

Quality Management Plan, 2020

Washington State Department of Ecology

December 2020– Version 5

Publication 20-03-014

Publication Information

This report is available on the Department of Ecology's website at https://apps.ecology.wa.gov/publications/SummaryPages/2003014.html

Suggested Citation

Ecology. 2020. Quality Management Plan, 2020. Washington State Department of Ecology. Publication 20-03-014. Washington State Department of Ecology, Olympia. https://apps.ecology.wa.gov/publications/SummaryPages/2003014.html.

The four previous versions of Ecology's Quality Management Plan are available at:

2015 - https://apps.ecology.wa.gov/publications/SummaryPages/1503030.html

2010 - https://apps.ecology.wa.gov/publications/SummaryPages/1003056.html

2005 - https://apps.ecology.wa.gov/publications/SummaryPages/0503031.html

1983 - https://apps.ecology.wa.gov/publications/SummaryPages/8303001.html

Website

Ecology's Quality Assurance website: https://www.ecology.wa.gov/quality

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Quality Management Plan, 2020

Washington State Department of Ecology

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Purpose of This Document

This *Quality Management Plan* is the Washington State Department of Ecology regulatory framework for applying the quality system to environmental programs.

The quality system is a structured and documented management system that provides the framework for (1) planning, implementing, documenting, and assessing environmental data operations, and (2) carrying out required quality assurance and quality control activities.

The quality system encompasses both managerial and technical activities. The active participation of all employees is required.

Acknowledgements

The author thanks the following Department of Ecology staff for their contributions to this report:

- Britta Voss, Ecology National Estuary Program Quality Coordinator, for reviewing the document and providing very useful comments.
- Samuel Iwenofu, Hazardous Waste & Toxics Reduction Program, for providing useful comments.
- Annette Hoffmann, Environmental Assessment Program Manager, for providing support and reviewing the document.
- Joan LeTourneau and Diana Olegre for formatting the document.

Chapter 1. Introduction

3.2 Background

The Washington State Department of Ecology (Ecology) develops this *Quality Management Plan* as a cornerstone of its participation in the U.S. Environmental Protection Agency (EPA) quality system. Ecology's quality system is defined in the agency's *Quality Management Plan* (Ecology, 2015 and 2020, this document) and is formally established in Ecology Policy 22-01 (Ecology, 2006). The *Quality Management Plan* is based largely on requirements set out by the EPA in their *Requirements for Quality Management Plans* (EPA, 2001, 2006).

Ecology's Quality Assurance (QA) Officer, who is designated by the Ecology Director, coordinates and manages QA activities throughout the agency. The QA Officer also is the chief QA liaison for intra-agency QA activities throughout the agency in consultation with the Program Quality Assurance Coordinators (QACs) per the Ecology QA policy as documented in Executive Policy 22-01. In addition, the QA Officer prepares this document and the periodic *Quality Report to Management*. Currently, the QA Officer is based in Ecology's Environmental Assessment Program.

All Ecology environmental programs have designated one or more QA Coordinators, who have a maximum commitment of 0.25 Full Time Employee (FTE)/program. Some programs due to the nature of their QA activities have more than 0.25 FTE assigned for QA. These QA Coordinators provide support/oversight of QA and quality control (QC) activities within their respective programs and have a wide range of potential responsibilities, which are defined in this document. The QA Coordinators also contribute to the *Quality Report to Management*.

Manchester Environmental Laboratory (MEL) has an integral role in the quality system at Ecology. MEL is the in-house laboratory and provides lab services for general chemistry, metals, organic chemistry, and microbiology. Laboratory QA practices are discussed in this *Quality Management Plan* and are formally described in the MEL *Quality Assurance Manual* (Ecology, 2016, internal publication).

The Laboratory Accreditation Unit (LAU) provides accreditation services to help establish and document laboratory proficiency for the reporting of data to Ecology. Accreditation requirements for data produced by and submitted to Ecology are detailed in Ecology Policy 22-02 (Ecology, 2008a). The LAU maintains a procedural manual (Ecology, 2010b) and several standard operating procedures (SOPs) (Ecology, 2019) documenting the QA practices and procedures of the unit.

3.3 Graded Approach to Quality Management

The graded approach to quality management is straightforward. Projects of different sizes, levels of risk, and rigor call for differing approaches to QA documentation. Generally speaking, the larger the project and the more risk the project carries, the more detailed and rigorous the quality documentation must be. Notwithstanding these differences, Ecology Policy 22-01 and Environmental Assessment Program Procedure 1-14 call out the development of Quality Assurance Project Plans (QAPPs) for all projects generating or analyzing environmental data, including those projects utilizing or evaluating secondary data. Ecology also requires that all field sampling, analytical, and laboratory activities be documented using formally approved

SOPs. To this end, Ecology has developed over 300 SOPs applicable to field, laboratory, data management, and accreditation activities. See Ecology (2019) for a comprehensive listing of agency and program SOPs.

3.4 Intended Audience

The intended audience for this document is diverse. Ecology staff and management fulfill the noted responsibilities and authorities stated herein. Ecology's partners in grants, contracts, and loans have a vital interest in adhering to the requirements of the plan. Ecology develops and maintains the plan to meet the requirements of the EPA quality system. Finally, the public and private environmental organizations may be interested in Ecology's plan to continuously improve quality in data generation activities, record-keeping and documentation, standardization, and quality assessment.

