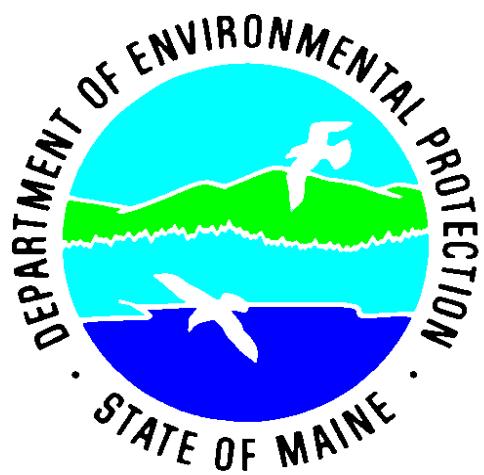


**Maine Department of Environmental Protection
Quality Management Plan**



**Revision No. 8.1
May 13, 2021**

**Maine Department of Environmental Protection
#17 State House Station
Augusta, Maine 04333-0017**

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Quality Management Plan
Maine Department of Environmental Protection

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Maine Department of Environmental Protection Quality Management Plan

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LIST OF ACRONYMS

<u>Word</u>	<u>Acronym</u>
American National Standard / American Society for Quality (formerly ASQC)	ANSI/ASQ
Bureau of Air Quality	BAQ
Bureau of Human Resources	BHR
Bureau of Water Quality	BWQ
Bureau of Land Resources	BLR
Bureau of Remediation and Waste Management	BRWM
Data Quality Indicator	DQI
Data Quality Objective	DQO
Environmental Protection Agency	EPA
Information Technology Coordinator(s)	ITC
International Standards Organization	ISO
Geographic Information System	GIS
Global Positioning System	GPS
Leaking Underground Storage Tanks	LUST
Maine	ME
Maine Department of Environmental Protection	Maine DEP
Maine Department of Health and Human Services	DHHS
Maine Revised Statutes	M.R.S.

National Pollutant Discharge Elimination System	NPDES
Office of the Commissioner	OC
Office of Information Technology	OIT
Performance Partnership Agreement	PPA
Quality Assurance Manager	QAM
Quality Assurance / Quality Control / Quality Improvement	QA/QC/QI
Quality Assurance Project Plan	QAPP
Quality Management Plan	QMP
Quality Management System	QMS
Quality Management Steering Committee	QMSC
Request for Proposal	RFP
Resource Conservation Recovery Act	RCRA
Sampling and Analysis Plan	SAP
Standard Operating Procedure	SOP
Toxic Substances Control Act	TSCA

Introduction

Each year, the Department of Environmental Protection (Maine DEP) collects, analyzes, and provides enormous amounts of information to the regulated community, the public, and to other agencies upon which important decisions are made.

To make sure this information is defensible, reliable, and is collected efficiently and consistently, the Maine DEP operates under a Quality Management System (QMS). The Maine DEP's QMS is described and implemented in this Quality Management Plan (QMP). The QMP provides the guidance used to maintain consistent and appropriate Quality Assurance, Quality Control, and Quality Improvement (QA/QC/QI) agency wide.

1.0 MANAGEMENT AND ORGANIZATION

Maine's Legislature established the Department of Environmental Protection (Maine DEP) as the State's administrative agency in charge of preventing, abating, and controlling the release of pollution generated by its citizens and protecting and enhancing its natural environment. The management of quality is of primary importance in all aspects of Maine DEP's operations.

1.1 Maine Department of Environmental Protection (Maine DEP) Mission

Maine law establishes that the Maine DEP:

“...shall prevent, abate and control the pollution of the air, water and land and preserve, improve and prevent diminution of the natural environment of the State. [DEP] ...shall protect and enhance the public's right to use and enjoy the State's natural resources and may educate the public on natural resource use, requirements and issues.” [38 M.R.S. § 341-A\(1\)](#).

1.2 Maine DEP Management

Pursuant to the authority vested in the commissioner, the agency is divided into four (4) programmatic units referred to as *bureaus*: Bureau of Air Quality (BAQ); Bureau of Water Quality (BWQ); Bureau of Land Resources (BLR); and Bureau of Remediation and Waste Management (BRWM). Additional Department functions are carried out by staff in the Office of the Commissioner (OC), by the Natural Resources Service Center for some financial and personnel responsibilities, and by the state Office of Information Technology (OIT) for information services and computer operations. By law, the Maine DEP's top manager is its *Commissioner*. Day-to-day operations of the agency as a whole and direct management of the OC are overseen by the *Deputy Commissioner* position. Each bureau has a top manager, referred to as *bureau director*, who reports directly to the Commissioner. Each bureau is further divided into divisions, each of which is managed by a *division director*. Each division is further divided into functional and programmatic units that are managed by *unit, section, or program managers*. These management relationships are illustrated in Appendix 2. The individuals holding each of these management positions are fully authorized to direct the actions of their staff within the scope of the staff member's employment.

The functions of the Maine DEP are carried out in four regions of the State from the primary Maine DEP offices in Augusta, and from regional offices in Bangor (Eastern), Presque Isle (Northern), and Portland (Southern). Each regional office is managed by a Regional Director who is outside the bureau management structure of the programs. Regional Directors represent the Commissioner (to whom they report) in the regions, address matters of Maine DEP interest where more than one program area may be involved, and represent the Maine DEP in inter-agency matters.

1.3 Quality Assurance, Quality Control, and Quality Improvement (QA/QC/QI) Policy

The Maine DEP seeks to maintain the highest appropriate standard of quality in each aspect of its operations in order to meet its obligation to protect Maine's natural environment and the health of Maine citizens. To this end, Maine DEP operates under a Quality Management System (QMS). As part of its QMS, this Quality Management Plan (QMP) provides the guidance Maine DEP uses to establish and maintain consistent and appropriate Quality Assurance / Quality Control / Quality Improvement (QA/QC/QI) operations agency-wide. This QMP is consistent with ANSI/ASQC-E4 (1994), ISO 9000: 2000, ISO 14001 (1996) and EPA QA/R-2 (2001). The Maine DEP Quality Management Policy is attached to this QMP at Appendix 1.

The individuals served by the implementation of Maine DEP's QMP and all other resulting quality efforts include: our agency's staff; Maine citizens and businesses; non-governmental interest groups; federal, state and local government administrative agencies; and, Congress and the Maine State Legislature. Maine DEP is committed to providing these customers with the highest appropriate standard of quality in all its services.

1.4 Management Responsibility for QA/QC/QI Functions

All managers are responsible for maintaining QA/QC/QI for the area within their span of control. As such, commitment to and responsibility for the quality objectives and operations detailed in this QMP and any Quality Assurance Project/Program Plan (QAPP) or Standard Operating Procedure (SOP) in place at Maine DEP begins with the commissioner and continues through all levels of management and staff. The State's Performance Management Plan for managers includes performance standards consistent with this QMP, which provides guidance for implementation. Likewise, managers should include appropriate responsibility for maintaining QA/QC/QI in the performance expectations and review of their staff.

The Maine DEP's ongoing implementation of its QMS uses the auditing regime established in Element Nine of this QMP to annually assess areas of interest identified for potential improvement by the agency's Quality Management Steering Committee (QMSC). Managers assure that Corrective Action Requests and Plans resulting from such audits are responded to and implemented in a timely manner by supervisors and employees in their units (see 9.9).

2.0 QUALITY MANAGEMENT SYSTEM COMPONENTS

The Maine DEP views its QMS as applicable to all aspects of its operations. The QMS is particularly applicable to environmental data operations, a list of which can be found in Appendix 6. To ensure data quality, the Maine DEP has adopted a practical approach to QA/QC/QI functions that includes this QMP as the guidance for implementing its QMS. QA/QC/QI functions are carried out by personnel throughout the Maine DEP who, pursuant to the provisions contained in this QMP, are fully informed of and trained in their quality-related responsibilities. The quality standards promulgated by Maine DEP – including the QMP, QAPPs, and SOPs – are applied as necessary after Quality Objectives (QO) commensurate with project needs have been defined. Each program area in the Maine DEP is responsible for establishing, documenting, implementing, and reviewing QA/QC and quality management procedures germane to its area of operations.

2.1 QA/QC/QI Staff

The Maine DEP organizes and oversees agency-wide QMS functions with a Quality Management Steering Committee (QMSC). Approximately six (6) management-level individuals comprise the QMSC, with at least one (1) representative from each bureau and two (2) members from senior management. QMSC encourages regional input with representation from each of DEP's regional offices. The QMSC meets at least quarterly to review quality issues and initiatives. Oversight of QMS activities by the QMSC assures that quality issues are integrated throughout the Maine DEP and that all levels of management are consistently apprised of and available to take action on such issues. Maine DEP's Quality Assurance Manager (QAM) serves as chair of the QMSC. The QAM convenes the QMSC; serves as Maine DEP's designated QA/QC/QI contact with EPA; and coordinates agency-wide activities with designated Quality Management Coordinators in each bureau. Those Coordinators are responsible for assuring that QMSC decisions, and audit requests and findings, are implemented in the programs of the bureau; they may differ from the bureau representative serving on the QMSC. Appendix 3 identifies QA/QC/QI management responsibilities.

Each Maine DEP employee is responsible for planning the work that is done, documenting all work, and ensuring that the quality of work completed meets or exceeds the Quality Objectives (QOs) for the activity. Managers will work collaboratively with staff to ensure that decisions made when performing assigned tasks or making policy for the Maine DEP are based on quality standards.

2.2 QA/QC/QI Objectives

The quality requirements of a specific program function or project are defined prior to undertaking activities when a Quality Assurance Project Plan (QAPP), Sampling and Analysis Plan (SAP), Standard Operating Procedure (SOP), or similar planning document is developed. By defining the quality objectives of a function or project prior to taking action, the Maine DEP believes its processes will operate as efficiently

and effectively as possible while at the same time creating results that are appropriately informative, transparent, and legally and technically defensible as accurate.

2.3 Quality Management Tools

2.3.1 Quality Management Plan (QMP)

This QMP is the guidance Maine DEP uses to design, document, and implement its QMS. The QMS includes the process of planning, implementing, and assessing QA/QC/QI operations. The Commissioner and Senior Management Team reviewed and approved this QMP at the time of its original composition, and designated the QMSC to review and approve subsequent changes. This QMP will be renewed every five years or when significant changes have been made to its program elements. The QMSC annually evaluates this QMP as part of its regular functions and includes any findings in its annual report to EPA. This review and any recommendations resulting there from will be primarily based on findings made while implementing the auditing regime described in Element Nine of this QMP.

2.3.2 Quality Assurance Project/Program Plans (QAPPs)

QAPPs are project or program-specific planning documents that establish the method by which QOs will be met or exceeded. QAPPs are typically needed where data collection and analysis will be associated with a project or an entire program area. A QAPP dictates the minimum requirements for project management, data measurement, data acquisition, assessment, oversight, data validation and data usability. Each QAPP should include the main elements listed in the document "[EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations \(EPA OA/R-5\)](#)"¹ (March, 2001)). Additional guidance for writing a QAPP can be obtained from the EPA documents "[EPA Guidance for Quality Assurance Project Plans \(EPA QA/G-5, December 2002\)](#)"² and "[EPA-New England Quality Assurance Project Plan Program Guidance](#)" (January 9, 2010, revisions 2).³ Each monitoring project or program utilizes the Data Quality Objective (DQO) process outlined in the document "[Guidance for the Data Quality Objectives Process \(EPA QA/G-4\)](#)" (February 2006)⁴. QAPP use, development, and requirements are detailed in Element Seven of the QMP.

2.3.3 Standard Operating Procedures (SOPs)

An activity that is performed regularly and requires uniform conduct each time it is performed should be done according to a standard accepted methodology that is documented in a written SOP. Details on Maine DEP's SOP development,

¹ https://www.epa.gov/sites/production/files/2016-06/documents/r5-final_0.pdf

² <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf>

³ <https://www.epa.gov/sites/production/files/2015-06/documents/QAPPProgram.pdf>

⁴ <https://www.epa.gov/sites/production/files/2015-06/documents/g4-final.pdf>

preparation, content, format, review, approval, release, revision, archival, and procedure withdrawal are contained in Element Eight of this QMP.

2.3.4 Guidance Documents

Information compiled to inform staff or other individuals of legal requirements, SOPs, or QAPPs may be contained in a written guidance document. Such documents do not create new SOPs or legal requirements. An example of a guidance document is the compilation of legal memoranda, statutory language, and regulatory provisions compiled by Maine DEP's wastewater discharge program to assist its licensers with carrying out their day-to-day functions.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 Commitment to Quality Assurance Training

All Maine DEP employees receive training, and participate in professional development, pertinent to their responsibilities and work assignments. Maine DEP provides, or arranges for, training specific to QA/QC/QI as needs are identified by the QMSC on the basis of audit results, management review, and/or information received from Bureau quality coordinators.

3.2 Qualifications

The Maine Department of Administrative and Financial Services, Bureau of Human Resources determines and maintains the classification system for positions needed by the Maine DEP. Each classification is defined by a minimum set of requirements including experience, education, and/or certification. Personnel hired by the Maine DEP must meet these minimum requirements to qualify for a certain position. The Natural Resources Service Center Personnel Officer assigned to the Maine DEP is responsible for review of job classifications and for arranging audits of existing positions as requested, to ensure employees are classified correctly. The Personnel Officer also maintains position descriptions specifying the general and quality assurance knowledge and skill required for job tasks.

Specific types of work or specific projects require specific skills which are identified by Project Managers, supervisors and managers. If possible, skill needs are met by existing staff. If no DEP employee with the necessary skills is available to perform a specific type of work, management may identify the necessary resources, and initiates the procedures to hire or contract for the needed skills.

3.3 Professional Development and Training

Management identifies needs at the Maine DEP for professional development, learning new techniques, and qualifying for / maintaining required certifications (*e.g.*, 40-hour Occupational Safety and Health Administration training). Agency policy (Policy OC-PD-01, Professional Development, revision 1, 12/02) encourages staff to seek advanced degrees or professional training as needed to ensure that the Maine DEP mission is fulfilled and its objectives are met. Maine DEP employees regularly are sponsored to, and participate in, regional and national professional conferences and workshops relevant to their job responsibilities. The State Performance Management System documentation requires the identification of individual development objectives at the beginning of each employee year, and the accomplishment of these objectives is a part of performance review. These expectations are developed through discussion between the employee and supervisor, and should reflect the identification of knowledge, skills, and competencies to be developed through training and professional development. The individuals development objectives should also reflect the Department's, Bureau's, and program

area's needs and goals, as reflected in planning documents such as operational workplans.

The State Bureau of Human Resources provides a wide range of learning opportunities useful to Maine DEP employees.

All internal classes are based on pre-defined learning objectives documented in the professional development/training management system. Training and professional development activities, both internal and external, including those related to QA/QC/QI, are tracked, and individual training records are maintained at the program level. Records of QA-specific training are also documented in employee personnel files, and/or in tables maintained by the various program areas of the Department. Some of the latter are included in QAPP's covering environmental data operations.

All Maine DEP employees are trained in the following areas:

State and Maine DEP Orientation;

- Core training for managers and supervisors;
- Computer software;
- Harassment and domestic violence awareness;
- Customer service;
- Job-required safety and health; and
- Defensive driving when applicable.

Each Bureau, division, and program provides and documents the provision of additional training as needed to ensure that new staff members understand and can carry out job requirements to meet identified levels of competency. Resources for training and professional development are allocated at the Bureau level, based on program-specific funding streams.

Assessment of the status and adequacy of existing training and professional development programs and identification of future training needs is made regularly as part of Maine DEP's Performance Partnership Agreement (PPA) processes and/or in available bureau, division, and program work plans.

3.4 Training for Quality

All Maine DEP employees are required to be familiar with this QMP. Information about the QMS is provided to all new employees at their initial orientation. Division and/or program managers annually review the QMP with staff, including specific aspects pertaining to the work of that unit. The QMSC assures that periodic refresher sessions on the QMS are delivered at the division or program level.

All data-related programs requiring QAPPs have, within those documents, standards and procedures for assuring that program staff receive training in QA/QC related to their activities and maintain proficiency in the QA/QC requirements of that program. In other programs and activities, supervisors and program managers are responsible

for assuring such training. Individual programs conduct workshops and training activities specific to their needs to assure quality, test employee proficiency, etc.

Maine DEP provides training that specifically enables staff to carry out the auditing functions described in 9.0, and assures that staff maintains necessary qualifications and proficiency. The QAM tracks all training based upon input from the QMSC, managers, and programs.

3.5 U.S. EPA Competency Policy

The Department, when applying for U.S. EPA grant applications that exceed \$200,000, must take into consideration the requirement to comply with EPA's new ["Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements", Agency Policy Directive Number FEM-2012-02, effective October 1, 2013](#) (http://www.epa.gov/fem/lab_comp.htm).⁵

⁵ <https://www.epa.gov/sites/production/files/2015-03/documents/competency-policy-aaia-new.pdf>

4.0 PROCUREMENT OF ITEMS AND SERVICES

Maine DEP procures a variety of commodities and services generally and specifically for environmental data collection needs through various vendors including laboratories and technical firms. The procurement of items and services is controlled and documented to assure conformance with specified quality management requirements. These requirements are included or referenced in procurement documents. The acceptability of purchased items and services is verified and documented by the individual who has requested the goods or services.

The Division of Purchases within the Department of Administrative and Financial Services establishes the broad framework for the purchase of goods and services and for the awarding of grants within Maine state government. The Maine DEP conducts its purchasing practices in accordance with all requirements of the Division of Purchases.

Procurement within the Maine DEP is conducted by designated personnel in each of the four program bureaus, the Regional Directors, and in the Office of the Commissioner.

4.1 Documents

All procurements are defined in writing in one or more procurement documents (purchase requisitions, requests for proposals, procurement contracts, and other agreement documents). Routine commodity purchases are made through the use of a purchase requisition. A Request for Proposal (RFP) is sometimes developed for procurement of services and stipulates any requirements of Maine DEP. The nature of the work, the location, and the anticipated cost are factors that contribute to the determination of when an RFP is necessary. Quality assurance requirements of all potential contractors are clearly identified within the RFP and are required in all contract documents. Program managers determine such quality assurance requirements with the assistance of quality assurance staff. An RFP has a set of screening criteria that ensure the potential contractors meet the quality requirements. A designated group is responsible for review of proposals, for scoring the proposals by preset criteria, and for selecting the contractor(s). Occasionally, a bidders' conference is scheduled to address any questions which bidders may have. The Maine DEP notifies the successful contractor(s) and contracts are established.

