EPA Region 3

EPA
United States
Environmental Protection
Agency

# Quality Management Plan

**U.S. EPA Region 3**
Philadelphia, PA
Annapolis, MD
Fort Meade, MD
Wheeling, WV

U.S. Environmental Protection Agency
Region 3, Mid-Atlantic
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**EPA REGION 3 QUALITY MANAGEMENT PLAN**

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# GLOSSARY & ACRONYMS

A glossary, available on the EPA's website (Appendix 1), includes terms commonly used in the context of EPA's Quality System. Acronyms used in this QMP are listed below.

**LIST OF ACRONYMS**

| | |
|---|---|
| AA | Accrediting Authorities |
| AB | Accrediting Bodies |
| ADQ | Audits of Data Quality |
| ADR | Alternative Dispute Resolution |
| AHERA | Asbestos Hazard Emergency Response Act |
| AMNP | Annual Monitoring Network Plans |
| APTI | Air Pollution Training Institute |
| AQAB | Air Quality Analysis Branch |
| AQS | Air Quality System |
| ARD | Air & Radiation Division |
| ARTB | Air, RCRA & Toxics Branch |
| AS | Air Section |
| ASHAA | Asbestos Hazard Abatement Act |
| ASQAB | Applied Science & Quality Assurance Branch |
| ATTAINS | Assessment, TMDL Tracking & Implementation System |
| BMP | Best Management Practice |
| BUILD | Better Utilization of Investments Leading to Development |
| CAA | Clean Air Act |
| CBI | Confidential Business Information |
| CBP | Chesapeake Bay Program |
| CBPO | Chesapeake Bay Program Office |
| CBWA | Chesapeake Bay Watershed Agreement |
| CCS | Contract Compliance Screening |
| CDC | Center for Disease Control |
| CERCLA | Comprehensive Environmental Response Compensation & Liability Act |
| CFR | Code of Federal Regulations |
| CID | Criminal Investigation Division |
| CIO | Chief Information Officer |
| CLP | Contract Laboratory Program |
| COC | Chain of Custody |
| COOP | Continuity of Operations |
| COR | Contracting Officer Representative |
| CPIC | Capital Planning & Investment Control |
| CPRC | Conflict Prevention & Resolution Center |
| CSB | Computer Services Branch |
| CWA | Clean Water Act |
| DAI | Data Audit Inspection |
| DAO | Delegated Approving Official |
| DC | District of Columbia |
| DE | Delaware |

| | |
|---|---|
| DEP | Department of Environmental Protection |
| DES | Design & Engineering Services |
| DMR | Discharge Monitoring Reports |
| DMRQA | Discharge Monitoring Reports Quality Assurance |
| DNREC | Department of Natural Resources & Environmental Control (Delaware) |
| DOC | Demonstration of Capability |
| DOEE | Department of Energy & Environment (D.C.) |
| DPM | Designated Project Manager |
| DQA | Data Quality Assessment |
| DQO | Data Quality Objective |
| DQI | Data Quality Indicator |
| DSPB | Data, Support & Prevention Branch |
| DUET | Data Upload & Evaluation Tool |
| DWSRF | Drinking Water State Revolving Funds |
| DWS | Drinking Water Section |
| EAP | Employee Assistance Program |
| EC | Executive Council |
| ECAD | Enforcement & Compliance Assurance Division |
| EEO | Equal Employment Opportunity |
| EIMP | Enterprise Information Management Policy |
| ELMS | EPA Lean Management System |
| EPA | U.S. Environmental Protection Agency |
| EPAAG | Environmental Protection Agency's Acquisition Guide |
| EPCRA | Emergency Planning & Community Right to Know Act |
| EQMD | Office of Mission Support's Environmental Quality Management Div. |
| ERRS | Emergency & Response Services |
| ESO | Environmental Services & Operations |
| ESS | Enforcement Support Section |
| ESTP | Enhancing State and Tribal Programs |
| EXES | Electronic Data Exchange & Evaluation System |
| FAC | Field Activities Coordinator |
| FACT | Field Activities Coordination Team |
| FAR | Federal Acquisition Regulations |
| FEM | Forum on Environmental Measurements |
| FIFRA | Federal Insecticide, Fungicide, & Rodenticide Act |
| FIPS PUBS | Federal Information Processing Standards Publications |
| FITARA | Federal Information Technology Acquisition Reform Act |
| FMFIA | Federal Manager's Financial Integrity Act |
| FOG | Field Operations Group |
| FOIA | Freedom of Information Act |
| FOMS | Field Operations Management System |
| FQM | Field Quality Manager |
| FS | Feasibility Study |
| FSB | Field Services Branch |
| FSP | Field Sampling Plan |
| FTE | Full Time Employee |

| | |
|---|---|
| FY | Fiscal Year |
| GAP | General Assistance Program |
| GIS | Geographic Information Systems |
| HRS | Hazard Ranking System |
| IAW | In accordance with |
| IA | Interagency Agreement |
| ICIS | Integrated Compliance Information System |
| IGMS | Integrated Grants Management System |
| IP | Internet Protocol |
| IQG | Information Quality Guidelines |
| IQGO | Information Quality Guidelines Officer |
| IRT | Interagency Review Teams |
| ISB | Information Services Branch |
| ISO | International Organization for Standardization |
| IT | Information Technology |
| JD | Jurisdictional Determination |
| LAN | Local Area Network |
| LCRD | Land, Chemicals, & Redevelopment Division |
| LER | Labor & Employee Relations |
| LSASD | Laboratory Services & Applied Sciences Division |
| LTSB | Laboratory & Technical Services Branch |
| LUST | Leaking Underground Storage Tank |
| MACT | Maximum Attainable Control Technology |
| MARAMA | Mid-Atlantic Regional Air Management Association, Inc. |
| MAWWG | Mid-Atlantic Wetland Workgroup |
| MD | Maryland |
| MDE | Maryland Department of the Environment |
| MDL | Method Detection Limit |
| MPRSA | Marine Protection, Research, & Sanctuaries Act |
| MSD | Mission Support Division |
| MSR | Management Systems Review |
| NAAQS | National Ambient Air Quality Standards |
| NATA | National Air Toxics Assessment |
| NCC | National Computer Center |
| NCP | National Contingency Plan |
| NELAC | National Environmental Laboratory Accreditation Conference |
| NELAP | National Environmental Laboratory Accreditation Program |
| NEPA | National Environmental Policy Act |
| NEPPS | National Environmental Performance Partnership System |
| NESHAP | National Emission Standards for Hazardous Air Pollutants |
| NHPA | National Historic Preservation Act |
| NOAA | National Oceanic & Atmospheric Administration |
| NPDES | National Pollution Discharge Elimination System |
| NPEP | National Performance Evaluation Program |
| NPL | National Priorities List |
| NS | NPDES Section |

| | |
|---|---|
| NSPS | New Source Performance Standards |
| NSR/PSD | New Source Review/Prevention of Significant Deterioration |
| NWCA | National Wetland Condition Assessment |
| OAM | Office of Acquisition Management |
| OAR | Office of Air and Radiation |
| OBLR | Office of Brownfields and Land Revitalization |
| OCR | Office of Civil Rights |
| OCSPP | Office of Chemical Safety and Pollution Prevention |
| OCTEA | Office of Communities, Tribes, & Environmental Assessments |
| OECA | Office of Enforcement & Compliance Assurance |
| OEP | Occupant Emergency Plans |
| OGC | Office of General Counsel |
| OLEM | Office of Land & Emergency Management |
| OMB | Office of Management & Budget |
| OMS | Office of Mission Support |
| OPA | Oil Pollution Act of 1990 |
| OPA | Office of Public Affairs |
| OPES | Oil & Prevention Enforcement Section |
| ORA | Office of the Regional Administrator |
| ORC | Office of Regional Counsel |
| ORD | Office of Research & Development |
| OSC | On-Scene Coordinator |
| OSRTI | Office of Superfund Remediation & Technology Innovation |
| OSS | Open Source Software |
| PA | Pennsylvania |
| PADEP | Pennsylvania Department of Environmental Protection |
| PB | Permits Branch |
| PCB | Polychlorinated Biphenyl |
| PDR | Pre-dissemination Review |
| PE | Performance Evaluation |
| PIA | Planning, Implementation & Assessment |
| PIB | Planning & Implementation Branch |
| PII | Personally Identifiable Information |
| PO | Project Officer |
| PPA | Performance Partnership Agreement |
| PPA | Pollution Prevention Act of 1990 |
| PPG | Performance Partnership Grant |
| PPGB | Partnership Programs & Grants Branch |
| PQAO | Primary Quality Assurance Organization |
| PRC | Peer Review Coordinator |
| PRP | Potentially Responsible Party |
| PSD | Prevention of Significant Deterioration |
| PT | Proficiency Test |
| PWSS | Public Water System Supervision Program |
| QA | Quality Assurance |
| QAARWP | Quality Assurance Annual Report & Work Plan |

| | |
|---|---|
| QAC | Quality Assurance Coordinator |
| QAFAP | Quality Assurance Field Activities Procedure |
| QAM | Quality Assurance Manager |
| QAO | Quality Assurance Officer |
| QAPP | Quality Assurance Project Plan |
| QAPrP | Quality Assurance Program Plan |
| QA/QC | Quality Assurance/Quality Control |
| QARF | Quality Assurance Review Form |
| QATS | Quality Assurance & Technical Support |
| QC | Quality Control |
| QMP | Quality Management Plan |
| QS | Quality System |
| QSA | Quality System Assessment |
| R3 | U.S. Environmental Protection Agency Region 3 |
| RA | Regional Administrator |
| RACT | Reasonably Available Control Technology |
| RAF | Remedial Action Framework |
| RCRA | Resource Conservation & Recovery Act |
| RES | Remediation Environmental Services |
| RFC | Request for Correction |
| RFR | Request for Reconsideration |
| RFQM | Regional Field Quality Manager |
| RI | Remedial Investigation |
| RPM | Remedial Project Manager |
| RQAM | Regional Quality Assurance Manager |
| RQC | Regional Quality Council |
| RRC | Regional Response Center |
| RS | RCRA Section |
| SAM | Site Assessment Manager |
| SAP | Sampling & Analysis Plan |
| SARA | Superfund Amendments & Reauthorization Act |
| SDWA | Safe Drinking Water Act |
| SDWIS | Safe Drinking Water Information System |
| SEE | Senior Environmental Employee |
| SEMD | Superfund & Emergency Management Division |
| SEMS-RM | Superfund Enterprise Management System – Records Management |
| SEP | Special Emphasis Program |
| SF | Superfund |
| SIO | Senior Information Official |
| SIP | State implementation Plan |
| SIRG | State Indoor Radon Grants |
| SLCM | System Life Cycle Management |
| SME | Subject Matter Expert |
| SOP | Standard Operating Procedure |
| SRF | State Review Framework |
| SOW | Statement of Work |

| | |
|---|---|
| SRO | Senior Resource Official |
| SSP | Smart Sectors Program |
| START | Superfund Technical Assistance & Response Team |
| STS | Standards & TMDLs Section |
| SWS | SDWA & Wetlands Section |
| TAG | Technical Assistance Grants |
| TEP | Technical Evaluation Panel |
| TMDL | Total Maximum Daily Load |
| TOCOR | Task Order Contracting Officer Representative |
| TRI | Toxics Release Inventory |
| TS | Toxics Section |
| TSA | Technical Systems Audit |
| TSCA | Toxic Substances Control Act |
| UIC | Underground Injection Control |
| UFP | Uniform Federal Policy |
| USFWS | United States Fish & Wildlife Service |
| UST | Underground Storage Tank |
| VA | Virginia |
| VADEQ | Virginia Department of Environmental Quality |
| WAM | Work Assignment Manager |
| WB | Water Branch |
| WB | Wetlands Branch |
| WD | Water Division |
| WIP | Watershed Implementation Plan |
| WOTUS | Waters of the U.S. |
| WPDG | Wetland Program Development Grants |
| WPP | Wetland Program Plans |
| WRR | Watershed Resources Registry |
| WV | West Virginia |
| WVDEP | West Virginia Department of Environmental Protection |

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# EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) Region 3 (R3)'s Quality Management Plan (QMP) documents the Region's consistency with the policy and program requirements for the mandatory Agencywide Quality System. This executive summary is a synopsis of key requirements and provisions of R3's Quality System as set forth in this QMP.

***Region 3's Quality Policy***

*R3's policy is that all environmental data and information collected or used are of known and documented quality, suitable for their intended use, with all aspects of collection, analyses or use thoroughly documented; and such documentation being verifiable and defensible. This policy applies to all data collected under environmental operations and environmental technology activities performed directly by or for the Region and includes all data and information from outside sources that are used by the Region. These sources include all Federal, State, Tribal and local partners under interagency and financial assistance agreements; contractors funded by EPA; regulated entities and potentially responsible parties. The Regional Administrator, Senior Leadership and managers ensure adequate allocation of resources (intramural and extramural money, travel and training funds, and personnel) to achieve the Region's Quality Policy. All individuals in the Region who are directly or indirectly involved with environmental data operations have some responsibility for ensuring data quality.*

R3's Quality System described in this QMP has been planned, developed, and documented in accordance with the following requirements:

- Policy and Program Requirements for the Mandatory Agencywide Quality System, CIO 2105.0;
- EPA Quality Manual for Environmental Programs, CIO 2105-P-01.0;
- EPA QA Field Activities Procedure, CIO 2105-P-02.0; and
- EPA CIO Notification Procedure for Environmental Data Quality Issues, CIO 2105-P-03.0.

This QMP describes Regional processes and policies for ensuring the quality of environmental data collected, produced, and used by or for:

- R3 programs and projects;
- Other Federal, State, Tribal and local partners, funded by EPA under:
  - Grants;
  - Cooperative Agreements; and
  - Interagency Agreements.
- Contractors funded by EPA (contracts); and
- Regulated entities (e.g., compliance orders) and potentially responsible parties.

Consistent with U.S. EPA Quality Policy, Chief Information Officer (CIO) Quality Policy 2105.0, overall responsibility for the quality assurance program in R3 rests with the Regional Administrator (RA). The RA, Senior Leadership, and managers ensure that all Regional components and programs comply fully with the Agency QA requirements. The responsibility for developing and documenting Regional QA policies, procedures, and guidance; overseeing implementation and assessment of the Regional Quality System; and providing QA training has been delegated to the RQAM. The RQAM is located in LSASD/ASQAB but has organizational independence and maintains direct communication with senior management and the ORA.

R3's QMP has been signed and authorized for implementation by Senior managers in the Region and by the Office of Mission Support (OMS)/Environmental Quality Management Division (EQMD) Director. This QMP will remain approved for five years from the date of the EQMD approval letter. Revisions during that 5-year period may be necessary as determined by periodic internal assessments and annual reviews conducted by R3; external assessments conducted by EQMD or other EPA organizations; significant changes to R3's organization, resources, or scope of mission; and revised Agency QA policies and requirements.

The summaries below provide succinct information on each QMP section; complete details are in the main body of the document.

