MARYLAND DEPARTMENT OF THE ENVIRONMENT

QUALITY MANAGEMENT PLAN

September 2020

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APPENDICES

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ADMINISTRATIVE QMP APPROVAL

U.S. Environmental Protection Agency (EPA) policy requires that all environmental programs conducted by, or on behalf of, the EPA shall establish and implement effective quality systems to support those programs (*EPA Order 5360.1A2*, US Environmental Protection Agency, 2000a). EPA defines "quality system" as a structured and documented management system describing the quality control program assurance (QA) policies and procedures for ensuring that work processes, products or services satisfy necessary expectations or specifications. Any organizations conducting programs on the EPA's behalf must document their "quality systems" in an approved Quality Management Plan (QMP).

The following is the QMP for environmental data collected, generated and/or assessed by the Maryland Department of Environment (MDE). The purpose of this plan is to document MDE's quality systems and to provide a blueprint for how the Department plans, implements, and assesses its quality assurance systems for environmental work funded by the EPA.

The Maryland Department of the Environment is committed to providing quality data for use in environmental decision making. MDE ensures accountability for its environmental data through quality systems and meets all the commitments and applicable requirements under federal and State laws regarding quality management, quality assurance and quality controls. Although the Department is involved in a wide range of environmental protection and management activities, this Plan details quality systems currently in place with programmatic activities funded by the EPA.

This Quality Management Plan has been reviewed and approved by:

Secretary	*(signature)*	Feb. 2, 2021
Deputy Secretary	*(signature)*	Jan. 29, 2021
Assistant Secretary	*(signature)*	January 29, 2021
Assistant Secretary	*(signature)*	01/29/21
Director, Air and Radiation Administration	*(signature)*	01/29/21
Director, Water and Science Administration	*(signature)*	1/29/21
Director, Land and Materials Administration	*(signature)*	01/29/21
Director, Operational Services Administration	Thomas J. French *Digitally signed by Thomas J. French Date: 2021.01.29 17:37:46 -05'00'*	
Director, Office of Information Management & Technology	*James M Purvis*	1/29/21
Director, Office of Budget and Infrastructure Financing	*(signature)*	01/29/21
Director, Internal Audit Services	*Cierra Neville*	1/29/21
EPA Region III Approval		

<u>DEFINITION OF TERMS</u>

<u>Activity</u> - An all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

<u>Assessment</u> - The evaluation process used to measure the performance or effectiveness of a system and its elements. In this document, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection or surveillance.

<u>Audit</u> - A planned and documented investigative evaluation of an item or process to determine the adequacy and effectiveness, as well as compliance with established procedures, instructions, drawings, QAPPs, and other applicable documents. Any one type of audit (of which there are several types) does not cover the total measurement system, but rather a specific aspect (e.g. field, laboratory, or management).

<u>Corrective Action</u> - Measures taken to rectify conditions adverse to quality and accuracy, where necessary, to preclude their recurrence.

<u>Data Quality Assessment (DQA)</u> - A statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical testing, and to determine the adequacy of the data set for its intended use.

<u>Data Quality Objectives (DQO)</u> - Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQO's provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

<u>Environmental Data</u> - Any measurement or information that describes environmental processes; location or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data includes information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature.

<u>Environmental Technology</u> - A term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from the environment or prevent pollutants from entering the environment. It is usually used to refer to hardware based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

<u>Extramural Agreement</u> - A legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, State and local grants, and EPA funded interagency agreements.

<u>Process</u> - An orderly system of actions that are intended to achieve a desired end or result. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

Quality - Is defined by the expectation of the user. If a product or service meets or exceeds the stated or implied needs or expectations of the user, then it will be described as being of quality.

Quality Assurance (QA) - An integrated system of management activities that includes planning, implementation, documentation, assessment, reporting to ensure environmental data are of known and documented quality, and that the environmental technology produces the desired result.

Quality Assurance Project Plan (QAPP) - A critical, formal, planning document for a project or task, that describes in comprehensive detail how data collection and assessment activities are planned, implemented, and assessed. This document is required for all EPA funded environmental data operations. Grantees must have an EPA approved QAPP before any project implementation.

Quality Control (QC) - The overall system of technical procedures that measure the performance of a process, item, or services against defined standards to ensure that the work meets stated requirements of the customer.

QA/QC - A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The QA/QC system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA/QC.

Quality Management Plan (QMP) - A document that describes a quality assurance system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted.

Quality Review - A qualitative evaluation of all components of field, laboratory, and data management QA/QC measurement systems. The purpose of the review is to determine if the measurement systems are being used appropriately. Quality reviews may be conducted before; during or after the measurement system becomes operational. A quality review typically involves a comparison of the activities given in this plan and/or the approved sampling and analysis plan with those actually scheduled or performed. A special type of quality review is the data management review. This review addresses only data collection and management activities.

Record - A completed document that provides objective evidence of an item or process. Records may include photographs, drawings, electronic files, and other data recording media.

Self-Assessment – An annual review of a project's QAPP and related processes.

Technical Expert - A staff member who is knowledgeable in the technical discipline being audited but is not qualified as an auditor.

I. MANAGEMENT AND ORGANIZATION

A. Introduction

In 1987, the Maryland Department of the Environment was created to protect and preserve that State's air, water, and land resources and safeguard the environmental health of Maryland's citizens. Prior to that time, various programs within the Department of Health and Mental Hygiene and the Department of Natural Resources were responsible for protecting and preserving the State's environmental resources. Currently, MDE's duties primarily consist of enforcement of environmental laws and regulations and long-term planning and research. The Department also provides technical assistance to Maryland industry and communities for pollution and growth issues and responds to environmental emergencies. MDE accomplishes its mission by assessing, preventing, and controlling sources of pollution in order to protect the health and well-being of all Marylanders.

B. Mission, Vision, Values, Goals and Customers and Stakeholders

Mission
To protect and restore the environment for the health and well-being of all Marylanders

Vision
Healthy, vibrant and sustainable communities and ecosystems in Maryland

Goals
1. Service. Providing value to citizens, customers, colleagues, and communities by being responsive, inclusive respectful, and resourceful and transparent in how we operate programs and invests the public's money.

2. Science and Technology. Using science-driven regulation and policy to protect the environment more effectively and information technology to serve customers more efficiently.

3. Innovation. Embracing creativity to achieve better results, while encouraging the use of market-based and partnership-driven tools and strategies for improvements in environmental technologies, regulation, and finance.

4. Integration. Integration of air, water, land, and science programs for more effective and efficient results, and better use of ecosystem-based permitting to increase efficiency, offer better consistency and improve environmental protection.

5. Partnership. Increasing outreach and openness to broaden the range of public and private sector participants and strategies that foster better solutions through broader stakeholder involvement in environmental challenges.

6. Performance. Focusing on results and tracking outcomes to accelerate progress in how to manage for cleaner air, water, and land and to reduce risks from pollution, climate change, environmental emergencies, and other threats.

7. Employees. Cultivating and fostering a talented and diverse workforce and providing opportunities for development of professionalism, innovation, productivity, teamwork, and leadership

C. Organizational Structure

The Maryland Department of the Environment is comprised of the Office of the Secretary, Coordinating Offices, Operational Services Administration and Environmental Administrations. MDE's organizational structure is presented and briefly described and below.

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Maryland Department of the Environment
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Deputy Secretary

Suzanne Dorsey
Assistant Secretary

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Assistant Sectretary

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Terri Wilson
Director
Budget and Infrastructure Financing

- Budget Oversight
- Water Quality Financing
- Engineering and Capital Projects

George Aburn
Director
Air and Radiation Administration

- Air Quality Permits
- Air Quality Planning
- Air Quality Compliance
- Air Quality Monitoring
- Climate Change
- Mobile Sources Control
- Radiological Health
- Operational and Administrative Services

Lee Currey
Director
Water and Science Administration

- Compliance
- Wastewater Permits
- Wetlands and Waterways
- Water Supply
- Sediment, Stormwater and Dam Safety
- TMDL Technical Development
- Environmental Assessment and Standards
- Water Quality Restoration and Protection
- Field Services

Kaley Laleker
Director
Land and Materials Administration

- Lead Poisoning Prevention
- Solid Waste
- Land Restoration
- Oil Control
- Mining
- Resource Management
- Technical Services and Operations

Thomas J. French
Director
Operational Services Administration

- Human Resources
- Fiscal Services
- Procurement and Contract Management
- Central Services
- Financial Services

Updated 06/30/2020

1. <u>Office of the Secretary/Coordinating Offices</u> - provides administrative guidance and management support to the Department. The personnel consists of the Secretary of MDE, Deputy Secretary, Assistant Secretaries, Operational Services Administration, Office of Information Management and Technology, Office of Budget and Infrastructure Financing, Office of Communications, Office of Emergency Preparedness and Planning , Office of Fair Practices, Office of Internal Audit, Office of Legislative and Intergovernmental Affairs, and Senior Policy Advisors.

2. <u>Operational Services Administration </u>- provides financial and administrative support to the Department. The Administration is comprised of the Office of the Director, Human Resources, Fiscal Services Central Services, Procurement and Contracts, and Financial Monitoring.

3. <u>The Air and Radiation Management Administration</u> is responsible for improving and maintaining air quality and controlling sources of radiation. The Administration is comprised of the Office of the Director, Air Quality Planning, the Air Quality Monitoring Program, the Air Quality Compliance Program, the Air Quality Permits Program, the Mobile Sources Control Program, the Radiological Health Program, and Operational and Administration Services Program.

4. <u>The Land and Materials Administration</u> is charged with protecting human health as well as preserving and restoring land and water resources. The Administration includes the Office of the Director, the Land Restoration Program, the Lead Poisoning Prevention Program, the Oil Control Program, the Solid Waste Program, the Mining Program, the Resource Management Program, and the Technical Services and Operations Program.

5. <u>The Water and Science Administration</u> is WSA is responsible for managing Maryland's water resources. WSA has approximately 300 engineers, scientists, and natural resource professionals responsible for implementing and enforcing federal Clean and Safe Drinking Water Acts, as well as regulatory water programs established under State law. These programs ensure sustainable water quantity and quality to support human health and well-being, aquatic resources, and agricultural and industrial uses. WSA accomplishes this by: setting science-based standards; issuing legally enforceable permits and approvals; monitoring water bodies and water and wastewater systems; performing inspection and compliance activities; and responding to water pollution events and emergencies.

D. Products and Services

The Maryland Department of the Environment provides Maryland citizens, businesses, local governments, and stakeholders with the following products and services:

1. Permits and registrations to businesses and local governments for activities or sources that emit air pollution or have the potential to expose people to radiation, water, and waste operations; tidal and non-tidal wetlands permits to businesses and individuals, licenses to individuals for well drilling, wastewater treatment operators, asbestos

contractors, lead paint contractors, hazardous waste hauling, and more. The Department currently issues 89 different types of regulatory authorizations.

2. Financial assistance to local governments and businesses via loans, grants and pass through funding for restoration, cleanup, innovative technology, construction of water supply, wastewater and sewage treatment facilities, water sewerage infrastructure, sediment control and storm water management, small creek and estuary projects, abandoned mine cleanups, scrap tire cleanups, and wetland mitigation.

3. Technical assistance to local governments, businesses, State agencies, community colleges, and other entities for environmental compliance, restoration, and pollution prevention.

4. Emergency response, planning and cleanup of hazardous materials and oil spills for businesses, local governments, and citizens around the State. MDE also leads the State's emergency preparedness and response for nuclear power plant emergencies to ensure protection from unnecessary exposure to radiation.

5. Inspections of facilities and activities, and   response to citizen complaints to ensure compliance with environmental laws.

6. Education and outreach to citizens, businesses, governments, and stakeholders on environmental protection, restoration, and public health.

7. Collect environmental data resulting from various air, soil and water quality measurements for use by federal and State agencies, researchers and the public.