3.5 Period of Applicability

The period of applicability for this *Quality Management Plan* is five years from the date of publication. At the end of that period, the plan will be reissued without changes, revised and reapproved, or rewritten.

Notwithstanding the five-year review cycle, the *Quality Management Plan* may be revised anytime EPA policies change or the Ecology quality system is modified.

3.6 Supersession

This document supersedes all previous Ecology Quality Management Plans.

3.7 Legal Basis for Ecology Authorities and Requirements

EPA requires Ecology to document its quality system in an approved *Quality Management Plan*. This requirement, and other quality system requirements, can be found in the following regulations, orders, and policies.

- 48 CFR Part 46, Federal Acquisition Regulations, for contractors.
- 2 CFR 1500.4 and 40 CFR Part 35 for assistance agreement recipients.
- EPA Science Advisor Policy on Lab Competency EPA, 2016.
 https://www.epa.gov/sites/production/files/2017-05/documents/policy to assure the competency of organizations.pdf
- EPA Order 2105.0, on a Mandatory Agency-Wide Quality System, EPA, 2000. https://www.epa.gov/sites/production/files/2013-10/documents/21050.pdf
- Other relevant EPA orders and policies regarding quality system requirements can be found in the References section of this document in EPA 2001, 2000b, 2002a, 2002b, 2004, 2006b, 2006c 2008a, 2008b, 2011, 2012a, 2012b, and 2012c, 2012d.

Chapter 2. Requirements of the Quality Management Plan

3.8 Policy

Several aspects of the Ecology *Quality Management Plan* are required by either EPA or Ecology policy. *EPA Requirements for Quality Management Plans* (EPA, 2001) states that any environmental data generation funded by EPA must be performed using an appropriate quality management plan. EPA requirements include QAPPs for environmental data generation, secondary data (generated by others), and modeling projects, which may include secondary data and direct generation.

Ecology Policy 22-01 (Ecology, 2006) requires the development of QAPPs for all environmental data generation performed by Ecology or performed by Ecology grantees, contractors, or loan recipients, when those data are submitted to Ecology. Policy 22-02 (Ecology, 2008a) requires the use of laboratories accredited by Ecology when Ecology performs the environmental data generation or when any entity submits environmental data to Ecology. Labs must maintain a general accreditation, and also be accredited for the specific parameter, method, and matrix used to generate the data. Exceptions to this requirement are very infrequent and need the approval of the QA Officer in consultation with the program QA Coordinator.

Standard operating procedures (SOPs) are required for all Ecology sampling, field analytical, product testing, and laboratory analytical operations. Additionally, SOPs may be required for processes involving data acquisition, entry, analysis, and interpretation. An example of this type of SOP is the MEL SOP for contract lab data review, 770005. See EPA (2016) for the EPA Policy requiring demonstration of lab and field competency, which also requires full implementation of SOPs for field work.

3.9 Purpose

The ultimate purpose of the *Quality Management Plan* is to ensure, to the extent possible, that data generated by Ecology or submitted to Ecology are of known quality and usable for intended purposes. To this end, the Ecology quality system touches many aspects of agency operations including:

- Project planning (QAPPs).
- Document development (SOPs and reports), document control, and document standardization.
- Internal laboratory operations.
- Laboratory accreditation.
- Data management and independent data validation.
- Field sampling and analytical procedures, field auditing, and field proficiency.
- Other activities as appropriate.

3.10 Applicability

The *Quality Management Plan* is applicable to all staff in Ecology and all entities generating data required by Ecology regulations, contracts, or interagency agreements.

3.11 General Content and Management

The required contents of all *Quality Management Plans* are defined in EPA (2001). Every effort has been made to conform with these requirements with regard to both content and format.

3.12 Preparation

Ecology's Executive Leadership Team (ELT) is responsible for preparing the *Quality Management Plan*. In practice, however, preparation is delegated to the Ecology QA Officer, who may also involve the Program QA Coordinators and other staff as required or appropriate.

3.13 Submittal and Approval

The *Quality Management Plan* must be approved by the following members of the ELT:

- Ecology Agency Director
- Ecology Deputy Director
- Ecology Quality Assurance Officer
- Ecology Environmental Program Managers:
 - Air Quality Program
 - o Environmental Assessment Program
 - Hazardous Waste and Toxics Reduction Program
 - Nuclear Waste Program
 - o Shorelands and Environmental Assistance Program
 - o Solid Waste Management Program
 - o Spill Prevention, Preparedness and Response Program
 - o Toxics Cleanup Program
 - o Water Quality Program
 - Water Resources Program
 - o Director of Office of Chehalis Basin
 - o Director of Office of Columbia River
 - o EPA Region 10 Quality Assurance Manager
 - o EPA Grant Project Officer

3.14 Revisions

The *Quality Management Plan* is revised or rewritten, at a minimum, on a five-year cycle. The Plan may be revised more frequently, if required by quality system changes or changes in EPA requirements. It is reviewed on an annual basis.

Chapter 3. Elements of the Quality Management Plan

3.1 Content Requirements

EPA, 2001, Requirements for Quality Management Plans, contains requirements for Quality Management Plan content and format. This Ecology document strictly aligns with the stated topic areas in EPA, 2001.

3.15 Management and Organization

The mission of Ecology is to protect, preserve, and enhance the environment for current and future generations.