**Section A: Quality System, Management, Organization, and Components**

The RQAM has the authority and responsibility to approve all extramural and intramural environmental data operation QA documents (e.g., QAPPs), unless delegated to a Delegated Approving Official (DAO) or Quality Assurance Officer (QAO) (as described in Section B.4). The RQAM, QAOs, and DAOs maintain independence from environmental data operations, and consequently are able to serve without potential conflict of interest. The RQAM collaborates with all R3 Quality staff and works with the Regional Quality Council (RQC), which consists of Quality Assurance Coordinators (QACs) from each Division and major program that collects, evaluates, or manages environmental data and information.

Effective and regular communications between and among all Regional QA elements are essential in implementing and maintaining the Region's Quality System. On a regular and as-needed basis, the RQAM, ASQAB Chief, and Field Quality Manger will keep the LSASD Director, RQC, Field Activities Coordination Team (FACT) and senior managers apprised of QA issues that impact the Region's Quality System.

Each R3 organization that conducts environmental data operations shall develop and maintain QA documentation described within or appended to, as appropriate (including lists), this centralized Regional QMP. This documentation shall describe the organization's QA objectives and internal procedures.

The R3 Quality System consists of personnel, functions, tools, and procedures used to ensure that data of known quality and sufficient quantity are generated for Regional data users and decisionmakers. A variety of tools and procedures are employed for planning, implementing, and assessing the R3 Quality System.

**Principal Components of R3's Quality System:**

| Organization-level | Program-level | Project-level |
|---|---|---|
| R3 Quality Management Plan | Quality Assurance Program Plans (QAPrP) | Systematic Planning including Data Quality Objectives |
| Tiered-Training Program | Standard Operating Procedures | Quality Assurance Project Plans (QAPPs) |
| Field Operations Management System | Laboratory & Chesapeake Bay Program Quality Manuals | Technical Assessments, including peer review, proficiency testing & laboratory audits |
| QA Document Control system | External Quality Management Plan Status Reports | Data Assessments, including verification and validation & data quality assessments |
| Management Assessments, including QA Annual Report & Work Plan & Quality System Assessments | Templates & checklists | Pre-dissemination reviews (Information Quality Guidelines) |

**Section B: Personnel Qualifications & Training**
Region 3's policy is to ensure that all persons involved in handling environmental data are appropriately trained to understand the Region's Quality System and understand their QA roles and responsibilities. R3 has a tiered training program designed to fit the QA needs and responsibilities of R3 personnel and external stakeholders. Tables B.1 and B.2 illustrate the R3 QA tiered-training program. Completion of QA training shall be documented and certified by the RQAM or appropriate authority.

Managers, with assistance from the RQAM, FQM, and QACs, have the responsibility to ensure staff meet minimum QA training requirements for their assigned activities and determine the need for DAOs for their organizational unit (Section A.4.a). The RQAM has the authority to certify DAOs and QAOs through the R3 tiered training program (Section B.4).

**Section C: Procurement of Items & Services**
R3 staff involved with environmental data operations performed under receipt of financial assistance (i.e., grants, cooperative agreements, contracts, and interagency agreements) are responsible for incorporating QA requirements into grant conditions; contracts; and voluntary, consensual, and unilateral enforcement agreements, decrees and orders. R3 financial recipients involving environmental data operations shall submit a QMP and QAPP(s) (or combined QMP/QAPP, if appropriate (not equivalent to a QAPrP)).

**Section D: Documents & Records**
The RQAM, QACs, ASQAB Quality staff, and QAOs are responsible for managing all regional and divisional quality-related policies, procedures, and documents, in accordance with Agency policies, guidance and the R3 QMP. Designated Project Manager(s) are responsible for managing program- or project-level quality-related documents and records.

Controlled documents, hard copy and electronic, relating to QA activities at R3 must be developed and managed in a systematic, consistent manner. These documents include QMPs, QAPrPs, QAPPs, policies, SOPs, manuals, guidance, plans, templates, checklists, and other similar documents. The roles/steps to prepare, review, approve, issue, revise, revoke, distribute, and archive controlled documents are shown in Table D.1. Approvals of QA documents cannot be rendered by the same individuals who authored or prepared those QA documents and should follow procedures as detailed in Section D.

**Section E: Computer Hardware & Software**
Technology and data management is the responsibility of all regional personnel with specific roles listed in Table E.1. It is the policy of R3 to comply with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards.

**Sections F-H: Planning, Implementation & Assessment**
R3 has adopted the Planning, Implementation and Assessment (PIA) quality model as the foundation of its Quality System. Application of the quality model is appropriate for all R3 environmental operations, administrative activities, and extramural agreements.

**Planning** (Section F) establishes objectives and processes necessary to deliver results in accordance with desired outputs or goals. Quality planning must occur at three levels to ensure such data meet Regional programmatic and quality goals:

- *Organization-wide*
  The QMP is the foundation for the QAPrPs, QAPPs and other QA documents.
- *Program-level*
  R3 accepts the use of QAPrPs whenever practicable and where an overarching QMP exists. QAPrPs are typically used to describe QA/QC procedures across recurring or like activities within a single program. QAPrPs shall describe the QA elements that remain constant among the different projects, activities, or sites. Most QAPrPs shall be supported by project-specific, activity-specific or site-specific documentation (e.g., FSPs, SAPs, Work Plans, inspection checklists, or equivalent).
- *Project-specific*
  Project-level planning ensures efficient appropriation of resources (avoids rework and re-sampling) and maximum quality, objectivity, utility & integrity of data. QAPP requirements apply to all environmental data operations, including secondary data, conducted by Regional staff or through grants, cooperative agreements, contracts, Interagency Agreements and compliance orders. QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

**Implementation** (Section G) is the execution of the planned activity. The RQAM is responsible for overseeing the implementation of the Regional Quality System. R3 is responsible for ensuring that its contractors, grantees, and other partners have and implement Quality Systems of their own that will be sufficient to ensure that their environmental data operations fulfill the Region's needs. To ensure the effective implementation of the R3 quality system:

- *Organization-wide*
  R3 shall annually submit a Quality Assurance Annual Report and Work Plan (QAARWP) to

the Director of EQMD. The QAARWP summarizes the QA-related resources, training, accomplishments (i.e., innovative practices, technical assessments, QMP revisions, QA guidance, technical assistance, etc.) and Quality System assessments/audits that have been conducted in the previous fiscal year.

- *Program-level*
  At the program-level, R3 personnel who are directly or indirectly involved with environmental data operations in areas of work authorized by statutory reference (e.g., Air Toxics Program) or by Executive or Agency direction (e.g., Volunteer Monitoring Program) have responsibility for ensuring data quality as outlined in this QMP, their group's QA procedures (including QAPrPs), and applicable national program documents.
- *Project-specific*
  At the project-level, approved QAPPs must be implemented as prescribed; however, a QAPP may be modified and amended, with changes appropriately documented, at any time to ensure project objectives are met. Use of standard operating procedures (SOPs) serves as a mechanism to ensure comparability across programs and individual environmental data operations.

All R3 personnel who are involved in field activities shall implement and comply with the EPA QA Field Activities Procedure (QAFAP) as outlined in the R3 Field Operations Management System (FOMS). As part of FOMS implementation, R3 has nine Field Standard Operating Procedures (SOPs) that cover the 10 QAFAP elements.

LSASD's Laboratory & Technical Services Branch (LTSB) acts as the Regional Sample Control Center to coordinate analytical support for all regional programs and acquisition and delivery of routine and specialized analytical services conducted by external providers. LTSB's Sample Submission Procedures specify procedures to be followed when submitting samples to LTSB, which help ensure field and laboratory aspects of the sampling event are linked in a way to produce reliable data of known quality

**Assessment** (Section H) monitors and measures process performance through assessment of the project or program. To verify effectiveness of the regional Quality System, R3 uses management, technical, and data assessments, which evaluate if procedures documented in this QMP, other QA documents (e.g., QAPPs, QAPrPs, SOPs), and program requirements are being implemented. Assessments must be documented and reports to management must be completed in a timely manner, including appropriate level of review and approval. The assessed organization is responsible for implementation of corrective actions.

- *Organization-wide*
  R3 conducts internal management assessments of its quality system, which may also be assessed independently by EQMD or other authorizing entities. In addition, R3 may perform management assessments of external entities as needed. Extramural organizations may also conduct periodic internal management assessments of their own quality systems.
- *Program-level & Project-specific*
  The goals of technical and data assessments are to determine whether implemented environmental data operations and related results comply with the documented activity as outlined in planning documents (e.g., QAPP, QAPrP, SOPs, manuals, methods) and program

requirements and are suitable to achieve data quality goals and criteria. DPMs are responsible for ensuring that technical and data assessments are accomplished as outlined in the QAPP, QAPrP, grant terms and conditions, contract statement of work (SOW), SOPs, program requirements, or equivalent document. Some technical assessment tools include readiness reviews, Technical Systems Audits (TSAs), surveillance, performance evaluations (PEs), and peer reviews. Data assessment tools can include data verification and validation, Audits of Data Quality, and Data Quality Assessments (DQAs).

**Section I: Quality Improvement**

The quality assurance procedures described in this QMP establish a foundation and processes for ensuring that conditions adverse to quality and scientific integrity are prevented or promptly identified and corrected, and that any actions taken are documented and tracked to avoid future reoccurrences. All Regional personnel are encouraged to raise issues that impact quality and scientific integrity of data and information, establish QA communications, identify process improvement opportunities, and suggest solutions for problems.

**Section J: Information Quality Guidelines (IQG)**

The IQG contains EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates. EPA's quality system serves as a framework to ensure that information products meet the specifications of the IQG. Pre-Dissemination Reviews (PDRs) ensure information disseminated by or on behalf of EPA organizations is consistent with EPA's IQG. R3 has established PDR procedures, with emphasis on using existing Regional processes and procedures wherever possible. The R3 IQG Officer works with communications and web coordinators in each division when an information product is proposed to be disseminated.

# SECTION A: QUALITY SYSTEM MANAGEMENT, ORGANIZATION, & COMPONENTS

## A.1 MISSION, POLICY, & SCOPE

The Environmental Protection Agency's (EPA's) principal mission is to protect human health and the environment. To accomplish this mission, EPA utilizes environmental data and information from a variety of sources. The R3 Quality Management Plan (QMP) describes policies and, procedures, and management systems within the organization that govern quality control activities of environmental information collection and use. Links for guidance documents, references, and other resources are listed in Appendix 1.

> ***Environmental information & data*** *are defined as measurements or information that describe environmental processes, location, or conditions; ecological or health effects & consequences; or the performance of environmental technology. For R3, environmental information also includes data produced from models or compiled from other sources such as databases or literature.*

Activities involving environmental information and data covered by the R3 Quality System include, but are not limited to, the following activities:

- Characterize and evaluate states and conditions of environmental or ecological systems and health of human populations;
- Characterize and evaluate chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;
- Establish ambient conditions in air, water, sediments, soil, etc. in terms of physical, chemical, radiological, or biological characteristics;
- Determine and categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and impact on human health and ecological systems;
- Quantify and monitor the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production, domestic sewage treatment), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);
- Develop and evaluate environmental technology for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control and the use of the technology to generate and collect data (e.g., treatability and pilot studies);
- Map environmental processes and conditions, and human health risk data, etc. (e.g., geographic information system, geospatial data analyses);
- Support enforcement and compliance monitoring efforts, including sampling and laboratory work;
- Develop or evaluate methods for use in the collection, analysis, and use of environmental data;

- Develop, evaluate, and use models to characterize environmental processes or conditions; and
- Develop, revise, compare, or otherwise use information technology and management systems that impact environmental data quality (e.g., electronic databases with environmental information including data entry, handling, transmission and analysis, and laboratory information management systems).

R3's Quality System described in this QMP has been planned, developed, and documented in accordance with the following EPA requirements (Appendix 1):

- *Policy and Program Requirements for the Mandatory Agencywide Quality System, Chief Information Officer (CIO) 2105.0;*
- *Quality Manual for Environmental Programs, CIO 2105-P-01.0;*
- *QA Field Activities Procedure, CIO 2105-P-02.0;*
- *CIO Notification Procedure for Environmental Data Quality Issues, CIO 2105-P-03.0*.

The primary goal of R3's Quality System is to ensure all environmentally-related data activities, including secondary data usage, performed by or for R3, are of adequate quality to support specific decisions or actions. In order for such data to be used with a high degree of certainty by the intended user, its quality must be known and documented. This goal will be achieved by ensuring that appropriate resources are made available and proper procedures followed throughout each environmental project's planning, implementation, and evaluation phase.

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***Region 3's Quality Policy***

*R3's policy is that all environmental data and information collected or used are of known and documented quality, suitable for their intended use, with all aspects of collection, analyses or use thoroughly documented; and such documentation being verifiable and defensible. This policy applies to all data collected under environmental operations and environmental technology activities performed directly by or for the Region and includes all data and information from outside sources used by the Region. These sources include all Federal, State, Tribal and local partners under interagency and financial assistance agreements; contractors funded by EPA; regulated entities and potentially responsible parties. The Regional Administrator, Senior Leadership, and managers ensure adequate allocation of resources (intramural and extramural money, travel and training funds, and personnel) to achieve R3's Quality Policy. All individuals in the Region who are directly or indirectly involved with environmental data operations have some responsibility for ensuring data quality.*

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This QMP establishes the foundation for implementing an effective Quality System and applies to all R3 programs, activities, grants, contracts, and interagency agreements that collect, evaluate, or use environmental data and information. Section A.8 lists specific examples of environmental programs and activities within each regional organization that is covered by the R3 Quality System. This

QMP also applies to the Region's use of data and information from outside and third-party sources (Sections A.5 and C).

Generally, the following guidelines apply to all environmental data collection, generation, or use; and conducted by R3 personnel or its contractors, grantees, or interagency agreement recipients:

- Appropriate quality assurance (QA) planning documents (e.g., Quality Management Plan (QMP), Quality Assurance Program Plan (QAPrP), Quality Assurance Project Plan (QAPP) or equivalent QA document, Sampling and Analysis Plan (SAP), and Field Sampling Plan (FSP)) are developed and approved for each environmental data collection activity prior to the initiation of data collection, utilization/evaluation or use of secondary data.
- Intended use(s) and data quality objectives (DQOs) of environmental data are identified prior to collection of data in the appropriate QA planning document(s).
- Implementation of projects and tasks involving environmental data generation or use conforms to information provided in approved QA planning documents.
- Oversight of data collection activities is performed by an individual or organization that is independent of data generation activities and any identified deficiencies are promptly corrected.
- Programs and projects that use existing data or data from secondary sources must have an EPA approved QAPP, QAPrP, or equivalent QA document. The QA document should specify the quality system that will be used to determine the suitability of the data for the proposed use.
- QA oversight is performed to ensure that laboratories generating environmental data used in Agency and Regional decision-making are providing usable and defensible results.

The level of QA resources needed for an environmental program and project is determined by the relevant Regional program. R3's Quality System relies on the commitment of Regional decision makers to sufficiently support QA with operational funds and staff resources. The RQAM and ASQAB Chief monitor and report to R3's senior leadership on the relationship between QA resources and effective implementation of the R3 Quality System. Most resources needed for QA are provided from a variety of program elements that utilize QA functions and services. Each Division Director and major office shall ensure adequate resources are available to successfully implement QA requirements for their environmental programs.