Procurement documents may include pre- and post-award source inspections, supplier audits, readiness reviews, evaluations of objective evidence of quality furnished by the supplier, acceptance testing, and other requirements as determined by program managers to be appropriate.

Procurement of services through financial assistance agreements for environmental programs follows the same general guidelines, whether or not the procurement uses a formal RFP process. Agreements specify the services to be delivered. Program managers are responsible for developing and documenting procedures to review such agreements for quality considerations, including documentation of a recipient's quality system.

4.2 Acceptance of Items and Services

Items and services received from suppliers are evaluated upon delivery against acceptance criteria (task and product specifications and technical, quality, administration and other requirements) contained in procurement documents to ensure quality compliance. Vendors of contracted services are required to submit a certification of project completion for endorsement by the DEP program or project manager in order to receive final payment, unless the DEP program has a documented alternative method of assuring project completion. Program managers, or their designates, determine whether acceptance criteria have been met and whether items and services are adequate and appropriate for use, and document the Department's acceptance in project files. This standard applies to work carried out by sub-contractors engaged in remediation and other environmental operations under the terms of a DEP contract.

Items and services that do not meet acceptance criteria are not accepted for use. Corrective actions are initiated in accordance with state requirements, contract provisions, and procurement procedures. Corrective actions may range from repair or replacement of defective deliverables to return of unacceptable items or refusal of payment for goods or services rendered.

The Division of Purchases coordinates resolution of disputes regarding quality through use of one of several methods available.

4.3 Acceptance of Environmental Data

Quality assurance of analytical work conducted by a laboratory is determined, in part, through the State of Maine Department of Health and Human Services (Maine DHHS) laboratory certification program, as private laboratories may apply to the Maine DHHS for certification for analysis of certain media (wastewater, drinking water) or for certain analytes (e.g. gasoline and diesel range organic compounds). Maine DEP QA staff assures that DEP employees have access to the most current listings of approved laboratories for methods used to analyze data for DEP use. In cases when requests for services are outside of the scope of certification program standards, Maine DEP staff will establish QA guidelines in accordance with Department standards. The laboratory must meet these guidelines, including the certified use of EPA or other accredited methods, to be considered for work by Maine DEP. See also 7.5, 9.1. DEP QA staff regularly review the certification of laboratories providing analytic data used in making environmental decisions.

Where contracts for environmental services include any provision for sampling and analysis, the contract includes the requirement of compliance with the Department's *Laboratory Performance Standards*. DEP contract managers assure that vendors receive the most current version of these *Standards* prior to completing the contract. Analytical data submitted to DEP by contracted providers are assessed by DEP staff to assure that data quality requirements have been met.

Entities regulated by Maine DEP provide environmental data, including analytic results from monitoring conducted by the entity or its contractor(s), which is then analyzed by

the facility or a certified laboratory. Such data are assessed by DEP staff to assure that data quality requirements have been met (see 9.1). Regulated entities are responsible for assuring that all methods and protocols used for monitoring meet all relevant DEP requirements, and that their contractors and laboratories meet designated certification standards. Data that do not meet DEP standards are not used in making environmental decisions.

4.4 Grant Recipients

Several program areas in Maine DEP are responsible for allocating funds through grants to outside entities carrying out environmental operations. Activities carried out through the use of such grants are considered procurement of goods and services for quality management and assurance purposes. DEP program managers are responsible for assuring that grant projects meet identified quality standards, including the development and approval of QAPPs for activities involving environmental data collection; and that grant recipients ensure the quality of any operations conducted by their sub-contractors. This standard is included in all contracts between the DEP and grant recipients.

If Maine DEP is the recipient of a grant that exceeds \$200,000 then the requirements outlined in the EPA document, “[Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements](#)”, apply⁶. This policy requires:

Organizations performing activities involving the use or generation of environmental data under covered assistance agreements shall provide the Agency with:

Quality documentation such as a quality management plan (QMP), and/or other documentation that demonstrates conformance to U.S. EPA quality program requirements; and demonstration of competency in the field(s) of expertise.

4.5 Contracted Services

Where the Department contracts with a vendor for environmental or other services through a pre-approved vendor list, or a retainer contract, the initiating RFP (or equivalent) and any resulting contract specifies that the Department will carry out a regular documented review of contractor performance. Program managers develop procedures to document ongoing vendor performance and for conducting performance reviews. Contract managers are responsible for assuring that performance is documented and reviews are carried out. Programs determine the frequency of such reviews which in all cases take place prior to contract renewal.

5.0 Documents and Records

Each bureau and office at the Maine DEP is responsible for establishing and implementing procedures for controlling, filing, storing, protecting, and accessing

⁶ <https://www.epa.gov/sites/production/files/2015-03/documents/competency-policy-aaia-new.pdf>

documents and records in conformance with Maine DEP QMS / R-1, *Control of (Department) Documents and Records* (see Appendix 4, Part 5.), and applicable Maine State Government requirements

5.1 Document and Record Development and Identification

Documents that specify quality-related requirements and instructions include:

- Maine DEP Quality Management Plan;
- program guidance documents;
- quality assurance project/program plans (QAPPs);
- technical standard operating procedures (SOPs);
- sampling and analysis plans (SAPs);
- data management plans;
- letters and correspondence; and
- internal Department and bureau policies

Program guidance documents are proposed, reviewed, and approved by staff and managers of relevant areas of the department. Revisions to guidance documents are made as necessary and reviewed in the same manner as new guidance documents. New guidance documents and revisions to existing guidance documents are uniquely identified. The Division Director or the management team of the respective bureau or office approves each new or revised guidance document, prior to issuance. Program managers assure that only the most recent version of a document is in use by DEP personnel and outside parties.

QAPPs are prepared, reviewed, approved, distributed, maintained, and revised according to procedures described in 7.3.

Sampling and analysis plans (SAPs) and similar quality assurance plans are prepared, reviewed, approved, distributed, maintained, and revised according to Maine DEP procedures described in 7.4.

SOPs (see 8.0) are proposed, reviewed, and approved by staff and managers of relevant areas of the department. Revisions to SOPs are made as necessary and reviewed in the same manner as new SOPs. New SOPs and revisions to existing SOPs are uniquely identified. The Division Director, the Bureau Director, or the Commissioner, depending on the scope of the SOP, approves each new or revised SOP prior to issuance. The decision of who will approve technical SOPs rests with the QA Coordinator in consultation with staff who is responsible for the SOP in question.

Department –level SOPs will conform to SOP OC-PE-001, “Standard Operating Procedure Development, Format, Approval and Distribution,” Appendix 4.1 of this QMP. Department-level policies are reviewed and approved by the Senior Management Team prior to signature by the Commissioner. Originals are filed in the

Office of the Commissioner. Copies are distributed to all staff, and posted electronically on the Department's intranet site.

Quality assurance records are items that furnish objective evidence of the quality of items or activities that have been verified and authenticated as technically complete and correct. Quality assurance records may include photographs, drawings, forms, reports, and electronically recorded data.

Public records are records produced by Maine DEP and maintained as official records of the State ([1 M.R.S. § 402\(3\)](#)). Public records are documented in the Records Retention Schedule (a State-generated document) for each bureau or office ([5 M.R.S. § 95\(7\)](#)). Assignments of authority and procedures concerning the identification, verifications, authentication, handling, retention, and disposition of documents and records needed to safeguard the legal and financial rights of the state of Maine and any person directly affected by activities of the Maine DEP are contained in SOPs in each bureau.

Other quality assurance records are records that furnish objective evidence of the quality of items or activities but are not listed in the Records Retention Schedule. Written procedures have not been established to manage other quality assurance records; however there is an effective standard practice in place that is described below.

Documents and records received by Maine DEP from regulated entities, or as a part of extramural agreements involving the use of contractors or the recipients of financial assistance, are treated in the same manner as those generated internally in conformance with QMS R/1 (2001). When using documents created outside DEP, program managers assure that DEP staff use the most recent revision.

It is the responsibility of program managers and Division Directors to determine whether other records are required to reflect the achievement of required quality for completed work and to fulfill any statutory, regulatory, or contractual requirements for environmental programs. If such records are required, it is the responsibility of program managers and Division Directors to ensure these records are identified, verified, authenticated, handled, retained, and disposed of so that the records are accessible and protected from damage or deterioration. Project-specific quality assurance records are identified in quality assurance project plans (QAPPs).

The Quality Assurance Manager maintains quality assurance records relating to the Maine DEP quality system that are not otherwise identified in the Records Retention Schedule.

Program and project managers and Division Directors maintain quality assurance records relating to their respective programs that are not otherwise identified in the Records Retention Schedule.

Each of these individuals specifies the location of and procedures for identifying, verifying, authenticating, handling, retaining and disposing of these records. These

individuals also keep a current listing of all types of quality assurance records that relate to their respective areas of responsibility.

5.2 Document and Record Storage

Document and record storage within each bureau or office is the responsibility of individuals charged with performing the tasks associated with this function. Some bureaus or offices have established controlled-access central file systems while others regulate storage to a lesser degree. The policies for each bureau or office are found in each record repository and in the office of the bureau or regional director. All Maine DEP employees have access to appropriate Department files during normal business hours. Members of the public are required to schedule an appointment to review Department files. All files will remain in the possession of the Department at all times.

Confidential documents are stored in secure areas within each bureau or office. Procedures for chain of custody and confidentiality for evidentiary documents and records are documented in all QAPPs, Sampling and Analysis Plans (SAPs), and other quality assurance plans.

File maintenance is the responsibility of all Maine DEP employees. Each division or program area, as appropriate, establishes documented protocols for file maintenance. Employees are required to file their own documents or have this task done by the documents and records managers according to regional policy.

Files are kept on-site within the Department or are in storage at the State Records Center or at the State Archives, according to the terms identified in the Record Retention Schedule for each bureau or office.

5.3 Archival Storage

Once files have been kept at the Department for the appropriate length of time, as defined in the Records Retention Schedule, they are sent to archival storage at the State Records Center or at the State Archives. When archiving documents and records, individuals designated with this responsibility follow a protocol established by the Records Center. Individuals assigned responsibility for documents and records management are required to maintain a record of the files that are being recalled from permanent storage at the State Records Center or at the State Archives.

5.4 Requests from the General Public

In the event that a member of the general public wishes to review Maine DEP files, individuals assigned the responsibility for documents and records management follow bureau-, program-, or office-specific procedures to assure availability of the requested material to the extent possible.

Documents and Records managers respond to written Freedom of Access Law requests in accordance with the requirements codified in that statute and applicable DEP policies and procedures.

6.0 COMPUTER HARDWARE AND SOFTWARE

The Department recognizes that Information Technology (IT) is critical to the performance of the mission of the Department of Environmental Protection. IT systems are used to gather, store, analyze, and publish data for use by Departmental staff, strategic partners, and the general public. Virtually every aspect of the Department's activities is supported by some type of IT tool. For these reasons, it is imperative that these IT tools are managed to ensure the safety, accessibility and quality of agency data.

Within the Department, the Environmental Information Management Team (EIMT) strives to provide the IT environment that best supports Departmental objectives. The IT environment encompasses hardware, software, and data management guidance. With guidance from the State of Maine Office of Information Technology (OIT), the EIMT responds to existing and emerging data management needs with proper IT solutions.

One of the guiding principles of the EIMT is to foster holistic data life cycles which result in quality information being used within the Department and delivered to customers outside of the department. Without high quality information, confidence in business decisions made and trust in the both the data management systems and decision makers would be severely compromised.

The strong relationship between OIT and EIMT supports the Department's quality objectives. This relationship is sustained by several key components, of which the following are particularly relevant to quality management:

The Department's Business Analyst is the head of the EIMT, which is comprised of an IT Coordinator for each Departmental Bureau and IT Coordinators for each Regional Office. The EIMT provides policy guidance and support for business process modifications which may be enhanced by IT tools.

OIT's Technology Business Consultant provides the Department with information regarding OIT policy, software licensing and fees, emerging state IT initiatives and monitors the effectiveness of OIT services.

OIT provides an application development team which works closely with the EIMT to support and modify the Departments custom IT systems such that they meet Departmental needs.

6.1 Development and Revision of Information Technology Standards

The EIMT manages Departmental specific IT standards / policies. These policies are updated when necessary as best practices evolve or IT trends dictate. Policies are approved by the Department's SMT and made available via the Department's intranet page. Overarching statewide IT policy is maintained by OIT. New OIT policies and procedures are developed in response to emerging needs from state agencies or national IT trends. Changes to OIT polices must be drafted and then vetted through

the upper management team of OIT. A full listing of OIT policies can be found on the State of Maine's internet site at: <http://www.maine.gov/oit/policies/> A look at OIT's strategic policy, aka "General Architecture Principles" might also provide insight:

<http://www.maine.gov/oit/architecture/GeneralArchitecturePrinciples/index.shtml>

6.2 Hardware

Computer hardware used by the DEP is approved by the EIMT and OIT. Policies have been developed to standardize the equipment used and the software installed on them.

For traditional desktop and laptop machines, the policies have resulted in comprehensive controls over the processing environment provided by those machines. These controlled environments result in significant benefits to the stability of the workstation and the security of our data, both of which are critical starting points for any business process which intends on providing quality data.

Policies regarding mobile devices are not as comprehensive as for traditional workstation environments, and are currently under development by both OIT and EIMT. In the meantime, the use of these devices is intended to be limited to data collection, not the more produced realms of storage, analysis, and publishing, thereby some of the more complex issues related to those realms can be avoided.

6.3 Software

The Department has a mix of Commercial Off The Shelf (COTS) software and custom designed and built software. Both have support provided by OIT which is brokered by EIMT.

6.3.1 COTS Software

A standard suite of office software and other commonly used programs is specified by OIT for all state PCs. Installation and configuration is carried out by OIT personnel. Other off the shelf software required by the Department is tested to ensure that it meets user needs and will function properly on the Department network, providing the stability required to produce quality work. This is done in accordance with a number of OIT policies including, but not limited to, ones dealing with Accessibility, Architecture, Security, Project Management, and Web development. When COTS software is deployed as part of a business process that manages or produces data, it is largely up to the business unit to enforce procedures which will maintain data integrity.

6.3.2 Custom Developed Software

Due to the unique business needs of our Department, COTS software has not had the ability to satisfy the full scope of the Department's needs. All custom software is developed in accordance with the General Architecture Principles mentioned earlier. These principles treat information as an asset and promote security and privacy as core missions. These State of Maine guidelines are based upon the Federal Enterprise Architecture Framework Version 2.0 (FEAF-II). In contrast to COTS software, custom software can have the unique quality objectives of a business process integrated into the application. By implementing domains, cross-attribute validation and other checks, comprehensive data quality controls have been provided for several business critical systems.

6.3.3 Testing

After planning has been completed and implementation has begun, all new implementations of software solutions at the Department must go through a testing phase. This testing phase is managed by EIMT in order to make a final determination that the solution is able to support the productivity and quality requirements of the Department. All software, whether it is COTS or custom developed, must pass through a strict Deployment Certification process required and administered by OIT. This process includes testing for functionality, performance, code security, backup and recovery, accessibility under Federal Section 508, and platform security.

6.3.4 User Training

Even the most intuitive IT solutions need user training in order to ensure that the solution is being used as intended and thus properly integrated into the overall IT environment at the Department. In order to ensure successful implementation, training is provided whenever an individual is introduced to a new application which is used to manage business critical data.

Training for COTS IT solutions which have been set up for a particular business process is provided by personnel in the corresponding business unit. For custom applications training is handled as part of overall operations of that system and is the responsibility of the Application Product Manager. Training for standard office productivity software is provided by OIT.

6.4 Data and Information

Responsibility for quality of data that is produced from or collected by computers or computerized equipment lies with program staff. User requirements for developed or purchased systems identify the requirements for data quality and the inspection and testing procedures needed to ensure that the delivered system meets those requirements. Guidance documents (QAPPs, SOPs, equipment manuals and other operational documents) set forth the procedures and means of managing data to ensure their quality during their useful life. When possible, systems are designed and

constructed with built-in checks and safeguards to ensure the highest possible data quality.

6.4.1 Archiving Source Data

Operating plans (e.g. SOPs) for environmental programs address the needs and methods for archiving source documents according to the procedures set forth in Section 5, Documents and Records of this plan. Programs that receive electronically submitted data that needs to be archived will ensure that the receiving system creates an appropriate archival record of who submitted the data, when it was submitted along with a copy of the contents of the submission. Any software and media for archiving these data must be maintained and upgraded in such a manner that it is possible to retrieve and reproduce the archived records during their required archival period. Software is often designed and constructed to maintain records of who creates, edits, or deletes data.

6.4.2 Safeguarding Current Data

Operating plans for programs that store data electronically address the needs and methods for safeguarding the data from loss and corruption during their useful life. OIT has policies governing the regular backup of data on all its server hardware, including shared file space. Desktop PCs within the DEP are configured to automatically store data to network storage devices that are backed up according to these policies.

6.4.3 Assuring Quality of Data Content

Operating plans for programs that manually enter data into electronic systems address the needs and methods for the data to be validated and verified. To the extent feasible, systems will be designed to assist data entry operators in detecting and correcting invalid entries.

Operating plans for programs that maintain databases address the needs and methods to ensure that the contents conform to specifications and that data have not become corrupted over time. These methods may include periodic audits of database contents.

6.5 System Safeguards

Systems and data are protected against malicious and unintended loss and corruption through a variety of measures designed to restrict access, detect threats, and reduce the probability of loss.

6.5.1 System Access

Access to systems is currently administered through OIT's User Request process. This process is initiated by an employee's supervisor and requires supervisor approval before any permissions are granted or changed. Users are set up to access only the systems they need to do their work. Access is controlled by user ID/password authentication both at the desktop level and program application level. Access from equipment not physically connected to the State of Maine WAN is further authenticated by the use of SecurID technology.

6.5.2 Virus Protection

Computer viruses pose a significant threat to computer systems and the data stored on them. *OIT's Enterprise Security Group* maintains an enterprise license for a security suite to manage all virus and malware protection strategies.

The Office of Information Technology maintains first level detection at the firewall to the Internet and the state government MS EXCHANGE server for e-mail. OIT deploys third level detection at the desktop. This is supported by an automated updating routing that regularly checks to ensure that each state PC has the most recent virus software and support files. Any PC that tries to connect to the State's Wide Area Network is scanned to see if it has an approved Virus Scanning system installed on it. If it does not, it is denied access to the WAN.