Ecology Policy 22-01, *Establishing Quality Assurance*, was adopted on August 25, 1993, revised in October 1999 and in May 2006. The policy applies to environmental data-collection studies conducted or funded by Ecology and those studies conducted through interagency agreements or contracts. It is the responsibility of agency management to promote the consistent application of QA and QC principles to the planning and execution of these studies and activities.

It is the intent of the policy that (1) the quality of all environmental data be documented, (2) the data satisfy the requirements for their intended use, and (3) the data are legally defensible. The policy is implemented by Ecology managers and staff. Appropriate QA and QC practices are used in all phases of environmental studies and activities, from developing the initial plan through sampling, measurement, assessment, and use of the data. The QA/QC requirements should be commensurate with the importance of the work, available resources, unique needs of Ecology, and the consequences of potential decision errors.

The Ecology QA Officer reports to both the Program Manager of the Environmental Assessment Program and has a dotted line reporting to the agency Deputy Director (See Appendix A). The QA Officer does not have any direct responsibility for sampling or analysis (i.e., data generation).

Ecology programs responsible for environmental data are listed in the *Concurrences by Ecology Management Team* section of this document.

The following *Quality Management Plan* elements list the QA/QC roles, authorities, and responsibilities of the personnel involved in Ecology QA activities.

QA/QC Responsibilities

Management

Several Ecology executive members are accountable for accomplishing the mission and conducting overall operations of Ecology. These members are the signatories of this document (see *Concurrences by Ecology Management Team* section). Resources needed to implement the Ecology QA policy are identified and budgeted by the Program Managers. The agency Director or his/her designee is responsible for designating the QA Officer, and Program Managers are responsible for designating QA Coordinators. In addition, Ecology

management is responsible for:

- Preparing and revising this *Quality Management Plan*. Preparation may be assigned to staff, with senior managers participating in and supporting the effort and also signing approval.
- Understanding fully the content of this plan and concurring with its implementation.
- Allocating resources to implement the QA policy and this plan.
- Ensuring that Ecology QA policy and this plan are implemented.
- Delegating responsibilities for implementing a quality system at appropriate levels of the agency.
- Building success measures into the quality system to determine when it is working well.
- Assessing the adequacy of the quality system.
- Deciding whether to employ peer review in particular instances in order to ensure that technical documents provide credible science and are reliable and readable.
- Ensuring that agency staff, inter-agency partners, and the regulated community are provided educational training on agency policies and procedures related to quality management.

Quality Assurance Officer

The QA Officer is responsible for:

- Reviewing and approving QAPPs prepared by and for Ecology staff. QAPPs submitted to the EPA must be approved by the QA Officer. Approval means that the QA Officer determines that the QAPP reflects adequate planning and contains sufficient information to allow competent staff to acquire and document the quality of data necessary to meet the objectives of the project.
- Providing technical and consultative support to agency programs and often working with the QA Coordinators to provide this support.
- Acting as the liaison between Ecology and other agencies on QA/QC matters.
- Informing Ecology management of QA/QC process improvements, issues, and problems.
- Assisting management, as requested, in preparing QA/QC documents, including this agency *Quality Management Plan*.
- Providing technical assistance to Ecology staff in implementing QAPPs and assessing the quality of the results obtained.
- Preparing and maintaining guidance for the preparation of OAPPs.
- Assisting Ecology staff with preparing documents involving the application of QA and QC principles.
- Coordinating training on QA and QC principles and practices to meet the needs of Ecology staff.
- Preparing a *Quality Report to Management* every three years.
- Coordinating and conducting, when necessary, audits of Ecology QA operations and project reports. The QA Officer has stop-work authority when reports contain demonstrable errors, or when field or laboratory QA processes are insufficiently documented or implemented.
- Reviewing and concurring on technical reports issued by programs when requested or required.

- Identifying Ecology needs regarding SOPs; coordinating development of those SOPs; and ensuring the review of those SOPs on a periodic cycle.
- Maintaining the internal QA website and producing content for the external QA website.
- Serving as a back-up for all other QA Coordinators.
- Reviewing request to waive the use of accredited laboratory per the guidelines outlined in Ecology Policy 22-02.
- Granting approval to begin work in special circumstances to commence sampling before QAPP approval. This approval is only provided by the QA Officer in consultation with the program QA Coordinator.
- Providing QA oversight, technical assistance, and QAPP approval to the sub-recipients of EPA's Natural Estuary Program (NEP) funding. The updated QMP Addendum for NEP can be found on Ecology's QA website: https://apps.ecology.wa.gov/publications/SummaryPages/1903015.html.

Quality Assurance Coordinators

The program QA Coordinators are responsible for:

- Acting as point of contact within their programs for data quality issues.
- Coordinating with the agency QA Officer to identify needs related to QAPP preparation, SOP preparation and maintenance, and QA/QC training.
- Reviewing and approving QAPPs submitted by and for their program staff.
- Coordinating and approving the development of program field sampling and field analytical SOPs, unless the program QA Coordinator is the author of the SOP, in which case the QA Officer will approve.
- Assisting project managers who review QAPPs prepared within their program.
- Assisting project managers who oversee the preparation of QAPPs submitted to Ecology by responsible parties, contractors, and grant recipients.
- Providing technical assistance to program staff who implement QAPPs and assess the quality of the results obtained.
- Assisting with preparing and presenting QA/QC training for program staff.
- Assisting program staff and grant recipients in meeting QA/QC requirements.
- Providing information to the QA Officer for the *Quality Report to Management*.
- Updating the QA Officer about quality successes and failures in their programs.
- Attending the QA group meetings, once every quarter.