## A.2. PRINCIPAL COMPONENTS OF THE QUALITY SYSTEM

The R3 Quality System consists of personnel, functions, tools and procedures used to ensure that data of known quality and sufficient quantity are generated for Regional data users and decision makers. All divisions and offices will periodically inventory and identify places in programs where environmental data is being obtained and used to make decisions. Successful implementation of the R3 Quality System requires a consistent and graded approach for QA practices commensurate with the intended use of the data. A variety of tools and procedures are employed for planning, implementing, and assessing the R3 Quality System. Managers and personnel are informed of the availability and use of these tools through their Divisional Quality Assurance Coordinators (QACs) or Field Activities Coordinators (FACs). The principal components of the R3's Quality System exist at the organization, program, and project levels (Table A.1).

**Table A.1. R3's Quality System Principal Components & Tools**

T=Training, P=Planning, I=Implementation, A=Assessment, FR=Financial Recipients, QI=Quality Improvement, IQG=Information Quality Guidelines

| Component / Tool | Implemented Through | Implemented by Whom |
|---|---|---|
| **Organization-level** | | |
| R3 Quality Management Plan (QMP) | T, P, I, A | All R3 personnel directly or indirectly involved with environmental data operations, RA, RQAM, RQC, Sr. Managers |
| Field Operations Management System (FOMS) | T, P, I, A | FQM, FACs, & all R3 field personnel |
| Tiered-Training Program | T | RQAM, RQC, & ASQAB Quality Staff |
| QA Document Control system | T, P, A | RQAM, QACs, ASQAB Quality Staff |
| Management Assessments, including QA Annual Report & Work Plan (QAARWP) & Quality System Assessments (QSAs) | T, A, FR, QI | RQAM, RQC |
| **Program-level** | | |
| Quality Assurance Program Plans (QAPrP) | T, P, I, A, FR | Any R3 Divisions & Offices & sub-organizations, Financial Recipients |
| Standard Operating Procedures (SOPs) | T, I, A | Any R3 Divisions & Offices and sub-organizations |
| Laboratory Quality Manual | T, P, I, A | LSASD LTSB |
| Chesapeake Bay Program Quality Manual | T, P, I, A, FR | CBPO |
| External Quality Management Plan Status Reports | FR | ASQAB Quality Staff, DPMs |
| Proficiency Testing | A | LSASD LTSB, Other R3 Divisions & Offices as needed |
| Templates & checklists | P, I, A | Any R3 Divisions & Offices & sub-organizations |
| **Project-Level** | | |
| Systematic Planning including Data Quality Objectives (DQOs) | T, P, I, A, FR | All R3 Divisions & Offices & sub-organizations, Financial Recipients |
| Quality Assurance Project Plans (QAPPs) | T, P, I, A, FR | All R3 Divisions & Offices & sub-organizations, Financial Recipients |
| Field Sampling Plans (FSPs) and Sampling & Analysis Plans (SAPs) | T, P, I, A, FR | All R3 Divisions & Offices & sub-organizations, Financial Recipients |
| Technical Assessments, including peer review & laboratory audits | T, P, I, A, FR | All R3 Divisions & Offices & sub-organizations, Financial Recipients |
| Data Assessments, including verification and validation & data quality assessments (DQAs) | T, I, A, FR | All R3 Divisions & Offices & sub-organizations, Financial Recipients |
| Pre-dissemination reviews (Information Quality Guidelines) | T, IQG | All R3 Divisions & Offices & sub-organizations, Financial Recipients |

## A.3 REGION 3 ORGANIZATIONAL STRUCTURE

R3's organizational structure centralizes the leadership, oversight, and management of the regional Quality System through the Regionals Quality Assurance Manager (RQAM) within the Applied Science & Quality Assurance Branch (ASQAB), which is housed in the Laboratory Services & Applied Science Division (LSASD). The RQAM is located in ASQAB but has organizational independence and maintains direct communication with senior management and the Office of the Regional Administrator (ORA). As shown in Figure A.1., the ten units are the ORA; Air & Radiation Division (ARD); Chesapeake Bay Program Office (CBPO); Enforcement & Compliance Assurance Division (ECAD); LSASD; Land, Chemicals, & Redevelopment Division (LCRD); Mission Support Division (MSD); Office of Regional Counsel (ORC); Superfund & Emergency Management Division (SEMD); and Water Division (WD).

Currently, ORC does not perform or manage environmental data operations. MSD administratively manages (i.e., competes, funds, ensures completion of deliverables) Performance Partnership Grants (PPGs) and discretionary funded grants involving environmental data operations. However, a technical representative is assigned to assist in the management of such grants. These grants will adhere to the respective program QA requirements and those specified in this QMP, as applicable.

The RQAM and FQM lead the RQC and FACT respectively for internal coordination of QA/QC activities.

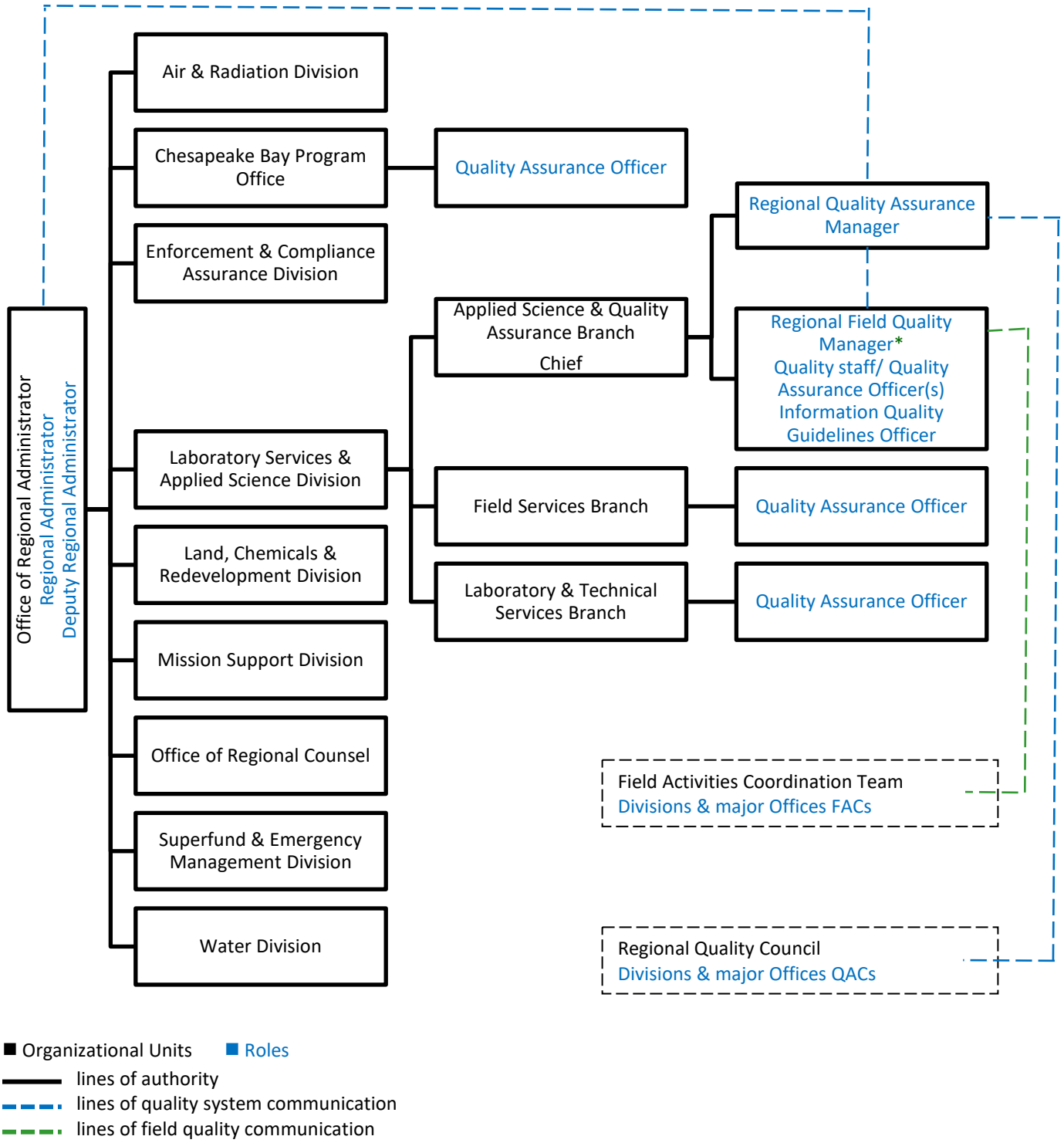


**Figure A.1. Organizational Structure for EPA Region 3's Quality System**

Divisions and major Offices can also have DAOs that are certified by the RQAM and DPMs.

## A.4 EPA QUALITY SYSTEM ROLES & RESPONSIBILITIES

All individuals in the Region who are directly or indirectly involved with environmental data operations have some responsibility for ensuring data quality.

Consistent with EPA Quality Policy, CIO 2105.0, overall responsibility for the quality assurance program in R3 rests with the Regional Administrator (RA). The responsibility for developing and documenting Regional QA policies, procedures, and guidance; overseeing implementation and assessment of the Regional Quality System; and providing QA training has been delegated to the RQAM. The RQAM has authority and responsibility to approve all extramural and intramural environmental data operation QA documents (e.g., QAPPs), unless delegated to a Delegated Approving Official (DAO) or Quality Assurance Officer (QAO) (Section B.4). The RQAM, QAOs, and DAOs maintain independence from environmental data operations, and consequently are able to serve without potential conflict of interest.

Although implementation of the R3 Quality System resides with all Regional staff and managers, the following positions have key roles and authorities. Contact names for certain positions are located in Appendix 2.

### A.4.a Regional Managers & Supervisors

Managers and supervisors have overall responsibility for ensuring all Regional components and programs comply fully with the Agency QA requirements and for resolving disputes regarding Quality System requirements, quality assurance/quality control (QA/QC) procedures, assessments and corrective actions. EPA CIO 2105.0 requires that performance agreements of all supervisors, senior managers, and appropriate staff have critical element(s) that are commensurate with the quality management responsibilities assigned by QA orders and this QMP. Managers and supervisors will assure their understanding and implementation of quality practices in programs and practices by:

- Providing and managing adequate resources to ensure all environmental data in their respective programs are of known quality, defensible, and adequate for the intended use;
- Determining need for DAOs for their organizational unit and coordinating with RQAM, Division QAC, and relevant senior management for initiation and completion of DAO certification program;
- Ensuring that all environmental data operations, extramural, internal, and in the field, are covered by the appropriate documentation (i.e., QAPPs, QAPrPs, SOPs);
- Confirming that all individuals working with environmental data and information have the appropriate QA training commensurate with those responsibilities;
- Assigning a representative to serve on the Regional Quality Council (RQC) as a Quality Assurance Coordinator (QAC) and, if appropriate, a representative to serve on the Field Activities Coordination Team (FACT) as a Field Activities Coordinator (FAC) for each major R3 organization that collects, evaluates, and uses environmental data or performs field activities;
- Cooperating with QA assessments and audits and implementing appropriate corrective actions recommended by the findings; and
- As necessary, ensuring a pre-dissemination review (Section J.1) will be planned and implemented at the start of each applicable project.

### A.4.b Applied Science & Quality Assurance Branch (ASQAB) Chief

The ASQAB Chief provides guidance on the R3 Quality System and oversight of the ASQAB Quality staff. Specifically, the ASQAB Chief is responsible for the following:

- Ensuring Quality staff carry out fully their respective QA responsibilities and work collaboratively to implement R3's Quality System;
- Securing sufficient resources for regional QA training to implement the Quality System; and
- Overseeing resolution of QA disputes working through the Quality staff and with appropriate Senior Management.

### A.4.c Regional Quality Assurance Manager

The Regional Quality Assurance Manager (RQAM), located in LSASD/ASQAB, has been delegated primary responsibility for the oversight and implementation of the R3 Quality System in relevant programs of the Region, external programs that use Agency resources in developing information and data, and in the Agency's use of all secondary data and information.

Specifically, the RQAM is responsible for the following:

- Encouraging a culture of QA in R3;
- Serving as principal advisor, including dispute resolution, to Senior Management and quality staff on all matters concerning the Agency's Quality System;
- Leading and facilitating the RQC as the chairperson;
- Communicating between and among all QA elements, including representing R3 in national meetings; coordinating with staff in EQMD, other regional RQAMs, and R3 state, tribal, and interstate compacts QA contacts; and disseminating Agency QA guidance documents, policies, and procedures;
- Reviewing and approving QMPs for R3, states, tribes, interstate compacts, and other regional organizations (approval of QMPs cannot be delegated to DAOs);
- Reviewing and facilitating development and updates as applicable to national and regional QA documents, including reviews of this QMP, and submitting the Quality Assurance Annual Report and Work Plan (QAARWP);
- Authorizing DAOs and organizations (i.e., state, tribal, and interstate compacts) to review and approve QAPPs;
- Overseeing the Regional QA Training Program, including extramural; leading QA training; and ensuring training levels match responsibilities of QA positions;
- Participating in contract awards as prescribed by contracting regulations;
- Leading internal and external QA assessments, including state, tribal, and interstate compacts, unless covered by EPA program staff; and
- Serving as Regional Alternate Test Procedure Coordinator supporting the Clean Water Act (CWA) National Pollutant Discharge and Elimination System (NPDES) and the Safe Drinking Water Act (SDWA) programs.

### A.4.d Field Quality Manager

The Regional Field Quality Manager (FQM), located in LSASD/ASQAB, ensures the R3 Quality System embodies the Agency's Quality Assurance Field Activities Procedure (QAFAP) for field

activities conducted by EPA or on behalf of EPA. The FQM oversees the Regional Field Operation Management System (FOMS), a component of the overall R3 Quality System.

Specific responsibilities of the FQM include the following:

- Reviewing and facilitating development and updates as applicable to national and regional field QA documents, including reviews of this QMP, and submitting FOMS information for the QAARWP;
- Maintaining FOMS documents (e.g., policies and procedures), records, and the field portion of the document control system;
- Coordinating and managing any internal and external field audits and assessments;
- Leading the Field Activities Coordination Team (FACT);
- Participating on national program meetings and teleconferences to report and represent regional needs and communicates the performance of FOMS to senior management;
- Providing expert technical assistance and training to R3 managers and staff on field-related activities; and
- Serving as back-up and RQAM pro tempore during extended absences of the RQAM.