Users are trained to check that their desktop anti-virus software is current and to practice "safe computing" procedures to prevent the infection and spread of computer viruses. These procedures are set forth in the "Maine DEP SOP for Preventing and Dealing with Computer Viruses."

6.5.3 Backup and Recovery

OIT assumes all responsibility for the backup and recovery of all data stored on State of Maine servers. This is done in accordance with policies developed by OIT. Backups are periodically verified to ensure that they in fact are occurring and will provide the required data should a restore be required.

7.0 PLANNING

A systematic planning process is essential for ensuring that individual data operations will produce environmental data or information of the needed and expected quality for the intended use. Following such a process helps to ensure the ultimate success of any individual environmental data operation. Bureau directors are responsible for ensuring that a systematic planning process is used by directing planning teams to follow section 7.2 below. In addition to planned and long-term routine environmental data operations, there are also instances where the immediate need for a data operation arises from an unplanned event, emergency situation, or some other cause that imposes a constraint on the amount of time realistically available to meet the requirements of the formal systematic planning process and the development and approval of QAPPs as described below. Bureau directors shall use their discretion and best judgment in determining the flexibility needed from the requirements of this section in these instances, and document such in a memo to the file for that data operation.

In addition to planning specifically related to environmental data operations, Maine DEP and its several bureaus and program areas regularly engage in other planning processes, including, but not limited to:

- Strategic planning to meet EPA, Maine State Government, and other requirements, including development of the PPA;
- Budget planning and financial management;
- Program planning on an annual or multi-year basis to meet external requirements to receive grants and other funding;
- Division, program, and unit work planning.

Each unit of the Department, depending on its scope, is responsible for determining how such planning should take place, how frequently, and how the resulting plans are implemented and evaluated. All planning processes shall be documented, at a minimum, in a written plan. As appropriate, planning documents include commitments related to QA/QC and quality management. The EPA PPA and its annual updates include specific commitments by both parties related to this QMP.

The documented results of planning processes are also used to identify priorities for employee training and professional development; and to set individual performance expectations as part of the Performance Management Plan process (see 3.0). Managers and supervisors are responsible for assuring that employees are aware of their individual responsibilities and roles in implementing all applicable workplans.

7.1 Planning Teams

Before an environmental data operation begins, a planning team may be organized by the responsible bureau. The team will consist of: 1) appropriate staff members who have knowledge and/or experience in the key areas of the data operation, such as sampling, analysis, quality assurance, quality control, and statistics; and 2) other appropriate stakeholders and interested or involved parties, such as members from EPA, outside participating laboratories, municipalities, the regulated community, etc. For multi-media and/or cross-bureau operations, the Commissioner shall designate a lead Bureau to be responsible for organizing the planning team and ensuring staff representation from all appropriate bureaus.

7.2 Systematic Planning Process

The planning team at the outset will ensure that the following required elements ([see EPA QA R/5](#))⁷ of the systematic planning process for an environmental data operation are addressed:

- a description of the goals, objectives, questions, and issues to be addressed by the data operation;
- identification of schedules, milestones, and any applicable regulatory or contractual requirements;
- identification and allocation of resources (including a budget);
- identification and description of the type and quantity of data needed and how the data will be used to support the operation's goals and objectives;
- specification of performance criteria for measuring quality;
- specifications of quality assurance and quality control activities needed to assess the quality performance criteria (e.g. laboratory and field QC samples, performance audits, technical assessments, etc.);
- a description of where (sampling design), when, and how (sampling and analysis procedures) the data will be obtained as well as any constraints on data collection; and
- a description of how the data will be reviewed, evaluated, and assessed against stated quality performance criteria and its intended use.

The above steps follow EPA's systematic planning process as described in the EPA document, "[Guidance for the Data Quality Objectives Process \(EPA OA/G-4\)](#)" (February 2006)⁸. The planning team will find it advantageous to refer to this document for additional background and information in addressing these required steps.

⁷ https://www.epa.gov/sites/production/files/2016-06/documents/r5-final_0.pdf

⁸ <https://www.epa.gov/sites/production/files/2015-06/documents/g4-final.pdf>

7.3 Quality Assurance Project Plans

The information, findings, and descriptions resulting from the planning team's application of the systematic planning process for the environmental data operation shall serve as the basis for the development of a Quality Assurance Project Plan (QAPP) for that operation. Many of the required elements for an acceptable QAPP closely follow the steps described in the systematic planning process. The planning team shall refer to the EPA documents, "[Guidance for Quality Assurance Project Plans](#)" (QA/G-5)⁹, EPA NE QAPP Policy, dated February 3, 2005, and the [EPA NE QAPP Guidance, dated April 2005](#)¹⁰, for help in developing an acceptable QAPP. Program managers are responsible for insuring that QAPPs utilized in their programs are current, accurately reflect actual data operations practices, and that any minor revisions are documented.

QAPPs for data operations overseen by BRWM's Division of Remediation may be written by the site owners, other responsible parties, and even EPA in lieu of a Bureau planning team. In such instances, the Division's approved SOP DR#016 (Attachment B in the "*Quality Assurance Plan for Maine DEP's Division of Site Remediation (2004)*" for QAPP development shall be followed.

The Maine DEP QA Manager is responsible for developing and implementing procedures for the development, review, approval, and periodic review or auditing of QAPPs for delegated and contracted activities written by entities outside Maine DEP's span of control.

7.3.1 Review and Approval of Quality Assurance Project Plans

Once a planning team has completed a Quality Assurance Project Plan (QAPP) for the environmental data operation under consideration, the QAPP shall be submitted for review and approval according to OC-QM-002, "QAPP Review" (Appendix 4.3), prior to the start of the data operation.

The mutual responsibilities between EPA Region 1 Quality Assurance Branch (QAB) and the Maine Department of Environmental Protection (Maine DEP) pertaining to quality assurance review and approvals of QAPPs and Brownfield Site Specific Quality Assurance Plan (SSQAPs) addenda are stated below. The following text supersedes the Memorandum of Understanding (MOU) of July 24, 2009 (Appendix 7 in QMP revision # 7.4). The procedures detailed below are only in effect under a current Quality Management Plan (QMP). If Maine DEP's QMP expires, partial QAPP delegation does, too.

In addition to sharing joint review and approval responsibilities with QAB, Maine DEP also has partial delegation for certain QAPPs. Partial delegation is defined as Maine DEP having sole responsibility for the review and approval of 5-year updates of Clean Water Act §106, §319 and §604(b) water quality program QAPPs that contain no, or no substantive, changes as defined below in item 2. Under partial delegation, QAB will no longer review and approve these specific QAPPs. However, the EPA R1 Project Officer and the EPA Technical Lead for programs included in Maine DEP's Performance

⁹ <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf>

¹⁰ <https://www.epa.gov/sites/production/files/2015-06/documents/QAPPProgram.pdf>

Partnership Grant (PPG) will continue to review and approve these plans. The QAPPs included in the partial delegation are listed in Appendix 7 below.

The purpose of partial delegation for QAPPs generated by Maine DEP's Bureau of Water Quality (BWQ) Division of Environmental Assessment (DEA) for projects funded by EPA R1 with the criteria outlined above is to streamline the required quality assurance procedures. Partial delegation expedites QAPP review and approval for Maine DEP program staff, has no adverse impact on product quality, and reduces the required time commitment for both Maine DEP and QAB staff.

Brownfields SSQAPs generated for 128(a) Brownfield projects for which Maine DEP is the grantee will be delegated for sole Maine DEP review and approval. EPA R1 will still approve site work, but not individual SSQAPPs. Likewise, QAPPs that outside entities generate for non-EPA funded projects and submit to the Maine DEP BWQ DEA for review and approval are processed solely by Maine DEP.

Quality assurance review and approval of all QAPPs, including related documents such as SOPs, generated by Maine DEP BWQ DEA programs shall be handled as follows:

1. Entirely new QAPPs are submitted to QAB for co-review and approval.
2. Updates of existing QAPPs that have undergone prior co-review by, and have received approval from, EPA R1 QAB
 - a. Review and approval of regular 5-year updates where no or no substantive changes were made are delegated to Maine DEP (partial delegation). This type of QAPP review and approval is the most common type encountered by Maine DEP. Non-substantive changes are those that do not affect data quality or implementation of the QAPP. Examples of such changes are: acquisition of new instruments that are substantially the same as existing instruments; switch to a new analytical methodology that has the same, or better, data quality objectives as previously used methods; change in personnel if qualifications are substantially the same as those of previous personnel.
 - b. Review and approval of 'substantive' updates will be done jointly by Maine DEP and EPA R1 QAB. Substantive changes are those that are expected to affect data quality or QAPP implementation or where the range of QAPP activities is expanded. Examples of such changes are a switch to a new analytical methodology that has inferior data quality objectives than previously used methods, reduction in staff support for QAPP activities, or the addition of new methodologies.
 - c. If questions arise whether a change is substantive or not, Maine DEP staff will confer with QAB staff.

To successfully implement QAPP review and approval responsibilities, the following activities shall be completed by the parties involved.

7.3.2 Maine DEP Responsibilities

The Maine DEP will:

- a. Adhere to the requirements and guidance contained in the current versions of *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5) and *Guidance for Quality Assurance Project Plans* (EPA QA/G-5).
- b. Use the graded approach to QAPP and SAP development and approval, with the understanding that data generated and supporting documentation must be of sufficient quality to meet the objectives of the project or program.
- c. Commit to prepare, review, and document approval of QAPPs and SAPs prior to the initiation of data collection.
- d. Maintain a filing system for QAPPs and water program SAPs.
- e. Maintain appropriate communication with EPA R1 program personnel by sharing all QAPPs with the EPA Project Officer, EPA QAB, and the EPA Technical Lead. (For QAPPs where no substantive changes were made, only the EPA Project Officer and EPA Technical Lead will review and approve.) Any substantial updates to sole reviewed QAPPs will be shared with the QAB state coordinator.
- f. Collaborate with QAB staff to address any problems or deficiencies in the documents if any are encountered by QAB staff.
- g. Include a list of QAPPs and SAPs approved by Maine DEP on the Maine DEP QAPP inventory list. All of these documents will be available to QAB upon request.
- h. Submit the QAPP inventory list to QAB with its quality management system annual review. The inventory list will include information regarding annual QAPP reviews.

7.3.3 EPA R1 Responsibilities

EPA R1 Quality Assurance Branch will:

- a. Provide co-review and approval for entirely new QAPPs or QAPPs that were determined by Maine DEP and QAB jointly to have been updated in a significant manner.
- b. Provide technical support in reviewing other QAPPs when requested by Maine DEP.
- c. Periodically assess implementation of this delegated state authority, as desired. Findings will be reported to the Maine DEP QA Manager and the relevant EPA R1 Project Officers. If QAB determines that significant negligence in implementing delegation has occurred, it will attempt to resolve such issues through discussion with Maine DEP. EPA R1 may terminate partial delegation if resolution of issues cannot be obtained.

Data operations may commence when signed approval for a QAPP has been received, from either Maine DEP or both Maine DEP and QAB, as well as the EPA Region 1 Project Officer and the EPA Technical Lead for any programs included under a PPG. The master copy of a QAPP shall be maintained in the program area responsible for the specified operations. All approved QAPPs shall be reviewed annually by the Maine DEP employee responsible for maintenance of the document and the results reported to the QAM. Minor revisions shall be documented and incorporated. Substantive revisions shall follow the requirements of OC-QM-002. For a list of currently approved QAPPs, see Appendix 7.

All QAPPs must be revised and resubmitted for Maine DEP review and approval after 5 years. In the case of grantee organizations, failure to perform an annual review and update of a QAPP after 5 years may result in withholding or termination of funds by Maine DEP. A list of QAPPs covered under this delegated authority is provided in Appendix 7.

7.4 QA Program Plans

Certain DEP program areas have QAPPs approved by EPA-NE that cover a wide range of activities and operations at the program rather than project level. These QAPPs specify that program managers are required to produce annual Sampling and Analysis Plans (SAPs), also called work plans, which are then reviewed and approved prior to the beginning of sampling and monitoring activities, according to DEP SOP OC-QM-003 (see Appendix 4.4).

7.5 Other Quality Assurance Plans

Each bureau or program area develops procedures for the review and approval of Sampling and Analysis Plans (SAPs, also known as project plans or workplans) for the collection of environmental data for projects that do not require the development of a separate QAPP, following DEP SOP OC-QM-003 (see Appendix 4.4). Where such plans involve the use of new or experimental methodologies, the relevant procedures shall include a provision for external or other peer review prior to use, and a post-event effectiveness review.

Certain DEP program areas that fall outside the universe of environmental data operations requiring a QAPP may develop documented approaches to assuring quality. Examples include internal document and data storage systems and program areas that do not generate environmental data. Such plans are referred to as Quality Assurance Plans (QAPs). These QAPs are reviewed, approved, and maintained according to OC-QM-002.

7.6 Evaluating Data Collected Outside of this Planning Process

For data collected by an operation outside of the planning processes described here, or by an organization outside of Maine DEP that attests a systematic planning process was used, an existing or previous Maine DEP planning team for the environmental data operation having the closest similarities to the outside data in question may be asked to evaluate them for usability. This may be done by comparing as many documented aspects of the outside data operation as possible to the elements of its approved-QAPP counterpart. The team will need to evaluate how closely they agree, and where differences exist determine if they are substantial enough to allow the use of the data with qualifications (e.g. greater or lesser statistical confidence levels), or not allow the use of the data at all. The evaluating team will document their findings in a written report along with their recommendations on the usability of the data.

Each program area shall be responsible for developing and documenting standards of acceptance, and procedures for reviewing, verifying, and validating environmental data

procured or provided by entities outside Maine DEP's span of control (2nd party data) not otherwise subject to a QAPP. SOPs, DQOs, DQIs, SAPs and related documentation of such standards and procedures shall be maintained in a central location in each DEP division.

8.0 IMPLEMENTATION OF WORK PROCESSES

Maine DEP uses SOPs to ensure that certain kinds of regularly performed activities, such as sampling and monitoring techniques, operational procedures, or boilerplate document drafting, are conducted uniformly and appropriately given the needs of a task. Written SOPs help to ensure standardization of work on a site or for a program. SOPs are required with a QAPP for certain types of site work to allow the Maine DEP to verify acceptable procedures are being used. SOPs submitted with the QAPP must be used in implementing the project and will be used when auditing work. All program areas are responsible for developing, documenting, and implementing standard procedures for appropriate routine, standardized, special or critical operations, particularly those involving collecting, compiling, storing, or analyzing environmental data.

8.1 Activity Standardization

In conjunction with the auditing program described in Element 9 of this QMP, Maine DEP uses its *Standard Operating Procedure Development, Format, Approval, and Distribution* (OC-PE-001, Revision02, 12/11/12) document to guide staff and management in standardizing regularly performed activities. This document is included in this QMP as Appendix 4.1. This procedure defines the process for procedure standardization, SOP preparation, content, format, review, approval, release, revision, archival, and procedure withdrawal.

8.2 SOP Implementation

Maine DEP uses the auditing program described in Element Nine and the management oversight and performance appraisal programs described in Element One of this QMP to ensure that approved QAPPs and SOPs are implemented. These channels of authority and implementation mechanisms address scheduled and unanticipated changes to SOPs.

8.3 Maintenance of SOP's

The Office of Policy Services in the Office of the Commissioner is responsible for developing, maintaining, and tracking SOPs that apply to multi-program or department-wide operations and is responsible for approving, maintaining, and tracking SOP's that apply to operations within each bureau. Individual programs develop SOPs for activities and operations within their scope of responsibility. SOP's related to scientific work, sampling, and data analysis are maintained independent of the Office of Policy Services. These technical SOPs are developed through the QAPP process.

9.0 ASSESSMENT AND RESPONSE

Maine DEP has developed a program to monitor conformance to and assess the effectiveness of the Quality Management System. Assessments will take a number of forms within the Department, including:

- data quality assessments;
- employee performance evaluations;
- program reviews;
- peer reviews;
- formal audits;
- management system reviews; and
- EPA assessments.

Assessments, including formal audits, are based on quality objectives as documented in this QMP, Quality Assurance Project Plans (QAPPs), standard operating procedures, technical or professional standards, or other requirements set prior to work being performed. The type and frequency of assessments are determined in the systematic planning process (7.2), and recorded as part of a QAPP, SAP, or similar document. Assessment results are reported to appropriate management, supervisory, and other personnel for review and action as necessary. The assessors or auditors are qualified individuals from the Department who are independent of the area being assessed or from a contracted source.

Where program or project areas have yet to develop documented standards against which to assess conformance, management may request that the QMSC develop and carry out an evaluation audit. The audit team will work with program staff to determine the scope of the proposed audit, and will then compile an audit checklist based on the relevant ANSI/ASQ E-4 and QMP standards. The audit will follow the standard “condition expected / condition found” protocol for quality auditing. Program, division, and bureau management will receive an audit report and Corrective Action Requests, outlining actions needed to reach the standard (see Appendix 4). In addition, the audit report will include findings and recommendations intended to provide guidance for process improvements.

The Department procedure for quality auditing is included in Appendix 4.2.

As part of the processes associated with development and implementation of the PPA with EPA-NE and department-level, bureau, and division annual work plans, the various units of the Department conduct program assessments according to standards and procedures established by each. Staff responsible for QA/QC or quality management include quality-related findings in such assessments and reports.

9.1 Data Quality Assessments

Laboratory data received by the Maine DEP are assessed based upon the intended use of the data. Each program or bureau establishes the acceptance criteria needed for data assessment. Some programs use checklists to review and validate lab data (sampling results as well as QC data) to ascertain whether data are acceptable as is, need to be qualified, or should be rejected. For example, the Marine Environmental Monitoring Program uses a basic data

review checklist developed by a Maine DEP chemist for staff use and reference the list as a QAPP Appendix. Other types of submitted data, such as field data or reports, are assessed for quality by qualified technical staff in each program using the QAPP or data quality assurance procedure established by that program. Program managers are responsible for assuring that data received are checked for completeness and assessed for usability in meeting project objectives.

Data submitted by the regulated community pursuant to a license condition are reviewed and verified by DEP technical staff as part of regular inspections. Each program receiving such data establishes and documents its own assessment standards and procedures. See also 4.3, 7.6.

Review of data is also done in compliance with EPA document, “[Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements](#)”¹¹.