Additional responsibilities may be defined in program-specific QA plans or on the programs individual SharePoint sites. For example, the *Air Monitoring Quality Assurance Plan* specifies some responsibilities of the QA Coordinator for the Air Quality Program. Additionally the Toxics Cleanup Program (TCP) and the Hazardous Waste and Toxics Reduction Program (HWTR) have specific QA responsibilities listed for their Corrective Action sites on their SharePoint sites.

Project Managers and Project Leads

Ecology project managers and project leads have overall responsibility for (1) specific environmental studies and (2) activities conducted through grants or contracts. They are responsible for:

- Preparing, or ensuring the preparation of, QAPPs.
- Obtaining QAPP approval before start of project sampling.
- Maintaining all documentation regarding any approved changes to the original QAPP in an easily accessible place.
- Ensuring that all contracted work is in accordance with RCW 39.26, with state procurement policies initiated by the state Department of Enterprise Services (DES), and with Ecology's procurement policies.
- Assisting contractors, grant recipients, and the regulated community with preparing QAPPs.
- Reviewing and approving QAPPs prepared by grant recipients and contractors in conjunction with the program QA Coordinator.
- Implementing QAPPs.
- Assessing and reporting the quality of data, based on the quality objectives defined in the approved QAPP.

Field Staff

Ecology staff collecting samples or data in the field have a vital role in the success of the projects. They are responsible for:

- Understanding and following the QAPP.
- Checking all equipment and supplies in advance of field operations.
- Ensuring that samples are properly collected, preserved, labeled, packaged, and shipped.
- Ensuring that all field data are recorded and preserved according to the approved QAPP.
- Following required chain-of-custody procedures and standard operating procedures (SOPs).
- Participating in any necessary training, side-by-side comparisons, and/or field audits on SOP use and performance, in order to document proficiency using those SOPs (EPA, 2016).

Manchester Environmental Laboratory (MEL) Director

The Ecology's MEL Director is responsible for:

- Directing and overseeing QA/QC for the laboratory.
- Designating the laboratory QA Coordinator.
- Approving QAPPs that involve laboratory services.
- Participating in and approving the preparation and revision of the MEL *Quality Assurance Manual* and the MEL *Lab Users Manual*.
- Ensuring that MEL participates in all required external system assessments and proficiency testing studies.
- Ensuring that MEL maintains accreditation for all parameters and methods used to produce environmental data.

MEL QA Coordinator

The QA Coordinator for MEL is responsible for:

- Reviewing QAPPs to ensure that the procedures specified for sampling and analysis are appropriate and that the number, type, and schedule of analyses required can be accommodated.
- Coordinating the preparation and revision of the MEL *Quality Assurance Manual* and the *Lab Users Manual*.
- Directing the preparation, maintenance, and recertification of administrative and technical SOPs every five years.
- Reviewing data produced by the laboratory for compliance with QA/QC requirements.
- Performing internal system and performance audits to identify and correct problems affecting data quality.
- Coordinating the laboratory's participation in all external system and proficiency testing studies, including those required for annual accreditation.
- Periodically updating the QA Officer about the status of SOPs being managed by MEL.
- Attend the QA Coordinators meeting every quarter.

MEL Staff

Laboratory staff provide analytical services, support services, and technical consultation, each of which includes QA responsibilities. Laboratory staff responsibilities include:

- Following the administrative and technical SOPs.
- Analyzing samples according to methods specified in the QAPPs and documenting any necessary changes in the methods.
- Analyzing QC samples according to guidance provided in the MEL *Quality Assurance Manual* and the QAPPs.
- Assuring that samples are analyzed within specified holding times and providing complete and accurate data reports in a timely manner.
- Contributing to the preparation of their *Quality Assurance Manual*, the *Lab Users Manual*, and SOPs in their area of expertise.
- Reviewing, verifying, and/or validating the results of analyses, including results from other laboratories when arrangements have been made for this service.
- Operating and maintaining the Laboratory Information Management System (LIMS).

Laboratory Accreditation Unit Staff

LAU staff administer Ecology's Environmental Laboratory Accreditation Program. This program is authorized by law in RCW 43.21A. Applicable rules are presented in WAC 173-50. Accreditation is granted to laboratories after assessing them to determine that they have a demonstrated capability to accurately analyze environmental samples. Details of the responsibilities for accrediting laboratories are given in the *Procedural Manual for the Environmental Laboratory Accreditation Program* (Ecology, 2010b) and also in Ecology Policy 22-02, Requiring Use of Accredited Environmental Laboratories (Ecology, 2008a).

Dispute Resolution

Oversight responsibilities for QA/QC may result in disagreements between the oversight group and the program reviewed. Such disputes may occur in situations involving technical issues (e.g., quality requirements, assessments, audits, surveillance, data quality [usability] assessments, reports and other publications) and management issues (e.g., *Quality Management Plan* reviews, management system reviews).

Disputes should be resolved at the staff level before escalating them to management.

All parties should make every effort to resolve disputes through discussion and negotiation.