E. Laws and Regulations

The role and responsibilities of MDE are governed by a myriad of different regulations as well as federal and State statutes implemented to protect and preserve the State's air, water, and land resources and safeguard the environmental health of Maryland's citizens. Federal and State environmental laws and regulations are some of the most comprehensive and complex laws enacted and require expertise in scientific, biological, chemical, legal, and financial areas. The Department also works with a variety of other federal and State laws and regulations regarding health, transportation, conservation and administration. These are as follows:

State: Annotated Code of Maryland (Environment I & II, Transportation, Natural Resources, Public Utilities, Health General, and Tax-Property Articles); Code of Maryland Regulations (Title 26 - Environment and Title 9 Labor, Licensing, and Regulation).

Federal: Clean Air Act; Clean Water Act; Resource Conservation and Recovery Act, Superfund Reauthorization Act; Safe Drinking Water Act; Toxic Substances Control Act, Emergency Planning and Community Right to Know Act; Federal Insecticide, Fungicide,

and Rodenticide Act; Oil Pollution Act; Comprehensive Environmental Response, Compensation, and Liability Act; National Environmental Policy Act; Energy Policy Act; Atomic Energy Act; Radiation Control for Health & Safety Act; Mammography Quality Standards Act ; Code of Federal Regulations (CFR) Title 40 – Protection of the Environment; 21 CFR Food and Drugs and 10 CFR Energy; United States Code (USC) Title 30 – Minerals, Land and Mining, and 42 USC – The Public Health and Welfare Act.

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II. Quality Assurance/Quality Control System and Description

A. Quality Management Plan Purpose

Environmental data is the foundation of all work at MDE. Proper quality assurance/quality control (QA/QC) enhances project planning, reducing the likelihood of duplicative and repetitive sampling, thereby reducing costs to the taxpayers. The quality of decisions made at MDE depends heavily on the quality of information used to make those decisions. Environmental data are used for setting priorities, assessing the health of our air and water, identifying potential enforcement actions, and measuring progress of clean-ups. Because data collected by MDE is frequently used for regulatory decision-making, it is critical that the data be appropriately documented, and scientifically and legally defensible. Results of poor data can negatively affect everyone. Citizens who want to swim at beaches, fish in clean water, and breathe cleaner air rely on our data being accurate and precise. Enforcement actions can only be taken against violators if the data collected is scientifically sound and legally defensible. QA/QC is essential to the functions of MDE because quality data ensures the scientific credibility of the data on which decisions are based.

This QMP has been developed to provide guidance to Senior and technical staff of MDE in the development, implementation, and assessment of QA/QC system procedures. Included in the procedures are methods used by MDE Senior Staff to assess the effectiveness of the QMP. This plan has been prepared in accordance with the EPA guidance *Requirements for Quality Management Plans (EPA QA/R-2)*, *revised March 2001.*

The Department's QA/QC operational framework is illustrated in Appendix A**.**

B. MDE's QA/QC Goals and Objectives

The goals of the MDE quality program are to:

- Ensure that all data collected and generated by or for MDE has a defined purpose and is of known and acceptable quality.
- Encourage the use of QA/QC systems and principles in the management of environmental projects.
- Facilitate the timely identification of problems and implement corrective actions.
- Identify training needs.
- Provide for continuous improvement in Departmental operations.

C. MDE's QA/QC Procedures

To carry out the Department's mission and achieve its goals, MDE relies on environmental data from a variety of sources to make decisions to protect the health of the public and the environment. To ensure that the basis of these decisions is sound, MDE's programs must have an appropriate QA/QC system in place. The QA/QC system is intended to provide

reasonable assurance that all environmental data generated and processed will be scientifically valid, of known precision and accuracy, complete, representative, comparable, and where appropriate, legally defensible. To ensure quality, MDE relies on one or more of the following procedures depending on the intended use of the final data and the degree of confidence required in the quality of the results:

1. Project Managers ensure that data generated by   or submitted to the Department is of appropriate quality for their intended use. Project Managers will conduct appropriate QA/QC planning and will be responsible for coordination of data quality issues among field, laboratory and data assessment staff.

2. EPA funded programs using or requiring the collection or assessment of environmental data will follow the requirements outlined in this QMP. A list of programs subject to MDE's QMP is included in Appendix B.

3. MDE Program Managers, with oversight by the Administration Directors, are responsible for the implementation of the Department's QA/QC requirements in EPA funded programs under their control. The Quality Manager and Quality Coordinators function as advisors to the Directors, Program Managers and other employees who have responsibility for project and program implementation.

4. All EPA funded environmental data operation require, a Quality Assurance Project Plan (QAPP) is developed in accordance with EPA guidelines. QAPPs are prepared by the originating program detailing activities under the regulatory program and contain information regarding the project and Standard Operating Procedures (SOPs). SOPs are incorporated either in full or by reference within the QAPP. QAPPs are reviewed and approved by the Project Manager before submittal to EPA.

5. The objectives for generating any new environmental data is determined prior to data collection or assessment activities so that appropriate resources and QA/QC control methods can be applied to ensure a level of data quality commensurate with the intended use(s) of the data.

6. Quality self assessments are conducted annually by staff familiar with QA/QC needs of each EPA funded program and are stored in the shared network directory.

7. The Quality Manager reviews quality self assessments prepared by programs and conducts periodic reviews of EPA funded projects to ensure they comply with MDE's QMP.

8. Standard Operating Procedures (SOPs) address QA/QC and are available to field sample collectors. They are stored with QAPPs on the shared network directory.

9. Outside laboratories performing analyses of environmental samples have acceptable QA/QC plans.
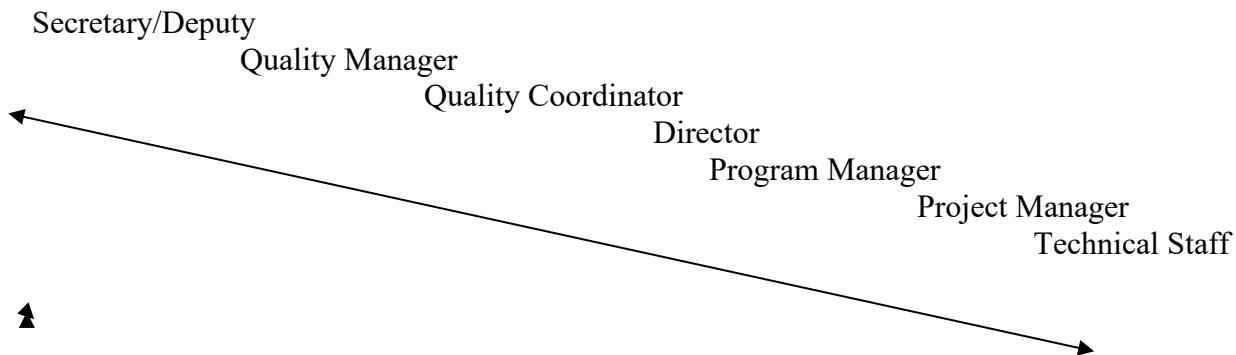
10. Project Managers prepare quality assurance/quality control language, and where necessary address specific QA/QC procedures in agreement with organizations contracted to perform data collection or assessment and other activities such as sampling, monitoring, analyses, research, inspection and enforcement, cleanups, etc. In addition, Project Managers will ensure such organizations comply with this plan.

11. Program/Project Managers verify that staff understand all applicable elements of and criteria for the QA/QC system by conducting periodic training sessions for employees, publishing the Quality Management Plan, conducting periodic reviews of the Department's QMP and the Programs' annual reports (quality self assessments), and incorporating QA/QC into job performance standards and performance appraisals.

12. Internal coordination of QA/QC is accomplished at MDE as follows:

- Quality Coordinators are appointed for each Administration. Quality Coordinators are responsible for coordinating QAPP activities within the Administration, and serve as the Quality Manager's contact for each Administration.
- Periodic QA/QC meetings are held between the Quality Manager and the Quality Coordinators.
- Technical data is shared between the Administration's QA/QC staff such as information related to laboratories, contractors, new procedures, etc.
- The QMP, QAPPs, quality self assessments and other QA/QC information are maintained on the shared QA/QC network directory.
- The Quality Manager, Quality Coordinators and QA/QC staff provide advice, guidance and suggested improvements in MDE's QA/QC system and QMP.

13. The Project Manager is responsible for ensuring that the Department's and other applicable policies and procedures including QA/QC are provided to staff. Field or laboratory manuals, Standard Operating Procedures (SOP) and QAPPs may be updated periodically. Project Managers should ensure that current versions are available for consultation and those out-of-date versions are properly archived and are not used except for historic reference.

D. MDE's Quality Organization Description

The Maryland Department of the Environment uses a decentralized approach to quality management, in that each Administration is responsible for deciding how they will specifically implement the general policies and procedures of this QMP. Any unit that collects or assesses environmental data or is involved in QA/QC issues has responsibility for ensuring data quality. This may include staff level personnel, Project Managers, Program Managers, Quality Coordinators, the Quality Manager and Senior Staff.

The Department's QA/QC management chain is illustrated below.

Secretary/Deputy
      Quality Manager
             Quality Coordinator
                    Director
                        Program Manager
                              Project Manager
                                  Technical Staff

Program Managers supervise Project Managers who are responsible for ensuring general QA/QC quality requirements and project specific commitments are met on EPA funded programs. Project Managers directly oversee field, laboratory and analytical staff who are responsible for the implementation of QA/QC processes related to data collection and assessment. Project Managers supervise technical staff collecting or assessing environmental data or meeting specific project commitments.

Questions and disputes regarding QA/QC system requirements, QA/QC procedures, assessments, or corrective actions are to be elevated through the Program Manager and, if necessary, to the Administration's Director and Quality Coordinators.

E. Roles and Responsibilities

Senior Staff – Consist of the MDE Secretary, Deputy Secretary, Assistant Secretaries, Directors of Administrations, Directors of Coordinating Offices, and other administrators. The Secretary or his designee provides final approval of a Quality Management Plan. Senior Staff also plays a key role in verifying that MDE's QMP is developed, implemented, and improved. Each Director is accountable to the Secretary for ensuring specific QA/QC policies, processes, procedures, assessments, training, documentation and improvements are carried out in conjunction with State and federal laws and policies, and grant commitments. Senior Staff is ultimately responsible for ensuring information generated and/or collected is appropriate for its intended uses.

Program Managers - Supervise Project Managers and are responsible for ensuring that the Department's QMP is complied with for EPA funded programs. Program Managers/Division Chiefs role includes, but is not limited to:

1. Confirm information generated or collected is appropriate for its intended use.
2. Ensure Project Managers develop QAPPs for EPA funded programs.
3. Review and approve QAPPs prepared by MDE Project Managers.
3. Coordinate technical and data quality issues with appropriate personnel such as field staff and laboratory staff.
4. Verify quality self assessments are completed in a timely manner.

5. Ensure corrective actions are developed, and then implemented for deficiencies discovered during the conduct of quality self assessments or quality reviews.
6. Confirm that EPA funded projects managed by organizations on behalf of MDE have contractual language specifying the requirement for preparation of a QAPP and completion of an annual self-assessment.
7. Assist contractors, grant recipients and the regulated community with the preparation of QAPPs.
8. Provide recommendations to the Quality Manager for improvements in the Department's QMP or quality controls.

Project Managers - Are responsible for assigning tasks to technical staff, supervising technical staff in the collection or assessment of environmental data; ensuring specific project commitments are met for collection of environmental data; planning, following, implementing, assessing or improving QA/QC procedures and overseeing the management of environmental data. The responsibilities of this position include, but are not limited to:

1. Understanding and complying with the QMP.
2. Preparing the QAPP for EPA funded programs.
3. Ensuring staff have access to and understand the QMP, QAPP, project plan and applicable SOPs.
4. Confirming all equipment and supplies are checked in advance of field operations.
5. Ensuring that samples are properly collected, preserved, labeled, packaged, and shipped.
6. Verifying that all field data are carefully recorded and preserved according to the QAPP.
7. Complying with and ensuring technical staff is complying with the QA/QC management chain, QAPP and SOPs.
8. Completing annual quality self assessment and maintaining it for future reference.