9.2 Employee Performance Evaluations

Employee performance evaluations are conducted following guidance provided by the Bureau of Human Resources and are documented on Performance Management Forms. See Section 3.3. Individual performance plans specify appropriate general or specific responsibilities for carrying out the provisions of this QMP. Managers and supervisors are evaluated for their implementation of QMS responsibilities.

9.3 Unit/Program Assessment and Review

Management at each level is responsible for assuring that functional units and programs are assessed on a regular basis to ensure that identified objectives, such as those delineated in annual work plans, are being met. Division and bureau directors may request a program review team to assess whether program objectives, policies, methods, documents and procedures are up-to-date and consistent with Legislative and Department goals and priorities. Review teams or the QA Coordinator conduct program reviews using the Department’s auditing approach. Bureau Directors, in consultation with Division Directors, will determine the need for and timing of program reviews. The QMSC may recommend to senior management that a program be reviewed, based on results of a management review or audit (See Section 10.2).

9.4 Peer Reviews

A peer review process may be used when the Commissioner or a Bureau Director determines that an action by the Department or sponsored by the Department requires an independent, technical review of data or analyses in order to ensure accuracy, credibility, and applicability

9.5 Formal Audits

The Department carries out a program of formal audits to assess conformance to each element of this QMS and to individual QAPPs, SOPs, Department rules, or other Department policies or requirements. A program manager, according to quality objectives and risk, may

¹¹ <https://www.epa.gov/sites/production/files/2015-03/documents/competency-policy-aaia-new.pdf>=

schedule audits of outside laboratories, contractors, or suppliers. Audits are conducted according to the procedure established by the Department (Appendix 4.2, SOP OC-QMP-001) plus any additional requirements that may be established by each bureau, office, or program. Additional requirements are documented as part of a specific audit plan.

Qualified individuals who are independent of the area being audited conduct audits. They are conducted in a rigorous and systematic manner, using objective evidence to make findings regarding conformance to requirements and the need for any corrective action. Audit findings are documented and reported in a timely fashion to management. Proposed corrective actions are evaluated and tracked by project managers and quality assurance staff and the effective implementation of corrective actions is verified before the audit is closed.

Audit findings are presented to Program/Bureau management in the form of a formal Audit Report. The Audit Report shall include observations and Corrective Action Requests (CAR) (See Appendix 4.2 definitions). A formal Corrective Action Plan (CAP) shall be required in response to audit findings that are presenting to management in the form of a CAR. A CAP shall be tracked through implementation until complete. Upon closure of the CAP, responsible management shall report the closure of the CAP to the QAM and quality assurance staff associated with that Bureau. The Department's QAM may request a CAP implementation update report from the responsible management six months from the completion of an audit.

The Department may rely on or require third party audits, such as laboratory certification or ISO 9001 certification, in lieu of conducting its own audits.

9.6 Management System Reviews

The QMS will be assessed on an annual basis by an internal management system review team, as described in Element 10.

9.7 EPA Assessments

EPA-sponsored programs are subject to periodic review or audit by EPA. Scope and timing of audits may vary depending on the program and its enabling legislation, rules or authorities. Formal assessment of performance under EPA PPAs occurs as part of a comprehensive review and evaluation of Department programs. The process is governed by EPA's Policy on Oversight of Delegated Programs, which states evaluations should focus on overall program performance.

9.8 Deficiencies and Non-conformances

Significant deficiencies and non-conformances to QAPPs, SOPs or Department requirements observed outside of a formal audit or assessment process are reported by Department staff to supervisors.

Each Division Director or program manager shall establish who has authority to suspend or stop work upon detection and identification of an immediate adverse condition affecting data quality or personnel health and safety.

Supervisors shall ensure that the deficiency or non-conformance is documented and shall forward reports to the appropriate project manager and lead quality assurance staff. A formal Corrective Action plan may be required and tracked until closure.

9.9 Corrective Actions

Corrective actions generally are developed on a case-by-case basis. Once a problem has been identified, the problem is documented and individuals involved with the project are notified of the problem. Involved parties (including project managers) meet to discuss the problem.

When deficiencies or non-conformances have been identified, project managers determine and document the following:

- the nature and scope of the problem;
- the root cause(s);
- the programmatic impact;
- required corrective action(s);
- action(s) needed to prevent recurrence, including training;
- method of assessing and verifying the effectiveness of the corrective action;
- timetable for implementation; and
- the staff responsible for implementation and follow up reporting.

The project manager forwards copies of corrective action plans to supervisory and lead quality assurance staff involved in monitoring corrective actions. Lead quality assurance staff forward copies of corrective action plans, as appropriate, to affected division directors, grant, and program managers.

Managers and supervisors ensure that corrective action plans are effectively implemented in a timely manner and that activities necessary to carry out such plans are included in annual workplans or other planning documents as appropriate. Bureau directors and lead quality assurance staff monitor the implementation of corrective action plans. Managers and supervisors shall include completion of corrective actions in employees' performance management plans and annual performance review.

Non-conformances and corrective actions are documented in the project or program file to ensure that future individuals involved with the project or activity will be able to trace the evolution of procedural or policy change (including what was done, by whom, and why).

10.0 QUALITY IMPROVEMENT

Maine DEP understands “quality improvement” to be a continuing process by which the Department identifies opportunities to improve the QMS itself, as well as individual programs and work processes. It thus continues, but is distinct from, efforts to assure QA and QC.

All Maine DEP employees and contractors are encouraged to identify, plan, implement, and evaluate quality improvement activities for their areas of responsibility. Individual employees prevent quality problems whenever possible, and report opportunities for improvement as well as quality system problems as they are identified.

The method for addressing deficiencies and non-conformances is described in Element 9.8.

10.1 Quality Management System

Maine DEP’s Senior Management Team requires the QMSC (see 2.1) to report annually on the state of the QMS. This report, based on an internal review or formal audit (see 9.6), identifies areas of the QMS in need of correction or improvement, makes recommendations for implementing needed change, and specifies the resources needed for implementation. Senior Management then determines how the recommendations should be carried out and allocates the necessary resources.

On an annual basis, bureau quality management coordinators review quality-related deficiencies, non-conformances, and programmatic improvements and advise the affected program manager, bureau director, and quality assurance manager of any significant trends.

On an annual basis, the QAM provides the EPA-New England QA Officer with a report describing the status of the QMS.

10.2 Organizational Improvement

Opportunities for improvement of Maine DEP processes and programs beyond the requirements of this QMP are identified in a number of ways, among which are:

- Ongoing processes associated with annual and multi-year Strategic Planning; and the PPA with EPA;
- The auditing and assessment processes described in Element 9.0; and
- Ongoing management review at the program and Division level (see 9.3)

Where opportunities for improvement are identified, management determines how these might be implemented and allocates the necessary resources.

10.3 Customers and Stakeholders

In addition to opportunities identified within Maine DEP, the Department uses a number of different methods to receive and act on suggestions for improvement from customers and stakeholders. These include, but are not limited to:

- Solicited comments from the regulated community and general public through workshops, focus groups, and other formal stakeholder processes;
- Unsolicited comments from the regulated community, general public, and other interested parties;

- Consultation with legislators and other state agencies; and
- The rule-making process overseen by the Board of Environmental Protection.

Management is responsible for receiving such comments and suggestions, and determining how best to act on them to fulfill the Department's mission.

10.4 Quality Recognition

Maine DEP has instituted an annual Quality Improvement Award, given each year at the Employee Recognition Day event, to recognize outstanding contributions by individuals or teams to the ongoing quality effort of the Department. In addition, the "Employee of the Month" program, as well as both Department and state-level awards to individuals and teams, includes quality as a component in the selection criteria.

APPENDIX 1:
QUALITY MANAGEMENT POLICY

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OC-QM-004, Revision 1

May, 2002

Quality Management

Intent: It is the policy of the Maine Department of Environmental Protection (MEDEP) to ensure that its operations are consistent with defined standards, criteria, and procedures in order to maintain the highest appropriate levels of quality. To this end, the Department operates in accordance with a Quality Management Plan (QMP, May, 2001, as revised)) that defines such standards, and provides the basis for quality improvement. The Quality Management System described in the Plan applies to all areas of DEP operations and includes consideration of the needs and expectations of the Department's customers and stakeholders.

Quality Control (QC), Quality Assurance (QA), and Quality Improvement (QI) activities related to the collection, analysis, storage, and use of environmental data are prescribed in the Department's Quality Management Plan (QMP). These activities, responsive to the criteria in the ANSI/ASQC – E4 and ISO 14001 (1996) standards, are necessary to ensure that decisions made by the Department are based on data management methods and practices that meet or exceed relevant quality standards.

Standards: It is the policy of the MDEP to ensure that:

- Management provides the resources necessary to develop, implement, maintain, and improve the QMS; and regularly reviews the performance of the QMS for effectiveness in supporting the stated mission of the DEP;
- Standard Operating Procedures (SOPs) are established for key processes as determined by each Bureau, Division, or Office;
- Environmental data meet documented standards for accuracy, precision, representativeness, comparability, and suitability to their intended purposes;
- Environmental data are verifiable and defensible, and all components related to their generation are properly documented;
- Environmental technologies, including those for sampling and monitoring, are designed, constructed, and operated according to defined expectations;
- Data integrity is maintained and documented, including chain-of-custody and archival control;
- Quality audits of QMS elements are carried out on a scheduled and documented basis, as is resulting necessary corrective action;
- Managers, supervisors, and staff throughout MEDEP, and its contractors understand their roles in managing quality; receive the training necessary to meet quality standards for job tasks; and are encouraged to identify and suggest improvements to be made to the QMS.

Responsibility:

1. The Senior Management Team (SMT) of MEDEP shall appoint a Quality Management Steering Committee (QMSC), convened by the MEDEP Quality Assurance Manager, charged with oversight of all QMS activities.
2. SMT is responsible for ensuring that QMS programs and requirements are implemented in the several Bureaus and other organizational units of MEDEP. This responsibility includes, but is not limited to, ensuring that personnel and other resources are available to meet the standards above, and the requirements of the QMP.

Martha G. Kirkpatrick, Commissioner

May 15, 2002

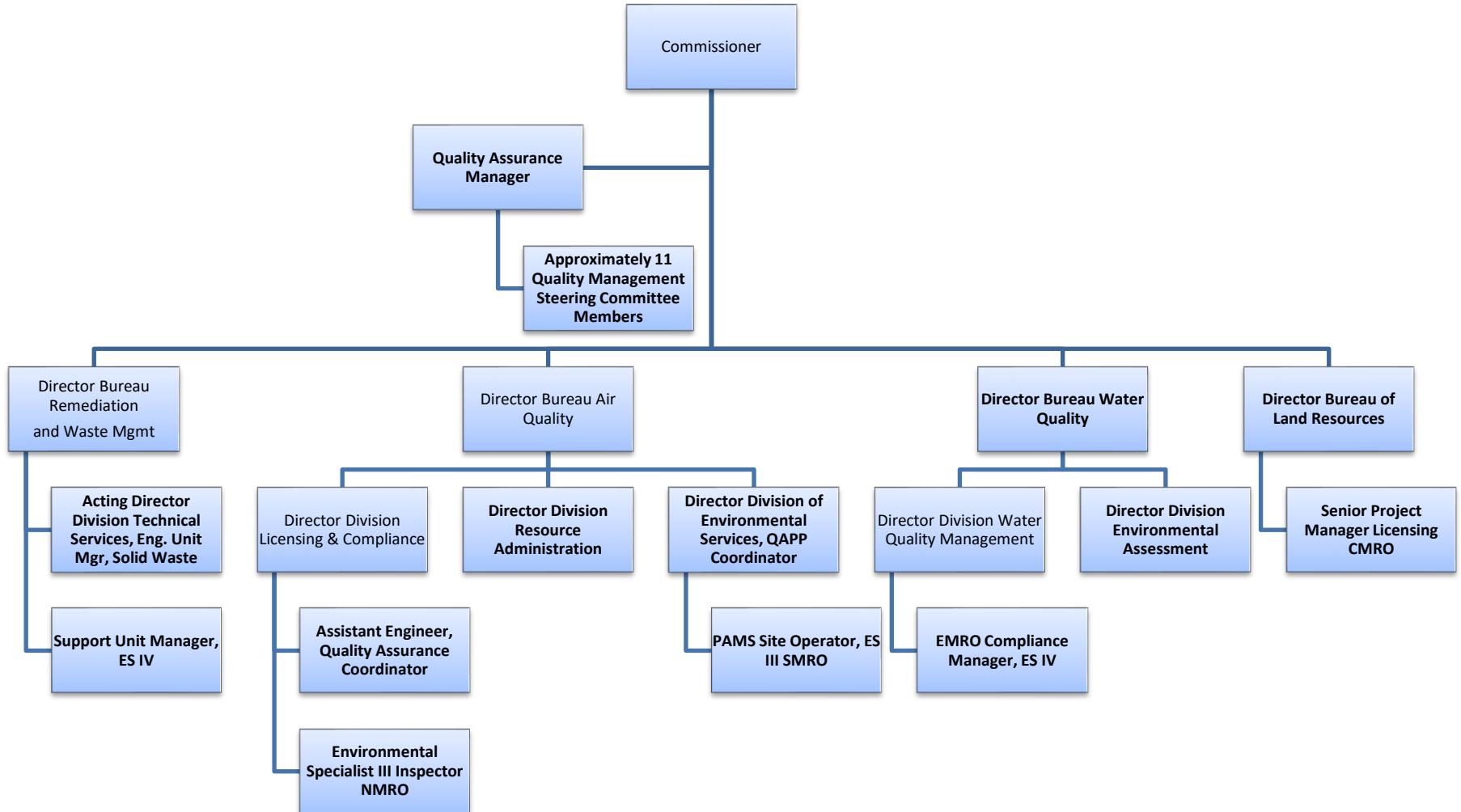
APPENDIX 2:

ORGANIZATIONAL CHART

Showing Quality Management Responsibilities:

Positions in **bold** include designated QA/QC functions and service on the Quality Management Steering Committee.

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APPENDIX 3:
QUALITY MANAGEMENT STAFF

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Maine DEP has no position wholly dedicated to QA/QC/QI functions; as detailed in Element 2 of this QMP, our approach to quality management integrates this function throughout the agency rather than concentrating responsibilities in a few individuals. The following list reflects the structure and positions identified in Element 2.1, as well as bureau-level individuals whose job responsibilities have significant quality components.

QUALITY MANAGEMENT STEERING COMMITTEE

NAME	POSITION	ADDRESS	TELEPHONE AND FAX #	EMAIL
William Longfellow	QAM, Director Innovation & Assistance	17 State House Station Augusta, Maine 04333	207-287-2821	William.Longfellow@Maine.gov
Kevin Martin	Assistant QAM, QA Coordinator – SOPs, QMP, Compliance & Procedures Specialist	17 State House Station Augusta, Maine 04033	207-287-4305	Kevin.Martin@Maine.gov
Andy Johnson	QA Coordinator - QAPP , Division Director Environmental Services, BAQ	17 State House Station Augusta, Maine 04333	207-287-7047 207-287-7641	Andy.Johnson@Maine.gov
Don Witherill	Director, Division of Environmental Assessment, BWQ	17 State House Station Augusta, Maine 04333	207-215-9751 207-287-7826	Donald.T.Witherill@Maine.gov
David McCaskill	Senior Environmental Engineer, BRWM	17 State House Station Augusta, Maine 04333	207-592-8054 207-287-7826	David.McCaskill@maine.gov
Beth Callahan	Senior Project Manager, Licensing, BLR	17 State House Station Augusta, Maine 04333	207-446-1586 207-287-7826	Beth.Callahan@Maine.gov
Clarissa Trasko	Compliance Manager, ES IV, BWQ	106 Hogan Road Bangor, Maine 04401	207-941-4570 207-941-4584	Clarissa.Trasko@Maine.gov
Michael Kuhns	Director, Bureau of Land and Water	17 State House Station Augusta, Maine 04333	207-287-2827 207-287-7826	Mick.Kuhns@Maine.gov
Jim Gramlich	Inspector, ESIII, BAQ	1235 Central Drive Presque Isle, ME 04769	207-764-0477 207-760-3143	Jim.F.Gramlich@Maine.gov
Mary James	Support Unit manager, ES IV, BRWM	17 State House Station Augusta, Maine 04333	207-287-7758 207-287-7826	Mary.R.James@Maine.gov
Peter Carleton	Assistant Engineer, BAQ & Bureau QA Coordinator - Audits	17 State House Station Augusta, Maine 04333	207-287-8105 207-287-7641	Peter.G.Carleton@Maine.gov
Sherrie Kelley	Division Director, Resource Administrraion	17 State House Station Augusta, Maine 04333	207-287-4852 207-287-5987	Sherrie.M.Kelley@Maine.gov
Marylee Mullen	PAMS Site Operator, ESIII, BAQ	312 Canco Road Portland, Maine 04103	207-822-6300 207-822-6303	Marylee.T.Mullen@Maine.gov

OTHER KEY QMSC RESOURCE PERSONNEL

NAME	POSITION	ADDRESS	TELEPHONE AND FAX #	EMAIL
Brian Beneski	Remediation Division, BRWM	17 State House Station Augusta, Maine 04333	207-287-7799 207-287-7191	Brian.Beneski@Maine.gov
Susanne Meidel	Div of Envir. Assessment, BWQ	17 State House Station Augusta, Maine 04333	207-287-7778 207-287-7191	Susanne.Meidel@Maine.gov
Kelly Perkins	Environmental Chemist, Chemistry Unit Manager, BRWM	17 State House Station Augusta, Maine 04333	207-287-7878 207-287-7826	Kelly.Perkins@Maine.gov
Danni Twomey	Environmental Chemist, Field Services Laboratory, BAQ	17 State House Station Augusta, Maine 04333	207-287-3653 207-287-7191	Daniel.M.Twomey@Maine.gov

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APPENDIX 4:

STANDARD OPERATING PROCEDURES, ETC.