If the parties are unable to resolve the dispute, the following dispute resolution process should be followed:

- 1. The process begins when either disagreeing party declares an issue to be irresolvable and sends a memorandum to the other party (1) invoking this dispute resolution process, (2) defining the disputed issue, and (3) presenting supporting arguments for the first party's position on the issue.
- 2. Within 15 days, the second party must send a draft dispute resolution package to the first party. As soon as possible after this, the two parties, working together, must submit a dispute resolution package to the Environmental Assessment Program (EAP) Program Manager and the Agency QA Officer. This package should contain all relevant arguments, relevant rebuttals, and any supporting materials.
- 3. The EAP Program Manager and the agency QA Officer shall schedule a meeting for resolving the dispute within 15 days from receipt of the dispute resolution package, and notify both parties of this date. Both parties are invited to attend the resolution meeting to present arguments and answer questions. Management may get advice from a third party.
- 4. If the issue cannot be resolved at this level, the agency Deputy Director, in consultation with the EAP Program Manager and the Ecology QA Officer, will make the final decision on disposition of the issue. If the quality dispute involves the QA Officer, then the QA Officer will not participate in the final management decision. The final decision of management shall be binding on both parties.

3.16 Quality System Components

The quality system is a structured and documented management system that provides the framework for (1) planning, implementing, documenting, and assessing environmental data operations, and (2) carrying out required QA and QC activities.

The quality system encompasses both managerial and technical activities; and requires the active participation of all employees.

QA is primarily a management activity; QC is primarily a technical activity. However, there is no sharp division between these two functions.

QA is a system for assuring the reliability of measurement data and by definition also includes Ecology QC activities. QC involves applying statistical procedures to evaluate and control bias, sensitivity, and precision for measurement data.

The principal components of Ecology's quality system and the corresponding tools for implementing them include:

- Quality Assurance policy (Ecology Policy 22-01)
- Lab Accreditation policy (Ecology Policy 22-02)
- Water Quality Data Act (RCW 90.48.570-590) and associated policies
- EAP QAPP and SOP procedures (EAP procedures 1-04, 1-08, and 1-14)
- Ecology field and laboratory SOPs
- Ecology stormwater-related SOPs
- Ecology Air Quality Program SOPs
- Ecology Spills Program SOPs
- Quality system documentation (*Quality Management Plans*)
- Periodic reviews and planning (*Quality Report to Management*)
- QA/QC training
- Systematic planning for projects (QAPPs and/or Data Quality Objectives Development Process)
- Project and data assessments (Data Verification and/or Validation and Data Quality Assessment)
- Management assessments (Quality Systems Assessments or Audits)

Other tools for implementing Ecology's quality system include:

- Air Monitoring Quality Assurance Plan
- Manchester Environmental Laboratory Quality Assurance Manual
- Manchester Environmental Laboratory Lab Users Manual
- Guidelines for Preparing Quality Assurance Project Plans for Environmental Studies
- Procedural Manual for the Environmental Laboratory Accreditation Program
- Spills Program sampling SOPs (available internally only)
- Hazardous Waste and Toxics Reduction (HWTR) Program generic QAPP
- Nuclear Waste Program (NWP) sampling and sample shipping SOPs

3.17 Qualifications and Training

The QA Officer and staff, supported by the QA Coordinators and other designated staff, are responsible for QA/QC training of Ecology personnel. Those responsible for training must maintain competence in QA/QC principles and practices through (1) the literature, (2) training offered by outside sources, and (3) participating in relevant regional and national conferences.

Ecology staff must have sufficient education and training in QA/QC practices to carry out their assigned responsibilities. Training is designed to raise the awareness of and competence in good QA/QC practices. Training is provided on subjects such as sampling, statistics, the data quality objectives process, preparing QAPPs, environmental measurements, and analytical QC.

The QA Officer and staff identify and make use of resources from inside and outside of Ecology in providing training. Many Ecology staff have extensive experience in their areas of specialization that can be incorporated into the training.

Ecology programs may have unique requirements for QA and QC training, and program QA Coordinators help identify training needs. They arrange for training by using resources within their programs or by securing assistance from the QA Officer or external resources.

At the agency level, training resources are primarily directed toward "Core" requirements. Technical training is addressed program by program, on an as-needed basis.

3.18 Procurement of Goods and Services

The Contract and Purchasing Office, located in the Fiscal Section of Financial Services, is responsible for procuring all supplies, equipment, and services used by the agency statewide. Chapter 13 of the *Ecology Policy and Procedure Manual* includes the policies and procedures on purchasing/inventory/payables.

Ecology's MEL contracts with other laboratories to perform analyses that MEL is unable to perform. Such laboratories must be accredited by Ecology, in accordance with Ecology Policy 22-02. Analyses of samples are contracted in accordance with RCW 39.26, with state procurement policies initiated by the state Department of Enterprise Services (DES), and with Ecology's procurement policies. Laboratory SOPs related to contracting include SOP 770003, *Contracting Analytical Services*, and SOP 770005, *Review of Contract Lab Data*. Data from analyses performed by contracted laboratories are reviewed by MEL to determine if the quality of data meets agency needs and conforms to the contract requirements.

3.19 Documents and Records

Chapter 20 of the *Ecology Policy and Procedure Manual* includes the policies and procedures on records/forms/public disclosure.