## A.4.e Quality Assurance Coordinators/ Regional Quality Council

Each Division and major program that collects, evaluates, or manages environmental data and information assigns a Quality Assurance Coordinator (QAC) to serve on the Regional Quality Council (RQC). The RQC is chaired by the RQAM and also includes the FQM, the ASQAB Chief, and LSASD Senior Management Representative; ASQAB quality staff and QAOs may participate as ad hoc members. QACs are responsible for coordinating implementation of the Quality System within their organization. For QA-related activities, QACs have organizational independence within their divisions/offices and maintain direct communication with divisional management. Responsibilities of the QAC include the following:

- Foster QA awareness and disseminate QA information to managers and staff in their organizations;
- Coordinate review of their organization's QA procedures and documentation at least annually or per the prescribed schedule;
- Assist DPMs with the QA document review process and QA-related questions on extramural agreements, review forms, and project guidance, including dispute resolution;
- Coordinate with ASQAB quality staff on QA documentation entries in QA database;
- Assist in preparation and review of the QAARWP;
- Participate in and conduct assessments of R3, their organizations, and related external QA programs to ensure they adhere to this R3 QMP or the applicable EPA-approved QMPs for the external entity being assessed;
- Communicate training needs to the RQC and RQAM and assist with the R3 training program as needed;
- Raise any quality issues or areas of improvement to the RQC as relevant; and
- May provide input with the RQAM, the ASQAB chief, and managers of the applicable programmatic organization to delegate QAPP review and approval authority to States, Tribes, and Interstate Compacts on a case-by-case basis or to accept QMP reciprocity.

## A.4.f Field Activities Coordinators/ Field Activities Coordination Team

Each Division and major program that performs field activities assigns a Field Activities Coordinator (FAC) to serve on the Field Activities Coordination Team (FACT) (Appendix 2). The FACT is led by the FQM and also includes ad hoc members who provide expertise and support. FACs are responsible for coordinating implementation of the Regional Field Operations Management System (FOMS) (Section G.5) within their organization. Responsibilities of FACs include:

- Fostering field QA awareness and disseminate field QA information to managers, staff, and subject matter experts in their organizations;
- Assisting in review and implementation activities to ensure consistent regional field operations;
- Coordinating and maintaining organization's document control process and record system regarding field activities and training;
- Raise any field quality issues or areas of improvement to the FACT as relevant;
- Coordinating and providing organization's field operations training; and
- Assisting and coordinating internal and external assessments (e.g., two assessments of other units per fiscal) of the FOMS to ensure compliance with QAFAP.

## A.4.g Designated Project Manager

A Designated Project Manager (DPM) describes any regional employee with immediate managerial, administrative, or technical control of an internal or external project, program, or extramural agreement involving generation or use of environmental data.

DPMs may have a variety of job titles or functions; some examples are:

Project Officer (PO)
Contracting Officer Representative (COR)
Project Manager
Program Specialist
Site Assessment Managers (SAM)
Remedial Project Managers (RPM)
On-Scene Coordinators (OSC)

Due to the similar QA responsibilities these job titles have, they are referred to as DPMs in the QMP for terminology purposes only (i.e., simplifying text by reducing repetitiveness of all the job titles/functions). The use of the term DPM in the QMP does not replace the use of the job title/function in the actual program/project work.

Specific responsibilities of DPMs are detailed throughout the QMP (e.g., Section C- Procurement of Items and Services and Financial Assistance) and include the following:

- Ensuring internal and extramural projects that generate and handle environmentally-related data adhere to QA requirements and have appropriate documentation (e.g., QAPPs/QAPrPs that fall under the external organization's QMP), including specifying the quality of the data generated/used so they are of defensible and of known quality;
- As applicable for procurements (i.e., contracts), completing and signing the Quality Assurance Review Form (QARF) or Remedial Action Framework (RAF) QARF to determine what, if any, QA documentation is needed and submitting to the RQAM or designee (i.e., QAO) for review and signature;

- For QA document review, submitting the R3 QA Document Review Request to respective Division QAC and ASQAB Quality Staff, discussing review comments with submitting organization as applicable, and sending final approved QA document to submitter (with copy to QAC and ASQAB quality staff);
- Maintaining communications with stakeholders (e.g., document submitters, QACs/ASQAB Quality staff, approving authorities, management staff) and helping coordinate necessary QA-related training for major assistance agreement holders as applicable and needed;
- Working with their Divisional QAC to ensure that QA requirements, data quality issues, and disputes are addressed, and requesting the appropriate resources needed from management;
- Identifying work products subject to peer review, determining the type and timing of such review, and documenting the process and outcome of each peer review;
- Determining whether an information product will be disseminated and ensuring that a pre-dissemination review is completed (Section J.1);
- Receiving the appropriate QA training according to this QMP; and
- Participating in or coordinating internal/external QA assessments of programs, projects, grants, cooperative agreements, contracts, interagency agreements, or other extramural agreements, and as applicable assisting with corrective actions that may be required by findings.

### A.4.h Delegated Approving Official

The RQAM has the authority and responsibility to approve all extramural and intramural environmental data operation QA documents (e.g., QAPPs, SAPs), unless delegated to a Delegated Approving Official (DAO) (Section B.4). DAOs have the responsibility to review and approve QA documents (coordinated through ASQAB quality staff and QAC) to ensure consistency with Regional and Agency Quality policy. Prior to pursing certification, potential DAOs must obtain supervisory and Divisional Senior Management approval which then will be communicated to the RQAM and LSASD Senior Management for confirmation. All DAOs assigned responsibility for QA documents' reviews and approvals have the following requirements:

- Be knowledgeable of EPA requirements for QAPPs and other equivalent QA documents;
- Follow the review process outlined in this QMP, specifically Sections D.2 and F;
- Acquire certification as outlined in Section B.4;
- Have professional knowledge of the subject area; and
- Not approve QA documents they authored or prepared, or for projects/programs they manage.

### A.4.i Quality Assurance Officer

Quality Assurance Officers (QAOs) have the same delegated responsibilities and requirements as listed above for the DAOs and are also responsible for:

- Managing their group's quality practices by ensuring that appropriate quality requirements are included in their group's work that entail data collection, scheduling internal assessments, etc.;
- Assisting their organization's QAC, staff scientists, and DPMs in identifying needs for and developing quality documents and in obtaining answers to technical quality questions;

- Maintaining and regularly reviewing their group's QA-related documentation and managing program- or project-level quality-related documents, data, and records, in accordance with the procedures specified in the Agency policies, guidance, and the R3 QMP;
- Coordinating with the relevant Division QAC and ASQAB Quality Staff for entry of QA documentation in QA database;
- Providing quality training as needed in their organizational unit; and
- Coordinating and managing any internal audits and assessments and as applicable assisting with corrective actions that may be required by findings.

Currently, the following groups have QAOs in R3: ASQAB, CBPO, Regional Laboratory, and LSASD/Field Service Branch (FSB) (Appendix 2).

#### A.4.i.1 Laboratory QAO

Additional details on the responsibilities the Laboratory QAO may perform are the following:

- Developing annual plans and priorities for internal audits, SOP reviews and revisions, and studies, and establishing long-term QA/QC goals;
- Overseeing quality control data (e.g., trend analysis);
- Providing unbiased feedback to management, independent of the laboratory operations, and participating in decisions on laboratory policies and an annual management review;
- Coordinating development of proficiency testing procedures;
- Conducting technical system audits (TSAs) of technical operations (review of SOPs, Demonstration of Capabilities (DOCs), Method Detection Limits (MDLs), and Proficiency Test (PT) sample performance, and procedures and documentation relative to the Laboratory Quality Manual and mandated Agency methods); and
- Coordinating laboratory quality procedures and ethics training.

### A.4.j Information Quality Guidelines Officer

The Information Quality Guidelines (IQG) Officer, located in LSASD's ASQAB, coordinates regional IQG activities with the RQAM, FQM, and R3 Product Review officer. Specific responsibilities of the IQG include the following:

- Provides technical assistance to Regional staff on IQG policies, requirements, and procedures;
- Assists in implementing IQG pre-dissemination review procedures in the Region; and
- Facilitates communication on IQG policies and procedures within the Region and with EQMD staff.

### A.4.k Other Related Positions

The following positions have ancillary QA duties, which are listed below each title.

*Deputy Scientific Integrity Official (LSASD)*
Addresses any R3 questions or concerns regarding the Scientific Integrity Policy.

*Records Liaison Officer (MSD)*
Assist as needed with records management technical assistance and training.

*Regional Peer Review Coordinator (LSASD)*
Provides advice, guidance, and materials to R3 managers and staff for the performance of peer reviews.

*Regional Product Review Officer (ORA/OPA)*
Ensures communications and outreach products provide high-quality information and data to customers and meet the Agency's Product Review requirements.

*Regional Geographic Information Systems (GIS) Coordinator (LSASD)*
Ensures sufficient quality review of GIS and geospatial data, metadata, information, analyses, and products that will be disseminated or used to support R3 decision making, through coordination with DPMs.

*Regional Science Liaison (LSASD)*
Seeks opportunities to bring ORD research products to R3 and its clients (e.g., states, tribes, local governments) and therefore has a responsibility to ensure QA during the process.

## A.5 STATE, TRIBAL, & INTERSTATE COMPACTS ROLES & RESPONSIBILITIES

State, tribal, and interstate compacts are partners with R3 environmental programs, and are vital to achieving the Region's primary mission. R3 enlists the cooperative participation of these agencies in achieving the Region's mission through financial assistance in the form of grants, cooperative agreements (including primacy agreements), and performance partnership agreements (PPAs). As needed, these organizations may use the *Guidance for Developing Quality Systems for Environmental Programs (EPA QA/G-1)* (Appendix 1) to develop their necessary quality components.

### A.5.a Quality Assurance Requirements for Extramural Organizations

Extramural organizations are required to conform to applicable QA requirements, 2 CFR 1500.11, and 40 CFR 30, 31, and 35 (Appendix 1). CFR Title 40 Part 31.45 (Appendix 1) states: “If the grantee's project involves environmentally related measurements or data generation, the grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards, and documentation sufficient to produce data of quality adequate to meet project objectives and to minimize loss of data due to out-of-control conditions or malfunctions.” Extramural organizations, which conduct environmental data operations and receive financial assistance from R3, shall submit a QMP, QAPP, QAPrP, or other appropriate QA documentation for R3’s approval (Sections C.2 and F.1.d).

## A.5.b Region 3 Program Oversight

R3's oversight responsibilities for state, tribal, and interstate compacts quality systems include:

- review of updates and revisions of QA documentation;
- review of annual reports on quality system implementation;
- development and assessment of QA goals in organizations' work plans, PPAs, etc;
- conducting periodic quality system assessments (QSAs) to assess the implementation and effectiveness of the approved quality system;
- oversight of any corrective actions identified in QSAs or other oversight activities; and
- reporting extramural QA activities to EPA Headquarters in the R3 QA Annual Report and Work Plan (QAARWP).

## A.5.c Requirements for Extending Delegation of Approval Authority

R3 can delegate QAPP review and approval authority (QAPrP or other equivalent documents are included and referred to as QAPP for this section) to States, Tribes, and Interstate Compacts on a case-by-case basis, via approval by R3 senior management with input from the RQAM, the ASQAB chief, and the QAC and managers of the applicable programmatic organization. Non-EPA organizations shall request delegation of QAPP approval authority from the RQAM. The delegation request must indicate measures the organization proposes to implement to assure their internal Quality System produces and effectively reviews QAPPs and to provide oversight or assessments to verify adequacy of these measures during the life of the delegation. The QA Manager of the requesting organization must concur with the delegation request.

Some programs such as Superfund pre-remedial, remedial, and removal programs, RCRA Corrective Action, and Clean Air Act air monitoring programs require by regulation that EPA review and approve all QAPPs that support environmental data operations for those programs. In these instances, final QAPP approval cannot be delegated to States, Tribes, or Interstate Compacts.

Consideration for QAPP approval delegation require the following:

1. The requesting organization shall have an approved and current QMP in place prior to the proposed date of delegation. The QMP, which is implemented following approval by the organization's executive leadership and the R3 RQAM, must describe the organization's quality policy and system and identify environmental programs to which the quality system applies. The QMP must also address the following quality system components for delegated approval:
    a. A quality assurance manager (QAM), or person assigned to an equivalent position, who functions independently of direct environmental data generation, model development, or technology development responsibility;
    b. Sufficient resources to implement the quality system defined in the approved QMP.
    c. Assessments to determine effectiveness of the quality system at least annually;
    d. Annual organization report submitted to the R3 RQAM that summarizes the previous year's QA and quality control (QC) activities and outlines the work proposed for the current year;
    e. Use of a systematic planning approach based on the scientific method to develop acceptance or performance criteria for all work covered by EPA Order 2105.0;

f. Approved QAPPs, or equivalent documents defined by the QMP, for all applicable projects and tasks involving environmental data with review and approval having been made by the authorized representative defined in the QMP. QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers;
g. Assessment of existing data, when used to support decisions or other secondary purposes, to verify they are of sufficient quantity and adequate quality for their intended use;
h. Implementation of Agencywide Quality System requirements in all applicable EPA-funded agreements;
i. Implementation of corrective actions based on assessment results; and
j. Appropriate training for all levels of management and staff, to assure that QA and QC responsibilities and requirements are understood at every stage of project implementation.

2. The requesting organization shall have a QSA of their organization conducted by EPA with participation by the organization's QA manager (or equivalent). If either EPA or the requesting organization has conducted a QSA or equivalent assessment within the past year, the assessment is optional, provided that the results were deemed acceptable by the QA Managers of both organizations. The QSA must verify that the requesting organization's Quality System is in conformance with its own approved QMP and with CIO 2105.0 and that the quality practices of the organization are suitably and effectively implemented. The RQAM will notify the QAC of the programmatic organization, who will coordinate the assessment with appropriate DPMs. This assessment shall be led by the RQAM, or designee, with assistance from the applicable programmatic organization.

3. The requesting organization shall have demonstrated a past history of producing and internally reviewing QAPPs (e.g., non-EPA funded) that assures a high level of technical competency is in place prior to the proposed date of delegation. Program/Project Managers from the organization, responsible for QAPP review, shall assure this competency exists by reviewing QAPPs that they previously submitted to R3 QA personnel for review and approval.

If the request for delegation of QAPP approving authority is deemed acceptable and approved by R3, the correspondence memo documenting such approval shall be coordinated by the RQAM and include any limitations or exceptions to the delegation. The requesting organization shall define the delegated process in their QMP. However, the correspondence may also grant the requesting organization the authority to use the approval memo as an interim change to their QMP, until the next routine revision is completed. Following R3's approval, the organization is required to ensure that QAPPs are reviewed and approved prior to initiating environmental data operations for programs and projects encompassed by the approved QMP.

## A.6 QUALITY SYSTEM COMMUNICATIONS

Effective and regular communications between and among all Regional QA elements are essential in implementing and maintaining R3's Quality System. The RQAM and ASQAB Chief are principally responsible to ensure Quality System communications are effective and regular. On a regular and as-needed basis, the RQAM and FQM will keep the LSASD Director, ASQAB Chief, RQC, FACT, and senior managers apprised of QA issues that impact the Region's Quality System. In addition, the R3 QMP, QA developments, policies, and procedures will be distributed to all management at the division and branch levels, QACs, FACs, DAOs, and QAOs, and posted on the R3 Quality System intranet page, as applicable. Each revision of R3's QMP will be similarly posted and older versions archived. QAPPs, extramural QAPrPs, other QA documents, and status of QMPs will be posted on the Region's internet/intranet site, as applicable. QA communications of an Agencywide nature take place at the national level during regular teleconferences, meetings, and electronic messaging and involve EQMD, other EPA Regions and program offices, and include the RQAM, RQC, FQM, ASQAB Quality staff, QAOs, and other RQAMs/FQMs.