Technical Staff - Responsible for collecting or assessing environmental data; meeting specific project commitments for collecting data; following or implementing QA/QC procedures and assisting the Project Manager in the management of environmental data. The responsibilities of this position include, but are not limited to:

1. Understanding and complying with the QMP.
2. Complying with the QAPP and project plan.
3. Following the QA/QC management chain and SOP's as required.
4. Checking all equipment and supplies in advance of field operations.
5. Ensuring that samples are properly collected, preserved, labeled, packaged, and shipped.
6. Ensuring that all field data are carefully recorded and preserved according to the QAPP.
7. Assisting the Project Manager in completing annual quality Self Assessment and maintaining it for future reference.

Quality Manager - The responsibilities of the Quality Manager have been given to the Director of Internal Audit and are supported by the Quality Coordinators from each Administration. The Director of Internal Audit reports directly to the Secretary and is responsible for overall oversight and coordination of QA/QC activities, maintaining and updating the QMP and verifying compliance with the QMP.

The Quality Manager function is independent of programs and staff that generate, compile and evaluate environmental data. However, the Quality Manager helps each administration develop, implement, and oversee the QA/QC system but does not directly participate in data collection or assessment. In addition, the role of this function includes, but is not limited to:

1. Assist Senior Staff in numerous areas throughout the Department including oversight of: quality management planning, improvements, and training; and efforts to improve operational performance in such areas as, data management and quality control.
2. Make recommendations to the Secretary or designee as to changes in policy with regard to the QMP or quality controls.
3. Periodically review with the Quality Coordinators and Program/Project Managers the Department's QMP and recommend specific improvements to the Plan, if warranted.
4. Ensure the QMP is reviewed, approved and signed by Senior Staff and forwarded to EPA Region III every five years for approval.
5. Ensure any changes made to the QMP within the five-year time frame will be forwarded to EPA Region III for approval.
6. Communicate changes to the QMP to appropriate MDE staff as required.
7. Coordinate completion of annual quality self assessment by programs. This includes, developing a schedule for quality self assessments, updating the checklist for the quality self assessments, and maintaining the quality calendar.
8. Review quality self assessments to   identify improvements or areas of concern regarding QAPPs or quality controls.
9. Discuss results of reviewed quality self assessments with the appropriate management in each Administration.
10. Follow up on any findings or issues related to QAPPs or quality controls to ensure adequate corrective action has been taken.
11. Perform periodic quality reviews to ensure EPA funded programs comply with QMP.
12. Coordinate or assist Administration's in providing periodic quality training to QA/QC staff.
13. Maintain the shared QA/QC network directory.

Quality Coordinators - One or more point persons from each of the Department's following five Administrations: Office of the Secretary/Coordinating Offices, Air and Radiation Management Administration, Land and Materials Administration and Water and Science Administration. The role of the Quality Coordinator is to:

1. Work with the Department's Quality Manager and Program/Project Managers to ensure the QMP is implemented throughout the agency.
2. Participate in a technical exchange of information among administrations/units.
3. Assist in preparing the Department's QMP.
4. Provide assistance to Program/Project Managers in the development of QAPPs and completion of quality self assessments.
5. Assist the Program/Project Managers in drafting a response to findings noted in quality reviews.

6. Assist the Program/Project Managers in maintaining an inventory of all projects that require a QAPP and projects that are exempted.
7. Ensure that QAPP's and quality self assessments are maintained in the shared QA/QC network directory.

F. Tools Used in the QA/QC System

1. <u>Agency Performance Evaluation</u>:

   ● <u>Managing For Results</u> - Maryland's MFR is a strategic planning, performance measurement, and budgeting process that emphasizes use of resources to achieve measurable results, accountability, efficiency, and continuous improvement in State government programs. It is the key component of the State's customer-focused management model which encompasses budgeting, Continuous Quality Improvement, and Employee Performance Planning and Evaluation. Agency MFR details are available online from budget books prepared by the Department of Budget and Management.

   ● <u>BayStat </u>- This is an interagency program designed to assess, coordinate, and target Maryland's Bay restoration programs, and to inform the citizens of Maryland on progress. BayStat was created by executive order in 2007 and it is comprised of Secretaries from the Departments of Agriculture, Environment, Natural Resources, Planning, Transportation, scientists from the University of Maryland, and representatives from the Governor's Office.

   ● <u>Appreciative Inquiry</u> - This strategic management initiative aims to improve agency-wide performance by identifying what works well, analyzing why, and doing more of it. During this process, a broad cross-section of staff members such as permit writers, engineers, and field inspectors are asked to contribute feedback. Ideally, the information obtained during the "discover" process is used to deliver sustainable organizational initiatives going forward.

2. <u>Interstate Agencies</u> – The following regional partners work collectively with MDE on a variety of environmental issues: The Mid-Atlantic Region Air Management Association, New England States for Coordinated Air Use Management, Appalachian States Low-Level Radioactive Waste Commission, Mining Compact Commission, Oil and Gas Compact Commission, Ozone Transport Commission, Interstate Commission on the Potomac River Basin, and Susquehanna River Basin Commission.

3. <u>Advisory Boards, Commissions, Councils, Committees and Task Forces</u> - A number of advisory groups provide advice to the Department on specific policy and program issues. These groups include Air Quality Control Advisory Council, Bay Restoration Fund Advisory Committee, Board of Environmental Health Specialists, Board of Waterworks and Waste Systems Operators, Board of Well Drillers, Maryland Climate Change Commission, Controlled Hazardous Substance Advisory Council, Environmental Boards,

Lead Poisoning Prevention Commission, Critical Area Commission for the Chesapeake and Atlantic Coastal Bays, Maryland Green Building Council, Pesticide Advisory Committee, Scenic and Wild Rivers Review Board, Land Reclamation Committee, State Soil Conservation Committee, and the Radiation Control Advisory Board.

4. <u>MDE Environmental Management System (EMS)</u> – This effort was established September 2008. The EMS team is comprised of staff from each Administration and is responsible for identifying applicable environmental regulatory requirements and other environmental aspects of the Department's operations that have an influence on the environment. This commitment to environmental protection and restoration aims to meet or exceed relevant environmental laws, regulations, and other requirements.

5. <u>MDE's Annual Quality Self Assessment Process</u> - EPA funded programs that are required to implement a QAPP must perform an annual quality self assessment. Self assessment is a standardized process where programs in each Administration review their specific QAPP to determine if they are meeting State and federal requirements and grant commitments. An annual report of this assessment process is submitted to the Quality Manager and includes a standard structure for assessment, response, and improvement or corrective actions in accordance with the Department's QMP.

6. <u>Quality Assurance Project Plans (QAPPs)</u> - All environmental data collection and assessment activities conducted by MDE or one of its subcontractors for EPA funded programs that require a QAPP. All QAPPs must be developed as specified in *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* (EPA 2001).

7. <u>Data Quality Objectives (DQOs)</u> - DQOs are qualitative and quantitative statements of a study's technical and quality objectives that define the appropriate type of data and specify tolerable levels of potential decision errors. DQOs will be established and documented prior to data collection and/or assessment activities, following the guidance provided in *Guidance for the Data Quality Objectives Process* (US Environmental Protection Agency, 2006b) and *Data Quality Assessment: A Reviewer's Guide* (US Environmental Protection Agency, 2006c) and *Data Quality Assessment: Statistical Methods for Practitioners* (EPA, 2006d).

8. <u>Standard Operating Procedures (SOPs)</u> - These documents describe approved procedures for performing certain routine or repetitive tasks. SOPs are necessary to ensure comparability among activities performed on different occasions or by different individuals.

9. <u>Management System Reviews</u>. MDE's Quality Manager reviews the annual quality self assessments and also conducts periodic assessments of EPA funded programs, if deemed necessary, to ensure conformance with MDE's QMP. These assessments will be conducted in accordance with *EPA QA/G-3: Guidance for the Management System Review Process*.

10. <u>Corrective Action Plans (CAP)</u> – These plans are developed to address findings or deficiencies identified in Management System Reviews. CAPs are reviewed by the Program Manager and Quality Manager to ensure that it adequately resolves the noted deficiency.

11. <u>QA/QC Shared Directory</u> – This is an electronic shared directory which is used to maintain information related to MDE's QMP, QAPPs, quality self assessments and other key QA/QC information. The directory is housed on MDE's internal network, and is accessible to Senior Management and Quality Coordinators. The Quality Manager is responsible for maintaining the shared QA/QC network directory.

12. <u>Program Meetings</u> - All MDE programs have scheduled meetings at which QA/QC issues may be discussed including regular staff meetings at Project, Program or Administration level, meetings with Principal Investigators or contractors, MDE-sponsored meetings, symposiums or presentations.

13. <u>Newsletter/Reports</u> - Periodic newsletters such as the Heron and reports such as the Annual Enforcement and Compliance Report; State of Maryland's Comprehensive Water Monitoring Strategy; and Asbestos 101 are published and may contain QA/QC related issues.

14. <u>Employee Performance Planning and Evaluation (PEP)</u> - Statewide evaluation of employee performance is a regularly scheduled component of the State's performance-based pay system. This regularly scheduled process requires a self-evaluation and that of the immediate supervisor, whereby relevant issues involving environmental data collection, training needs, assessment, analysis and communications may be addressed.

15. <u>Other Tools</u> - The Quality Manager will make available general information from the U.S. EPA, the Governor's Quality Council, and other organizations that can provide valuable insight into managing quality and quality improvement. Information will be available via MDE's Intranet, the Internet, and during the feedback process of the Department's annual review.

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III. Personnel and Training

A. Personnel Requirements and Responsibilities

1. The Maryland Department of the Environment is required by law to ensure that its personnel operation complies with the pertinent law, rules and regulations governing the State Personnel Management System. The State Personnel Management System is governed by the State Personnel and Pensions Article that was enacted by Chapter 10 in 1993 and Chapter 6 in 1994 of the Annotated Code of the Public General Laws of Maryland.

2. In the State Personnel Management System, the Secretary of the Department of Budget and Management (DBM) establishes classes, rates of pay, ensures that each position within a class has similar duties and the general qualifications. DBM has delegated responsibility for the selection of eligible candidates to MDE.

3. MDE's Office of Human Resources (OHR) is responsible for evaluating position descriptions based on established job standards, determining appropriate classification and salary grade level of all positions, certifying eligible candidates based on levels of education and experience, and overseeing MDE's Employee Appraisal (PEP) process.

B. Staff Requirements and Employee Selection

1. MDE staff working in environmental programs must be qualified to perform the assigned work, according to project-specific requirements. Some staff have unique qualifications or classifications unique to the Department such as Environmental Compliance Specialists; Environmental Enforcement Inspectors; Environmental Specialists; Geologists I – III, Lead/Advanced and Supervisor - Environmental Programs; HazMat Emergency Response Officer I – II and Lead; HazMat Emergency Response Supervisor; Health Physicist Trainee, I – III and Supervisor; Natural Resources Planners I –V; Nursing Program Consultant Administrator I – IV; Meteorologist I – III and Senior; Principle Geologist; Regulatory and Compliance Engineer I – III, Advanced/Senior and Supervisor; and Sanitarian - Registered I –VI. Employees are certified as eligible for the above classifications based on education, experience, training and/or certifications criteria.

2. Employee selections are made from lists of individuals that have been certified by either the DBM Office of Personnel Services and Benefits, or OHR. When a candidate is selected for a position, references from past employers and credentials (e.g., degrees) are verified by the employing Administration and/or OHR in accordance with the Code of Maryland Regulations 17.04.03.10C, Background Investigations.