Two principal forms of quality system documentation are required by the EPA quality system: an agency *Quality Management Plan* and QAPPs.

MEL prepares a Quality Assurance Manual and a Lab Users Manual.

Standard operating procedures (SOPs) are prepared for laboratory and field activities. See Ecology (2019) for a comprehensive listing of current program and agency SOPs.

EPA QA requirements documents are used to supplement the information in Ecology publications when preparing quality system documents. QA requirements for both *Quality Management Plans* and QAPPs can be found at EPA's Quality System website, www.epa.gov/quality/qa_docs.html.

Documents and records, including revisions, must be reviewed for conformance with the EPA quality system requirements and be approved by authorized Ecology staff.

3.20 Information Management

Chapter 16 of the Ecology *Policy Manual* contains guidance documents and procedures for many aspects of the Information Technology (IT) infrastructure at Ecology. Some of the covered topics include:

- Software development
- Computer security
- Software piracy
- Phone and voicemail services

Environment Information Management (EIM) System

Ecology's EIM database is the agency repository for the great majority of environmental information generated by Ecology. The database is a robust and powerful web-based, geographic information system (GIS)-friendly reporting tool for analysis and production of reports and maps detailing environmental conditions throughout Washington State.

The EIM database implements two levels of QA. First, each project is evaluated and assigned a QA planning level. This is a numerical score representing the rigor of the quality planning process: from no QAPP (a common occurrence in pre-1980 work) to an approved QAPP implemented before any field work. Secondly, there is a QA assessment level, which evaluates the level of assessment attained by finished projects: from no assessment to full verification, validation, and data usability determination.

Result qualifiers submitted by MEL are incorporated into the results stored in the EIM system. Contract data validated by MEL or any other qualified third party contractor are assessed for usability by the project officer and qualified per EPA functional guidelines before submittal into EIM.

MEL maintains an extensive data review and verification process for MEL-generated data. This consists of several levels of peer review and supervisory review. There is an extensive data verification process, followed by issuance of a Case Narrative, which is a report discussing an assessment of the dataset QC sample results and any non-conformance with method quality criteria.

Data entry standardization is an important concern for EIM managers and staff. Trainings on the EIM system, for both Ecology staff and external users, are conducted periodically. Ecology also uses an inter-program agreement which commits all EIM user programs to QA protocols for EIM data-entry processes. This agreement is provided as Appendix H in Ecology, 2010a.

Lab Information Management System (LIMS)

MEL has a long history and involvement with data management. The lab maintains a commercial-off-the-shelf (COTS) LIMS system with electronic interfaces to both lab instrumentation and the EIM system.

Lab Accreditation Database

The Laboratory Accreditation Unit maintains a database to track accreditation status of the labs in the program. This database tracks accredited parameters and status and also issues renewals and accreditation certificates.

Quality Assurance Website

The Ecology *Quality Assurance* website (http://www.ecy.wa.gov/programs/eap/quality.html) is a key component of the Ecology quality system. The website helps ensure transparency of the Ecology quality operations. Several key documents are found here, including:

- Ecology Quality Reports to Management
- Ecology Quality Management Plans, current and historical
- Ecology QAPP Guidance
- Ecology Air Program SOPs
- Ecology EAP SOPs
- Ecology Field Sampling and Field Analytical SOPs
- Ecology Water Quality Program stormwater SOPs
- Various EPA SOPs and Requirements Documents
- Several EPA guidance documents on quality-related topics
- QAPP templates, guidance, and review checklists for the National Estuary Program, Ecology's Water Quality Program grantees, and general use by Ecology staff.
- Ecology Spills Program SOPs are only available internally.

3.21 Planning

Data QA begins with careful planning. The goal and specific objectives for the environmental project are clearly defined, including how the data will be used. Then quality objectives, as well as qualitative and quantitative statements about the data needed to support decisions or regulatory actions, are developed. Finally, the methods to collect samples, make measurements, document data quality, and interpret and report results are selected or developed.

A systematic planning process is recommended. Systematic planning is a process in which you identify the problem to be studied and/or the decision to be made, and then define the project's objectives; type, quantity, and quality of information needed; technical and QC activities, and level of oversight that will ensure project criteria are satisfied. Additional information on systematic planning processes can be found in the following documents: Guidance for the Data Quality Objectives Process (EPA QA/G-4, 2006) and Guidelines for Preparing Quality Assurance Project Plans for Environmental Studies (Ecology, 2004).

QAPPs

Preparing a QAPP helps ensure that the project manager follows a systematic planning process. The completed plan (1) facilitates communication among managers, QA coordinators, field personnel, and laboratory personnel who implement the project, (2) promotes consistency in data collection activities, and (3) provides the basis for project

reports.

Guidelines for Preparing Quality Assurance Project Plans for Environmental Studies provides the project manager with guidance for preparing QAPPs suited to Ecology projects. The guidelines, which follow and expand upon EPA Requirements and Guidance (EPA Documents QA/R-5 and QA/G-5), describe the elements to be considered for inclusion in a QAPP.

QAPPs are developed in advance for emergency response situations and samples of opportunity. Templates are prepared for projects that are repetitive in nature, such as compliance inspections.

Program-specific guidance documents are prepared, when needed, to address the unique QA requirements of Ecology programs as well as requirements of the EPA Quality System documentation.