The RQAM and FQM shall ensure the RQC and FACT meet on a regular basis for internal coordination of QA activities. These groups are the primary cross-Divisional groups for addressing QA topics and field activities respectively that impact the entire Region and should meet at least quarterly to discuss and resolve issues about QMP or FOMS implementation and its impact on data quality. The RQC also considers ways to improve the Region's Quality System. The RQAM and FQM will attend other internal meetings in which QA is discussed, such as ongoing quarterly Project Officers' Forum.

## A.7 DISPUTE RESOLUTION

In order to resolve disputes related to QA, R3 will first utilize, to the maximum extent practicable, informal procedures by elevation through the R3 management chain, particularly for internal disagreements dealing with the R3's Quality System and QMP. The RQAM, ASQAB Chief, and appropriate Senior Management should always be notified of any R3 Quality System related disputes. Failing that process, R3 will utilize the Conflict Prevention and Resolution Center (CPRC) (Appendix 1) that supports EPA's regulatory, enforcement, and voluntary programs by providing alternative dispute resolution (ADR) services (Appendix 1) to the entire Agency. Expert CPRC staff, specialists in ADR in EPA's 10 regions, as well as professionals engaged through the CPRC's Conflict Prevention and Resolution Services contract, help EPA and its stakeholders exchange ideas and information, identify areas of concern and common interest, develop recommendations, prevent and overcome disputes, and reach agreements. Every office at EPA has access to this contract to quickly hire professional neutral facilitators and mediators to assist with preventing and reducing conflict associated with their environmental projects. The CPRC supports ADR across the Agency, pursuant to EPA's ADR Policy.

## A.8 ORGANIZATIONS' QUALITY COMPONENTS IN THE REGIONAL QMP

R3 organizations (i.e., divisions and major offices) that perform QA-related activities through their management of environmental data and information shall develop and maintain QA documentation (e.g., SOPs, QAPPs, QAPrPs, program guidance) that meets the requirements outlined in this

Regional QMP. The organization's QA requirements may be more, but not less, stringent than those presented in the R3 QMP. All organizations' QA documentation shall be approved by appropriate authorities and documented as detailed in Section D. Changes to any organization's QA documentation shall be documented and reported in the QAARWP.

This section includes major (not all inclusive) program areas/activities for each R3 organization that may include QA responsibilities. Additional organizational information (e.g., general description, QA document list) is included in each organization's respective appendix.

### A.8.a Office of the Regional Administrator (ORA)

ORA provides the overall supervision of the Region, with all Division Directors reporting to the RA. ORA's offices perform QA activities that may include reviewing, analyzing, retrieving, and conveying environmental information and corresponding existing data (and sometimes primary data).

Environmental data and information programs within ORA include the following:

- environmental justice;
- tribal and international affairs;
- children's health;
- environmental education programs; and
- National Environmental Policy Act (NEPA).

Additional information on ORA's responsibilities and functions are included in Appendix 6.

### A.8.b Air & Radiation Division (ARD)

The ARD implements the programmatic aspects of Clean Air Act (CAA) within the geographic boundaries of R3 (except for inspections and enforcement which are managed by ECAD).

The ARD is organized into four Branches with a wide variety of functions and QA responsibilities described in Appendix 7.
Environmental data programs and some QA responsibilities include the following:

- Implementing the National Performance Evaluation Program (NPEP) programs;
- Distributing technical QA information and related training to monitoring organizations;
- Elevating QA needs of states, tribes, and local monitoring organizations to EPA Headquarters that are national in scope;
- Analyzing, modeling and conducting quality assurance on air quality data;
- Administering grants program and related QA requirements; and
- Conducting QA functions in support of these activities, including approving QAPPs, reviewing SOPs, conducting technical systems audits (TSA), and evaluating secondary data.

### A.8.c Chesapeake Bay Program Office (CBPO)

The CBPO promotes the facilitation and coordination of the interests of federal agency partners as stated in Section 117 of the Clean Water Act (CWA) to implement the Executive Council (EC)

Agreements (most current version, Appendix 1). The CBPO supports the EC by implementing and coordinating science, research, modeling, monitoring, data collection, and other activities and represents EPA on the Chesapeake Bay Program's (CBP's) Federal Office Directors group.

Some of the environmental programs and their associated data/information products and services supported by the CBPO are below:

- Mainstem, Tidal Tributary, and Shallow-Water Monitoring Programs;
- Nontidal Water Quality and Stream Flow Monitoring Programs;
- Biological and Benthic Invertebrate Monitoring Programs;
- Monitoring and Assessment of Toxic Contaminants in the Chesapeake Bay;
- Bay-wide Submerged Aquatic Vegetation Aerial Survey Programs;
- Modeling Programs;
- Best Management Practices and Verification; and
- Bay grants program.

The description of the CBPO organizational structure can be found in Appendix 8. The CBPO Quality Program developed a Quality Manual that complies with requirements set forth in this QMP.

### A.8.d Enforcement & Compliance Assurance Division (ECAD)

ECAD is responsible for developing and implementing R3 enforcement and compliance assurance programs and statutes that EPA administers. ECAD's three branches have a wide range of activities that generate data including compliance monitoring inspections, field sampling, and other compliance assurance activities.

Environmental data and information programs within ECAD are the following:

- Data systems support, analysis and reporting of enforcement data using systems such as ICIS, ICIS-NPDES, ICIS-Air, SDWIS, RCRAInfo, ECAD's Pipeline Case tracking system, etc.;
- Maintenance of required training and credentials for inspectors; and

Field and laboratory data-generated activities used for investigations of environmental impacts or facilities' compliance with EPA's statutes and regulations.
Additional information on ECAD's responsibilities and functions are included in Appendix 9.

### A.8.e Laboratory Services & Applied Science Division (LSASD)

LSASD's three branches provide technical expertise, program support, and are responsible for oversight of the R3 quality system, laboratory and field services, and geospatial and scientific analyses.

LSASD's environmental data programs and some QA responsibilities include the following:

- R3 Quality System, including FOMS;
- Laboratory analyses and assessments;
- Field services and data analyses, including:
    - Condition evaluation and biological sampling of aquatic resources; and

    - Development & refinement of biocriteria, bioassessment tools, and environmental indicators;
- GIS & geospatial analyses and environmental modeling; and
- Scientific integrity and peer review.

Additional information on LSASD's responsibilities and functions are included in Appendix 9.

## A.8.f Land, Chemicals, & Redevelopment Division (LCRD)

LCRD's five branches implement programs through oversight and assistance including state and tribal delegated programs, direct program implementation, issuing permits, tribal projects, grants management, oversight of trust funds, partnership efforts, program approvals, technical assistance, community engagement and outreach, and projects to promote sustainable environmental results.

Environmental data and information programs within LCRD include:

- Asbestos Hazard Emergency Response Act (AHERA) and Asbestos Hazard Abatement Act (ASHAA);
- CAA- National Emission Standards for Hazardous Air Pollutants (NESHAP);
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);
- Toxic Substances Control Act (TSCA);
- Resource Conservation and Recovery Act (RCRA);
- Pollution Prevention Act of 1990 (PPA); and
- Emergency Preparedness and Community Right-to-Know Act (EPCRA).

The description of the LCRD organizational structure and additional QA information can be found in Appendix 11.

## A.8.g Mission Support Division (MSD)

Environmental data and information programs within MSD's eight branches are contained principally within its responsibilities for procurement of items and services and financial assistance agreements, including:

- Managing the National Environmental Performance Partnership System (NEPPS); and
- Managing, assisting, and overseeing administrative aspects of contracts and assistance agreements (including grants and cooperative agreements), including QA requirements and procedures.

The description of the MSD organizational structure and additional QA information can be found in Appendix 12.

## A.8.h Office of Regional Counsel (ORC)

The ORC's seven branches provide legal counsel and assistance in the implementation and enforcement of environmental programs and does not have any direct QA activities. The description of the ORC organizational structure is in Appendix 13.

### A.8.i Superfund & Emergency Management Division (SEMD)

The SEMD's five branches conduct and oversee assessment, remedial, and removal activities at hazardous waste sites and responds to disasters in R3. SEMD environmental data and information programs are related principally to the following statutes:

- Comprehensive Environmental Response Compensation and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA);
- Section 311 of the Clean Water Act (CWA), as amended by the Oil Pollution Act of 1990 (OPA);
- National Oil and Hazardous Substance Pollution Contingency Plan (the National Contingency Plan or NCP); and
- National Response Framework (e.g., Robert T. Stafford Disaster Relief and Emergency Assistance Act).

The description of the SEMD organizational structure and additional QA information can be found in Appendix 14.

### A.8.j Water Division (WD)

The WD's four branches implement the programmatic aspects of the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) within the geographic boundaries of R3, except for inspections and enforcement, which are principally managed by ECAD.

Under these statutes and in accordance with implementing regulations and Agency guidelines, the Division conducts environmental data and information programs, which:

- Ensure drinking water is safe;
- Restore and maintain watersheds and their aquatic ecosystems to protect human health and recreation; and
- Provide healthy habitat for fish, plants, and wildlife.

The description of the WD organizational structure and additional QA information can be found in Appendix 15.

## A.9 PLANNING, IMPLEMENTATION & ASSESSMENT MODEL

R3 has adopted the Planning, Implementation, and Assessment (PIA) quality model as the foundation of its Quality System. The model, Figure A.2., is an iterative three-step approach and serves as the theme for this QMP and its approach is integrated into all aspects of this document. Application of the quality model is appropriate for all R3 environmental operations, administrative activities, and extramural agreements.

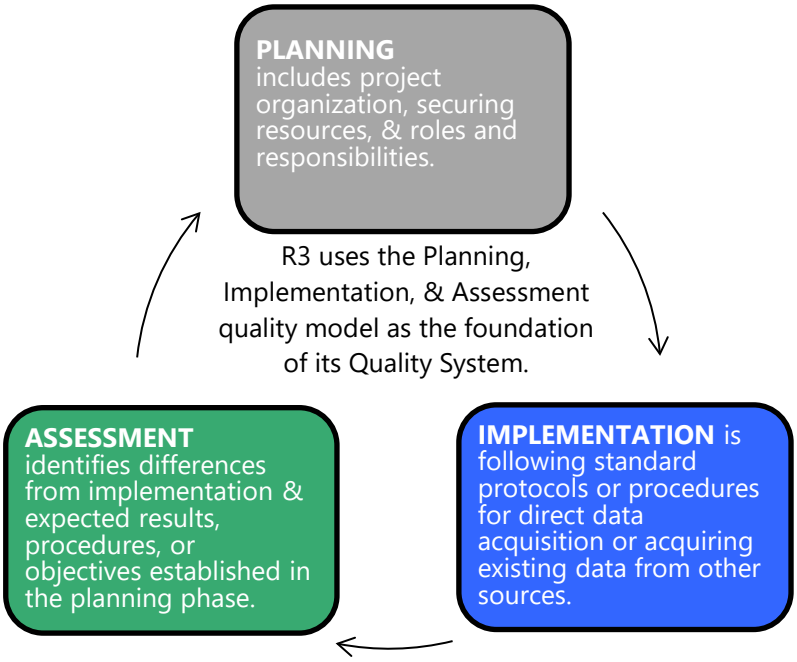


**Figure A.2. R3 Quality Model**

PLANNING establishes the objectives and processes necessary to deliver results in accordance with the desired output or goals. (Section F).

IMPLEMENTATION is the execution of the planned activity. (Section G).

ASSESSMENT monitors and measures the process performance through the assessment of the project or program. Assessment also encompasses corrective action(s) taken for significant differences between actual and planned results. (Section H).

Figure A.3. shows an example of how the PIA model works at the project level.

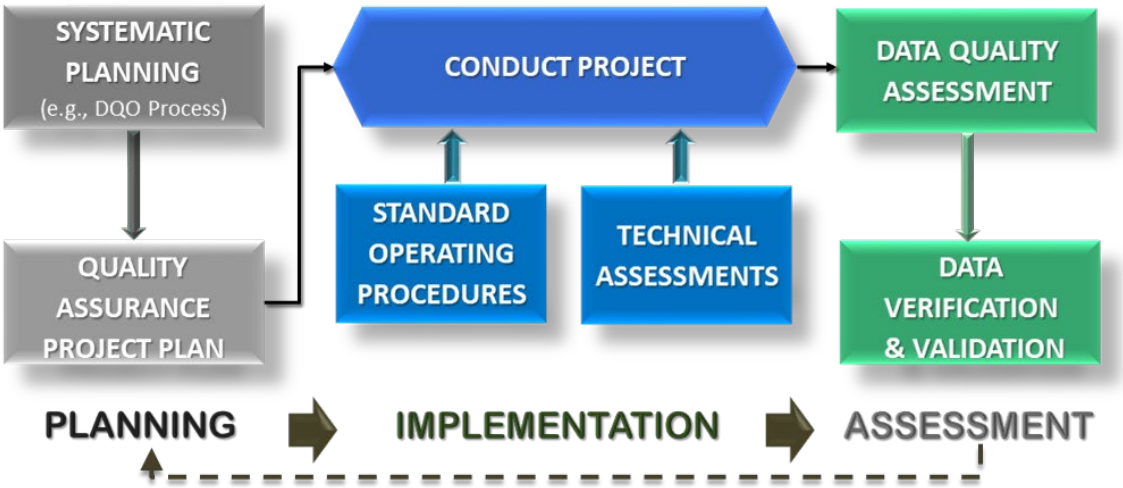


**Figure A.3. Example of the PIA model at the project level.**

# SECTION B: PERSONNEL QUALIFICATIONS & TRAINING

The Region is committed to ensuring that all personnel have the necessary skills to effectively accomplish their assigned tasks to carry out EPA's mission. The R3 QA training program shall be administered through a collaborative effort between ASQAB and the RQC. Additional training support for non-routine topics may be provided by the EQMD, other Regions, other Federal Agencies, local universities, contractors, or professional organizations.

All Regional personnel involved with environmental data operations shall have the appropriate QA training and understand their QA roles and responsibilities. Managers, with assistance from the RQAM, FQM, and QACs, have the responsibility to ensure staff meet the minimum QA training requirements for their assigned activities and determine the need for DAOs for their organizational unit (Section A.4.a and B.4). Senior Managers must ensure that adequate resources are available for the successful execution of the QA training program.

R3 staff must be trained to the level of their tasks and functions related to data quality for Regional programs. Additionally, they will use their educational background, experience, and on-the-job training to help them assure the quality of data. Training may include PO Certification, which is required of all grant managers in the Region, and inspector training for relevant staff. In addition, under EPA's contracting policy, quality training for CORs is required.

***Region 3 Policy***

*R3's policy is to ensure that all persons involved in handling environmental data are appropriately QA trained to their level of responsibility and understand the relevant portions of the Region's Quality System.*

## B.1 IDENTIFICATION OF TRAINING NEEDS

Each R3 organization shall collaborate, through the QACs and FACs, with the RQAM and FQM respectively to determine their organization's QA training needs in accordance with the procedures specified in this QMP. EPA's *Guidance for Developing a Training Program for Quality Systems, EPA QA/G-10* (Appendix 1) may be used as a tool for this exercise.