C. Training Development

As a regulatory and enforcement agent for environmental and health issues, MDE is mandated by federal and State regulations to provide specific training that is technical in

nature in order for employees to be qualified to perform the duties of their assigned jobs. Each Administration is responsible for identifying the training needs including quality related issues of its employees taking into consideration the technical proficiency of staff and new or modified requirements. OHR assists the Administrations in determining those areas of training improvements/course implementation that will provide employees an opportunity to further their education, develop specific job skills, and to participate in various employee development activities that will allow them to be more effective in carrying out the mission of the Department. Training offered by OHR for employees must comply with the State Personnel and Pensions Article Title 10 which describes the processes that govern training operations.

D. Training Activities

Training needs are met with on-the-job training and other formal training opportunities offered by federal or State agencies and/or private groups. For instance, MDE staff members can participate in events such as Inspector and Permit Writer forums, meetings organized by the Northeast Environmental Enforcement Project (NEEP), and the recently formed in-house Leadership Development program. These events provide staff with access to industry-wide best practices and the latest technical resources. Also, QA/QC training programs may be offered through additional resources such as colleges and universities, U.S. Department of Agriculture Graduate School, the EPA, NOAA, and scientific organizations such as the Smithsonian Institution.

E. Identifying the Need for Retraining

The work product review process also provides managers with the opportunity to identify any new training or retraining needs employees may have. Work that is less than adequate can be used as a strong indicator that additional employee training or retraining is necessary. Each Program monitors and tracks training provided to staff.

F. Employee Appraisal Process

The Performance Planning and Evaluation (PEP) process is an effective mechanism for documenting individual employee performance plans and maintaining records for levels of performance. This process is based on the essential duties of the job and performance standards identified as acceptable for satisfactory performance, including identified training needs.

Semiannually, staff member's performance, proficiency, and training needs (including QA/QC needs), are reviewed and evaluated by supervisors. Training needs are evaluated by OHR to determine training programs to be developed or contracted.

MDE staff with specific QA/QC duties such as field and laboratory staff, Project Managers, Program Managers, Quality Coordinators and the Quality Manager have language included in their MS-22 (position description and performance standards form) that describes the QA/QC responsibilities for each position.

G. QA/QC Staff Required Knowledge

Individuals responsible for the management of the Department's QA/QC system, such as the Program/Project Managers, Quality Coordinators and the Quality Manager must be knowledgeable of EPA Quality System Requirements for Environmental Programs and the Management System Review Process. Staff uses EPA Guidance Documents: *QA/R-1: EPA Quality System Requirements for Environmental Programs* Guidance Document and the *QA/G-3: Guidance for the Management Systems Review Process,* March 2003 (EPA/240/R-03/002).

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IV. Procurement of Items and Services

A. State Procurement Law

The Board of Public Works (BPW) comprises the Governor, Treasurer, and Comptroller. The Board has authority over procurement by most State agencies (including the direct review and approval of most State contracts exceeding $200,000, $100,000 for Sole Source contracts or $100,000 for single bid contracts) in accordance with the State Financial Procurement Article of the Annotated Code of the Public General Laws of Maryland; adopts regulations (COMAR Title 21); sets procurement policy; and establishes internal operational procedures. Board operations are directed by the Executive Secretary with the Board's Procurement Advisor and General Counsel serving statutorily delineated duties.

> The control agency, the Department of General Services, is now the sole control agency for procurement of commodities, services, and IT, up to $200,000. DGS has delegated authority up to $50,000 to MDE for the procurement of items within their respective area of authority. If the desired procurement is greater than $50,000, MDE must submit a request to procure to DGS for a detailed review and approval. Procurements that exceed $200,000 (or $100,000 for Sole Source contracts and $100,000 single bid contracts) must also be approved by the BPW.

MDE Contracts are reviewed and approved by MDE's Attorney General for legal sufficiency and shall contain at a minimum:

- Specific items or duties to be procured
- Reference all parties involved
- Beginning and ending dates
- Dated authorized signatures from both parties,
- Detailed description of the use of funds
- List CFDA# if federally funded and attach federal award conditions
- Maximum dollar amount to be paid to the Contractor
  - Specify payment arrangements
  - Contractor's Address
  - Required supporting documentation (ie. maps, charts, and other attachments)

> In accordance with these regulations, the Department ensures that all extramural agreements involving or affecting environmental activities address QA/QC requirements. This is an integral item in the evaluation criteria of applicable procurement documents and final agreements. Program/Project Managers are responsible for reviewing extramural agreements to ensure all technical requirements are met. In addition, extramural agreements are reviewed by the Office of the Maryland Attorney General, the Director of Operational Services Administration, and the Office of Procurement to confirm their completeness, accuracy, and that they satisfy all requirements (i.e. grant provisions, laws, policies, etc.).

B. Procurement Evaluation/Selection Process

The purchase of services or materials from an established budget plan often is required to achieve project objectives. A procurement solicitation includes specifications that will meet the needs of the project, selection criteria, and may include QA/QC and other certification requirements from a vendor.

The Office of Procurement is available to assist any Administration that is navigating through the procurement process to ensure that State procurement laws are followed. A solicitation for bid package is developed by the Office of Procurement in conjunction with the Program/Project Manager. When responses are received from vendors, the proposals are reviewed by a selection team consisting of appropriate program staff and the Office of Procurement. The team is selected by the Office of Procurement to ensure that members have sufficient expertise in the subject matter to render a competent and relevant evaluation of the proposals. The evaluation takes into consideration the following:

- Has the vendor met the specifications, including QA/QC?
- Does the vendor meet the minimum qualifications?
- Has the vendor documented acceptable QA/QC criteria that meet EPA requirements? This should be specific and related to the procurement. It also may be a warranty if it is an equipment purchase, or include detailed lab QA/QC documents.

The proposals that meet the above requirements will be evaluated according to the criteria outlined in the solicitation and a successful vendor will be selected. Adequate documentation of the procurement process shall be maintained by the procuring office through the contract period and in accordance with the Department's record retention schedule. Once a selection has been made by the team, the Office of Procurement prepares a recommendation for review and concurrence by the Director of Operational Services Administration.

C. Contracts, MOU's and Grants

Organizations or individuals contracted by MDE to perform environmental data collection or assessment are required to follow specified QA/QC protocols. These requirements are specified in the agreement within the Scope of Work and should also be described in detail in the QAPP. Some contracts, memoranda of understanding (MOU) and grants may include QA/QC-specific language. In all instances, an approved QAPP includes data quality standards and specifications.

Upon receipt of purchased items, the Project Manager or other designated technical staff inspects the item for adherence to the standards and specifications required by the agreement and QAPP. The Project Manager is responsible for ensuring that vendors comply with the agreement provisions including QA/QC standards and specifications.

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V. Documents and Records

A. Record Retention Policy

MDE's Record Retention Policy and Procedure ensures a continual, economical, efficient and secure records management program consistent with State regulations (COMAR 14.18.02 - records and retention schedule), Department of General Services' Records Management Procedures (*DGS-RM-5 re: transfer of records; DGS-RM-2 re: disposal of records*) and State law (State Government Article, Title 10-633). For some environmental data collection efforts funded by EPA, documentation requirements may be defined through federal statute (e.g., Clean Water Act §305(b)-State water quality report), EPA regulation (e.g., Quality Assurance Project Plan) or under EPA guidance.

B. Accessibility, Protection and Retention

Virtually all of the Department's activities are documented through some form of electronic media or paperwork. Files needed for current tasks are maintained by each Administration. Program/Project Managers are responsible for ensuring that filing practices conform to the Department's Records Retention and Disposal Schedule. MDE's Records Retention and Disposal Schedule identifies and describes the Department's records and indicates when they shall be disposed of or directs their permanent retention.

The Program/Project Manager is responsible for managing all project level quality-related documents and records, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documents, disposal and disposition.

Current documents and records are stored in the areas of the Administration Program to ensure that responsible personnel have convenient access to the material and that they are protected from damage and deterioration. The Program/Project Manager is responsible for managing the custody and confidentiality of evidentiary quality-related documents and records in accordance with applicable regulations. Central Services staff and resources are available to assist each Administration in the management of these documents.

A State Records Center for non-current records provides a secure, clean and humidity-temperature controlled storage space and reference service for records transferred to its custody. Generally, MDE's permanent records are eventually stored at the Maryland State Archives. Also, an agency-wide initiative is currently underway to digitize all paper files and establish a comprehensive repository on the Department's network.

C. Identify Documents Requiring Control

The Project Manager, as part of the preparation of the QAPP, identifies quality-related documents and records that require control. The QA Coordinator, as part of their QAPP

review, may further expand the list of documents requiring control. All documents requiring control are listed in the QAPP.

D. Conformance Review and Approval

Documents and records prepared as part of quality system requirements and listed in an approved QAPP as requiring control are subject to a systematic procedure to ensure they accurately reflect completed work and conform to all technical requirements. The Project Manager is responsible for ensuring that records and documents accurately reflect completed work.

The QAPP indicates the names of individuals authorized to prepare, use, issue, authenticate, review, revise and approve such documents.

E. Ensuring Legal Compliance

The Project Manager is responsible for ensuring that the non-financial, substantive aspects of work are, and remain in, compliance with applicable statutory, regulatory and MDE policies requirements for documents and records.

F. Confidentiality Procedures

The QAPP describes confidentiality procedures to be used when a project involves the assessment, aggregation, management, and analysis of sensitive data, and specifies the types of documentation to be maintained in association with data sensitivity, if appropriate.

G. Record Access

Public access to documents and records of the Department is controlled under the General Provisions Articles 4-101 through 4-601 entitled Maryland's Public Information Act (PIA). The PIA law grants the public a broad right of access to public records while protecting legitimate governmental interests and the privacy of rights of individual citizens. A public record is defined as the original or copy of any documentary material in any form and includes the following:

Written materials	Books
Photographs	Photocopies
Films	Microfilms
Records	Tapes
Computerized records	Maps/Drawings

Anyone may request public documents. However, certain records are privileged by law and must be withheld because of their confidentiality. These records may include investigation records and inter/intra-agency memoranda and letters. The Department's Office of the Attorney General provides guidance on confidentiality procedures on a case-by-case basis. Details of any required confidentiality process is detailed in the QAPP.

More details on the Public Information Act and access to MDE records can be found at
http://www.mde.maryland.gov/CitizensInfoCenter/PublicInfoAct

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VI. Computer Hardware and Software

A. Information Technology Policies

MDE's Office of Information Management and Technology (OIMT) is responsible for managing the direction and application of MDE's Information Technology. MDE has established an Executive Steering Committee (ESC) chaired by the MDE Chief Information Officer and comprised of senior management from the Office of the Secretary and the Administration Directors and Deputy Directors. The mission of the ESC is to provide oversight, direction and budget approval for the Department's IT initiatives.

MDE has a Memo of Understanding with Maryland's Department of Information Technology (DoIT) for operational support. DoIT provides End User Hardware Services which includes standard computing hardware equipment leveraging statewide discount pricing. DoIT service prices are based on a 5-year refresh of all endpoints of End User Hardware Service customers. Actual hardware decisions will be made by DoIT based on the demonstrated business needs of the users.

B. Roles and Responsibilities

1. <u>Executive Steering Committee</u> - Provides oversight, direction and Budget approval for IT initiatives.

2. <u>OIMT</u> - Sets standards for computer hardware and software and reviews all purchases for hardware and software according to the criteria described in sections C, D and E below.

3. <u>Administration Program Managers and Budget Officers</u> – Review all purchases for hardware and software based on the established standards as described in sections C, D and E below.

C. Computer Hardware Technical Requirements and Quality Expectations

MDE ensures that computer hardware used in environmental and financial programs meets technical requirements and quality expectations through the following processes.