A QAPP generated by Ecology or through inter agency partnership is considered approved only after all the signatories and either the QA Coordinator or QA Officer has signed the project plan. A project cannot start before QAPP approval.

A QAPP is valid for 5 years after approval unless otherwise specified. After 5 years, the QAPP must be recertified with updates. Any exceptions or extensions must be approved by the agency QA Officer.

Any changes or updates to the QAPP need to be documented and approved by either the QA officer or the program QA coordinator. These updates can be documented in the form of a technical memo, an addendum, or an email. These updates need to be shared with all the signatories of the QAPP.

3.22 Implementation of Work Processes

Ecology maintains an extensive *Policy Manual* used to formalize routine work processes. The manual contains the following chapters:

- Chapter 1, Non-Discrimination
- Chapter 2, Hiring and Appointments
- Chapter 3, Hours of Work and Overtime
- Chapter 4, Training and Employee Development
- Chapter 5, Leave/Payroll
- Chapter 6, Travel
- Chapter 7, Workplace Safety, Health, and Security
- Chapter 8, Discipline
- Chapter 9, Grievances and Investigations
- Chapter 10, Reasonable Accommodation
- Chapter 11, Layoff/Reduction In Force
- Chapter 12, Classification and Compensation
- Chapter 13, Purchasing and Contracts
- Chapter 14, Facilities and Vehicles
- Chapter 15, Ethics/Use of State Resources

- Chapter 16, Information Technology
- Chapter 17, Organization and Authority
- Chapter 18, Sustainability and Walking Our Talk
- Chapter 19, Rules and Legislative Information
- Chapter 20, Public Information, Records, and Publications
- Chapter 21, Financial Operations
- Chapter 22, External Environmental Operations

The Ecology *Policy Manual* helps standardize many work processes, and can be viewed as a set of SOP-like documents covering work activities, ranging from purchasing and contracting to environmental lab accreditation and QA at Ecology. The *Policy Manual* can be found internally at http://teams/sites/EXEC/policies/default.aspx.

3.23 Quality System Assessment and Response

The effectiveness of the quality system is continuously evaluated. Available assessment tools include data quality assessments, peer reviews and technical reviews, proficiency testing studies, and technical systems audits. Technical audits and assessments (1) provide management with tools to determine whether data collection activities are implemented as planned, and (2) are the basis for taking action to correct any deficiencies that are identified.

Following are responsibilities of Ecology staff related to the quality system:

Project Manager

The project manager assures that a data quality (or usability) assessment is done for each project that involves environmental data. A data quality (or usability) assessment is a statistical and scientific analysis and evaluation of data to determine if data are of the right type, quality, and quantity to support their intended use.

Manchester Environmental Laboratory

MEL reviews the results of sample analyses to ensure that the QC requirements, as stated in the MEL *Quality Assurance Manual* and the QAPP, have been met. Corrective actions are taken when these requirements are not met.

As part of its accreditation requirement, MEL participates in proficiency testing and on-site assessments. Proficiency testing studies involve the analysis of unknown samples. On-site assessments correspond to assessments of the laboratory's managerial and technical capability by an outside assessor. Internal system assessments are also performed periodically.

Management

The purposes of internal assessments include: (1) improving the quality systems and (2) providing valid feedback to management on the adequacy, implementation, and effectiveness of the quality system.

Before initiating internal assessments, Ecology management identifies goals, chooses the assessors, defines acceptance criteria, determines the assessment procedures to be used, and approves checklists. Senior management assess (at least annually) the adequacy of the quality system.

Laboratory Accreditation Unit

The LAU performs on-site assessments and tracks the results of proficiency-testing studies from participating laboratories.

The LAU prepares and submits reports of assessments to Ecology management. When the assessment findings identify conditions needing corrective action, management responds promptly and appropriately. Corrective actions are documented by the responsible persons in order to confirm the implementation and effectiveness of the response action. Senior management is responsible for addressing any disputes concerning the assessments.

QA Officer

The QA Officer keeps the Program Manager for the Environmental Assessment Program informed of QA accomplishments and any problems that arise. The QA Officer discusses any relevant QA issues or problems with the appropriate Program Manager and/or program QA Coordinator.

The QA Officer prepares a status report, *Quality Report to Management*, every three years. This report contains, as a minimum, the following information:

- QA/QC training received by Ecology staff.
- Technical assistance and QA/QC support provided to Ecology staff.
- Significant problems related to data quality and recommended corrective actions.
- Accreditation status of Manchester Environmental Laboratory (MEL).
- Status and needs of documented information on QA/QC.
- Status and needs of human resources to implement the quality system.
- A review of the Ecology *Quality Management Plan* to determine if the approved quality management practices continue to be both suitable and effective.
- Other information specifically requested by management.

Environmental Assessment Program (EAP) side-by-side comparisons

The EAP Freshwater Technical Coordination Team conducts, on occasion, side-by-side comparisons for field measurement techniques. These comparisons are used to assess both Ecology and external organizations and usually occur in the field at an actual sampling location. These assessments provide important data regarding the technical competence of various sampling organizations in Washington State.

3.24 Quality Improvement

The QA/QC responsibilities of Ecology management and staff are specified in the *Management and Organization* section of this document. Quality improvement requires the active participation of all employees. Continuous quality improvement is an integral part of the quality system.