Personnel training needs can be identified during development of individual development plans, annual performance reviews, or divisional training needs assessments. When QA training is needed, Program Managers submit a training request to their organizational QAC or FAC, who then conveys the request to the RQAM and RQC or FQM and FACT respectively. The RQC shall annually review and determine if training needs for Divisions and Programs are being met and report their status in the QAARWP. When QA training needs are identified, the RQC shall determine the level of training required and path for implementation of such training. If the training is not currently available, the RQC will decide the best approach to develop and incorporate the training to the R3 QA tiered training program.

Implementation of QA requirements for extramural agreements is a critical component of R3's Quality System. DPMs should support major assistance agreement holders in obtaining necessary QA-related training.

## B.2 QUALITY ASSURANCE TRAINING PROGRAM

This section describes the R3 QA tiered-training program courses and descriptions (Table B.1). Courses follow a tiered approach to fit the QA needs and responsibilities of R3 personnel and external stakeholders. Other courses may be developed or modified as additional training needs are identified.

Other organizational units (i.e., divisions or branches) may also provide their staff or external stakeholders training on quality requirements and procedures specific to their group, which complements the R3 QA tiered-training program. For example, the Laboratory QAO will conduct a Laboratory QA Awareness and Operations course for LTSB staff that provides an overview of the R3 laboratory QA requirements, Laboratory Quality Manual, accreditation requirements, SOPs, and additional mandatory and optional QA training. Some programs also have strong QA training though a national program. The ambient air monitoring program has monthly QA calls between the EPA headquarters office and the Regions, a bi-annual national meeting, and QA training sessions in different locations as needed.

**Table B.1. Core Quality Assurance Courses**

| Course Title | Description | Frequency |
|---|---|---|
| **Tier 1** | | |
| R3 Quality System Awareness | Awareness training of the R3 Quality System. | Offered annually; required biennially as refresher (refresher may be substituted by national web-based QA awareness training). |
| Senior level Quality System Awareness (Regional Administrator & Senior Leadership only) | Awareness training for Senior Management covering roles and responsibilities for Quality System implementation. | Offered annually |
| Field Operations Management System awareness training (R3 Field Personnel only) | Awareness training covering R3 implementation of the Quality Assurance Field Activities Procedures. | Offered annually; required biennially as refresher |
| **Tier 2** | (requires QA Awareness training) | |
| Systematic Planning for Environmental Data Operations | A review of systematic planning in which participants will learn QA elements of a systematic planning approach based on the scientific method and includes training on data quality objectives. | Offered biennially or more frequently as needed |

| Course Title | Description | Frequency |
|---|---|---|
| Quality Assurance Project Plans | An overview of the 24 QAPP elements found in EPA QA/R-5 & Uniform Federal Policy (UFP)-QAPP with the need for systematic planning & EPA's graded approach to project plan development being emphasized. Based on training needs, the course may focus on how to write & review QAPPs & include more detailed training for those seeking to become Delegated Approving Officials (DAOs). | Offered biennially or more frequently as needed |
| Secondary Data QA | Overview of secondary data applications & evaluation for Quality Assurance. Possible scenarios & implications of data usage. | Offered biennially or more frequently as needed |
| Quality Management Plans | An overview of the requirements found in EPA QA/R-2 for quality management plans for organizations that conduct environmental data operations for EPA through contracts, assistance agreements, & interagency agreements. | Offered biennially or more frequently as needed |
| Field Operations | A synopsis of the R3 FOMS (including the regional 10 SOPs) that apply to all field data activities (sampling & non-sampling) to ensure quality & consistency across field activities in the Region. *Additional detailed courses may be offered under field operations, e.g. chain of custody, sample collection, calibration & field measurements, records & equipment management, etc.* | Offered biennially or more frequently as needed |
| Data Evaluation | This course shall provide an overview of data validation & usability. Participants will acquire knowledge of 1) the importance of data validation; 2) R3's data validation procedures; & 3) the usability of data against project objectives. | Offered biennially or more frequently as needed |
| Information Quality Guidelines | Participants will acquire: 1) knowledge of the origin & intent of the 2001 Data Quality Act; 2) information on the implementation of EPA's Information Quality Guidelines (IQGs); 3) insight on managing IQG requests; & 4) appreciation of the impact of the IQGs on enhancing EPA's Quality System. | Offered biennially or more frequently as needed |
| Standard Operating Procedures | Provides framework for development of both administrative & technical SOPs. | Offered biennially or more frequently as needed |
| **Tier 3** | (may require specific Tier 2 training as prerequisite) | |
| Quality System Assessments | This course is designed to prepare those who will either assess or be assessed as part of an EPA or EPA-supporting quality system, according to *Guidance on Assessing Quality Systems, EPA QA/G-3*. | Offered biennially or more frequently as needed |
| Field Quality Assessments | Participants will gain an understanding of what a field quality assessment entails & how to conduct one. | Offered biennially or more frequently as needed |
| Advanced data validation & verification | Provides a more detailed review of data validation levels & data verification procedures. | Offered biennially or more frequently as needed |

## B.3 TRAINING REQUIREMENTS

Regional personnel shall be required to have appropriate QA training and understand their QA roles and responsibilities. Table B.2 illustrates the required QA-related training courses by functional role/title.

To ensure R3 personnel maintain quality-related competencies, repetitive courses and refresher training can be taken through R3 or other relevant entities (e.g., other Regions, EQMD). The R3 QA Awareness course is required for R3 staff biennially to maintain general QA proficiency.

**Table B.2. Training Requirements by Functional Role/Title**

✧ Optional

| Functional Role/Title | Tier 1 | Tier 2 | Tier 3 |
|---|---|---|---|
| Regional Administrator & Senior Leadership | ✓ (Senior level only) | ✧ | ✧ |
| Managers & Supervisors | ✓ | ✧ | ✧ |
| Regional QA Manager | ✓ | ✓ | ✓ |
| Quality Assurance Coordinators | ✓ | ✓ | ✧ |
| Quality Assurance Officers | ✓ | ✓ | ✓ |
| Delegated Approving Officials | ✓ | ✓ | ✧ |
| Designated Projects Managers | ✓ | ✧ | ✧ |
| Field Quality Manager | ✓ | ✓ | ✓ |
| Field Activities Coordinators | ✓ | ✓ | ✧ |
| Information Quality Guidelines Officer | ✓ | ✓ | ✧ |
| R3 Field Personnel | ✓ | ✧ | ✧ |
| R3 Staff | ✓ | ✧ | ✧ |

## B.4 CERTIFICATION REQUIREMENTS

Prior to pursing certification, potential DAOs must obtain supervisory and Divisional Senior Management approval, which then will be communicated to the RQAM and LSASD Senior Management for confirmation. The RQAM can certify DAOs and QAOs through a formal memo after they complete and provide documentation for the courses listed in Table B.3 and demonstrate proficiency of the knowledge and skills acquired. Based on experience and previous equivalent and on-the-job training, the RQAM may also grant provisional certification until all training requirements are completed. To maintain certification, DAOs and QAOs must complete 4 hours of QA training annually (e.g., refresher, program-specific, professional conferences and meetings, on-the-job proficiency testing).

### Table B.3. Certification Requirements

✧ Optional

| Course Title | DAO Certification | QAO Certification |
|---|---|---|
| **Tier 1** | | |
| Region 3 Quality System Awareness | ✓ | ✓ |
| Senior level Quality System Awareness | N/A | N/A |
| Field Operations Management System awareness training | ✓ | ✓ |
| **Tier 2** | | |
| Systematic Planning for Environmental Data Operations | ✓ | ✓ |
| Quality Assurance Project Plans | ✓ | ✓ |
| Secondary Data QA | ✓ | ✓ |
| Quality Management Plans | ✓ | ✓ |
| Field Operations | ✧ | ✧ |
| Data Evaluation | ✓ | ✓ |
| Information Quality Guidelines | ✓ | ✓ |
| Standard Operating Procedures | ✧ | ✓ |
| **Tier 3** | | |
| Quality System Assessments | ✧ | ✓ |
| Field Quality Assessments | ✧ | ✧ |
| Advanced data validation and verification | ✧ | ✧ |

## B.5 DOCUMENTATION OF TRAINING

Completion of QA training shall be documented and certified by the RQAM or appropriate authority. Personnel are responsible for maintaining and providing evidence of training completion upon request. QA training evidence shall be entered into the QA database by ASQAB Quality staff, in coordination with the respective QAC. Web-based Agency courses shall be tracked online and entered into the QA database as needed.

QA-related training files (e.g., PO certification, inspector training, on-the-job training) will be maintained by supervisors and tracked online for web-based Agency course(s). ASQAB Quality staff will provide support and update the QA database as needed. MSD maintains attendance lists of certification courses for POs and CORs.

At the end of each fiscal year, the RQAM or designee shall provide a summary of the QA training courses held in the Region in the QAARWP. This summary shall include, but is not limited to the courses held, number of attendees, and a list of all non-EPA participating organizations.

Certifications of DAOs and QAOs shall be documented and tracked by the RQAM and ASQAB Quality staff, in coordination with the QAC, through appropriate documentation and QA database. It is the responsibility of the certified personnel to submit any additional documentation supporting their annual recertification requirement to ASQAB Quality Staff, in coordination with the QAC.

# SECTION C: PROCUREMENT OF ITEMS & SERVICES & FINANCIAL ASSISTANCE

The R3 QMP applies to all R3 contracts and financial assistance agreements (including grants, cooperative agreements, and interagency agreement), which collect, evaluate, or use environmental data and information.

## C.1 PROCUREMENT OF ITEMS & SERVICES- CONTRACTS

The Contracts Branch within MSD is responsible for developing and maintaining current Regional purchasing policies and procedures. The relevant federal QA regulation for contracts is 48 CFR 46 (Appendix 1). QA requirements for contracts are set forth in the EPA Acquisition Guide (EPAAG) Subsection 46.2.1 (Appendix 1) and the Federal Acquisition Regulation (FAR) 46.202-4 and 52.246-01 (Appendix 1).

To ensure that contractually procured environmental data operations are scientifically valid, defensible, and of known precision and accuracy, DPMs (i.e., COR) are responsible for adhering to EPAAG Subsection 46.2.1. Requirements include the QA Review Form (QARF) as shown in EPAAG appendix 46.2.1-D (see Appendix 14 for SEMD information). The QARF shall be completed and signed by the DPM. The DPM signature indicates that the agreement is complete and accurate, clearly describes the item or service needed, and that associated technical and quality requirements are defined. The RQAM or designee (i.e., QAO) reviews and signs the QARF to assure that all environmental data operations contractually funded by EPA are in compliance with CIO Policy 2105.0.

Where QA requirements apply, the DPM will assure that QA terms and conditions are included in contract statements of work. The QA terms and conditions require contractors to document its Quality System in a QMP and submit QAPPs or appropriate planning documents that meet EPA program-specific project goals and objectives. The DPM will assure that the contractor complies with the conditions and deliverables. The QMP shall be reviewed by the DPM and reviewed/approved by the RQAM or designee as described in Section F.1.d of this QMP as a condition for award of any contract involving environmental data operations. The QMP shall be submitted as part of the contract proposal.

If the QMP is not submitted as part of the contract proposal and EPA decides to award the contract, EPA will include terms and conditions requiring the contractor to submit the QMP within a specified timeframe after award of the contract. The contractor may not begin work involving environmental data operations until the EPA COR provides notification of QMP approval.

Prior to undertaking any work involving environmental data collection or use, the contractor shall also be required to submit QAPPs (or QAPrPs) to EPA for review by the EPA COR and approval by an EPA Reviewer/Approving Authority (i.e. RQAM, QAO or DAO) according to the procedures described in Sections F.2 and F.3 of this QMP.

The RQAM or designee (e.g., ASQAB quality staff, QAC, QAO, etc.) may be included as part of the Technical Evaluation Panel (TEP) to evaluate adherence to technical and quality requirements. The TEP develops evaluation criteria and SOW for the solicitation and performs the technical evaluation of offers. The COR is responsible for ensuring that procurement of items and services conform to specifications and needs of the program prior to payment as well as throughout the life of the contract or purchase. The quality requirements of the items or services to be purchased for a given project are defined in the project QAPP, SOP, or other planning document. When program needs and requirement changes affect the technical specifications of the required items and services, these changes need to be documented in the applicable QMP, QAPP, SOP, or other planning document prior to initiating additional purchases or change orders.

## C.1.a Competency Policy for Agency-Funded Acquisitions

EPA's Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions (Agency Policy Directive #FEM-2011-01, Appendix 1) requires organizations (e.g., laboratories, field sampling, and measurement) generating environmental data through measurements under Agency-funded acquisitions must submit documentation of their competency, which may include participation in applicable certification or accreditation programs.

Organizations performing environmental analyses for the Agency shall demonstrate their qualifications in the fields of analyses to be conducted, prior to performing such analyses. Where accreditation or certification is available for those fields of analysis, organizations may submit documentation of existing accreditations or certifications. Accreditation and certification granted by an organization that accredits environmental data operations to an international consensus standard, or a state accreditation or certification program acceptable to EPA, or the contracted laboratory's participation in the EPA Contract Laboratory Program for those fields of analyses, shall be valid at the time of award and must be sustained through the life of the period of performance.

Additional information on the requirements, including necessary documentation, are found in Questions Q12-15 of the Competency Policy's accompanying Frequently Asked Questions (Appendix 1).

## C.2 FINANCIAL ASSISTANCE

***Region 3 Policy***

*Recipients of R3 financial assistance (i.e., grants, cooperative agreements, contracts, and interagency agreements) that involve the generation, collection, compilation, and use of environmental data must develop and implement QA policies and practices that are sufficient to produce data of adequate quality to meet program objectives.*

### C.2.a Grants & Cooperative Agreements

EPA quality assurance requirements for grants and cooperative agreements are contained in 2 CFR 1500 and 40 CFR Part 35 for non-profits, universities, and state, tribal, and local governments.

The DPM, i.e., PO, will ensure the grant or cooperative agreement is complete and accurate, clearly describes the item or service needed, and that associated technical and quality requirements are defined. The DPM will also indicate on the Funding Recommendation whether the project involves environmental data operations and thus quality requirements apply. If they do, EPA will insert programmatic terms and conditions in the grant or assistance agreement per the *National Programmatic Terms and Conditions* (updated annually by Office of Grants and Debarment- Appendix 4). The terms and conditions require the financial assistance recipient to have in place a current EPA-approved QMP, or submit a new QMP within a specified timeframe. New QMP submittals shall be prepared in accordance with *EPA Requirements for Quality Management Plans, EPA QA/R-2,* and reviewed and approved by the RQAM or designee (Section F.1.d).

A condition will also be included in the assistance agreement requiring the recipient to submit a QAPP (or QAPrP) to R3 for review by DPMs and approval by a DAO or QAO (Sections F.2 and F.3). The QAPP (or QAPrP) shall be prepared in accordance with the specifications provided in the *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5*. The recipient may not begin work involving environmental data operations until the QMP and QAPP (or QAPrP) have been approved by the RQAM. The DPM will ensure the grantee complies with the terms and conditions. On a monthly basis, the RQAM reviews notifications of newly awarded grants, cooperative agreements, and IAs to determine whether QA requirements were appropriately addressed.