SOP DEVELOPMENT, FORMAT, APPROVAL, AND DISTRIBUTION

QUALITY AUDITING

QAPP REVIEW

SAMPLING AND ANALYSIS PLANS

CONTROL OF DOCUMENTS AND RECORDS

4.1 SOP DEVELOPMENT, FORMAT, APPROVAL AND DISTRIBUTION

COVERSHEET STANDARD OPERATING PROCEDURE

Operation Title: **Standard Operating Procedure Development, Format,
Approval and Distribution**

Originator Name: **Jim Dusch; Updated April 11, 2017, by Kevin Martin**

APPROVALS:

Bureau of Air Quality Director:

Print Name _____ *Signature* _____ *Date* _____

Bureau of Water Quality Director:

Print Name _____ *Signature* _____ *Date* _____

Bureau of Land Resources Director:

Print Name _____ *Signature* _____ *Date* _____

Bureau of Remediation and Waste Management Director:

Print Name _____ *Signature* _____ *Date* _____

QMSC Chair:

Print Name _____ *Signature* _____ *Date* _____

Commissioner:

Print Name _____ *Signature* _____ *Date* _____

DISTRIBUTION:

- () Bureau of Air Quality.....By: _____ Date: _____
() Bureau of Water Quality.....By: _____ Date: _____
() Bureau of Land Resources.....By: _____ Date: _____

() Bureau of Remediation and Waste Management.....By: _____ Date: _____
() Office of the Commissioner.....By: _____ Date: _____
() Quality Management Steering Committee.....By: _____ Date: _____

1. **APPLICABILITY.** This Standard Operating Procedure (SOP) applies to all programs in the Maine Department of Environmental Protection (Maine DEP). This Procedure applies to all staff involved in any task that is appropriate for or has an established SOP.
2. **PURPOSE.** Establishing standardized methods for performing common repetitive tasks improves the Maine DEP's efficiency, consistency, verifiability, credibility, and our ability to attain the highest levels of Quality Assurance, Quality Control, and Quality Improvement (QA/QC/QI). This document describes the Maine DEP's procedure for developing, formatting, approving, and distributing standard operating procedures (SOPs).

This SOP repeals and replaces OC-PE-001 (Revision 02), which contained provisions now addressed in this document.

3. DEFINITIONS

- 3.1 **COMMISSIONER.** The term *Commissioner* refers to the Commissioner of the Department of Environmental Protection.
- 3.2 **DEPARTMENT OF ENVIRONMENTAL PROTECTION.** The term *Department of Environmental Protection* or *Maine DEP* refers to the Maine Department of Environmental Protection, a State administrative agency.
- 3.3 **ORIGINATOR.** The term *Originator* refers to the individual primarily responsible for the development of a SOP, including drafting, review, finalization, and distribution. The term also refers to the individual who subsequently becomes responsible for a given SOP when the initial Originator no longer has this responsibility [see 4.6].
- 3.4 **QUALITY ASSURANCE MANAGER.** The term *Quality Assurance Manager* (QAM) refers to the individual at Maine DEP who is the primary point of contact for quality issues and the Quality Management Steering Committee (QMSC).
- 3.5 **QUALITY ASSURANCE COORDINATOR – SOPs.** The term *Quality Assurance Coordinator* (QA Coordinator) – SOPs refers to the individual at Maine DEP primarily responsible for tracking, reviewing, and implementing changes to all Department-Wide, Multi-Bureau, or Bureau-Specific SOPs
- 3.6 **QUALITY MANAGEMENT STEERING COMMITTEE.** The Maine DEP organizes and oversees agency-wide QA/QC/QI functions with a *Quality Management Steering Committee* (QMSC). Six (6) management level individuals comprise the QMSC, with at least one (1) representative being from each bureau and at least one (1) member being from senior management.

- 3.7 SENIOR MANAGEMENT TEAM. The term *Senior Management Team* (SMT) refers to the group of individuals existing at any point in time that have been chosen by the Commissioner to oversee Maine DEP management.
- 3.8 STANDARD OPERATING PROCEDURE. The term *Standard Operating Procedure* (SOP) is the description of a prescribed method that must be used by Maine DEP staff to complete certain routine or repetitive operations, analyses, or actions. SOPs do not establish policy and are not appropriate to describe procedures or requirements that apply to members of the public, other than persons acting as agents of, or under contract with, the Maine DEP.
- 3.9 TECHNICAL STANDARD OPERATING PROCEDURE. The term Technical Standard Operating Procedure (Technical SOP) refers to SOPs addressing aspects of data generation and acquisition, including but not limited to elements listed in Table 2 of EPA QA/R-5, "Requirements for Quality Assurance Project Plans." Technical SOPs ensure appropriate standard methods for sampling, measurements and analysis, data collection or generation, data handling, and QA activities.

4. RESPONSIBILITIES

- 4.1 COMPLIANCE. All staff engaged in operations, analysis or actions subject to or appropriate for the application of a SOP are responsible for becoming familiar, and complying, with the contents of this procedure prior to drafting or revising a SOP. Supervisors are responsible for ensuring that their staff are familiar with and adhere to the SOPs affecting their program functions.
- Pursuant to Section 4.6 of this SOP, OC-PE-0001 (06/15/01), any SOP in place prior to this document's effective date must be scheduled for annual review and periodic renewal by a responsible individual. At the time of any revision subsequent to the effective date of this SOP, an existing SOP must be brought into conformance with the provisions of this document. Until revision or renewal occurs, no changes are required to bring currently effective SOPs into conformance with this SOP.
- 4.2 DEVELOPMENT. The Originator is responsible for initial development. Initial development includes word processing and distribution for review.
- 4.3 APPROVAL. The Originator is responsible for obtaining preliminary and final approval of a proposed SOP.
- 4.4 DISTRIBUTION. After all approval signatures have been obtained, the Originator is responsible for distributing the SOP to any affected parties, as evidenced by a completed distribution list on the Coversheet. The Maine DEP's Quality Assurance Manager (QAM) is the point of contact

for receiving all final SOPs. The Originator must also arrange for access to all SOPs through the Maine DEP's Intranet pages. All SOPs that are used by parties outside the DEP, such as contractors and consultants, must be posted, made accessible, and maintained on the DEP website. Program and project managers are jointly responsible for assuring that the most current version is used.

4.5 **TRACKING.** The QA Coordinator for SOPs will track Maine DEP-wide SOPs. At a minimum, the name of responsible individuals, document titles, dates of last revision, and document numbers will be recorded.

4.6 **MAINTENANCE.** An individual, typically the Originator, will be assigned responsibility for ensuring that an SOP reflects current needs and standards. Whenever the initial SOP Originator ceases to be responsible for a given SOP, the appropriate division director, or Policy and Procedures officer in the affected bureau or in the Office of the Commissioner, will ensure that responsibility is re-assigned, and that the document database or other tracking list maintained by the bureau or Office of the Commissioner is updated to indicate the responsible person. Consistent with the Maine DEP's Quality Management Plan, the responsible individual will annually evaluate SOPs as part of their performance expectations to ensure that the document is adequate and correct and that current needs are being met. All SOPs will be reviewed, amended as needed, and reissued or withdrawn every five years.

5. GUIDELINES AND PROCEDURES

5.1 **ORIGINATION.** A staff member may originate a draft or concept for a draft SOP for any appropriate procedure or process.

5.2 **CONTENTS**

5.2.1 **APPLICABILITY.** The first section of a SOP contains a brief statement identifying the scope of the SOP and what individuals and programs are affected by the SOP.

5.2.2 **PURPOSE.** The second section of a SOP contains a brief statement explaining the objective of the procedure. It indicates what organization, documentation, and/or activities are involved or affected by the procedure and a concise background description of the program or procedure.

5.2.3 **DEFINITION.** The third section of a SOP lists the meaning of words or groups of words not commonly known to the potential user of the SOP. For example, technical terms and/or acronyms are described in this section.

5.2.4 **RESPONSIBILITY.** The fourth section of a SOP lists all the individuals or groups responsible for implementing the procedure or performing certain

tasks associated with the procedure and the duties assigned thereto.

5.2.5 **GUIDELINES AND PROCEDURES.** The fifth section of a SOP lists, in detail, all the steps required to perform the particular job task.

5.2.6 **REFERENCES.** The final section of a SOP lists any written reference materials used in compiling the procedure.

5.3 **FORMAT**

5.3.1 **CONFORMANCE TO STANDARD.** All SOPs must at least include the *Page Header Contents* information as detailed in Section 5.3.2 of this SOP. The standard text format detailed in FIGURE 2 of this SOP is required for SOPs that apply Maine DEP-wide. The format is recommended, but not required, for technical, bureau- or program-specific SOPs.

5.3.2 **PAGE HEADER CONTENTS.** Each page, including the coversheet, shall include a header containing the Department logo in the upper left corner, and a document identifier in the upper right hand corner that contains the following information in nine (9) point bolded type, Arial:

SOP No.....
Effective Date...
Revision No.....
Last Revision Date....
Page of

The coding system for document identifiers is detailed in FIGURE 3.

5.4 **SOP DEVELOPMENT AND APPROVAL PROCESS.** The SOP approval process consists of a preliminary draft cycle and a final approval cycle.

5.4.1 **PRELIMINARY DRAFT DEVELOPMENT.** In the preliminary draft cycle, the originator contacts their Supervisor and Division Director to gain approval for going forward with drafting a proposed SOP. Upon approval to proceed, the originator should work with appropriate staff to prepare a draft.

"Appropriate staff" should include a representative group of individuals who will be affected by the SOP. Any staff member who makes a request to review a draft SOP should be provided that opportunity.

5.4.2 **PRELIMINARY DRAFT APPROVAL.** The preliminary draft approval should be commensurate with the SOPs scope and applicability.

For example, SOPs applying Maine DEP-wide must be broadly approved, including preliminary draft approval by the Office of the Commissioner; while SOPs applying to a discrete unit within a division only need a single Unit Supervisor, Division Director,

and QAM to sign-off.

The preliminary draft must first be submitted to the Originator's supervisor for comment and approval to proceed with the review process. Upon receiving approval to proceed, if other supervisors on the same management level as the Originator's supervisor have staff affected by provisions in the draft SOP, the draft should then be circulated to them for review and comment. After review and comment at that level, the draft must then be circulated, as appropriate, to the QAM.

Reviewers are free to use their judgment to include additional individuals and groups whose input they believe would be valuable to the process. All required reviewers must submit a response to the Originator, indicating approval or changes necessary to obtain their approval.

5.4.3 **COMMENT RECONCILIATION.** The Originator of the draft SOP will resolve any issues raised in comments during the draft review cycle.

5.4.4 **FINAL APPROVAL.** Signatures necessary for final approval should be commensurate with the SOPs scope and applicability, as detailed below. Please note that all SOPs, regardless of its scope and applicability, require the signature of the Commissioner on draft and final approval versions. A sample SOP coversheet is provided in FIGURE 1

(A) BUREAU SPECIFIC SOPs. Preliminarily approved drafts of bureau specific SOPs must receive final approval from the relevant Bureau Director, the Maine DEP's QAM, and the Commissioner. Only these three (3) signatures should be on the SOP Coversheet.

(B) MULTI-BUREAU SOPs. Preliminarily approved drafts of multi-bureau SOPs that do not apply to all bureaus must receive final approval from the Bureau Director in each affected bureau, the Maine DEP's QAM, and the Commissioner. Only the relevant signatures should be on the SOP Coversheet.

(C) MAINE DEP-WIDE SOPs. Preliminarily approved drafts of Maine DEP- wide SOPs must receive final approval from all Bureau Directors, the Maine DEP's QAM, and the Commissioner. Only these six (6) signatures should be on the SOP Coversheet.

(D) Technical SOPs. Preliminarily approved drafts of technical SOPs must receive final approval from professionally competent staff in conjunction with QAPP Level II Technical Reviews.

6. REFERENCES

6.1 **MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION**
QUALITY
MANAGEMENT PLAN (Rev. 4, October 1, 2011, Minor Revision January 18, 2013)

Maine Department of Environmental Protection Quality Management Plan

Revision: 8

Revision Date: January 7, 2021

Page: 67 of 120

FIGURE 1 – SAMPLE COVERSHEET

**COVERSHEET
STANDARD OPERATING PROCEDURE**

Operation Title:

Originator Name:

APPROVALS:

Bureau Director:

Print Name

Signature

Date:

Quality Assurance Manager:

Print Name

Signature

Date:

Commissioner:

Print Name

Signature

Date:

DISTRIBUTION:

- () Bureau of Air Quality..... By: _____ Date: _____
- () Bureau of Water Quality..... By: _____ Date: _____
- () Bureau of Land Resources..... By: _____ Date: _____
- () Bureau of Remediation and Waste Management..... By: _____ Date: _____
- () Office of the Commissioner..... By: _____ Date: _____
- () Quality Management Steering Committee..... By: _____ Date: _____

FIGURE 2 – FORMAT SENARIOS

1. SECTION HEADING. Section Text. (see 4.4.2)

1.1 SUB-SECTION HEADING. Subsection text. (see 4.4.3)

1.1.1 PARAGRAPH HEADING. Paragraph text. (see 4.4.4)

(A) SUB-PARAGRAPH HEADING. Sub-paragraph text (see 4.4.5)

The following description establishes the standard format the is required for all Maine DEP-wide SOPs and suggested for any bureau- or program-specific SOPs.

TYPEFACE. All type, except the header, shall be 11 point, Arial.

PAGE MARGINS. Margins will be 1-inch top and bottom, and 1-inch left and right.

COVERSHEET CONTENTS. Each SOP must have a coversheet that contains the following information: (1) the page header described in section 4.3.2 of this SOP; (2) operation title; (3) Originator's name; (4) approval sign-off; and (5) a distribution check-off (see FIGURE 1, appended).

SECTIONS. The first level of written division in a SOP document is referred to as a “section”. Single digit numbers are used to identify a section. The heading of a section must have the “SOP SECTION HEADING” *character style* applied to it and the text of the section, including its heading must have the “SOP Section Text” *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the section number and heading activates the hanging indent, and two spaces between header title and any paragraph text are used to separate the heading from the body.

SUB-SECTIONS. The second level of written division in a SOP document that is part of, but separate from, a section is referred to as a “sub-section”. Two numbers, separated by a period, identify a sub-section. The numbers and words in the heading of a sub-section must have the “SOP SUB-SECTION HEADING” *character style* applied to it, and the text of the sub-section, including its heading, must have the “SOP Sub-section Text” *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the sub-section number and heading activates the hanging indent, and two spaces between end of the header title and beginning of any sub-section text are used to separate the heading from the body.

PARAGRAPHS. The third level of written division in a SOP document that is part of, but separate from, a sub-section is referred to as a “paragraph”. Three numbers, separated by periods, identify a paragraph. The numbers and words in the heading of a paragraph must have the “SOP PARAGRAPH HEADING” *character style* applied to it, and the text of the paragraph, including its heading, must have the “SOP Paragraph Text” *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the paragraph number and heading activates

the hanging indent, and two spaces between end of the heading title and beginning of any paragraph text are used to separate the heading from the body.

SUB-PARAGRAPHS. The fourth and final level of written division used in a SOP document is part of, but separate from, a paragraph is referred to as a “sub-paragraph”. An uppercase letter enclosed in parentheses identifies a sub-paragraph. The letter and any words in the heading of a sub-paragraph must have the “SOP SUB-PARAGRAPH HEADING” *character style* applied to it, and the text of the sub-paragraph, including its heading, must have the “SOP Sub-paragraph Text” *paragraph style* applied to it. By applying these *styles* to the heading and body, each will automatically be formatted and indented to its appropriate position. A tab between the subparagraph letter and heading activates the hanging indent, and two spaces between end of the heading title and beginning of the sub-paragraph text are used to separate the heading from the body.

TABLES AND FIGURES. The inclusion of illustrative tables and figures is appropriate in SOPs. Since the format of these items will vary, no prescribed method is established herein. All tables and figures must be identified with a number and title that will have the “SOP Tables and Figures Id.” *paragraph style* applied to it. By applying this *style* to the number and title, it will automatically be formatted and centered to its appropriate position.

FIGURE 3 – IDENTIFICATION AND CODING SYSTEM

OFFICE OF THE COMMISSIONER (OC)

OC-CU Clerical Unit
OC-EO Education and Outreach
OC-HR Human Resources
OC-OIA Office of Innovation and Assistance
OC-PE..... Procedures and Enforcement
OC-PP..... Policy and Planning
OC-QM..... Quality Management

AIR QUALITY (A)

A-A..... Administration
A-C..... Compliance
A-CU Clerical Unit
A-EI..... Field Services
A-IT Information Technology
A-L Licensing and Engineering
A-M Monitoring
A-MS..... Mobile Sources
A-RA..... Resource Administration
A-T Toxics

LAND AND WATER QUALITY (LW)

LW-CU Clerical Unit
LW-DMU Data Management Unit
LW-EA..... Environmental Assessment
LW-ETA..... Engineering and Technical Assistance
LW-LRR Land Resource Regulation
LW-WRR..... Water Resource Regulation

REMEDIATION AND WASTE MANAGEMENT (RWM)

RWM-CU..... Clerical Unit
RWM-HWFR ... Hazardous Waste Facilities Regulation
RWM-RS..... Response Services
RWM-SWFR....Solid Waste Facilities Regulation
RWM-TS Technical Services
RWM-RE..... Remediation
RWM..... Sustainability

4.2 QUALITY AUDITING

FRIDAY, MARCH 17, 2017
COVERSHEET
STANDARD OPERATING PROCEDURE

Operation Title: Quality Auditing
Identification No.: QMP-001
Revision No.: 05
Originator Name: David VanWie
Revisor: Peter Carleton for QMSC
Effective Date: 01/01/2017

APPROVALS:

Quality Assurance Manager (QAM):

Print Name _____ Signature _____ Date: _____

Quality Assurance Coordinator (QAC):

Print Name _____ Signature _____ Date: _____

Other:

Print Name _____ Signature _____ Date: _____

DISTRIBUTION:

() Bureau of Air Quality _____ By: _____
..... Date: _____
() Bureau of Water Quality _____ By: _____
..... Date: _____
() Bureau of Land Resources _____ By: _____
..... Date: _____
() Bureau of Remediation and Waste
Management By: _____ Date: _____
() Office of the Commissioner _____ By:
..... Date: _____
() Quality Management Steering
Committee By: _____ Date: _____

PURPOSE. The purpose of this procedure is to ensure an effective audit program in Maine DEP, including an auditing plan, auditing program, and auditor training.

Audits are conducted at many levels in the Department to determine conformance with Department rules, standard operating procedures (SOPs) and other applicable requirements. Other objectives of audits are to determine the accuracy of data collection and management systems, identify opportunities for program improvements, and to verify the effectiveness of Department programs. Other important benefits of auditing are cross training, assurance that policies and procedures are current and being followed by staff, and continuous improvement.