Quality improvement is achieved by assessing the effectiveness of the processes for collection and use of environmental data, and by taking preventive and corrective actions to improve those processes.

A triennial *Quality Report to Management* provides an assessment of the effectiveness of the quality system. Program and laboratory specific assessments evaluate the effectiveness of quality improvement activities. This helps ensure that conditions adverse to quality are:

- Prevented
- Identified promptly, including determining the nature and extent of the problem
- Corrected as soon as possible

All corrective actions will be documented and tracked until closure. A Corrective and Preventive Action Notice form, which documents corrective and preventive actions, is in use for the National Estuary Program's QA grant oversight process.

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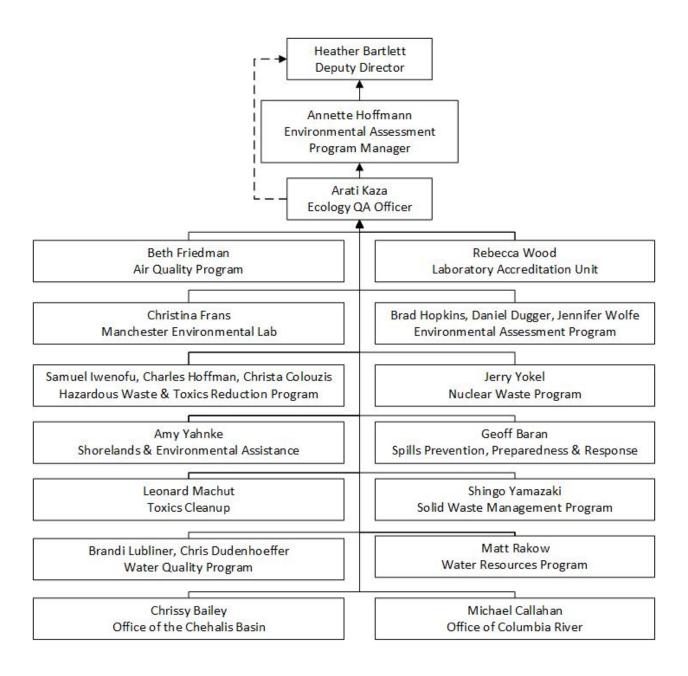
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Appendices

Appendix A. Ecology QA Organizational Chart

Following is a chart of Ecology's QA reporting relationships as of December 2020.



Appendix B. QA Coordinators for Ecology Programs

Program/ Manager	QA Coordinator	Location	Phone	Email
Air Quality/ Kathy Taylor	Beth Friedman	HQ	360-407-6374	beth.friedman@ecy.wa.gov
Ecology QA Officer	Arati Kaza	HQ	360-407-6964	arati.kaza@ecy.wa.gov
Environmental Assessment/ Annette Hoffmann	Brad Hopkins	HQ	360-407-6686	brad.hopkins@ecy.wa.gov
Environmental Assessment/ Annette Hoffmann	Daniel Dugger	Eastern Ops	509-454-4183	dan.dugger@ecy.wa.gov
Environmental Assessment/ Annette Hoffmann	Jennifer Wolfe	HQ	360-407-6772	jenny.wolfe@ecy.wa.gov
Hazardous Waste & Toxics Reduction/ Darin Rice	Samuel Iwenofu	HQ	360-407-6346	samuel.iwenofu@ecy.wa.gov
Hazardous Waste & Toxics Reduction/ Darin Rice	Charles Hoffman	SWRO	360-407-6344	charles.hoffman@ecy.wa.gov
Hazardous Waste & Toxics Reduction/ Darin Rice	Christa Colouzis	NWRO	425-649-7181	christa.colouzis@ecy.wa.gov
Manchester Environmental Laboratory/ Alan Rue	Christina Frans	Manchester	360-871-8829	frans.christina@ecy.wa.gov
Laboratory Accreditation/ Rebecca Wood	Rebecca Wood	Manchester	360-871-8844	rebecca.wood@ecy.wa.gov
Nuclear Waste/ Stephanie Schleif	Jerry Yokel	Richland	509-827-7186	jyok461@ecy.wa.gov
Shorelands and Environmental Assistance/ Joenne McGerr	Amy Yahnke	НQ	360-407-6527	amy.yahnke@ecy.wa.gov
Spills/ Dale Jensen	Geoff Baran	HQ	360-790-9725	geoff.baran@ecy.wa.gov
Toxics Cleanup/ Rebecca Lawson	Leonard Machut	HQ	360-890-6381	leonard.machut@ecy.wa.gov
Solid Waste Management/ Laurie Davies	Shingo Yamazaki	HQ	360-407-7563	shingo.yamazaki@ecy.wa.gov
Water Quality/ Vince McGowan	Brandi Lubliner	HQ	360-407-7140	brandi.lubliner@ecy.wa.gov
Water Quality/ Vince McGowan	Chris Dudenhoeffer	HQ	360-407-6445	chris.dudenhoeffer@ecy.wa.gov
Water Resources/ Mary Verner	Matt Rakow	SWRO	360-407-7669	matt.rakow@ecy.wa.gov
Office of Columbia River/ Tom Tebb	Michael Callahan	OCR Ops	509-454-4270	michael.callahan@ecy.wa.gov
Office of Chehalis Basin/ Andrea McNamara	Chrissy Bailey	OCB Ops	360-407-6781	chrissy.bailey@ecy.wa.gov