1. OIMT has established standards for computer hardware purchases. These standards are evaluated at least twice annually and specify industry standard business class machines. These standards are published on the Department's Intranet and provided to agency personnel who are responsible for purchasing computer hardware. No computer hardware can be purchased that does not meet the standards except under special exemption granted by the Department's Chief Information Officer (CIO.)

2. OIMT has established an approval path through the State of Maryland's Financial Management Information System (FMIS) for all IT related hardware purchases. Any

purchase of IT equipment must have the approval of OIMT. OIMT evaluates each purchase based on the following criteria:

- Does the product meet the Department's computer hardware standards?
- Does the product have specific technical standards (other than MDE standards), and if so, is there appropriate technical justification?
- Do the technical specifications require equipment to meet certain or specific test methods?
- Is there compatibility issues associated with the product?
- Are there any State or federal standards that must be met?
- Are there any sole-source requirements that must be met? If so, does adequate justification exist for such requirements?
- Is the projected cost of the product reasonable? (For example does it reflect a fair market value?)
- Does the procurement reflect adequate timelines for delivery?
- Does MDE need to request a demonstration or test by the manufacturer?

3. Prior to the initial use or any modification being made to the hardware configurations, the configurations are tested to ensure that the required technical and quality objectives of the environmental program are met.

D. Development and Testing of Computer Software and Evaluation for User Requirements

MDE ensures that computer software used in environmental or financial programs meets technical requirements and quality expectations through the following processes:

1. OIMT has established standards for personal computer (PC) operating systems, office automation software products, and other commonly used desktop applications to ensure that compatibility within the organization is not an issue and that quality is maintained. These standards are published on the Department's Intranet and made available to agency personnel who are responsible for purchasing computer software. No PC software can be purchased without the approval of OIMT via the methods described in Section C above.

2. OIMT also sets recommended standards for other types of software including database software, particularly where data integration is a key factor. These standards are based on departmental goals and objectives, technology performance, and compatibility issues (among State, federal, local, or business counterparts).

3. OIMT has established an approval path through FMIS for any software purchase or development effort. Any such purchase must have the approval of OIMT. Programs are required to document and justify any needs and testing requirements for specialized software. OIMT conducts a quality review based on the following criteria:

- Does the product meet the Department's needs and industry standards?

- Does the product have specific technical standards (other than MDE standards), and if so, is there appropriate technical justification?
- Do the technical specifications require software to meet certain or specific test methods, etc.?
- Is there compatibility issues associated with the product?
- Are there any State or federal standards that must be met?
- Are there any sole-source requirements that must be met? If so, does adequate justification exist for such requirements?
- Is the projected cost of the product reasonable? (For example does it reflect a fair market value?)
- Does the procurement reflect adequate timelines for delivery?
- Does MDE need to request a demonstration or test by the manufacturer?

4. Prior to the initial use or any modifications being made to the software configurations, the configurations are tested to ensure that the required technical and quality objectives of the environmental program are met.

E. IT Procurement

Delegated procurements under the control agencies of the Departments of General Services, Budget and Management, and Information Technology were moved under the delegated control of the Department of General Services Office of State Procurement. All of Maryland's procurement functions go through the Office of State Procurement.

State procurement has been consolidated in the Department of General Services. DoIT serves in its role as a policymaking and control authority over State IT procurements. MDE works closely with DoIT to ensure computer hardware and software meet the technical requirements and quality objectives.

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VII. Evaluation Process for New or Modified Projects

A. Consideration of a New or Modified Project

All environmental projects, especially those which require gathering ambient monitoring data, must have a clear purpose for their existence, have established scientific operating procedures, and report on findings at the completion of the project. Each Administration within the Department evaluates requests for new or modified environmental data projects based on the regulatory or customer's need and technical or scientific requirements and capabilities. Projects with no current regulatory requirement, no accepted scientific method for conducting measurements, unfunded or expensive equipment requirements, or which relate to a very small or localized concern will be undertaken only if absolutely necessary.

The planning phase for a new or modified project is carried out under MDE's Managing for Results (MFR) strategic planning process. For EPA funded programs, the planning process for a new or modified project might occur at any time throughout the year when MDE and EPA Region III meet to discuss regulatory matters.

B. Evaluation and Approval Process

Program Managers evaluate the specific requirements for any proposed (new or modified) environmental projects. This process includes: reviewing issues related to funding; determining the personnel, equipment, and support necessary; evaluating IT needs; identifying QA/QC requirements; and establishing the scope and content of the interim and final product desired.

This process also includes identifying customers and their needs and expectations, and determining both the technical and quality goals to meet these needs and expectations. The criteria for determining the acceptance of the product or service and any performance measures for interim and/or final evaluations must also be specified. Significant performance measures are documented in the MFR work plan.

Program Managers provide a summary of the results of this evaluation to the Administration Director. Based on this information, the Director makes a determination as to whether the project is viable based on need, existing or proposed funding, and priority when compared to existing projects and goals or other proposed projects. Both the Program Manager's evaluation of the program and the Director's review and decision are documented.

All projects with an IT component must be approved the MDE's CIO.

C. Planning Process

When a new or modified environmental project is approved, a Project Manager and, if necessary, technical staff, are assigned to manage the technical aspects of the project. The

Project Managers should involve all personnel in the planning process that will have a role, in or contribute to, the successful completion and quality of the project.

The Project Manager also gives careful consideration to the following areas:

- An environmental assessment of the program's Strengths, Weaknesses, Opportunities, and Threats (SWOT).
- A customer/stakeholder needs and expectation assessment and/or involvement by the public through MDE's public participation processes.
- A survey of personnel needs including job classification, training or certification, and whether the positions are new or reallocated from other duties.
- A survey of equipment needs including new technology, availability and cost (replacement, repair and operation).
- A survey of support services needed including laboratory, IT, QA/QC and data reports or presentations.

At the beginning of any environmental data collection or assessment activity, the Project Manager initiates the development of Data Quality Objectives (DQO) for the project. DQOs describe the project's technical and quality objectives which define the appropriate type of data and specify acceptable levels of data capture and tolerable levels of error. The Project Manager identifies a clear, intended use of the data, time and resource constraints, and the required data quality. This process requires effective communication between the Project Manager, appropriate field and laboratory technical staff and data users. The Project Manager may consult with other technical staff or advisors on complex technical DQO issues. Data quality indicators such as precision, accuracy, and comparability may become elements of the DQOs.

QAPPs are prepared by the Project Manager and reviewed by the Program Manager. QAPP's must also be submitted to the appropriate EPA office for review and approval. QAPPs provide a roadmap of the project and describe in detail the background, goals (DQOs), procedures (directly or referenced by SOPs including chain of custody and confidentiality), and assessment and reporting requirements. These comprehensive plans include the QA/QC aspects of data analyses and assessment procedures to be used.

EPA Order 5360.1 A2 defines secondary data as information data that is collected for other purposes or from other sources, such as literature, industry surveys, compilations from computerized databases and the results from computerized or mathematical models or environmental processes and conditions. The Project Manager is responsible for ensuring that the issue of secondary data is addressed in a project-specific QAPP. A project-specific QAPP is also required for those projects which involve only the compiling and use of secondary data. Per the graded approach, the level of detail for this type of QAPP will likely be less than for a project that includes the direct generation of environmental data.

Environmental projects must be fully examined and documented. This process includes, identifying new SOPs to be developed or changes to existing SOPs to be implemented,

evaluating training needs, determining supplies or services to be contracted, and establishing QA/QC or reporting requirements to be addressed.

Additional information related to project planning is reference in "EPA QA/G-4 (EPA 2000): Guidance for Data Quality Objectives Process" located at http://www.epa.gov/quality/dqos.html and "EPA QA/G-6: Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents March 2001, EPA/240/B-01/004" located at http://www.epa.gov/quality/sops.html.

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VIII. Work Plan Implementation

A. Roles and Responsibilities

1. <u>Program Managers</u> - Overall responsibility for environmental operations as it relates to quality management to ensure that the QMP is followed and the applicable provisions of the QAPP are met. The QAPP is reviewed to ensure that EPA's Data Quality Objective's (DQO) requirements (or equivalent requirements) were implemented as follows:

   - Sampling or project design is documented to ensure that data of the appropriate type, quality, and quantity are generated to support its intended uses, defensibility, and any needed decisions.

   - Project Managers evaluate the project's performance and determine changes needed to meet the QAPP goals including the approved project plan.

2. <u>Project Managers</u> - Responsible for preparing the QAPP, assuring that EPA requirements are satisfactorily addressed. Project Managers are responsible for day-to-day operation of environmental projects which include but are not limited to:

   - Assigning staff tasks related to data collection or assessment to accomplish project objectives.
   - Conducting or supervising field sampling.
   - Overseeing environmental technologies (e.g. monitoring equipment, remedial systems).
   - Compiling or assessing environmental data.
   - Assuring that work is performed in accordance with the QMP, QAPPs and all other applicable plans and procedures (like SOPs).
   - Assuring that data generated by, or submitted to, the Department is appropriate for the intended use. This may include evaluating scientific study design, performing adequate QA/QC planning, developing DQO's, preparing QA/QC planning documents and coordinating technical and data quality issues between field, laboratory and data assessment staff involved in the activity.

3. <u>Technical Staff</u> - Are responsible for performing assigned tasks to accomplish project objectives. During environmental data collection, technical staff ensures that the required primary, quality control, and meta-data are generated. Also, technical staff must comply with the QMP and QAPP, all applicable SOPs or other QA/QC procedures.

B. Planning Process

Project Planning includes but is not be limited to:

- Evaluating how the project or plan meets or aligns with MDE's goals under MFR.
- Establishing objectives to meet goals.

- Developing strategies to achieve objectives.
- Creating an action plan to implement the strategies.
- Identifying appropriate environmental indicators to measure outcomes.
- Identifying appropriate input and output activity measures.
- Identifying appropriate efficiency and quality measures.
- Establishing data needed to report performance of the project.
- Developing an adequate data management and reporting plan.
- Developing new or modifying existing SOPs for environmental activities when required.
- Identifying and obtaining any expertise needed to complete the environmental project.
- Establishing DQOs for the project.
- Preparing a QAPP.

QAPPs developed include the following information:

- Title page including grant number and signature of required approvals
- Table of contents page
- Project description
- Role and responsibilities
- QA/QC objectives
- Identification of customers and stakeholders
- Sampling procedures
- Custody chain of command related to sampling
- Calibration procedures
- Analytical procedures
- Data reduction, validation, and reporting procedures
- Internal quality control checks
- Performance and system audits
- Preventive maintenance or measures
- Additional required SOP's
- Corrective actions for issues identified or emergency situations
- QA/QC reporting requirements and procedures
- Appendices providing additional detailed information, if required

The requirements of a QAPP are referenced in "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)* EPA 2001" and can be found at http://www.epa.gov/quality/qapps.html

C. **Development of Standard Operating Procedures (SOPs) for Routine, Standardized or Critical Operations**

Project Managers, in conjunction with Program Managers, identify the need for the development, revision or withdrawal of SOPs for critical and/or routine technical and administrative tasks that are important in satisfying the project objectives. SOPs are developed through the consensus of those that do the repetitive tasks and the managers responsible for the completion of those tasks. SOPs are dynamic documents that are revised as needed. Revisions may be made as the result of changes in regulations, changes or

additions in instruments and equipment, or by inadequacies noted during implementation and/or audits.

