



**COVER SHEET
 STANDARD OPERATING PROCEDURE**

Operation Title: REQUIREMENTS FOR THE DEVELOPMENT OF A
 SITE SPECIFIC QUALITY ASSURANCE PROJECT
 PLAN TO MEET USEPA HRS REQUIREMENTS

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APPROVALS:

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QMSC Chair:

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Department Commissioner:

<u>Paul Mercer</u> Print name	<u>Paul Mercer</u> Signature	<u>1-3-2017</u> Date
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DISTRIBUTION:

() Division of Remediation.....By: _____ Date: _____



1.0 APPLICABILITY

This Standard Operating Procedure (SOP) applies to all programs in the Maine Department of Environmental Protection's (MEDEP) Division of Remediation (DR). It is also applicable to all parties that may submit data that will be used by the DEP/DR.

This SOP is not a rule and is not intended to have the force of law, nor does it create or affect any legal rights of any individual, all of which are determined by applicable statutes and law. This SOP does not supersede statutes or rules.

1.0 PURPOSE

The purpose of this document is to describe the MEDEP/DR procedure for developing a Site Specific Quality Assurance Project Plan (QAPP) for site activities where a QAPP is deemed necessary.

A QAPP will be generated for field work conducted specifically for an HRS. Additionally, a QAPP may be generated for a specific site if the QAC, the MEDEP/DR project manager and supervisor, and/or the appropriate project personnel at USEPA Region I determine one is necessary. Examples in which a site specific QAPP may be generated would a Site which is will in all likelihood be listed on the National Priority List (NPL), or a site in which there is a possibility of litigation.

3.0 RESPONSIBILITIES

All MEDEP/DR Staff must follow this procedure when performing this task. All Managers and Supervisors are responsible for ensuring that their staff are familiar with and adhere to this procedure. MEDEP/DR staff reviewing data by outside parties are responsible for assuring that the procedure (or an equivalent) was utilized appropriately.

The Quality Assurance Coordinator (QAC) will review and provide comments to the QAPP as necessary to assure that the requirements for a QAPP are met and assure consistency between QAPPs generated by MEDEP/DR. Appropriate peer review from USEPA Region 1 is also required for QAPPs generated for USEPA funded projects.

4.0 DEFINITIONS/ACRONYMS

- 4.1 MEDEP/DR - Maine Department of Environmental Protection's Division of Remediation
- 4.2 QAPP - Quality Assurance Project Plan
- 4.3 HRS - Hazard Ranking System
- 4.4 QAC - Quality Assurance Coordinator
- 4.5 QAM - Quality Assurance Manager
- 4.6 USEPA - United States Environmental Protection Agency, Region I
- 4.7 DQO - Data Quality Objectives



4.8 SOP - Standard Operating Procedure

4.9 QC - Quality Control

5.0 GUIDELINES AND PROCEDURES

5.1 INTRODUCTION

This procedure outlines the minimum specific requirements that must be included in a QAPP. It is intended to assure that the data generated will meet the Data Quality Objectives that are required (and identified in the QAPP) for a specific project and/or site.

5.2 GUIDELINES

Prior to developing a QAPP MEDEP/DR staff will develop Data Quality Objectives as described in the QAP section 5.0.

A QAPP must have the following elements.

5.2.1 TITLE PAGE

The following elements shall be included on the title page: title of plan, site name, program authority, and name of organization implementing the plan. Additionally, include names, titles and signatures of staff completing the QAPP and any approving officials, including dated signed.

5.2.2 TABLE OF CONTENTS

This section should list all sections, figures, tables, references and appendices, along with page numbers indicating location of each.

5.2.3 INTRODUCTION

5.2.3.1 Project Organization

The Project Organization must identify data generators, data-users and decision makers, as well as specific organizations, job categories, and job responsibilities. Also authorities associated with the QAPP, relationship between organizations, and lines of communication should be defined.

5.2.3.2 Project Goal and Data Use

The goal of the project and the end use of the data as described in the DQO section of the QAP will be stated in the introduction. The regulatory or exposure situation that determined the need for the project will be described in this section.



5.2.4 BACKGROUND

This section will include site historical and background information.

5.2.5 PROJECT DESCRIPTION

An identification of all measurements proposed, including physical measurements and characteristics, chemical analyses, and a schedule for performance of the activities will be contained in this portion of the document.