This procedure is applicable to all program activities defined in the Maine DEP's Quality Management Plan. A bureau or program may specify additional procedures or requirements for conducting audits within that organization. The QMSC and Bureau Directors will identify and prioritize audit issues, develop annual audit plans, and ensure that audits conform to this procedure.

2. DEFINITIONS AND ABBREVIATIONS

2.1 AUDIT: The term *Audit* refers to a systematic and documented verification process to objectively obtain and evaluate evidence to determine whether an organization is in conformance or compliance with legal requirements, internal policies, adopted standards, and defined procedures, and to ensure that necessary corrective actions are made in a timely manner.

2.2 AUDIT PROTOCOLS: The term *Audit Protocols* refers to written documents, data systems, checklists, procedures or guides that define the audit scope, to assist the auditor with completing the required elements of the audit plan, and to assist the audit area in preparing for the audit.

2.3 AUDIT PLAN: The term *Audit Plan* refers to the set methodology under which the Audit Team plans to undertake an audit. An Audit Plan can include audit scope/objective, team list, stake holder list, interview list (personnel to be interviewed & question set), key point of interest as well as establishing the audit dates.

2.4 AUDIT SCHEDULE: The term *Audit Schedule* refers to the annual plan of audits that are agreed upon by Department Management and the QMSC to undertake in a calendar year.

2.5 AUDIT TEAM: The term *Audit Team* refers to at least an audit team leader and other auditors assigned based on complexity and scope of the audit.

2.6 CORRECTIVE ACTION REQUEST (CAR): The term *Corrective Action Request* refers to an audit finding document that summarizes non-conformances found during the course of a program audit.

2.8 CORRECTIVE ACTION PLAN (CAP): The term *Corrective Action Plan* refers to the response by program management to a Corrective Action Request. The Corrective Action Plan describes the method by which a program will resolve the programs non-conformity as found in a program audit.

Approve a general annual auditing plan.

Approve (and revise as needed) audit procedures.

Receive reports of audit findings and communicate specific findings to appropriate levels of management.

Monitor overall implementation of corrective actions from audits.

Annually evaluate the audit program (and develop evaluation criteria and methodology).

2.9 DATA QUALITY ASSESSMENT: The term *Data Quality Assessment* refers to a specialized audit or portion of an audit focused on data collection, validation, and management according to specified data quality objectives.

2.10 NON-CONFORMANCE: The term *Non-Conformance* refers to the audit finding that a condition expected is different from the condition found. If the expected condition is rooted in a Federal rule, State rule or QAPP, the non-conformance can be considered “Major”. A “Minor” non-conformance is one in which the program is acting in compliance with established regulation but is not in conformance with program guidance or policy or not in conformance with the Department’s QMP.

2.11 OBSERVATIONS: The term *Observation* refers to an audit finding that does not rise to the level of a Corrective Action Request but the Audit Team determines that it is appropriate to include the finding in the Final Audit Report.

3. RESPONSIBILITY

3.1 Division Directors and program unit managers implement actions that will ensure conformance with internal policies, adopted standards and defined procedures, and to ensure that necessary corrective action are made in a timely manner.

3.2 The Quality Management Steering Committee (QMSC) is responsible for management of the audit program, including but not limited to the following functions:

Approve a general annual auditing plan.

Approve (and revise as needed) audit procedures.

Receive reports of audit findings and communicate specific findings to appropriate levels of management.

Monitor overall implementation of corrective actions from audits.

Annually evaluate the audit program (and develop evaluation criteria and methodology) include any findings in the annual QMS assessment report to SMT and EPA.

3.3 Bureau Directors are responsible for developing annual audit plans for their Bureaus, for receiving audit findings, and for ensuring timely implementation of appropriate corrective actions.

3.4 The Quality Assurance Coordinator (QAC) for Audits coordinates with the Quality Assurance Manager (QAM) in developing audit schedules, establishing audit team leaders, defining audit scope/objectives (with assistance from the audit team leader and management in the areas being audited) and conducting audit follow up work (CAR/CAP tracking, gaining sign off for audit deliverables by the appropriate management and distributing audit deliverables to appropriate management). The Quality Audit Coordinator for Audits also coordinates with audit team leaders in establishing an audit team, audit planning, procuring (as far as possible prior to the audit) guidance documents/informational material from the program being audited as well as audit follow up work (assist in audit document completion and securing final signatures).

3.5 Audit team leaders coordinate with the QAM and QAC with defining audit scope/objective, audit planning (for example: establishing audit team, pre-audit document searches, audit scheduling (audit meeting times and interview times)) and audit report completion. The audit team

leader manages the audit team and conduct audits according to the predefined scopes.

4. REQUIREMENTS

4.1 AUDIT TEAM

4.1.1 Auditors will be qualified by training and experience, and will follow generally accepted guidelines for auditors.

4.1.2 Audits will employ a team approach including, when possible, members from different parts of the organization.

4.1.3 MDEP staff will typically perform audits, provided that the auditors' duties and responsibilities are independent of the area and facility being audited.

4.1.4 Outside experts may be used on teams when necessary to ensure technical expertise, or necessary independence.

4.2 AUDIT PREPARATION/PLANNING

4.2.1 The QMSC/QAC will prepare annually an Audit Schedule. The QMSC will approve the Audit Schedule. Periodic updates and revisions will be made to accommodate revised schedules or priorities as they arise.

4.2.2 The plan will include areas and activities to be audited and the expected dates during the upcoming cycle.

4.2.3 The plan will identify the audit team, including the team leader, and

4.2.4 The plan shall include information about the planned scope and general methodology of each audit.

4.3 AUDIT EXECUTION

4.3.1 The Division Director(s) of the area to be audited should be notified of the audit at least 30 days prior to the audit. The notification will include any special areas or issues not addressed in established audit procedures, as well as a pre-audit questionnaire (if appropriate) and the Audit Plan. The Division Director, Program Manager, the QAC, and Lead Auditor will jointly determine the scope and objective(s) of the proposed audit.

4.3.2 The audit team will prepare, in advance, the Audit Plan to be used, including checklists, worksheets, interview questions and protocols. The Quality Assurance Manager will review and approve all plans.

4.3.3 The audit team will conduct an Opening Meeting with local management, including the Division Director. The purpose of this meeting will be to review the audit scope, methods, logistics, reporting requirements, Corrective Action Request (CAR) forms, and follow-up requirements.

4.3.4 Prior to the field portion of an audit, a desk or record audit may be performed by the audit team;

4.3.5 The audit team will use accepted methods to collect and document objective verifiable evidence. This evidence will include, but not be limited, to observations, file review, document review, interviews, testing or inspection.

4.3.6 Following the audit interviews, etc., the audit team will meet to review the findings and to document the need for corrective or follow-up action as necessary using Corrective Action Request (CAR) forms.

4.3.7 The audit team will conduct a Closing Meeting with the affected management, including the Division and Bureau Directors, to outline the major findings of the audit and to clarify any issues. The affected management will acknowledge receipt of audit findings, and may indicate disagreement with specific findings. Whenever possible, Corrective Action Requests will be presented and acknowledged at the Closing Meeting.

4.4 AUDIT REPORTING AND CORRECTIVE ACTION FOLLOW-UP

4.4.1 An audit report, including CAR forms, will be prepared by the audit team within two weeks of the audit. Copies will be forwarded to the Division Director(s) for the area that was audited. The Division Director is responsible for distributing the audit report, and assigning responsibilities for Corrective Action to program managers or other responsible staff.

4.4.2 Within four weeks of the Closing Meeting, or the receipt of CARs, whichever is later, the person(s) assigned responsibility will propose corrective actions and a timeline for completion of each, and submit the CAPs to the Division Director and QAM. The Division Director may request the assistance of the Lead Auditor to review findings and develop Corrective Actions.

4.4.3 Completion of the corrective actions will be monitored by Bureau Director, through the Bureau Liaison, on a monthly basis. Completed actions will be documented as "Complete" on the CAP form when evidence of completion is provided. Corrective Action Requests and Plans shall be tracked in an on-line database available to all DEP employees.

4.4.4 The Lead Auditor is responsible for assuring that all persons interviewed or otherwise involved in the audit receive a copy of the audit report.

4.4.5 The QAM is responsible, six months following the completion of the audit, for requesting from the division director(s) receiving CARs a progress report on CAP completion, and soliciting feedback on audit effectiveness. If necessary, the audit team may be asked to conduct a follow-up review of corrective actions to ensure effective implementation.

5. COMMUNICATION AND TRAINING. All auditors will be trained on the contents of this procedure and all applicable auditing standards.

6. EVALUATION. The QMSC will conduct an annual evaluation of the audit program and include any findings in the annual QMS assessment report to SMT and EPA.

7. SAMPLE TEMPLATES:

Template 7.1 Audit Report template

Template 7.2 Corrective Action Request (CAR) template

Template 7.3 Corrective Action Plan (CAP) template

Template 7.1 AUDIT REPORT

<u>AUDIT REPORT No.:</u>	
<u>Maine Department of Environmental Protection Internal Audit</u>	<u>PERSON REQUESTING AUDIT</u>
<u>Location</u>	<u>SCOPE OF AUDIT</u>
<u>Bureau</u>	<u>DATE OF INTERNAL AUDIT</u>
<u>Unit</u> <u>Contact Tel No.</u>	<u>AUDIT CRITERIA</u>
<u>Persons Interviewed</u>	<u>AUDIT TEAM</u>
	<u>PREVIOUS AUDIT DATE AND NO.</u>

SIGNATURE (Audit Team Leader)	SIGNATURE (Bureau Representative)
DATE:	DATE:

AUDIT REPORT No.:	
<u>Opening Meeting Attendees</u>	<u>Closing Meeting Attendees</u>
<u>Audit Notes</u> This audit was conducted in conformance with the Quality Auditing SOP (QMS-001 revision 5) found in Section 4.2 of the QMP Appendices. The audit scope was established to include 	
The following is an itemized list of the audit follow up requirements as established in Section 4.2 of the QMP appendices:	
4.4 AUDIT REPORTING AND CORRECTIVE ACTION FOLLOW-UP 4.4.1 An audit report, including CAR forms, will be prepared by the audit team within two weeks of the audit. Copies will be forwarded to the Division Director(s) for the area that was audited. The Division Director is responsible for distributing the audit report, and assigning responsibilities for Corrective Action to program managers or other responsible staff. 4.4.2 Within four weeks of the Closing Meeting, or the receipt of CARs, whichever is later, the person(s) assigned responsibility will propose Corrective Actions and a timeline for completion of each, and submit the corrective action plans to the Division Director and QAM. The Division Director may request the assistance of the Lead Auditor to review findings and develop Corrective Actions. 4.4.3 Completion of the corrective actions will be monitored by Bureau Director, through the bureau Quality Assurance Coordinator, on a monthly basis. Completed actions will be deleted from the Corrective Action Plan when evidence of completion is provided. Corrective Action Requests and Plans shall be tracked in an on-line database available to all DEP employees.	
<u>Audit Summary</u>	

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AUDIT REPORT No.:

<u>General Observations</u>

Observations are as follows:

(Attach CARs here)

Bureau and Unit:	Audit No. CAR No. Date of Audit	
Audit Criteria:		
Auditors	Bureau Representative	Area Audited
NON-CONFORMANCE Major Minor		
<u>Condition Expected:</u>		
<u>Condition Found:</u>		
SIGNATURE _____ Bureau Representative	SIGNATURE _____ Audit Team Leader	
Notes		

Template 7.2 Internal Audit Corrective Action Request

Template 7.3 Corrective Action Plan Template
Program(s) or Section(s) Audit Corrective Action Plan Form

CAR #	Area Audited	Condition Found	Proposed Corrective Action	Target Completion Date	Responsible Staff	Date Complete
#1			1. 2. 3.			
CAR #	Area Audited	Condition Found	Proposed Corrective Action	Target Completion Date	Responsible Staff	Date Complete
#2			1. 2. 3.			
CAR #	Area Audited	Condition Found	Proposed Corrective Action	Target Completion Date	Responsible Staff	Date Complete
#3			1. 2. 3.			
Further Action Required: Determined by: Date:						
No Further Action Required: Approved by: Date:						

4.3 QAPP REVIEW

APPLICABILITY. This Standard Operating Procedure applies to all programs in the Maine Department of Environmental Protection (MEDEP).

PURPOSE. This SOP specifies the process and procedures to be followed by MEDEP for reviewing and approving Quality Assurance Program / Project Plans (QAPPs) required for environmental data activities.

DEFINITIONS.

3.1 **QAPP.** A Quality Assurance Program / Project Plan describes in comprehensive detail the necessary Quality Assurance (QA) policies and Quality Control (QC) and technical activities that must be implemented to ensure the results of work performed, particularly for environmental data operations, will satisfy the stated performance criteria. QAPPs document the results of certain systematic planning processes (see QMP 7.0). QAPPs may apply to specific projects/data operations, or to a program area responsible for a number of different specific projects / operations.

SAP. A Sampling and Analysis Plan, also referred to as a Work Plan, documents the project-specific objectives, data quality measures, schedules, locations, field and analytic protocols, personnel, and related information needed to apply a program-level QAPP to a particular project or series of related activities. See SOP OC-QM-003, *Sampling and Analysis Plan Approval* for the procedures governing SAP development and review.

RESPONSIBILITIES.

4.1 **QAPP DEVELOPMENT.** Each MEDEP program area involved in planning and implementing environmental data operations is responsible for assuring that QAPPs and SAPs are developed in sufficient time prior to the beginning of data gathering to allow for review, comment, revision, and approval. The program manager is responsible for consulting with the QA Manager to determine the extent of review (e.g., internal or external; EPA-NE parallel review; degree of technical complexity) necessary for a particular QAPP, and thus how much time to allow.

4.2 **OVERSIGHT.** The Quality Management Steering Committee (QMSC), acting through the QA Manager, is responsible for assuring that necessary review and approval processes are scheduled and completed prior to the beginning of data operations.

4.3 **ARRANGING REVIEW.** The QA Manager and the Program Manager responsible for the QAPP shall identify persons to review the QAPP, and arrange for their participation. The QA Manager is also responsible for coordinating any required EPA-NE participation in the review/approval process, such as parallel review, technical assistance, etc.

4.4 **REPORTING.** The QA Manager is responsible for reporting the results of the review and approval process to the EPA-NE Quality Manager; for forwarding on request MEDEP-approved QAPPs to the EPA-NE Office of Environmental Measurement and Evaluation; and for maintaining records of the status of all QAPPs for which MEDEP has responsibility.

PROCEDURES.

5.1 The QA Manager should be notified whenever a Program Manager begins work on or contracts for the external development of a QAPP. An expected date of completion of the initial draft should be set at this point. The Program Manager and QA Manager should consult on the expected levels of review that may be required, the participation of EPA-NE or an external reviewer.

5.2 If possible, at least two weeks prior to the expected completion of the draft, or submission to MEDEP of a QAPP developed by an outside party, the Program Manager asks the QA Manager to convene a review team. Review team members shall be selected on the basis of professional expertise relevant to the content of the QAPP. Having selected a team, the QA Manager asks the MEDEP review team leader, and any outside reviewers, to specify a date by which initial review and comment will be completed.

5.3 QAPP review shall be comprised of two steps: a Level I QAPP Completeness Check, and a Level II Technical QAPP Review. Both levels of review shall use EPA QA/R-5, "Requirements for Quality Assurance Project Plans" as their standard of acceptability.

5.3.1 Level I Completeness may be carried out by any person nominated by the QA Manager on the basis of familiarity with the standards of EPA QA/R-5.

5.3.2 Level II Technical Review shall be carried out by one or more persons who are professionally competent to evaluate the methods, procedures, and protocols in the QAPP and are not themselves subject to the QAPP. A QAPP reviewer may have been involved in developing a portion of the QAPP, provided they are not the reviewer of that section. *Example:* someone who consulted on the development of the QAPP field operations protocols may review the analytic protocols.

5.3.3 The QA Manager and the MEDEP Division Director in whose Division the QAPP is to be used shall jointly determine the degree of independence (e.g., involvement in developing the QAPP; different program area, unit, division, etc.) required of each reviewer. Where there is doubt regarding the possible independence of the reviewer, the next degree of independence shall automatically be required.

5.4 Each separate reviewer and the review team acting as a whole shall document their comments in writing. Initial review comments shall be given to the author for inclusion in any revision of the QAPP. The review team leader specifies how any response to comments should be managed, and arranges an agreed upon date by which a revised QAPP will be returned for further review or final approval.

5.4.1 All drafts or red-lined edited versions of QAPP's shall be maintained on file by the DEP QAM or bureau-level equivalent. These may be maintained as electronic versions on the Department H: drive.

5.5 On receipt of the revised QAPP, the review team leader shall arrange for further review by both Level I and Level II reviewers, and set a date for an approval meeting.

5.6 At the approval meeting, the review team shall make a determination as follows:

Approved: Activities specified in the QAPP may begin immediately;

Conditionally Approved: Activities specified in the QAPP may begin subject to restrictions related to further required changes. *Example:* a revised field procedure incorporating a

requested change must be filed with the QA Manager before that procedure is implemented in the field. The review team leader shall verify successful completion of approval conditions prior to signature by the QA Manager.

Deferred: Activities specified in the QAPP may not begin until required changes are submitted and the full review team approves the revised QAPP.

5.7 The determination shall be documented in the records of the review team and communicated to the person responsible for the QAPP as soon as possible. The signature page of master copy of the QAPP shall be signed by the QA manager, and, if necessary, a copy of this page sent to the appropriate QA staff member at EPA-NE. A subsequent page of the QAPP documents the actual review process that occurred.

5.8 A QAPP subject to the parallel approval process referred to above (4.3) must be Approved or Conditionally Approved by both MEDEP and EPA-NE before activities specified in the QAPP begin.

5.9 SAPs are considered to be part of the QAPP under which site or project-specific activities are carried out. Generic or program QAPPs shall specify within their main text the procedures for the submission, review, approval, maintenance, and tracking of SAPs.

REFERENCES

Maine Department of Environmental Protection, *Quality Management Plan* (Revision 1, May, 2001), 7.3.

Memorandum of Understanding between EPA-NE and Maine DEP, January, 2002.

EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA R/5). Final, March, 2001.

4.4 SAMPLING AND ANALYSIS PLAN

APPLICABILITY. This Standard Operating Procedure applies to all programs in the Maine Department of Environmental Protection (MEDEP) that produce Sampling and Analysis Plans (SAPs) or work plans to describe annual or site-specific data gathering operations under the terms of a Quality Assurance Project/Program Plan (QAPP).