For certain financial assistance agreements, a combined QMP/QAPP (not equivalent to a QAPrP) may be submitted in place of individual QMP and QAPP documents. The suitability and content of the combined QMP/QAPP shall be determined by the DPM, in consultation with the RQAM or designee. At a minimum, the combined QMP/QAPP shall adhere to the QMP and QAPP elements as outlined in the most recent versions of *EPA Requirements for Quality Management Plans, EPA QA/R-2,* and *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5*, respectively.

## C.2.b Interagency Agreements

When R3 is providing funds to another Federal organization, the organization receiving the funds is responsible for complying with EPA's QA requirements, including the preparation of a QMP or equivalent document if required. Before any environmental data operations can be performed, the external organization must have an approved QMP and QAPP (or combined QMP/QAPP). If the external organization's documented Quality System meets the requirements found in the *EPA Requirements for Quality Management Plans, EPA QA/R-2* or the *Intergovernmental Data Quality Task Force: Uniform Federal Policy for Implementing Environmental Quality Systems, EPA-505-F-03-001*, their QMP, or equivalent document shall be deemed acceptable. If comparable QA procedures do not exist, the QA procedures agreeable to both parties must be negotiated for the Interagency Agreement (IA). These QA requirements are in accordance with specifications set forth in *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5* or the *Intergovernmental Data Quality Task Force: Uniform Federal Policy for Quality Assurance Project Plans, EPA-505-B-04-900A*, as appropriate.

In order to document compliance with the above policy, the EPA DPM shall indicate in the IA Program Decision Memorandum (Office Authorization for the Award) whether QA requirements apply. If so, the DPM will include a special condition in the IA that notifies the other Federal agency that it must submit a QMP and QAPP to the DPM. R3 will review and approve the QA documents. After the IA is executed by both parties, the DPM will ensure the recipient of the IA complies with the QA condition(s).

## C.2.c Competency Policy for Agency Funded Assistance Agreements

EPA's Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency Funded Assistance Agreements (Agency Policy Directive # FEM-2012-02, Appendix 1) requires organizations generating or using environmental data under certain Agency-funded assistance agreements (excluding IAs) to submit documentation of their competency prior to award of the agreement. If that is not practicable, those organizations shall submit documentation of their competency prior to beginning any work involving generation or use of environmental data under the agreement. This includes organizations performing environmental sampling, field measurements, or laboratory analyses under Agency-funded agreements.

While the policy can be used for lower thresholds, it applies to new competitive and non-competitive awards that at the time of solicitation, issuance, or award are expected to exceed $200,000 (in federal funding) in total maximum value (including any amendments). This Policy does not replace any existing requirements (e.g., general information, quality system requirements documentation) or prohibit an Agency program from placing additional requirements or stipulations on an organization receiving an award. DPMs are responsible for implementing the requirements under this Policy and ensuring that appropriate solicitation provisions and programmatic terms and conditions, if necessary, are included in solicitations and assistance agreements.

Organizations performing activities involving use or generation of environmental data under covered assistance agreements shall provide R3 with the following:

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

Additional information on the requirements are found in questions Q11-15 of the Competency Policy's accompanying Frequently Asked Questions (Appendix 1).

## C.3 EVALUATION OF DELIVERABLES

DPMs establish the framework for monitoring the quality of items or services by incorporating inspection and acceptance criteria into contract statements of work or work plans for grants and IAs. DPMs are responsible for oversight and for ensuring that deliverables are complete, accurate, and meet contract, grant, cooperative and IA requirements. Oversight of contractor QA-related products is accomplished principally by the efforts of the RQAM, DAOs, and QAOs and other designated technical specialists (e.g., scientists, risk assessors, hydrologists) as requested by the DPM.

# SECTION D: DOCUMENTS & RECORDS

Maintaining QA documents and records assures that quality-related documentation requiring management control is accessible and protected. This process ensures compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs, while providing adequate preservation of key records necessary to support the mission of the Region.

R3 adheres to the most recent version of the Agency's *Records Management Policy (CIO 2155.4)* (Appendix 1), divisional Record Management SOPs as applicable, and the R3 QAFAP Document Control SOP (most current version). Records disposition schedules, federal laws, and additional records management policies and information are available on the EPA National Records Management Program web site (Appendix 1). The required qualifications for personnel working with records include being familiar with Agency Records Management procedures and topic-specific procedures outlined in this QMP.

> ***Per the Federal Records Act 44 U. S. Code, Chapter 33, Section 3301, records are defined as****: "all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data in them."*

## D.1 DOCUMENT & RECORD MANAGEMENT

The RQAM, QACs, FACs, ASQAB Quality staff, and QAOs are responsible for managing regional or divisional quality-related policies, procedures, and documents, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, deterioration, theft or unauthorized removal), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with Agency policies, guidance and the R3 QMP. ASQAB Quality staff are responsible for the oversight, overall management, and support of all QA information in the QA Database. DPMs are responsible for managing program- or project-level quality-related documents and records, including transmittal, distribution, retention, access, preservation (including protection from damage, loss, deterioration, theft or unauthorized removal), traceability, retrieval, removal of obsolete documents, and disposition, in accordance with the procedures specified in the Agency policies, guidance and the R3 QMP. Document authors and DPMs may have removal and archiving responsibilities based on validity or version of document.

Each Division and Office is responsible for establishing and implementing chain of custody (COC) and confidentiality procedures including confidential business information (CBI) and

evidentiary quality-related documents and records in accordance with applicable regulations. Regional Records Center staff and resources are available to assist in carrying out these responsibilities. R3 staff may also contact their organization records manager or the R3 Records Liaison Officer with requests for technical assistance and training.

## D.2 DOCUMENT CONTROL & REVIEW PROCESS

Controlled documents, hard copy and electronic, relating to QA activities at R3 must be developed and managed in a systematic, consistent manner. These documents include QMPs, QAPrPs, QAPPs, FSPs, SAPs, SOPs, policies, manuals, guidance, plans, templates, checklists, and other documents. The roles and actions to prepare, review, approve, issue, revise, revoke, distribute, and archive controlled documents are shown in Table D.1 below. Approvals of QA documents cannot be rendered by the same individuals who authored or prepared those QA documents. Figure D.1 shows the document review process.

**Table D.1. Document Control Actions by Role**

| Role | Action |
|---|---|
| **Author(s)/Originator(s)** External (e.g., grantees, contractors, etc.) or internal (e.g., R3 program/project staff) | • Develops draft or revises document using current guidelines for QA document development.<br>• Evaluates & incorporates (as appropriate) comments from reviewers.<br>• Signs finalized documents (signature does not indicate QA approval). |
| **Designated Project Manager(s) (DPM)** (e.g., PO, COR, Project Manager, Program Specialist, SAM, RPM, OSC, etc.)<br><br>For internal projects, DPMs may also be the author. | • As applicable for extramural agreements (i.e., contracts), the DPM completes the QARF or RAF QARF to determine what, if any, QA documentation is needed (Appendix 2) & submits to the RQAM or designee (i.e., QAO) for review & signature. The QAC shall be copied on these communications.<br>• Completes & submits R3 QA Document Review Request (Appendix 2) to the Divisional QAC & ASQAB Quality Staff.<br>• Should perform a preliminary review of document.<br>• Identify the need for additional technical review.<br>• Maintains communications with all stakeholders (e.g. authors, QACs/ASQAB Quality staff, approving authorities, management staff, etc.)<br>• Re-submits revised documents from authors for review process & approval.<br>• After approval by Reviewer/Approving Authority, may sign document signature page per their program requirements. (DPM signature does not indicate QA approval.)<br>• Sends final approved QA document to submitter, copy respective Division QAC & ASQAB quality staff, and incorporate to file. |
| **Technical Reviewers** (e.g., subject matter experts (SMEs), grants specialists, etc.) | • Reviews QA document(s) (i.e., QAPPs, QAPrPs, SOPs, SAPs, & FSPs) from a technical standpoint & provides comments within a specified timeframe to the Reviewer/Approving Authority. |
| **Field Activities Coordinators (FACs)** | • Assists in tracking & maintaining field-related QA records of author/technical reviewer reviews, revision dates, & approvals.<br>• Coordinates with FQM & ASQAB Quality Staff on who will review & approve (e.g., DAO / ASQAB Quality Staff) field-related QA documents being submitted from their respective Divisions. Ensures process completion. |

| Role | Action |
|---|---|
| | • Coordinates with FQM & ASQAB Quality Staff on publishing & information management in QA Database for field-related QA documents. |
| **Quality Assurance Coordinators (QACs)** | • Assists in tracking & maintaining records of author/technical reviewer reviews, revision dates, & approvals.<br>• Coordinates with ASQAB Quality Staff on who will review & approve (e.g. DAO / ASQAB Quality Staff) QA documents being submitted from their respective Divisions. Ensures process completion.<br>• Coordinates with ASQAB Quality Staff on publishing & information management in QA Database.<br>• Notifies & sends approved document to DPM. |
| **ASQAB Quality Staff** (may include RQAM) | • Track & maintain records of author/technical reviewer review, revision dates, & approval.<br>• Coordinate with QACs on who will review & approve (e.g. DAO / ASQAB Quality Staff) QA documents being submitted. Ensures process completion.<br>• Lead Regional QA information input, management, & maintenance in QA Database.<br>• Notify & send approved document to QAC & DPM. |
| **Supervisors & Senior Managers** | • Supervisors shall review & sign document signature page to approve QA work products applicable to their unit, e.g., checklists, SOPs (does not include QAPPs, QAPrPs, QMPs, etc.). QA Reviewer/Approving Authority signature is also necessary for approval.<br>• Senior managers shall review & authorize the R3 QMP. |
| **Reviewer/Approving Authority** (i.e., RQAM, DAOs, QAOs, FQM as applicable) | • Reviews QA document to ensure consistency with Regional & Agency Quality policy (cannot approve QA documents they authored or prepared or for projects/programs they manage).<br>• May complete a review checklist.<br>• Complete a review memo with comments or QA approval.<br>• If not approved, returns document with comment memo to DPM or author(s), copying the QAC.<br>• If approved, signs QA approval memo & document signature page & forwards document to QAC & DPM for distribution. |

## D.3 ENSURING DOCUMENTS & RECORDS ACCURATELY REFLECT COMPLETED WORK

Each Division and Office is responsible for establishing and implementing procedures for ensuring consistency and technical accuracy of its work outputs and products. Senior Leadership has responsibility to ensure that each organization uses established procedures to ensure that disseminated information products are of adequate quality for their intended use and comply with EPA's Information Quality Guidelines (Section J) and R3's Information Quality Guidelines Pre-Dissemination Review (Appendix 5). All personnel with QA related duties are also responsible for ensuring that records and documents accurately reflect completed work.

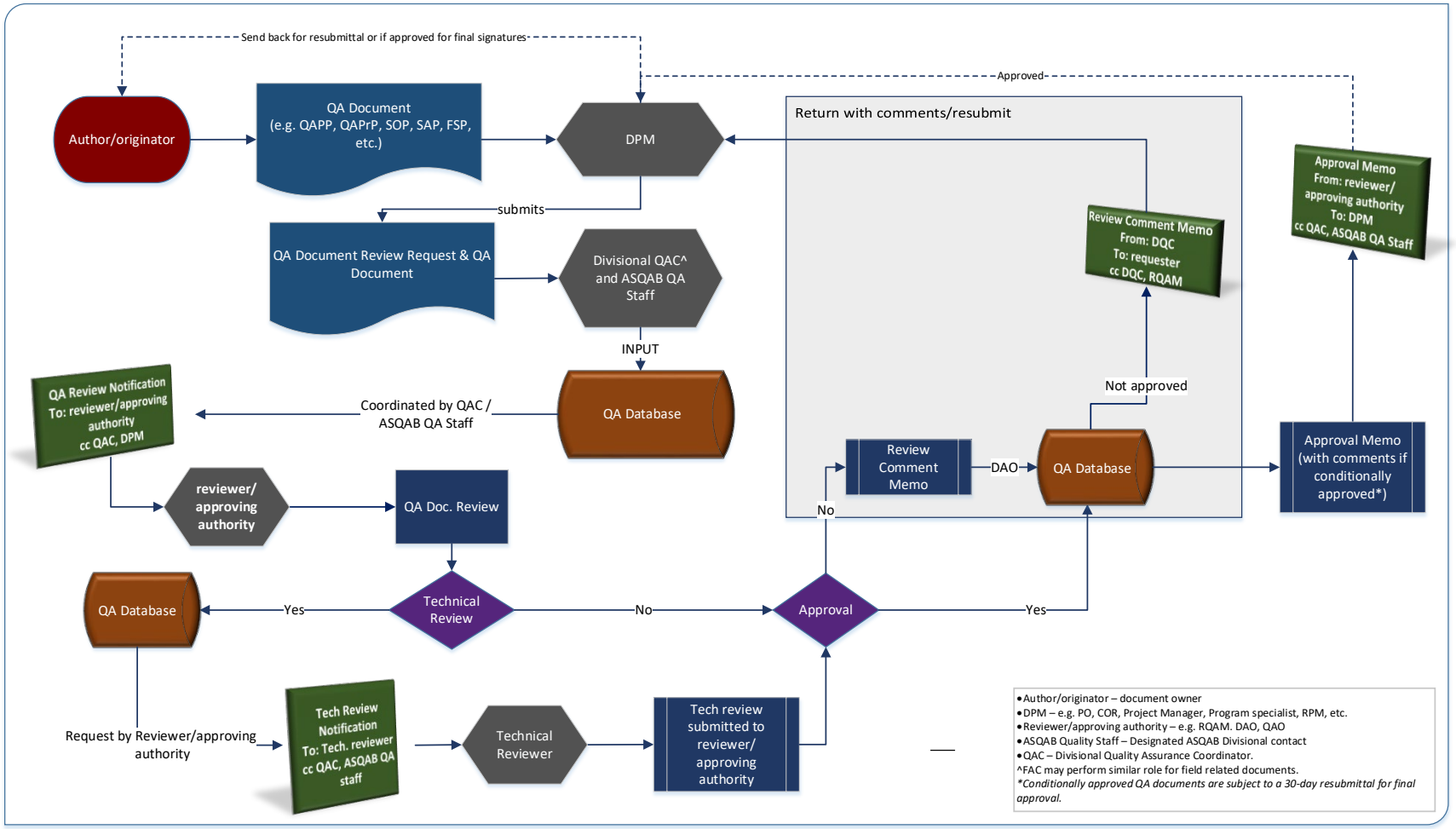


**Figure D.1. R3 QAPPs & QAPrPs Review Process**
Details of each role in Table D.1

# SECTION E: COMPUTER HARDWARE & SOFTWARE

EPA's ability to fulfill its mission depends upon a strong information technology infrastructure. Mission objectives rely on an infrastructure capable of supporting environmental information and dynamic communication among EPA organizations. One of the most critical components of the infrastructure is information technology. The hardware (e.g., computers, servers, etc.), software (e.g., models, databases, programs, etc.), and communications components that are encompassed by information technology form the foundation for environmental information and EPA-wide communication. The management of information technology, therefore, is critical to the success of EPA.