5.2.6 SAMPLING PROCESS DESIGN (EXPERIMENTAL DESIGN)

This section will present the rationale for sampling design. Sampling design can include the elements of sample location, sample matrices, measurement parameters, geographical spacing, sampling methods and equipment, monitoring device design and installation (e.g. Monitoring wells), sampling intervals (vertical, horizontal and time), sample documentation, corrective action and schedule of work.

This section should provide the justification for the measurements and activities proposed in the project description to meet the project DQOs.

5.2.7 SAMPLING METHODS REQUIREMENTS

Standard Operating Procedures (SOPs) or site-specific procedures for performance of field sampling activities should be provided in this section (reference MEDEP/DR SOPs and/or USEPA procedures used for collecting samples).

Description of the sample collection devices and procedures for decontamination of equipment and materials should be outlined in this section.

5.2.8 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

A description of the documentation, sample packaging, and shipping procedures will be contained in this section. All observations regarding sample location will be recorded in a field logbook or log sheets.

5.2.9 ANALYTICAL METHOD REQUIREMENTS

The methods used to analyze both field and laboratory samples are cited or described in this section. In the case of laboratory methods a reference to the identification number and source of the method must be stated, the method itself need not be reproduced.

If several analyses are proposed, a table identifying each analysis for each sample location and medium is recommended.



5.2.10 QC REQUIREMENTS

This section refers to both the number of QC samples that will be collected in the field and the QC samples analyzed in the Laboratory to allow data validation. Field QC samples such as field replicate and rinsate blanks are collected at a rate of 5 percent, or at least one per sampling event. The procedures indicated below in Sections 4.12 and 4.13 of this document are to be performed where appropriate.

5.2.11 FIELD QC

The sampling component of the QAPP shall include:

- A. Procedures for documenting and justifying any field actions contrary to the QAPP;
- B. Documentation of all pre-field activities such as equipment check-out, calibrations, and container storage and preparation;
- C. Documentation of field measurement QC data;
- D. Documentation of field activities;
- E. Documentation of post-field activities including sample shipment and receipt, field team de-briefing and equipment check-in; and
- F. Generation of QC samples including duplicate samples, field blanks, equipment blanks, and trip blanks. Table 1 shows the frequency and number of QC samples that should be collected during a sampling event.

5.2.12 INSTRUMENT CALIBRATION AND FREQUENCY

A description of the calibration procedures and frequency for field instruments used must be included in this section. For instruments that have an approved DR SOP which includes a description of calibration of the instrument the SOP number will be included here. At a minimum, calibration procedures and frequency must meet the manufacturer's requirements. The manufacturer's instructions for calibration may be included as an attachment to the QAPP. Calibration of laboratory equipment used for sample analysis will be described in the laboratory SOPs. If the analytical method selected prescribes the calibration procedures and frequency, citation of the method number is adequate in the QAPP.



TABLE 1
Guidelines for Minimum QA/QC Samples
For Field Sampling Programs

Medium	Replicates ³	Field Blanks ²	Trip Blanks ⁴	Rinsate Blanks ³	Background Samples
Aqueous	One in twenty	As conditions necessitate.	One per shipping container with VOC samples	One per 20 decontamination procedures	Minimum of one per sampling event per medium
Soil, sediment	One in twenty	As conditions necessitate.	One per shipping container with VOC samples	One per 20 decontamination procedures	Minimum of one per sampling event per medium
Air	One in twenty		One per shipping container with VOC samples	One per decontamination procedures	Minimum of one per sampling event per medium
Source material	One in twenty	As conditions necessitate.		One per 20 decontamination procedures	

Notes: 1) QA/QC requirements on a site-specific basis may dictate a more stringent frequency. Laboratory blanks and spikes are method-specific and are not included in this table. However, as a minimum, 10% of laboratory analyses must be QC samples.

2) Field Blanks are required when background contamination of the breathing zone is detected. One should be collected from each different industrial or functional area sampled during the most active time of day.

3) Replicate and rinsate samples are collected at the minimum rate of 1 per 20 samples/decontamination procedures. If fewer than 20 samples are collected, one replicate and one rinsate sample must be collected.

4) Trip blanks are prepared in the laboratory or at another off-site location from de-ionized water. They are never prepared on-site, or from soils or other solid material.