PURPOSE. This SOP specifies the process and procedures to be followed by MEDEP for reviewing and approving annual sampling and analysis plans or work plans required for environmental data activities.

DEFINITIONS.

QAPP. A Quality Assurance Program/Project Plan describes in comprehensive detail the necessary Quality Assurance (QA) policies and Quality Control (QC) and technical activities that must be implemented to ensure the results of work performed, particularly for environmental data operations, will satisfy the stated performance criteria. QAPPs document the results of certain systematic planning processes (see QMP 7.0). QAPPs may apply to specific projects/data operations or to a program area responsible for a number of different specific projects / operations. QAPP's generally specify the requirement of a SAP or work plan.

SAP. A Sampling and Analysis Plan documents the project-specific objectives, data quality measures, schedules, locations, field and analytic protocols, personnel, and related information needed to apply a program-level QAPP to a particular project or series of related activities. SAPs are considered to be part of the QAPP under which site or project specific activities are carried out. Generic or programs QAPPs specify within their main text the procedures for the submission, review, approval, maintenance, and tracking of SAPs.

Work Plan. An annual specification of locations, dates, and data objectives completed prior to the beginning of a field operation or season.

SSQAP. Site Specific Quality Assurance Plan. An addendum / SAP used in the Brownfields program to document work carried out on a particular site by a contractor whose activities have been previously approved in a contractor-specific QAPP.

RESPONSIBILITIES.

4.1 SAP DEVELOPMENT. The ME DEP program manager or principal investigator identified in the QAPP develops the annual or site-specific SAP/Work Plan. This may be a contractor outside of DEP.

4.2 OVERSIGHT. Program Managers and Division Directors are responsible for assuring that SAPs/Work Plans are developed and approved prior to the beginning of field operations.

4.3 ARRANGING REVIEW. The Program Manager responsible for the QAPP shall identify persons to review the SAP, and arrange for their participation.

4.4 APPROVAL. The Division Director, or designee, is responsible for receiving and appraising the results of the SAP review and for approving the Plan in writing.

4.5 FILING. The staff member responsible for the QAPP assures that a copy of each Plan, with approval page, is filed with the printed master copy of the QAPP (but see 6.4).

CONTENTS.

5.1 At a minimum, a SAP/Work Plan shall include the following:

- 5.1.1 Title and Approval Page
- 5.1.2 Project framework: summary of work to be done in the current year, including identification of specific locations with maps as appropriate; personnel not otherwise identified in the QAPP; work schedule(s); training;
- 5.1.3 Specification of sampling and analytical methods by reference to the QAPP;
- 5.1.4 Any planned deviations from methods, protocols, materials, equipment, and procedures in the QAPP, and an explanation of the rationale for doing so, including additional SOPs as appropriate;
- 5.1.5 Specification of any data quality objectives, QA/QC considerations, or other data-related matters that differ from, or add to, those specified in the QAPP;
- 5.1.6 A certification page to be signed by all persons overseeing work under the terms of the SAP, indicating that they have read and understand its provisions, and will assure that field staff, volunteers, and others are familiar with QAPP requirements.

PROCEDURES.

Prior to the beginning of field operations, the program manager, contractor, or principal investigator drafts a Work Plan/SAP that includes the items above. The QAPP will also be reviewed to assure that the proposed operations conform to its requirements. The manager / investigator, in consultation with the Division Director as appropriate, identifies a DEP reviewer who works in a program area other than the one covered by the SAP, and delivers the draft SAP for review.

6.1.1 In the Bureau of Remediation and Waste Management, Division of Remediation, Uncontrolled Sites Program only, the SAP review may be carried out by a geologist whose activities would be governed by the completed SAP.

6.1.2 In the Bureau of Remediation and Waste Management, Division of Remediation, Brownfields Program, review and approval of an SAP developed by an outside contractor is carried out by the project manager or project geologist.

6.1.3 In the Division of Environmental Assessment, Bureau of Water Quality, review and approval of SAPs is carried out by the Division Director.

6.2 Each reviewer returns written comments on the SAP to the investigator/manager, and the Division Director. The investigator incorporates suggested changes, and presents the final copy to the Division Director, or designee, for final approval.

6.3 On receipt of the final SAP, the approver documents approval on the title page of the document. The approval copy is filed with the QAPP to which it refers. Copies of the SAP are distributed for field use and reference as appropriate.

6.3.1 In the Brownfields program, approved SSQAP's are filed in the project file.

REFERENCES.

Maine Department of Environmental Protection, *Quality Management Plan 7.4.*

4.5 CONTROL OF DOCUMENTS AND RECORDS

QUALITY MANAGEMENT SYSTEM REQUIREMENTS, QMS / R-1 (2001)

Intent: Maine DEP's Quality Management Plan, the ANSI/ASQ E-4 standard on which it is based, and the applicable Federal Assistance regulations require that the organization document the manner in which documents and records are controlled. The standards below should be considered the minimum requirements and do not preclude DEP bureaus, offices, and program areas from implementing more stringent standards. The standards below provide a fuller description of the quality system requirements outlined in Element 5 (Documents and Records) of Maine DEP's QMP.

Definitions: For purposes of these requirements,

Documents are all publications and forms, in hard copy and electronic media, which are generated by the Department for use by staff or the public. This category particularly includes internal documents that specify quality-related requirements and instructions, such as QAPPs, SOPs, sampling and analysis plans, etc.

Forms are a sub-set of documents used to record or compile data. When entries are made on a form, it may become a record.

Records furnish evidence of activities carried out by the Department and by external entities such as regulated facilities. Any record entered into a file for official purposes (e.g., discharge monitoring report; facility correspondence; payroll vouchers) is considered a public record (1 M.R.S. §402 (3)¹². Records may include photographs, drawings, objects, samples, reports, and electronic data.

General Requirements

Beginning on the date of approval of this document, all Maine DEP bureaus are responsible for planning, documenting, and implementing the procedures and practices needed to bring documents and records under their control into conformance with these standards.

Each Bureau shall designate a person responsible for overseeing interpretation and implementation of these guidelines.

Control of Documents

All DEP documents shall carry, on each page, either the official seal of the Maine DEP and/or the printed name (Maine DEP / Department of Environmental Protection) of the organization. It shall also carry, on each page, an identifiable title that reflects its use, and a page number. On multi-page documents, this information can be presented a less prominent location, and/or in a smaller font, than on the first or title page.

Exceptions:

Materials produced entirely by another entity (e.g., EPA) but provided to the public by DEP. Multi-page documents providing non-regulatory public information need these data only on the cover page.

Web pages intended to provide general information.

Reportsmith generated documents.

¹² The statutory exceptions to the category of public records would not affect these requirements.

All DEP documents shall carry, in some location on each page, an indication of the date of composition or revision. Bureaus shall determine whether, and which, documents also require a tracking designation unique to the document. Bureaus shall determine whether, and how, to track documents for purposes of assuring the use of the most current revision, identification of author, inventory, etc.

Documents, including forms that are in draft form shall be clearly identified as such, including any restrictions on circulation or use.

Control of Forms

Because many forms, when filled in, become public records, the standards of control are more stringent. Thus, in addition to the requirements in (I) above,

All DEP forms shall carry a document tracking designation that includes an identification of the issuing bureau; a unique number or alpha-numeric designation; a date of composition or revision; and a revision number.

Each bureau shall implement a system to control forms in order to assure that when forms are revised, previous versions are removed from use in a timely manner depending on the significance of the revision, etc.

Any form which may become a public record must include, at a minimum, the following fields:

Date when the form was used / completed;

Record identification (e.g., facility permit number)

Name of the person(s) completing the form.

Control of Records

All records documenting the activities of entities regulated by Maine DEP or subject to enforcement actions by Maine DEP, shall be uniquely identified with at least the following information, which may be contained in the body of the record or added separately:

The number of the associated permit, license, or enforcement action if one exists;

Name and location, or a unique identifier, of the facility or activity recorded;

Date of action or activity recorded or documented in the record;

Date of receipt of the record;

Name of the DEP employee responsible for the record.

This standard shall apply to records created by outside entities when received for use by Maine DEP. This category of record includes correspondence, including electronic mail, initiated or received by Maine DEP, and any filed copies of the same.

Each bureau shall determine the level of identification and control applicable to other records, whether public records or not. Records for which a unique identifier cannot readily be created must be stored in such a manner that any particular record can be found on request.

Temporary records (e.g., field notes, logs, data sheets), the data from which is entered into more permanent records, shall be maintained and archived according to record retention standards developed by each division or program unit.

Standards specific to the control of electronic records and data will be developed in a separate requirements document.

Approved:

Martha G. Kirkpatrick

Martha G. Kirkpatrick, Commissioner

June 27, 2001

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APPENDIX 5:

**SUMMARY TABLE OF CURRENT QAPPS AND RELATED
DOCUMENTS**

January 2021 Report

Revision 20, December 2015

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CURRENTLY ACTIVE QUALITY ASSURANCE PROJECT OR PROGRAM PLANS and SAMPLING & ANALYSIS PLANS

Media Program: AIR

Media Contact: Mike Kenyon, OEP; Bob Judge, OEME; MaryJane Cuzzupe

Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Rationale for Priority	Status / Maine DEP Comments	5-year Resubmittal Due in 2021? (Y / N)
NAAQS Particulate Matter Pollutants Monitoring Program (PM _{2.5} , PM ₁₀ , Lead)	Bob Judge	Danielle Twomey	A: 7/1/99; A(R): 6/1/07; 10/15/11	H	Priority high, EPA will base important non-attainment designations on data.	The QAPP has undergone a complete review and update with revisions reflecting changes in equipment, staff, monitoring locations and quality control criteria. The final draft document and associated SOPs were submitted to EPA on 12/11/18 for their review. EPA replied with their comments on 11/25/19. Staff addressed EPA comments and resubmitted documents on 6/22/2020. Awaiting final approval from the EPA.	N

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Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Rationale for Priority	Status / Maine DEP Comments	5-year Resubmittal Due in 2021? (Y / N)
AAQS Gaseous Pollutants Monitoring Program (O ₃ , CO, SO ₂ , NO ₂)	Bob Judge	Danielle Twomey	A: 2/6/03; A(R): 6/09	H	EPA will base important 8-hour ozone non-attainment designations on data. EPA and state also use real-time data for public health warnings. Maine is likely to have data close to non-attainment.	The QAPP has undergone a complete review and update with revisions reflecting changes in equipment, staff, monitoring locations and quality control criteria. The final draft document and associated SOPs were submitted to EPA on 12/11/18 for their review. EPA replied with their comments on 6/28/19. Staff is currently in the process of addressing these comments with a completion target date of 4/30/2021.	N

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Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Rationale for Priority	Status / Maine DEP Comments	5-year Resubmittal Due in 2021? (Y / N)
Air Toxics Pollutant QAPP for VOCs	Bob Judge	Danielle Twomey	A: 9/28/04	H	Air toxics data will increasingly be used to identify areas and pollutants of concern.	QAPP is currently being updated. A modified revision of the draft that was used for the 2017 and 2018 Long Island Sound Tropospheric Ozone Study (LISTOS), is available. The updated QAPP will represent a switch from the TO-15 protocols to the more stringent NATTS* protocols for use with routine HAPS monitoring for the Air Toxics Program. The full update is scheduled for completion and release by October 31, 2022 *TECHNICAL ASSISTANCE DOCUMENT FOR THE NATIONAL AIR TOXICS TRENDS STATIONS PROGRAM. Revision 2. Prepared for: U.S. Environmental Protection Agency Office of Air Quality Planning and Standards (C304-06) Research Triangle Park, NC 27711	Y
Photochemical Analytical Monitoring System (PAMS)	Bob Judge	Danielle Twomey	A: 5/29/98; A(R): 6/9/00; A(R): 5/06	M	No regulatory decisions are directly based on PAMS data. However PAMS is a National priority program with line item funding.	The 2015 Ozone NAAQS revisions made changes to the requirements for PAMS monitoring, and consequently Maine is no longer required to do such monitoring. Maine is required to submit an Enhanced Monitoring Plan (EMP) since we are still part of the Ozone Transport Corridor. This will be updated along with the Air Toxics QAPP in 2022.	N

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Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Rationale for Priority	Status / Maine DEP Comments	5-year Resubmittal Due in 2021? (Y / N)
Regional Aerosol Intensive Network (RAIN)	--	Danielle Twomey	A: 4/12/05	M	No regulatory decisions are directly based on RAIN data. Data may be used for ongoing research into PM2.5, visibility and regional haze impacts.	This regional monitoring network has served its original purpose, but we have determined the data it produces to still be of value to BAQ, so in 2015 elements of this QAPP were and are being revised and incorporated in either an updated QAPP or incorporated in other existing QAPPs as appropriate.	N
National Atmospheric Deposition Program's NTN and MDN networks	Jeri Weiss	Danielle Twomey	NPQ. All of NADP's latest Quality Management Plan documents can be found on the NADP website at: http://nadp.slh.wisc.edu/lib/qa/plans/QAPNADPLab2020.pdf	M	No regulatory decisions are directly based on NADP data.	DEP follows national program's QAPP and SOPs; Letter of confirmation sent 9/15/01; Letter of reconfirmation sent 12/23/08.	N

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Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Rationale for Priority	Status / Maine DEP Comments	5-year Resubmittal Due in 2021? (Y / N)
IMPROVE Monitoring Network	Bob Judge	Danielle Twomey	NPQ. National approval document submitted 12/03.	M	No regulatory decisions are directly based on IMPROVE data. Data may be used for ongoing research into PM2.5, visibility and regional haze impacts.	DEP follows national program's QAPP and SOPs; Letter of confirmation sent 9/15/01; Letter of reconfirmation sent 12/23/08.	N

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Media Program: RCRA and UNCONTROLLED SITES

Media Contact: Steve DiMattei

Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Status / Maine DEP Comments	5-year Resubmittal Due in 2020? (Y / N)
Division of Remediation	Steve DiMattei	Becky Blais	A: 6/99; A(R): 10/09; A(R): 01/17	H	The Division of Remediation's Quality Assurance Plan covers the Uncontrolled Sites Program, RCRA Corrective Action Program, and the Brownfields Program. The QAP and its associated SOPs were updated and approved by DEP and US EPA in January 2017. In 2019 the Department updated its Sampling and Analysis Plan SOP to incorporate PFAS sampling requirements.	N
Lead/Asbestos Program	Jonathan Britt	John Bucci	A: 9/04; A(R): 11/11	M	In 2019, the QAPP was reviewed and updated. As of February 2020, the QAPP has been sent for review by the QAM and approval process completed once this review has been completed. (BL_2/20/20)	N
Leaking Underground Storage Tanks	Robert Reinhart	Kelly Perkins	A(R): 6/10/19	L	Minor revisions to the Department's organizational charts. Updates to existing SOPs and development of new SOPs initiated with anticipated completion in 2021.	N

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Media Program: AIR

NAAQS Particulate Matter Pollutants Monitoring Program (PM _{2.5} , PM ₁₀ , Lead)	Bob Judge	Danielle Twomey	A: 7/1/99; A(R): 6/1/07; 10/15/11	H	Priority high, EPA will base important non-attainment designations on data.	The QAPP has undergone a complete review and update with revisions reflecting changes in equipment, staff, monitoring locations and quality control criteria. The final draft document and associated SOPs were submitted to EPA on 12/11/18 for their review. EPA replied with their comments on 11/25/19. Staff addressed EPA comments and resubmitted documents on 6/22/2020. Awaiting final approval from the EPA.	N
NAAQS Gaseous Pollutants Monitoring Program (O ₃ , CO, SO ₂ , NO ₂)	Bob Judge	Danielle Twomey	A: 2/6/03; A(R): 6/09	H	EPA will base important 8-hour ozone non-attainment designations on data. EPA and state also use real-time data for public health warnings. Maine is likely to have data close to non-attainment.	The QAPP has undergone a complete review and update with revisions reflecting changes in equipment, staff, monitoring locations and quality control criteria. The final draft document and associated SOPs were submitted to EPA on 12/11/18 for their review. EPA replied with their comments on 6/28/19. Staff is currently in the process of addressing these comments with a completion target date of 4/30/2021.	N

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SITE SPECIFIC QUALITY ASSURANCE PLANS [SSQAPs]

Generic QAPP Name (Consultant)	SSQAP (site)	Town	DEP Project Manager	Approval Date
Nobis Engineering, Inc.	Eastern Surplus Co, Superfund Site	Meddybemps	Rebecca Hewett	A:12/20/2012 A(R): 6/28/2013 Note: Current ISB work (ongoing through 2020) by Nobis for EPA using QAPP approved 9/15/2017.
Nobis Engineering, Inc. (Nobis drafted for DEP to use for future LTM activities)	Eastland Woolen Mill Superfund Site	Corinna	Rebecca Hewett	A: 12/21/2018

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Media Program: BROWNFIELDS

SITE SPECIFIC QUALITY ASSURANCE PLANS [SSQAPs]

Generic QAPP Name (Consultant)	SSQAP (site)	Town	DEP Project Manager	Approval Date
Ransom Consulting	Ballard Hill School	Lincoln	Redmond	4/1/2020
Ransom Consulting	Former WestPoint Stevens Mill Boiler House	Biddeford	Redmond	4/17/2020
Ransom Consulting	Big Squaw Ski Area	Big Moose Township	Blais	6/2/2020
CES, Inc.	JR Redemption Center Property	Brewer	Sroka	4/6/2020
Credere Associates	Fort Williams Park- Small Arms Firing Target Range	Cape Elizabeth	Blais	1/31/2020
KGSNE, LLC	Great Northern Paper Mill	Millinocket	Redmond	9/28/2020
CES, Inc.	Fort Fairfield Community Center	Fort Fairfield	Chapman	1/16/2020
TRC	Former Charles A. Snow School	Fryeburg	Redmond	4/13/2020
Ransom Consulting	Augusta Tank & Culvert	Hallowell	Blais	1/14/2020
TRC	Hartland Consolidated School	Hartland	Currie	3/11/2020
TRC	Kennebunk Rest Area	Kennebunk	Redmond	3/12/2020

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Generic QAPP Name (Consultant)	SSQAP (site)	Town	DEP Project Manager	Approval Date
Ransom Consulting	111 Blake Street and 82 Pine Street	Lewiston	Sroka	4/16/2020
Campbell Environmental Group	Parcel 5-Lincoln Paper and Tissue Mill	Lincoln	Wolfertz	7/31/2020
Campbell Environmental Group	Parcel 3-Lincoln Paper and Tissue Mill	Lincoln	Wolfertz	7/31/2020
Beacon Environmental Consultants	Poacher's Paradise	Madrid	Wolfertz	3/27/2020
Ransom Consulting	Former Great Northern Paper (GNP) Steam Plant	Millinocket	Redmond	7/29/2020
TRC	Monmouth Middle School	Monmouth	Currie	9/22/2020
Ransom Consulting	1 and 2 Fourth Street	Old Town	Wolfertz	4/24/2020
Ransom Consulting	Vacant Lot (Former Smart's Auto)	Old Town	Wolfertz	5/26/2020
Campbell Environmental Group	Social Services Building	Pleasant Point	Hodgkins	12/1/2020
Ransom Consulting	Poacher's Paradise	Madrid	Redmond	1/21/2020
Ransom Consulting	37 and 63 Front Street	Portland	Wolfertz	8/13/2020

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Generic QAPP Name (Consultant)	SSQAP (site)	Town	DEP Project Manager	Approval Date
Woodard & Curran	Former West School	Portland	Blais	1/7/2020
Ransom Consulting	Liberty Shipyard Site	South Portland	Chapman	9/2/2020
Ransom Consulting	A.D. Gray School	Waldoboro	Chapman	3/31/2020
Ransom Consulting	Ash Ponds	Wiscasset	Chapman	6/22/2020
Credere Associates	Windham Landfill	Windham	Blais	2/27/2020
Wood	The Boat School	Eastport	Hodgkins	5/26/2020
Wood	Joy Enterprises	Machias	Hodgkins	1/14/2020
Wood	Mill Town Texaco	Calais	Hodgkins	10/5/2020
TRC	Stenton Trust Mill	Sanford	Hodgkins	9/21/2020
Campbell Environmental Group	Fiber Extrusion	Eastport	Hodgkins	9/21/2020
Ransom Consulting	Maine General Hospital	Gardiner	Currie	4/23/2020

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Media Program: WATER
 Media Contact: Karen McCarthy

Special note for 2020: most Projects had to adjust their activities in light of the COVID-19 pandemic. This usually consisted of curtailing sampling activities or eliminating analyses; all quality controls were maintained.