While QAPPs focus on data, SOPs focus on processes and upon the steps within the processes where decisions must be made. The SOPs may be developed independently by MDE program staff or may be adopted or modified from a previously approved SOP from an appropriate standards development organization such as the USEPA, the United States Geological Survey (USGS), the United States Army Corp of Engineers and the American Society for Testing and Materials (ASTM). Examples of areas where SOP's have been implemented by Program Administration are listed below:

1. Collection of field samples
2. Submittal of samples to laboratories
3. Analysis of samples
4. Certification of laboratories
5. Project management and oversight

The following objectives are considered when developing SOPs:

1. Adequate to establish traceability of standards, instrumentation, samples, and environmental data.
2. Straightforward, so a user with basic education, experience and/or training can properly use them.
3. Complete so that the user/reader follows the directions in a systematic manner through the

 sampling, analysis, and data-handling process.
4. Consistent with sound scientific/engineering principles.
5. Consistent with current EPA and/or MDE regulations and guidelines.
6. Consistent with applicable technical specification and/or manuals.

The use of SOPs is recommended to minimize the variability in tasks that are critical to meeting project data quality objectives. An inventory of SOPs is maintained in a shared directory by each Administration and is periodically updated to ensure the list remains current. Program staff have access to the inventory of SOPs through the shared directory. The Project Manager is responsible for ensuring that current SOP's are provided to program staff, obsolete SOP's are removed from the shared network directory and that changes to SOP's are adhered to by program staff.

The items listed below will typically be addressed in a SOP. However, specific items to be addressed in a SOP are dependent on the type and purpose of the SOP. For example, a SOP for a laboratory process may address different items than a SOP for a field process.

1. General sampling design.
2. Specific sampling site selection.
3. Sampling and analytical methodology.

4.   Probes, collection devices, storage containers, and sample additives such as preservatives.
5.   Special precautions, such as holding times and protection from heat, light, reactivity, and combustibility.
6.   Federal reference, equivalent, and alternate test procedures.
7.   Instrumentation selection and use.
8.   Calibration and standardization.
9.   Preventive and remedial maintenance.
10.   Duplicate, spiked, blank samples and analysis.
11.   Quality control procedures such as inter- and intra- field laboratory activities.
12.   Documentation, sample custody, transportation, and handling procedures.
13.   Safety.
14.   Data handling and assessment procedures.
15.   Precision, accuracy, completeness, representativeness, and comparability.
16.   Service contracts.
17.   Document control.

D. Implementation Process

Implementation involves performing the actual work of a project. However, consideration of more than just completing the work must be made during the implementation process. Project work must be accomplished in a way that provides reasonable assurance that all environmental data collected and assessed is scientifically valid, of known precision and accuracy, complete, representative and comparable and, where appropriate, legally defensible. To accomplish this, an adequate QA/QC system is required that includes detailed procedures to be followed throughout the life of the environmental project. These procedures include but are not limited to:

1. Documentation of each part of the project, from planning to approval, and operation to completion, is completed in a timely manner. Such documentation must include the personnel involved in the project stage, the responsible staff at each step and the approval signatures of the responsible parties.

2. Activities, policies, and procedures common to all programs are identified by each Administration and established in SOPs to ensure consistent and uniform application between all programs. Periodic reviews are conducted to ensure SOP's are maintained on a current basis.

3. Project Managers identify procedures for routine and standardized, special, or critical operations (including field protocols) and established in SOPs to facilitate consistent and uniform implementation across the entire project. Periodic reviews are conducted to ensure SOP's are maintained on a current basis.

4. Project Managers assign and coordinate the work for specific projects in accordance with the requirements of the project plan and QAPP. Also, Project Managers organize and plan work to ensure that QA/QC requirements are met consistently.

5. Each EPA funded program periodically updates QAPPs and improvement activities associated with quality issues.

6. Project Managers evaluate the knowledge and abilities of staff involved in environmental activities on a periodic basis to determine the training required by staff members to achieve and/or maintain technical proficiency.

7. Any methods used, criteria applied or assumptions made in evaluating the needs and goals for a project plan adhere to the approved QAPP.

8. Once projects are underway, periodic reports are prepared to facilitate an on-going evaluation of the project's performance in terms of data captured; data quality before and after QA/QC; and interim trends, analyses, and comparisons. The reports contain a comparison and analysis of actual data quality as compared to established and/or approved acceptable levels.

9. Any contractor, grantee, or support facility involved in a project adheres to the SOPs established in the QAPP or equivalent therein. Operations of such contractors, grantees or support facilities are periodically reviewed and evaluated based on criteria established in provisions contained in any agreement.

10. Data from other sources is evaluated based on a technical review of procedures, techniques, training, etc., used to obtain the data. Only those data obtained by an approved technique or procedure with acceptable QA/QC policies and procedures is used for comparison or inclusion in the project reports. Each data source is evaluated individually against the approved program plan requirements including the QAPP.

11. Exceptions to a QAPP are documented in a manner that is consistent with the breadth and scope of the plan and reflects the type of environmental data management or sampling performed by a project. For example, if a QAPP is generic in nature and intended to cover all of the data management performed by a unit within the Department, it may be appropriate to document exceptions or modifications as an addendum to the QAPP, and to update the QAPP periodically. However, if a QAPP is written for a specific task such as sampling a specific environmental site or documenting changes in field notes, a memorandum to the project file and Program Manager may be preferable.

12. Project Managers maintain documentation on a current basis. In addition, documentation maintained is accurate and defensible if audited.

13. Any employee who is required to adhere to a QAPP or SOPs may suggest revisions to these documents. Proposed revisions are reviewed and approved by the Project and Program Manager. Any proposed changes to an EPA-approved QAPP are forwarded to

EPA for approval. Revised QAPP and SOP's are distributed to appropriate staff. The Project Manager maintains a historical file of QAPPs and SOPs for future reference.

14. Timely completion of each phase of a project, as well as acceptable level of performance, is part of the PEP process for each staff member involved in an environmental project.

E. Project Oversight

MDE is responsible for assuring that all of its work which involves the collection, assessment, and use of environmental data; and the design, construction, and operation of environmental technology, is performed in accordance with the QMP, QAPPs and applicable SOPs. This includes but is not limited to:

Project Managers evaluate project performance and determine changes required to meet the QAPP goals as presented in the approved scope of work. After management review, interim and final reports prepared in accordance with the requirement of the project plan are sent to the customer. These reports include descriptions of the SOPs used (at least in an abbreviated form) and the criteria used for accepting data values, and any evaluation of the project's performance and results during the period.

Administrations establish and implement procedures to meet the requirements of the QMP and are consistent with the type of data generated or used by the Administration. These procedures include but are not limited to:

- Design an adequate system of management oversight.
- Designate a Quality Coordinator to provide assistance and support to Program/Project Managers in their oversight of QA/QC for environmental operations.
- Provide adequate training to ensure that only qualified and proficient staff members participate in environmental activities.
- Apply proper methods and criteria for assessing the quality of all environmental work encompassed by the QMP.

MDE has implemented the State of Maryland's customer-focused management model which includes budgeting, Continuous Quality Improvement (CQI), and Employee Performance Planning and Evaluation (PEP). This model represents a management system review process (including data quality) and is comprised of:

- Managing for Results (MFR) – MFR comprises the budget and CQI parts of this model. It is a strategic planning, performance measurement, and budgeting process that emphasizes the use of resources to achieve measurable results, accountability, efficiency, and continuous improvement in State government programs. MFR integrates current management tools and techniques, provides direction for the future based on what is important for meeting customer needs,

and leads government to do the right thing with the best use of resources. MFR is linked to the State budget process and decision making.

- Performance, Planning and Evaluation (PEP) - PEP is a process by which supervisors and employees can come together to discuss goals, objectives, and expected performance throughout the year. This process allows the supervisor and employee to improve their communication and plan for higher levels of output from the unit or program. It allows the supervisor and employee to appraise and discuss the accomplishment of certain standards and goals.

  These management tools work in concert with each other to assist in achieving performance excellence. This dynamic model helps to establish a clear focus on addressing customer and stakeholder needs, obtaining planned results, and providing for accountability through performance measurements. These reviews are conducted at least annually and include key staff.

The Department also is subject to an external review process defined as a management audit by the Department of Legislative Services. This external review occurs at least every three years. It provides an independent evaluation of the Department's fiscal operations, compliance with laws and regulations, and the efficiency and effectiveness of certain key programs (including data quality) selected for review.

Technical assessments are periodically performed by the Project Managers or other qualified professional staff designated by Management. These assessments are conducted as needed to determine whether or not data is being collected in accordance with the QAPP. From these assessments, quality assurance reports are generated that communicate the quality of environmental data collected and assessed, and identify needed or recommended improvements. The content and extent of these reports varies depending on the type of environmental samples or data involved. Project Managers discuss the findings contained in the reports with the Program Managers, the Quality Manager and technical staff.

For field samples and related data, periodic on-site surveillance to ensure that SOPs are used correctly and consistently, and reviews of data from the field study are performed. Performance evaluations (PEs) may also be conducted in which samples with known concentrations of target analyses are submitted blind to a laboratory to assess the laboratory's performance. For both sampling and non-sampling environmental data, other types of assessments may be performed, including:

- Thorough qualitative audits of the systems used to collect environmental data in which facilities, equipment, personnel, training, sample handling and analytical procedures, recordkeeping, data analysis, and reporting are reviewed.

- Audits of data quality (ADQ), which are qualitative and quantitative audits of the effectiveness of data management systems used to collect, analyze, interpret, and report environmental data as specified in the QAPP or an equivalent plan.

- Management and peer reviews or data quality assessments (DQA) are also conducted. DQAs are distinct from ADQs and are focused on determining whether data quality objectives (DQO) have been satisfied.

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IX. Assessing Environmental Operations

A. Assessment Planning, Development and Scheduling

Quality Coordinators in consultation with the Program/Project Managers plan, conduct, and evaluate environmental data in order to measure the effectiveness of the implemented quality system. The scheduling of assessments and allocation of resources are based on the status, risk, and complexity of sampling and analytical activities. Assessments shall be conducted consistent with USEPA *Data Quality Assessment: A Reviewer's Guide (QA/G-9R)*, and *Data Quality Assessment: Statistical Tools for Practitioners (QA/G-9S)*. Assessments include an evaluation to determine whether the technical requirements of activities are being effectively met. Written procedures are included in QAPPs, and describe the scope of the assessment and information needed.

The development of quality assessment procedures and scheduling of assessment activities are directed by Quality Coordinators and Project Managers. These individuals have sufficient authority to identify quality system problems and monitored these issues until a suitable solution is determined.

B. Determining What Environmental Operations to Assess

Each Administration identifies which environmental operations to assess by considering the evaluation method used, the nature and extent of the evaluation, and the following factors:

1. What work system is involved?

There are four distinct work systems to consider when assessing environmental operations: field sampling and measurement, laboratory analysis, field surveillance, and data management.

Field Sampling and Measurement – This is the process of collecting various types of environmental samples for various purposes, and collecting other real world data by the use of various measuring devices.

Laboratory Analysis – Laboratories are routinely used by MDE to analyze samples collected from several matrices (e.g. soil, water, air) for various analytes (e.g., organic chemicals, inorganic chemicals).

Field Surveillance – MDE relies heavily on a strong field presence to observe data collection efforts performed by the regulated community. This can include, but is not limited to, observing: the current condition of a site, site operations; sample collection; or remediation activities. These activities are typically documented in field observation reports.

Data Management – This is the process of collecting the data output from the various work systems described above and managing it through various independent and inter-related databases with the purpose of providing certain outputs to stakeholders.

2. What type of data is involved?

Data can range from analytical data provided from a laboratory, to observational data collected by a site inspector, to measurements from a field instrument, to database queries of raw data gathered over time. Data can be sourced by MDE staff, other agencies (e.g. United States Geological Society), and by the regulated community.

3. What is the complexity of the data?

The complexity of the data is determined by the circumstances under which it was collected. For example, analytical data generated from field samples to identify the extent of contamination is generally more complex than grab samples collected to determine if a business is subject to an environmental regulation. While the former situation may involve an in-depth validation of the analytical data by an experienced chemist, a more limited qualitative review of the data from the grab samples by an MDE inspector who performs compliance activities will suffice. Also, data validation may also be warranted for a group of samples which were analyzed for an extensive list of target analytes, whereas a less comprehensive review will be needed of data collected from continuous monitoring equipment used to assess if a specific parameter is within an acceptable range of values.

