structural organization to entire SOP. Jennifer Fullam, Acting QAO; Kris Barrios, SME/Program Manager MASS

Revision 2. February 26, 2020. Format change to SOP; 11pt font Calibri, updated format to be consisted with recently updated SOPs. Updated Personnel Responsibilities section of SOP. Minor updates to the Step-by-step Process section. Update to saving procedure in Data and Records Management section. Miguel Montoya, QAO/SME; Kris Barrios, Program Manager MASS

11.0 References

Environmental Protection Agency (EPA). April 2007. Guidance for Preparing Standard Operating Procedures (SOPs) QA/G-6. <u>https://www.epa.gov/quality/agency-wide-quality-system-documents</u>

New Mexico General Government Administration Public Record Regulation, 1.13 New Mexico Administrative Code (NMAC). Access at: <u>http://164.64.110.134/nmac/T01C013</u>

New Mexico General Government Administration Functional Records Retention and Disposition Schedule. 1.21.2 New Mexico Administrative Code (NMAC), October 1, 2015. Accessed at: http://164.64.110.134/parts/title01/01.021.0002.html

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New Mexico Environment Department / Surface Water Quality Bureau (NMED/SWQB). 2020. Quality Management Plan for New Mexico Environment Department Surface Water Quality Bureau *Environmental Data Operations*. <u>https://www.env.nm.gov/surface-water-quality/protocols-and-planning/</u>