Note: items that say 'Completed/closed out in (year), delete from inventory' stay in the inventory in the year of completion and are deleted the following year to ensure complete tracking of the item.

Name of Project or Activity	EPA Contact	DEP Contact	Completion Status *1	QAPP Priority *2	Status / Maine DEP Comments	5-year Resubmittal Due in 2020? (Y / N)
Lakes Assessment Program	Robert Reinhart, Karen McCarthy	Linda Bacon	A: 4/05; A(R): 4/11 A(R): 11/15	H	QAPP reviewed before field season, no changes needed in 2020. QAPP will be renewed in late 2020 or early 2021.	Y
Biomonitoring Program QAPP	Robert Reinhart, Karen McCarthy	Beth Connors	A(R) : 6/14 A(R): 6/19	H	QAPP reviewed before field season, no changes needed in 2020.	N
Maine NPS and TMDL Streams	Robert Reinhart, Karen McCarthy	Wendy Garland	A: 1/13/11 A(R): 2/17	H	QAPP reviewed before field season, no changes needed in 2020.	N
QAPP For River Water Quality Surveys	Robert Reinhart, Karen McCarthy	Rob Mohlar	A: 7/09 A(R): 5/17	H	QAPP reviewed before field season, 1 edit made to update lab information.	N
QAPP for Model Simulations	Robert Reinhart, Karen McCarthy	Rob Mohlar	A: 6/17	H	QAPP reviewed before field season, no changes needed in 2020.	N

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Volunteer River Monitoring Program (VRMP)	Bryan Hogan, Karen McCarthy	Kristin Feindel	A: 6/09 A(R): 4/14 A(R): 4/20	M	DEP approval on 4/24 EPA approval on 4/28.	N
NPS Lake and Stream Watershed Surveys QAPP	Bryan Hogan, Sandra Fanciullo	Wendy Garland	A: 12/09 A(R): 4/8/15 A(R): 5/20	M	DEP approval on 5/1; EPA approval on 5/14.	N
Marine Environmental Monitoring Program QAPP	Robert Reinhart, Karen McCarthy	Angela Brewer	A: 4/17	M	Maintaining an informal list of minor items that need to be modified at next 5-year revision. This QAPP does not include state-funded toxics programs, i.e. it excludes lobster, clam and mussel documents.	N
Maine Healthy Beaches Monitoring QAPP	Nora Conlon, Alicia Grimaldi	Meagan Sims	A(R): 7/16	M	QAPP reviewed before 2020 field season, no changes needed except for minor updates in 2 appendices.	Y
Friends of Casco Bay's Environmental Monitoring Program QAPP	Nora Conlon; Matt Liebman	Angela Brewer	A: 6/00; A(R): 4/11; 10/13; 7/17	---	Informal review of needed revisions completed in 2020.	N
319 Program (non-monitoring projects)	Rob Reinhart, Sandra Fanciullo	Wendy Garland	A: 2/06; A(R): 12/11 A(R): 1/18	---	QAPP reviewed in 2020, no changes needed.	N
Mt. Desert Island Biological Laboratory Environmental Health Lab QAPP for Volunteer Monitoring Projects	--	Jane Disney/ Angela Brewer	A: 6/07 A(R): 5/16	--	No changes in 2020. Intend to revise in 2021.	Y

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Long Creek Water Quality Monitoring	--	Jeff Dennis	A: 4/11; A(R): 1/14 A(R): 3/19	--	ME DEP reviewed/approved. QAPP was renewed in September 2018 but DEP approval was omitted, occurred on 3/29/2019. QAPP reviewed before 2020 field season, no changes needed.	N
Spruce Creek Volunteer WQ Monitoring	--	Addie Halligan	A(R): 6/11	---	Volunteer water quality monitoring (other than bacteria-see below) not currently occurring.	N
Saco, Ossipee, and Little Ossipee Rivers	--	Dalyn Houser, Saco River Corridor Comm.	A: 3/05; A(R): 6/11 A(R): 3/15 A(R): 8/20	---	DEP approval on July 27, 2020; approved/renewed by EPA and NH DES on August 24, 2020.	N
George's River Tidewater Association's Water Quality Monitoring Program QAPP	--	Jon Eaton/ Angela Brewer	A: 6/12 A(R): 6/14	--	Group defunct, no activity in 2020. This item will be removed in the next inventory because the group is considered truly defunct now.	N
Cumberland County SWCD QAPP for Monitoring Rivers and Streams	--	Wendy Garland	A: 7/14	-	No water quality monitoring conducted at present; if monitoring begins again, QAPP will be updated at that point.	N
Generic QAPP for Maine Stream Corridor Survey	--	Wendy Garland	A: 1/13 A(R):12/18	--	QAPP reviewed before field season, no changes needed in 2020.	N
Midcoast Conservancy	--	Jody Jones/ Susanne Meidel	A(R): 5/14 A(R): 9/19	--	No changes in 2020.	N
Kennebec Estuary Land Trust, Volunteer Water Sampling Program	--	Angela Brewer	A: 5/16	--	No changes in 2020. Intend to revise in 2021.	Y

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Spruce Creek Watershed-Scale Bacteria Monitoring	--	Addie Halligan	A: 9/15 A(R): 7/18	--	No changes in 2020.	N
York County SWCD QAPP for Monitoring Rivers and Streams	-	Wendy Garland	A: 8/17		No changes in 2020.	N
Mapping Eelgrass Beds in Casco Bay, Maine	--	Angela Brewer	A: 1/19	--	Document managed by Casco Bay Estuary Partnership, and covers work completed by Marine Unit. No changes in 2020.	N
Boothbay Region Land Trust Coastal Water Monitoring Project QAPP	--	Angela Brewer	A: 3/20	--	New QAPP. Active monitoring underway.	N
Field Geology Services, Mare Brook Fluvial Geomorphic Assessment QAPP	--	Kristin Feindel	A: 5/20	--	1-year project.	N
FB Environmental, Ogunquit River Watershed-Scale Bacteria Monitoring QAPP	--	Addie Halligan	--	--	New QAPP, development in progress.	N

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2020 WATER SAPs (SAMPLING AND ANALYSIS PLANS), APPs (ANNUAL PROJECT PLANS) AND SIPs (SURVEY IMPLEMENTATION PLANS)

Generic QAPP Name	SAP / APP / SIP	DEP Project Manager	Project Dates (2020 unless otherwise noted)	Approval Date	Status / Maine DEP Comments
Biomonitoring Program QAPP	Wetland Biological Monitoring APP	Beth Connors	June-September	6/5/20	
Biomonitoring Program QAPP	River and Stream Macroinvertebrate and Algae Sampling APP	Tom Danielson	June-July	6/6/20	
Biomonitoring Program QAPP	River and Stream Macroinvertebrate Sampling APP				Combined in 2020 with previous item – delete as a stand-alone item in 2021 inventory.
Biomonitoring Program QAPP	River and Stream Fish Sampling APP	Tom Danielson	--	--	No sampling in 2020.
Streams Program (state funded)	SWAT (Surface Water Ambient Toxics) – freshwater (rivers, lakes)	Barry Mower (Linda Bacon)	May-October	6/12/20	Technical Advisory Group review and approval.
Streams Program (state funded)	SWAT – lakes, cyanotoxins	Linda Bacon	Aug 2020 – June 2021	6/12/20	
QAPP in development	SWAT – marine SAP	Jim Stahlnecker	July-November	6/12/20	Technical Advisory Group review and approval
Marine Environmental Monitoring Program QAPP	Ambient Water Quality and Eelgrass Monitoring	Angela Brewer	May-October	5/29/20	
N/A	Marine - Salmon Rivers Water Quality Monitoring	Emily Zimmermann	February-December	2/20/20	Relatively new program, QAPP in development.

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Generic QAPP Name	SAP / APP / SIP	DEP Project Manager	Project Dates (2020 unless otherwise noted)	Approval Date	Status / Maine DEP Comments
QAPP for Monitoring NPS and TMDL Streams	DEP Watershed Management Unit (WMU) Stream Monitoring	Kathy Hoppe	May–October	5/13/20	
QAPP For River Water Quality Surveys	River Quality Studies Work Plan	Rob Mohlar	May–December	5/29/02	
NPS Lake and Stream Watershed Surveys QAPP	China Lake Watershed Survey (SIP)	Amanda Pratt	October 2020 – May 2021	9/3/20	
Lakes Assessment Program	Cross Lake Watershed-based Management Plan Monitoring	Kathy Hoppe, Linda Bacon	October 2019 – Jan 2022	5/12/20	
Lakes Assessment Program	Great Pond Watershed-based Plan Monitoring	Amanda Pratt, Linda Bacon	January 2019 – January 2020	9/2/20	
Lakes Assessment Program	Long Pond Water Quality Sampling	Amanda Pratt, Linda Bacon	4/1/20-12/31/21	3/12/20	
York County SWCD QAPP for Monitoring Rivers and Streams	Goodall Brook Watershed Project Phase II Monitoring	Addie Halligan	July 23 – Sept 15	7/27/20	
York County SWCD QAPP for Monitoring Rivers and Streams	#20180006 Kennebunk River Watershed Management Plan	Kristin Feindel	June 2019- September 2020	6/28/19	Project completed in 2019, remove from 2021 inventory.
Generic QAPP for Maine Stream Corridor Survey	Kennebunk River Stream Corridor Assessment (SIP)	Kristin Feindel	June-December 2019	6/17/19	Project completed in 2019, remove from 2021 inventory.
NPS Lake and Stream Watershed Surveys QAPP	Kennebunk River Watershed Inventory (SIP)	Kristin Feindel	June-December 2019	6/17/19	Project completed in 2019, remove from 2021 inventory.
VRMP QAPP (April 2020)	Androscoggin River Watershed Council SAP	Kristin Feindel	Ongoing	8/5/20	
VRMP QAPP (April 2020)	Friends of Merrymeeting Bay SAP	Kristin Feindel	Ongoing	5/22/20	

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VRMP QAPP (April 2020)	Friends of Weskeag SAP	Kristin Feindel	Ongoing	5/22/20	
VRMP QAPP (April 2020)	Presumpscot Regional Land Trust SAP	Kristin Feindel	Ongoing	5/22/20	
VRMP QAPP (April 2020)	Wells National Estuarine Reserve SAP (Kennebunk River)	Kristin Feindel	Ongoing	6/19/20	
VRMP QAPP (April 2020)	Wells National Estuarine Reserve SAP (Mousam River)	Kristin Feindel	Ongoing	6/19/20	
VRMP QAPP (April 2020)	Rockport Conservation Commission SAP	Kristin Feindel	Ongoing	8/6/20	
VRMP QAPP (April 2020)	Friends of Scarborough Marsh	Kristin Feindel	Ongoing	5/24/19	New draft SAP created and monitoring followed 2020 QAPP.

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APPENDIX 6

PROGRAMS AND TECHNICAL ACTIVITIES INVOLVING

ENVIRONMENTAL DATA OPERATIONS

(internal and external)

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Summary of Programs with Environmental Data Operations

Bureau of Air Quality:

- Ambient Air Quality Monitoring – Field Operations
- Ambient Air Quality Monitoring – Laboratory Operations
- Meteorological Modeling
- Emissions Inventory – Criteria Pollutants
- Emissions Inventory – Air Toxics
- Compliance
- Enforcement
- Licensing
- Rule Making
- State Implementation Plan Development
- Small Business Technical Assistance
- Mobile Sources

Bureau of Water Quality:

- State Revolving Loan Fund (SRF)
- Combined Sewer Overflow (CSO)
- Biological Monitoring
- Data Management
- Hydrogeology
- Lakes
- Invasive Species
- Marine Waters
- Rivers and Streams
- Surface Water Ambient Toxics Monitoring (SWAT)
- SWAT Dioxin Monitoring
- What is this blank bullet for?
- Municipal/Industrial Wastewater Licensing
- Overboard Discharge Licensing
- Marine Pump-Out
- Underground Injection Control
- DWRR Enforcement
- Watershed Planning

Bureau of Land Resources:

- Excavation and Quarry Notification
- Natural Resource Protection
- Shoreland Zoning
- Site Location of Development

- Stormwater Management (and Erosion and Sediment Control)
- Nonpoint Source
- Hydropower Licensing
- NOAA Coastal Zone Management
- Healthy Beaches Program

Bureau of Remediation and Waste Management:

- Resource Conservation and Recovery Act (C) – hazardous wastes
- Resource Conservation and Recovery Act (I) – underground storage tanks
- Toxic Substances Control Act – Asbestos
- Toxic Substances Control Act – Lead
- Toxic Substances Control Act – PCB
- Leaking Underground Storage Tanks Trust
- Superfund (multiple subprograms)
 - Department of Defense Federal Facilities Projects

Office of the Commissioner

- Technical Assistance and Compliance
- Pollution Prevention and Technical Assistance
- Nonpoint Source Training Center

Programs and Technical Activities Involving Environmental Data Operations Contracted or Delegated by Maine DEP (examples)

Note: May be included in activities of any of the above program areas.

- Self-monitoring activities by permitted entities, *e.g.*, water treatment facilities delegated under NPDES
- Activities carried out under the terms of assistance agreements, *e.g.*, Soil and Water Conservation Districts; Volunteer Lakes Monitoring Program
- Data in support of permit application provided by a contractor, *e.g.*, wetlands delineation carried out with the guidance of a Federal SOP
- Sampling and monitoring operations as part of contracted site remediation activities.
- Sampling and monitoring operations carried out by permittees or their agents as required by license

APPENDIX 7

List of Sole Review QAPPs

The following QAPPs originating in the Maine DEP Bureau of Water Quality (BWQ), Division of Environmental Assessment (DEA), are delegated for sole review by Maine DEP for non-substantive 5-year update per QMP section 7.3.1.

BWQ, DEA Program or Unit	QAPP Title	Most Recent Approval Date¹³	Most Recent Approval By¹⁴	Applicable Program¹⁵
Biomonitoring Unit	QAPP for Biological Monitoring of Maine's Rivers, Streams, and Freshwater Wetlands	8/2019		
Engineering Unit	QAPP for Model Simulations	6/2017		
Engineering Unit	QAPP for River Water Quality Surveys	5/2017		
Lake Assessment Section	Maine Lake Assessment QAPP	11/2015		
Maine Healthy Beaches Program	Maine Healthy Beaches QAPP ¹⁶	7/2016		
Marine Unit	Marine Environmental Monitoring Program QAPP	4/2017		
Watershed Management Unit	Maine Section 319 Nonpoint Source Grant Program QAPP	12/2019		
Watershed Management Unit	QAPP for Monitoring Nonpoint Source and Total Maximum Daily Load Streams	2/2017		
Watershed Management Unit	Volunteer River Monitoring Program QAPP	4/2020		

¹³ As of October 8, 2019.

¹⁴ EPA R1 or MEDEP

¹⁵¹⁵ CWA 106, 319, or 604b.

¹⁶ Maine DEP program as of 1/1/2019.

Watershed Management Unit	NPS Lake and Stream Watershed Surveys QAPP	5/2020		
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APPENDIX 8

SAMPLE INSPECTION FORM

“MEDEP BROWNFIELDS PROJECT REVIEW”



MEDEP Brownfields Project Review Form

Site/Project:	
Task:	
Assigned to:	
MEDEP PM MEDEP Geologist	
Date Assigned:	
Sampling Date:	<input type="checkbox"/> Early
Draft Due Date:	<input type="checkbox"/> On time
Draft Submitted:	<input type="checkbox"/> Late
Revisions Required:	<input type="checkbox"/> None or few minor <input type="checkbox"/> Many minor <input type="checkbox"/> Significant re-write required
Date of Comments to Consultant:	
Date Revised Draft Submitted:	<input type="checkbox"/> <5 days <input type="checkbox"/> 5-10 days <input type="checkbox"/> >10 days
Further Revisions Required:	<input type="checkbox"/> No <input type="checkbox"/> Yes
Date received final report:	
Estimated Budget: Final Budget:	<input type="checkbox"/> Under <input type="checkbox"/> Met <input type="checkbox"/> Over
Overall Work Performance	<input type="checkbox"/> Excellent <input type="checkbox"/> Satisfactory <input type="checkbox"/> Unacceptable

Comments:

Signature, Brownfields Coordinator