5.2.13 ASSESSMENT AND RESPONSE ACTIONS

Assessments required for most projects include:

- A. Management systems reviews;
- B. Technical systems audits; and
- C. Performance evaluation samples.



Reviews and audits are conducted periodically to check that activities described in the field QAPP and in the QA Program Plan have been appropriately conducted and documented.

In addition to describing the components of each type of review/audit, the section must describe how appropriate response actions for non-conformance will be addressed and documented, and who is responsible for implementing corrective actions. The QACC or QAM may conduct management systems reviews or technical systems audits at any time during the course of a project.

5.2.14 DATA REVIEW, VALIDATION AND VERIFICATION REQUIREMENTS

5.2.14.1 Data Review

This section should state the criteria used by the project manager to review and validate data; (i.e., accept, reject or qualify data). Additionally, the following questions should be answered: What recovery and other standards must the lab meet? How much precision and accuracy are desired/required of the analytical data to be acceptable? What percent of the data must be laboratory analytical data for it to be acceptable? The project DQOs should be considered when all data is reviewed.

5.2.14.2 Validation and Verification Methods

This section will describe how the data reviews identified above will be conducted. The equations for precision, accuracy and completeness are included in the general QAP, and equations for any other DQOs evaluations will be included in the QAPP.

This section should also describe how the data are handled if the described criteria are not met, and answer the following questions: At what point is the data rejected? At what point is it qualified? What types of qualifiers are applied? When is re-analysis by the lab required if the standards are not met? What are the consequences if adequate sample is not available, and/or holding times have been exceeded?

5.2.15 RECONCILIATION WITH DQOs

After each phase or major portion of a sampling event or project, the results must be compared with the quantitative and qualitative DQOs and project objectives identified in the QAPP. Any limitations on the data, the usefulness of the data, and changes to DQOs as a result of any limitations must be addressed. Applicable uses of the data that have been qualified will be compared to the original uses desired (DQOs). Additional data collection activities may be required if the usability of the data is not satisfactory. This section should identify the criteria for determining that additional data collection is needed.



5.2.16 DISTRIBUTION LIST

At a minimum, the following people will receive and/or review copies of a QAPP:

- MEDEP/DR Site Project Manager
- MEDEP/DR QAC
- Site Geologist
- Project Field Staff
- USEPA Project Manager

Anyone else determined necessary by the Site Project Manager, QAC, or USEPA Project Manager. A distribution list stating the names of persons receiving copies and/or reviewing the QAPP and their position will be included in the QAPP.

5.2.17 SPECIALIZED TRAINING

Need for specialized training will be stated in the QAPP. Documentation of staff attending training will be placed in the project file upon completion of said training.

5.2.18 DOCUMENTATION

All field notes will be kept as stated in MEDEP/DR SOP DR#013 - Documentation of Field Notes and Development of a Sampling Event Trip Report. Sample chain of Custody procedures for the project will be as stated in MEDEP/DR SOP DR#012 - Chain of Custody Protocol. Any variations or modifications to documentation procedure will be stated in the QAPP. All documentation will be placed in the Site file as a permanent repository, in accordance with Section 11.0 - Document Control, of the MEDEP/DR QAP.

5.2.19 INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS

Equipment used for projects will be inspected, maintained, and calibrated, in accordance with manufacturer's instructions and/or as outlined in the MEDEP/DR protocol stated in Section 7.0 - Equipment of the MEDEP/DR QAP. Documentation of such activities will be in accordance with Section 7.0 of the MEDEP/DR QAP.

5.2.20 INSPECTION OF SUPPLIES AND CONSUMABLES

A list of expected consumable supplies will be included in the QAPP. All consumable supplies will be inspected upon their receipt, and again prior to being taken into the field by field staff. Any supplies that are determined not acceptable will not be used for the project. If it becomes necessary to use material that may not meet specifications, this shall be stated in the field notes of the person conducting the inspection.



5.2.21 FINAL REPORT(S)

A final report will be generated at the end of the project that will summarize the data generated during the project by the project manager. Included in this report will be a recommendation for additional work, and the appropriate entity to conduct the additional work. If no additional work is determined to be necessary, a “no further action” conclusion will be stated, with the rationale for such a conclusion.