4. Who will be performing the assessment?

Internal staff such as inspectors, compliance engineers, and other field staff conduct assessments of environmental operations. In addition, independent laboratories are engaged to perform this work.

5. Are the decisions to be made from the data sensitive?

Yes. For instance, personal health records or details about private property are sometimes exposed during the assessment process. However, MDE limits it involvement to public health issues and environmental degradation.

6. Do the terms of a grant or agreement specify a level of assessment?

Yes. The level of assessment is often specified under the terms of a State or federal grant agreement. In some cases, however, professional judgment is used to determine what is needed on a program-specific or project-specific basis.

C. Roles and Responsibilities of Staff Involved

Program Manager:

1. Program Managers have overall responsibility to ensure appropriate environmental operations are assessed.

2. Program Managers review the findings resulting from assessments of environmental operations and ensure that any needed changes in operations are implemented and clearly communicated to appropriate staff.

3. Program Managers periodically perform "desk-top" reviews and DQA's of environmental operations, as deemed necessary, and communicate findings to Project Managers, appropriate staff and Management.

Project Manager:

1. Project Managers make recommendations to Program Managers as to Environmental Operations to be assessed.

2. Project Managers perform assessments of environmental operations or oversee technical staff and/or third parties performing assessments. Also, Project Managers communicate the results of assessments to Program Managers.
3. Project Managers periodically review SOPs for data collection to ensure that SOPs are current and still relevant to the activities being performed. Any required revisions are discussed with appropriate staff. Approval to make the revisions is obtained from the Program Manager.

4. Project Managers are cognizant during the planning and data collection or generation stages of a project as to what evaluations must be performed and who must perform them. Also, Project Managers communicate this information to laboratories analyzing samples or entities involved with the design and operation of an environmental technology.

5 Project Managers ensure assessments are properly documented either internally if the assessment is performed by staff or through the procurement process criteria development for extramural agreements (contracts).

Technical Staff:

1. Field personnel involved with environmental sampling perform "desk-top" reviews and, if appropriate, DQAs, and communicate findings to Project Manager.

2. Program staff whose work involves the collection and compilation of non-sampling environmental data performs qualitative assessments of the related data management systems.

Third Parties:

Private and treatment-facility laboratories conducting analysis under the federal programs conduct performance and system audits on a regular basis. As necessary, QA/QC audits of private and treatment facility laboratories may be conducted by the QA staff and make recommendations for correction. As part of the laboratory's requirements, the laboratory must submit the results of performance evaluation (PE) studies or other approved data, copies of home-state on-site evaluation reports (for laboratories not located in Maryland) as they occur, and immediate notification of any significant changes. Laboratories must also provide responses to "Not Acceptable" PE sample results and responses to on-site evaluation reports. At a minimum, private and water purveyor laboratories must analyze the sample(s) and submit the results of PE studies on an annual basis. The annual PE study must include all parameters (in-organics and/or organics) for which the laboratory is seeking to submit data.

D. Type of Assessments

Assessments are evaluations intended to provide an increased understanding of the program being examined, and to provide a basis for improving such programs. Audits are methodical examinations and reviews of the programs. Types of assessments include:

1. Data Quality Assessment (DQA) - a broad term that has been defined to encompass data validation, data reviews, QA/QC samples, quality assurance reports, and any other related tools for evaluating the quality of analytical data and the analytical process in accordance with established criteria. Criteria may be established by rule, contract or a QAPP. DQAs are performed in accordance with EPA's guidelines contained in *EPA QA/G-9* to determine if project objectives have been met. EPA has described DQA as a process to determine if data are adequate for their intended use, and as providing important information that allows a decision-maker to draw conclusions about the strength of evidence provided by the data.

2. Data Review - Is the process by which analytical laboratory reports are examined to evaluate their quality, the process may be rigorous or cursory depending on a project's objectives. Two types of quality samples may be used to monitor analytical system performance, blind and QA/QC check samples. Blind samples are samples that are submitted to the analyst as a routine sample. A QA/QC check sample may be provided to the analyst who knows it is an audit sample, but does not know the analyte concentrations.

3. Analysis of Audit Samples - used to judge the ongoing capability of the analyst and sample preparation procedure, the reliability of the instrumentation, and proficiency of the method. It also establishes a statistically valid estimate of the accuracy and precision of the measurement system and assesses whether or not the system is operating within the established control limits on a daily basis and over extended periods.

4. Data Validation - a formal, rigorous process in which experienced chemists evaluate the quality of analytical laboratory data, verify that results have been calculated correctly and that reported values have been correctly identified, and provide data qualifier flags or comments to assist the data user in determining the usability of the data for their project. Data validations ensure that the measured values are free of gross errors due to procedural or technical problems. Data validation is performed in accordance with *EPA QA/G-8*.

5. Independent Technical Audit - a process used to verify the quality of data obtained from a laboratory. For example, laboratory personnel within the U.S. EPA Region III perform an on-site audit for State compliance laboratories once every three years for the purpose of drinking water laboratory certification. Any comments or deviations noted during the on-site evaluation are responded to in writing. The response would include the corrective action implemented, or the proposed resolution and proposed schedule for its implementation.

6. Performance Evaluation Audit (PE) - a quantitative evaluation of the laboratory analytical system. PE audits are performed annually or more often, as new methods, equipment or personnel are introduced into the laboratory. The evaluation involves the measurement of a PE reference material that has a known value. Laboratories participate in the PE studies program. The results achieved from these studies verify the laboratory's capability to analyze drinking water samples for inorganic and organic analytes. The analyses of the PE samples independently demonstrate the laboratory's capability to perform required compliance testing, and to produce analytical results of known and documented quality.

7. Desktop Review - a less-rigorous process which enables Project Managers and other QA/QC staff that are not trained chemists to evaluate the quality of analytical laboratory reports. As described in the EPA guideline *Data Review Guidance Manual, RCRA Corrective Action Program*, desktop review includes a consideration of:

    ● Project objectives/DQOs.
    ● Sensitivity of the project and project decisions.
    ● Potential for enforcement actions/decisions.
    ● Data quality vs. data usability.
    ● Problems which, if corrected, could improve future data collection or assessment.
    ● Overall measurement system from sample acquisition through reporting.
    ● Laboratory performance, detection, and quantification limits.

    For non-sampling environmental data, such as data submitted by the regulated community to the Department in response to an environmental reporting requirement (e.g. the type and quantity of hazardous waste generated per calendar year) it is appropriate to perform other types of assessments, including:

    ● Review data submitted by staff in a timely manner for accuracy and completeness.

- Audits of the data management system (hardcopy or electronic) used to collect, compile, analyze, interpret, and report data.
- Qualitative audit of the extent to which the procedures specified in the QAPP or an equivalent document are being followed with respect to data management.

All data submitted to the EPA is validated in accordance with EPA Region III's guidelines *National Functional Guidelines for Inorganic Data Review (7/02), National Functional Guidelines for Organic Data Review (10/99) or Innovative Approaches to Data Validation (6/95).*

8. <u>Performance Audit</u> – a quantitative evaluation of the ability of a system to produce appropriate, accurate and reliable data. Performance audits involve submission of like samples, sometimes of known concentration, to laboratories generating data for the Department.

9. <u>Systems Audit</u> - an on-site, qualitative assessment of an organization's facilities, equipment, personnel, procedures and quality processes. Field audits verify that sample collection procedures are appropriate and are conducted by the project officer or their designee. Audits of laboratories may be required by EPA grant provisions. Required systems audits are described in QAPPs.

E. Procedures for Performing Assessments

1. The appropriateness and expected frequency of use of the assessments described in Section D above depends upon the type, quantity, and use of the environmental data that is generated or collected. Each Department Administration determines the type of assessments needed to ensure data quality with respect to the types of data it manages and describes when and how often the assessments are to be performed in the individual QAPP.

2. Assessments are performed by the Project Manager, or when appropriate, by other qualified professionals designated by management in accordance with the provisions of the QAPP.

3. Quality assurance reports are generated from the assessments that report the quality of environmental data collected and assessed, and identify needed or recommended improvements. The content and extent of these reports varies depending on the type of environmental samples or data involved. Improvements that need to be made in management, oversight, technique, deployment, or other activities are included in the report.

4. The Project Manager discusses the findings included in the quality assurance report with the Program Manager, Quality Manager and appropriate staff.

5. Results of assessments are included, when appropriate, in an employee's PEP.

F. Assessment Response and Documentation

The Quality Coordinator and Project Manager determine appropriate actions in response to assessments. In addition, in a timely manner, they determine the effectiveness of responses to assessments and maintain all documentation and correspondence relating to assessments and actions. Following any assessment event, a written summation of needed changes is prepared by the Project Manager, reviewed by the Quality Coordinator and presented in a timely manner to the Program Manager. The Program Manager has overall responsibility to ensure appropriate environmental operations are assessed, proper corrective action is taken and adequate documentation is maintained.

G. Assessment Conductor's Prerogatives

Persons conducting quality system assessments have no perceived conflict of interest with the project, are free to access and/or identify quality problems and noteworthy practices; make recommendations for resolving quality problems; assess implementation and effectiveness of solutions; and to assure management that work is monitored until problems are resolved by the appropriate staff.

H. Management's Role

Among the staff of MDE, each Administration Director bears the responsibility for the staff as a whole. The Administrative Director also serves in an advisory capacity on matters regarding QA/QC, as well as, overall authority for the variety of agency obligations as set forth by State statute. The Administration Director also is responsible to the Secretary, and thereby the State in matters related to authorities vested in MDE.

The Program Manager is responsible to the Administration Director, and has authorities pertaining to their specific program area. The Program Manager oversees the Quality Coordinator, Project Manager and other technical staff and has a high level of participation in the process, carrying out or overseeing the assessments and QA/QC activities of the agency.

X. Evaluating the QA/QC System

A. Purpose

Evaluating environmental operations through the conduct of assessments and audits is essential to any QA/QC system. Assessments are evaluations intended to provide an increased understanding of the environmental operations being examined, and to provide a basis for improving such operations. Audits are methodical examinations and reviews of an operation. Assessments and audits provide critical information about environmental activities and verify the following:

- Measurement systems are operating appropriately.
- Data generated by or provided to the Department is accurate, adequately documented, appropriate for the intended use and scientifically and legally defensible.
- Controls established to ensure quality are adequate, effective and suitable.
- Compliance with the QMP, QAPPs and SOPs.
- Resources are adequate to achieve project objectives.
- Project tasks are completed timely.
- Staff possess adequate skills and knowledge.

B. Authority to Conduct Evaluations

It is the Department's policy under the auspices of this QMP that personnel conducting assessments have sufficient authority, access to Senior and technical staff, access to documents and records, and organizational freedom to:

- Identify quality issues or problems.
- Identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products.
- Make recommendations for resolving quality problems.
- Independently confirm compliance and implementation, and effectiveness of solutions.

C. QA/QC Assessment Required Knowledge

Individuals conducting evaluations of the Department's QA/QC system, such as the Program/Project Managers and the Quality Manager must be knowledgeable of assessment and audit techniques and EPA quality guidelines. This EPA guidance includes but is not limited to, *Quality System Requirements for Environmental Programs and the Management System Review Process, QA/R-1: EPA Quality System Requirements for Environmental Programs and QA/G-3: Guidance for the Management Systems Review Process, March 2003.*

D. Roles and Responsibilities

<u>Quality Manager</u>**:**

1. Conduct periodic quality reviews of Administrations, programs and/or projects, if warranted.

2. Review results of annual quality self assessments performed by projects.

3. Communicate results of reviews with appropriate Senior Staff.

4. Conduct follow-up investigations to ensure adequate corrective action has been taken.

5. Be a partner with Administrations to ensure success of the Department's QA/QC system.

<u>Administration Director</u>**:**

1. Provide overall direction for and oversight of the Administration's QA/QC system.

2. Conduct periodic meetings, as needed, with Program Managers to monitor and evaluate efficiency and effectiveness of QA/QC system.

3. Review results of QA/QC reviews, if warranted.

4. Ensure proper corrective action is taken to address findings noted in QA/QC reviews.

5. Approve required changes to the Administration's QA/QC system to improve the efficiency or effectiveness of the program.

6. Discuss QA/QC issues with the Quality Manager, when appropriate.

7. Be a partner with the Quality Manager to ensure the success of the Department's QA/QC system.

<u>Program Manager</u>:

1. Conduct periodic QA/QCs review or request review under the authority of the Quality Manager of their Program, if warranted.

2. Review results of external QA/QC reviews.

3. Review results of annual quality self assessments performed by projects.

4. Recommend procedures for corrective action to address findings noted during quality reviews.

5. Conduct follow-up investigations to ensure adequate corrective action has been implemented.

6. Make recommendations for changes to the Administration's or Department's QA/QC system to improve the efficiency or effectiveness of the program.

Project Manager:

1. Conduct periodic quality review or request review under the authority of the Quality Manager of their project, if warranted.

2. Perform annual quality self assessment of project.

3. Review results of external QA/QC reviews.

4. Recommend procedures for corrective action to address findings noted during quality reviews.

5. Conduct follow-up investigations to ensure adequate corrective action has been taken.

6. Make recommendations for changes to the Administration's or Department's QA/QC system to improve the efficiency or effectiveness of the program.

Technical Staff:

1. Assist Project Manager in performing annual quality self assessment of project.

2. Review results of external QA/QC reviews.

3. Implement corrective action to address findings noted in QA/QC reviews or quality Self Assessments.

4. Make recommendations for changes to the Administration's or Department's QA/QC system to improve the efficiency or effectiveness of the program.

E. Annual Quality Self Assessment of Environmental Projects

Internal quality assessments provide MDE's Senior Staff with critical information about the effectiveness and efficiency of the Department's QA/QC system. Project Managers, with assistance from the technical staff, will complete an annual quality Self Assessment on the status of EPA funded programs. The results of this assessment will be presented in a report to be provided to the Program Manager and Quality Manager. This report will include of the following:

1. Program Description

2. Summary of results of performance and system audits. When was the last audit performed and what were the results?

3. Summary of non-conformance issues related to QAPP and recommended corrective actions with associated timelines for implementation.

4. Summary of periodic data quality assessments.

5. Summary of significant QA/QC problems and recommended solution.

6. Summary of other quality assurance/quality control and monitoring activities.

7. The status of, and any changes to, the QA Project Plan, including environmental measurement activities, organization, personnel, and training.

8. Significant QA/QC problems and their resolutions.

9. Development of SOPs to encourage uniform practices.

10. List of any projects or special studies for which sampling and analysis plans were prepared and reviewed.

11. Results of any performance or system audit conducted, and report appraising attainment of data quality objectives.

12. Funding and staff resources expended to implement the QA/QC system, in absolute numbers and as a percent of the total program resources. Absolute numbers can include the number of FTEs, the percentage of a single or multiple FTEs and any resources such as computers that are dedicated to QA/QC.

13. The status of any Quality Assurance or Quality Management training, for example types of training provided and/or taken, number of persons participating in each training course, how the training met the program's goals and objectives (or QA/QC needs), and future courses/training planned.

14. Any short-term and long-term goals and needs in the preceding areas.

15. Any information regarding innovative quality management practices that the program has developed or used.

16. Any other QA/QC activities or concerns.

F. Follow Up of Annual Quality Self Assessments

1. Project Managers review findings of the quality self assessments performed by staff and ensure that:

   - Any known problems with data quality are addressed.
   - Steps are taken to prevent similar problems from reoccurring.
   - Data are of sufficient quality to support the intended use of the data.
   - Findings are discussed with the Program Manager and Senior Staff when appropriate.
   - Staff receives any additional training needed to improve quality of data.
   - Information is shared with other programs and the Quality Manager relating to the results of assessments and recommendations that prove to be useful QA/QC tools or techniques or important information regarding private contractors, laboratories and other organizations regarding QA/QC issues.

2. Project Managers revise the QAPP and SOPs, as appropriate, and obtain approval for changes from the Program Manager. Material changes to QAPPs must resubmitted to EPA for review and approval.

3. Project Managers communicate findings of quality assurance reports, DQAs, and "desk-top" or other data reviews, including qualitative reviews of data management systems, to the Program Manager and Quality Manager to ensure that:

   - Identified deficiencies associated with data collection, assessment, or management are resolved.
   - Required changes to the QMP, QAPP, or SOPs are addressed.
   - Data are of sufficient quality to support the intended use of the data.
   - Additional training needs are identified and addressed.

4. Technical staff performing assessments communicate findings of "desk-top" and other data reviews and DQA's to the Project Manager, and, if appropriate, to the laboratory generating the data. This ensures that any known problems associated with sample collection or data assessment or management are identified and resolved, and data are of sufficient quality to support the intended use of the data.

5. Project Managers make recommendations to the Program Manager related to changes to the Administration's QA/QC system that improve the quality of data.

6. Program Managers review recommended QA/QC changes and approve as appropriate. Any changes that may have a Departmental effect are discussed with the Quality Manager.

7. The Quality Manager reviews Program Manager's recommended QA/QC changes and makes any required changes to the Department's QA/QC system including the QMP. Any changes to the QMP are approved by the EPA prior to implementation of the change.

XI. Quality Improvement

A. Quality Improvement Management Process

The process for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities is described throughout this document in sections I-XI. Throughout each section there is a common thread of Senior Staff involvement in QA/QC process, beginning from the planning of a project through the assessment stage. The following can be summarized as the management process for quality improvement:

1. Throughout MDE's QMP there is an "improvement" requirement if issues are identified. For most QA/QC activities there is a required step for planning, implementing, verifying, documenting, checking, and improving quality.

2. Several processes were identified for evaluating quality improvement such as the annual quality Self Assessment report, MDE shared quality directory, audit systems, and coordinator meetings.

B. Roles and Responsibilities for Quality Improvement

1. In Section I, the Department discusses and defines roles and responsibilities. Within these roles and responsibilities, it is explicitly stated that Senior Staff plays a strong role in ensuring improvement in the actual data quality and the QA/QC system.

2. Staff are trained and encouraged to identify quality deficiencies as soon as they are recognized and to ask that corrective action be taken immediately.

C. Quality Assessment Process

Quality improvement is intended to be an on-going process. Based on project assessments, as well as while working on projects, Program/Project Managers and staff may note changes that can either prevent situations that would result in poor quality data or improve SOPs, administrative processes, or the quality assurance system. It is the responsibility of the Program/Project Manager to build consensus about QA/QC recommendations. If there are disagreements, disputes are resolved at the lowest administrative level possible utilizing the existing management structure of Program Manager, Project Manager, and technical staff. Should agreement not be reached at this level, then the Program Manager will take the issue to the Administration Deputy Director for resolution. The Administration Director has final dispute authority on all QA/QC issues.

Recommendations for changes in quality systems that impact the QMP shall be made to the Quality Manager. The Quality Manager shall take such recommendations under advisement in the periodic assessment of the QMP and in other quality system activities.

To ensure that adverse conditions are prevented, where possible, or properly identified and resolved the following steps are taken:

1. Each QAPP requires a "corrective actions" section in the planning stage, and each annual quality Self Assessment report requires a "corrective actions" section in the self-assessment stage.

2. It is the responsibility of Project Managers for assuring staff participation in all project reviews. All deviations and discrepancies noted by staff during any independent or internal assessment review will be corrected promptly through a Corrective Action Plan. If necessary, staff may go directly to the Quality Manager or Program Manager to report quality deficiencies.

3. It is the responsibility of the Program/Project Managers to request reviews and/or audits to identify where improvements can be made. All corrective actions required during the life cycle of the project are filed in the official project file or with the project's final report.

4. It is the responsibility of the Quality Coordinators in conjunction with the Program Managers to monitor the results of assessments to ensure that appropriate corrective actions are taken in a timely manner, that the actions are effective and the process is documented as an audit trail.

D. Quality Improvement Communication

All users of data that are assessed, aggregated, and analyzed for projects shall be identified as part of a QAPP. Program/Project Managers have the obligation of treating such users as "customers," and ascertaining the types of data, form of presentation and the likely use of information by such customers. Customer feedback shall be encouraged and, where appropriate, mechanisms for soliciting such input shall be identified in the QAPP.

E. Quality Corrective Action Process

1. Each QAPP requires a "corrective actions" section in the planning stage, and each annual quality self assessment report requires a "corrective actions" section in the self-assessment stage.

2. It is the responsibility of Project Managers for assuring staff participation in all project reviews. All deviations and discrepancies noted by staff during any independent or internal assessment review will be corrected promptly through a Corrective Action Plan. If necessary, staff may go directly to the Quality Manager or Program Manager to report quality deficiencies.

3. It is the responsibility of the Program/Project Managers to request reviews and/or audits to identify where improvements can be made. All corrective actions required during the life cycle of the project are filed in the official project file or with the projects' final report.

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QA/QC OPERATIONAL FRAMEWORK

Secretary
Deputy Secretary
Assistant Secretaries

Director of Budget
(Financial Accountability and Responsibility)

Internal Audit Services
(Performs audits of financial and program activities)

Quality Manager Function
(Develops, Coordinates, Oversees & Ensures Policy Implementation)

QC (ARA)	QC (LMA)	QC (WSA)	QC (OS/CO)
Director Air & Radiation Administration (ARA) *(Administration Oversight and Implementation Accountability)*	Director Land and Material Administration (LMA) *(Administration Oversight and Implementation Accountability)*	Director Water and Science Administration (WSA) *(Administration Oversight and Implementation Accountability)*	Director Office of the Secretary/ Coordinating Offices (Administration *Oversight and (Implementation Accountability)*
Program Manager *(Implementation Accountability)*	Program Managers *(Implementation Accountability)*	Program Managers *(Implementation Accountability)*	Program Managers *(Implementation Accountability)*
Project Managers *(Establish DQO, QAPP, SOP)*	**Project Managers** *(Establish DQO, QAPP, SOP)*	**Project Managers** *(Establish DQO, QAPP, SOP*	**Project Managers** *(Establish DQO, QAPP, SOP)*
Technical Staff *(Collection & Assessment of Environmental Data)*	**Technical Staff** *(Collection & Assessment of Environmental Data)*	**Technical Staff** *(Collection & Assessment of Environmental Data)*	**Technical Staff** *(Collection & Assessment of Environmental Data)*

PROGRAMS SUBJECT TO QMP REQUIREMENTS

Air and Radiation Administration
1. Air Quality Permits Program
2. Air Quality Compliance Program
3. Air Monitoring Program
4. Air Quality Planning Program
5. Mobile Sources Control Program

Land and Materials Administration
1. Lead Poisoning Prevention Program
2. Technical Services and Operations Program
3. Solid Waste Program
4. Resource Management Program
5. Land Restoration Program
6. Oil Control Program
7. Mining Program

Office of the Secretary/Coordinating Offices
1. Office of Human Resources
2. Central Services (Procurement)
3. Office of Information Management Technology
4. Water Quality Financing Administration
5. Water Quality Infrastructure Program

Water and Science Administration
1. Compliance Program
2. Operational Services and Administration
3. Sediment, Stormwater, and Dam Safety
4. Wastewater Permits Program
5. Water Supply Program
6. Wetlands and Waterways Program
7. Integrated Water Planning Program
8. Environmental Assessment and Standards Program
9. Field Services Program