OMS is responsible for managing EPA's information technology infrastructure and components. In that role, OMS has established information technology standards to manage and ensure that information technology components integrate properly into the infrastructure. It is R3 policy to work closely with OMS on all phases of system development, improvements, and updates.

## E.1 TECHNOLOGY & DATA MANAGEMENT ROLES

Technology and data management is the responsibility of all regional personnel with specific roles listed in Table E.1.

**Table E.1. Technology & Data Management by Role**

| Role | Action |
|---|---|
| Divisions/Offices | • Coordinate activities relating to program-specific regional & national associated databases (requirements may be defined by the national program offices at headquarters)<br>• Periodically inventory databases to consider ways to improve data management or quality & ensure that the data is accessible to & usable by other groups. This review will include identifying data that could be consolidated or eliminated; documenting sources of data; clarifying the data's purpose; & identifying users. |
| DPMs | • Collect, process, & manage data in accordance with this QMP |
| MSD/Information Services Branch (ISB) | • Life cycle management of information systems (i.e., feasibility study, analysis, design, programming, implementation, testing, operations, maintenance & systems review)<br>• Management & operational support to the operating divisions for all information systems utilized by the region<br>• Managing & operating the R3 Library<br>• Overall information management for the Region in cooperation with LSASD & MSD/CSB for matters concerning information systems |

| Role | Action |
|---|---|
| MSD/Computer Services Branch (CSB) | • Local area & wide area network support<br>• Managing & operating the regional computer center<br>• Providing data communications services<br>• Personal computer planning & operational support<br>• Information technology security<br>• Management & evaluation of existing & newly purchased hardware, software & networking platforms, including development, installation, testing, maintenance, control, & documentation<br>• Coordination with programs on hardware & software issues, purchases & upgrades, & pilot programs<br>• Assessment & documentation of the impact of changes to user requirements or the hardware & software on performance<br>• Information management for the Region in cooperation with LSASD & MSD/Information Services Branch (ISB), focusing on desktop applications |
| EQMD | • Maintain national QA database<br>• Provide support for QA database |
| ASQAB/ QACs/ RQAM | • Provide regional support for the QA database & any other QA related information system. |

## E.2 INFORMATION MANAGEMENT SYSTEMS

All information management system development, improvements, and updates will include a systematic and comprehensive dialogue among data providers, data and system users, and system developers prior to design and installation of the system and will comply, as relevant, with the following information directives and policies (and associated procedures) (Appendix 1):

- *CIO 2101.1 Limited Personal Use of Government Office Equipment Policy;*
- *CIO 2102.0 Senior Information Officials Standard;*
- *CIO 2103.0 Forms Management Policy;*
- *CIO 2104.2 Software Management and Piracy Policy;*
- *CIO 2120.1 CPIC Program Policy for the Management of Information Technology Investments;*
- *CIO 2121.1 System Life Cycle Management (SLCM) Policy;*
- *CIO 2122.1 Enterprise Architecture Policy;*
- *CIO 2123.2 Configuration Management Policy;*
- *CIO 2124.0 Internet Protocol Version 6 (IPv6) Compliance Policy;*
- *CIO 2125.0 Interim Open Source Software (OSS) Policy;*
- *CIO 2126.0 Interim Application Review Policy;*
- *CIO 2130.1 Section 508: Accessible Electronic and Information Technology;*
- *CIO 2131 National Geospatial Data Policy;*
- *CIO 2133.0 Data Standards;*
- *CIO 2134.0 Information Collection Policy;*
- *CIO 2135.1 Enterprise Information Management Policy (EIMP); and*
- *CIO 2136.0 Electronic Signature Policy.*

R3 is required to work closely with information system customers, as well as OMS and National Program Offices, as appropriate, on all phases of system development, improvements, and updates, including contractor-developed systems and those developed by other entities. During all life cycle phases of information management systems, the Region will comply with requirements within the System Life Cycle Management (SLCM) Requirements Guidance, the System Life Cycle Management Policy, and the System Life Cycle Management Procedure (Appendix 1). The goal of this process is to have a uniform approach and review of applications under consideration by R3. The process will determine if an application has management support, can be accomplished in the timeframe needed, and is within the resource constraints identified. Compliance with applicable information resource management standards will ensure all hardware and software configurations are tested prior to use, to assure they perform as expected and meet user requirements.

For information technology contracts that involve applications development, the performance work statement will include requirements for system specification reviews; system development plans; data validation and transfer; acceptance testing; and report generation.

## E.3 DATA STANDARDS

All Federal agencies are required to adhere to federally-mandated data standards and regulations. R3 complies with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards. These include (Appendix 1), but are not limited to:

- The National Institute of Standards and Technology develops standards and guidelines to achieve the most effective use of Federal information;
- The Federal Information Processing Standards Publications (FIPS PUBS) are the Federal data standards for all data exchange among agencies; and
- The EPA Data Standards Program is established and documented in the Data Standards, CIO 2133.0.

Within EPA, adherence to data standards policy is accomplished through direction of OMS. EPA's data-related policies apply to all R3 organizations and personnel, including contractors, Senior Environmental Employee (SEE) Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems for R3 and EPA.

# SECTION F: PLANNING

A major goal of R3's Quality System is to promote effective planning for the collection, analyses, and processing of environmental information and data. Quality planning must occur at three levels to ensure such data meet Regional programmatic and quality goals: organization-wide, program-level, and project-specific (Table F.1). The QMP is foundational for the QAPrPs, QAPPs and other QA documents. Since they are connected, these documents should reference the applicable QMP.

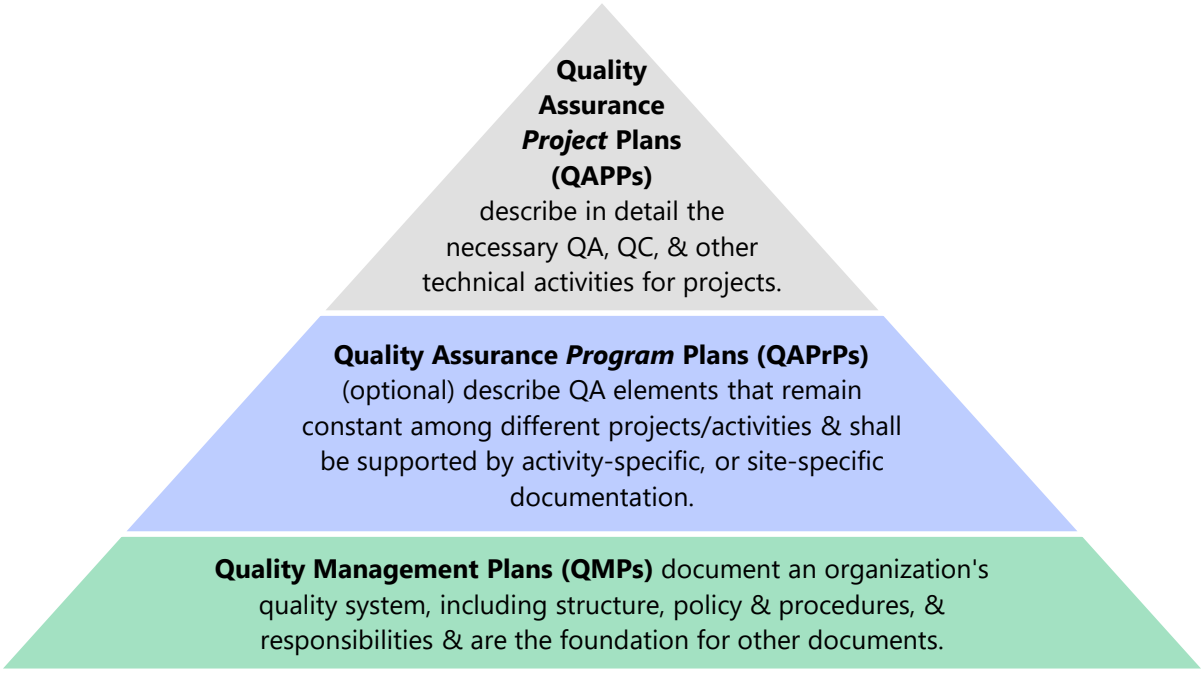


**Figure F.1. QA Planning Levels**

## F.1 ORGANIZATION-WIDE PLANNING

### F.1.a Strategic Planning

The EPA five-year Strategic Plan sets the direction for programmatic priorities and environmental operations. Annual national programmatic guidance is then developed each year, which outlines goals and milestones that support the objectives contained in the Strategic Plan. EPA's annual budget supports the goals and milestones contained in the annual guidance and is linked by code to objectives outlined in the strategic plan. National programs coordinate and negotiate with all regions in developing guidance and budget on work to be performed in any one year. R3 senior management, supervisors, and staff work with our state and tribal partners to provide input to the national goals that reflect regional priorities. Once the annual guidance and budget are finalized, action plans are developed by divisions and major offices that specify performance commitments and environmental data operations that will occur and corresponding requirements for QA and QC procedures.

## F.1.b Data Coordination

R3 also coordinates environmental data operations with numerous government agencies, states, tribes, academic, and private organizations. Close coordination and planning are essential to ensure that data are of sufficient quality to support the intended uses and can also be shared with other organizations. The Region encourages data sharing wherever possible and supports data quality planning to make that possible. In addition, the Regional Science Liaison (Appendix 2) seeks opportunities to bring ORD research data and associated products and services to R3 and its clients (states, tribes, local governments, etc.) and therefore has a responsibility to ensure QA during that process.

## F.1.c Region 3 Quality Management Plan

The R3 QMP complies with requirements found in the *EPA Quality Manual, CIO 2105-P-01.0* and *Policy and Program Requirements for the Mandatory Agencywide Quality System, CIO Policy 2105.0*. The QMP serves as the "umbrella" document for all Regional programs and describes the Quality System in terms of organizational structures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and evaluating QA activities conducted. R3 QAPPs and other internal QA documents must relate and refer to this R3 QMP.

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*The R3 QMP contains policies and procedures implemented to ensure environmental data generated, collected, compiled, analyzed, and utilized by and for the Region are of adequate quality for its intended use.*

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Development of the R3 QMP is led by the RQAM with assistance from the RQC and ASQAB Quality staff and applies to all Regional staff. The R3 QMP shall be reviewed and approved by all Directors of Divisions and major offices, RQAM, RFQM, ASQAB Chief, and the Regional Administrator. Final approval of the R3 QMP shall be granted by the Director of EQMD. The approval is valid for up to five years; however, pursuant to CIO Quality Policy 2105.0 and EPA QA/R-2, updates and revisions to the QMP are required as a result of organizational and Regional policy/process changes, and findings from Quality System assessments. The R3 QMP shall be reviewed at least annually for such changes and updated, as necessary. As determined by the RQAM, a revision to an appendix or an addition of a new appendix to the R3 QMP does not necessarily require a full QMP revision and reapproval. However, if the RQAM determines that a change or addition to an appendix is material in nature, then the R3 QMP shall undergo a revision and reapproval.

A material change, modification, amendment, revision, or alteration to the R3 QMP or its appendices means a substantial change, modification, amendment, revision, or alteration to a policy, process, plan, or procedure in the R3 QMP, rendering such policy, process, plan, or procedure in the R3 QMP inaccurate, incomplete, or misleading. Alteration to an organization's name or role constitute a material change that requires an update or addendum to the R3 QMP.

An immaterial change, modification, amendment, revision or alteration to the R3 QMP means minor corrections such as spelling, grammar, omissions, or other similar errors not affecting the

substance of the R3 QMP. Changes to the RQC Membership, senior leadership positions, and titles, including changes to the RA position, program managers and titles, program title changes and functions, RQC, RQAM, and any change to any other position or title provided for under the R3 QMP also constitute an immaterial change. Any immaterial change to the R3 QMP or appendix to the R3 QMP will not require the R3 QMP to be resubmitted for regional concurrence and reapproval.

## F.1.d Quality Management Plans for Extramural Projects

Recipients of R3 financial assistance, including grants, cooperative agreements, and interagency agreements involving environmental data operations, shall document and submit quality policies and practices in a QMP prepared in accordance with specifications provided in the most current version of *EPA Requirements for Quality Management Plans, EPA QA/R-2* (Appendix 1).

Should there be multiple programs involved in a grant, cooperative agreement. or interagency agreement, at the recipient's discretion, they may submit one of the following:

1. A single QMP covering all programs in the grant or agreement with specific QAPPs for each project;
2. A separate QMP for each program receiving the grant or agreement funds with specific QAPPs for each project;
3. A combined Quality Management Plan/Quality Assurance Project Plan (QMP/QAPP)[1]; or
4. A single Quality Management Plan with QAPrPs for programs with recurring activities supported by project-specific, activity-specific or site-specific documentation (e.g., FSPs, SAPs, work plans, inspection checklists, or equivalent).

The recipient's QMP or QMP/QAPP shall be approved internally by its Quality Assurance Manager or equivalent and the organization's senior management. Financial assistance recipients at all levels, must submit their QMP or combined QMP/QAPP to the EPA DPM at least 45 days prior to initiation of environmental data operations. The DPM must submit a completed R3 QA Document Review Request (Appendix 3) to ASQAB for the RQAM, or designee, to review and approve the document. The most recent version of the R3 QMP Review Checklist (Appendix 3) may be used to facilitate the review. When applicable, R3 QACs, DAOs, and QAOs can facilitate review of the QMP or combined QMP/QAPP by conducting a review of technical activities and programs documented in QMPs for extramural organizations being funded by their organization.

Upon receipt of a QMP or QMP/QAPP, the RQAM will add the document to the R3 QMP Status Report and update the status accordingly (Table F.1). This report contains the name of the submitting organization, receipt date, review status, and approval status. QMP information will also be entered and tracked in the national QA database.

[1] For certain grants and agreements, the EPA Project Officer may allow the recipient to submit a combined Quality Management Plan/Quality Assurance Project Plan (QMP/QAPP) (not equivalent to a QAPrP). At a minimum, the QMP/QAPP shall adhere to the QMP and QAPP elements as outlined in the most recent versions of *EPA Requirements for Quality Management Plans, EPA QA/R-2,* and *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5*, respectively.

**Table F.1. QMP Status Definitions**

| QMP Status | Definition |
|---|---|
| **Expired:** | The QMP or QMP/QAPP on file with R3 is no longer current and needs to be revised and resubmitted for review if necessary. |
| **In Progress:** | The document has been received by R3 and is undergoing review. |
| **Approved:** | The document adheres to requirements found in *EPA QA/R-2, EPA Requirements for Quality Management Plans*. The QMP or QMP/QAPP is valid for five years from date of approval, unless revisions are necessary. |
| **Conditional:** | Review of this document indicates the basic components of a Quality System have been documented. However, minor revisions to the recipient's QMP or QMP/QAPP are required which are administrative in nature & do not affect quality of data collected/used to ensure conformance to *EPA QA/R2, EPA Requirements for Quality Management Plans*. Conditional approval allows recipients to perform activities that include the generation & use of environmental data while making revisions to finalize their plan. A revised version of the document must be resubmitted for final approval within 30 days of being conditionally approved. |
| **Resubmit:** | The document needs significant revision in order to meet the basic components of a Quality System. The recipient is required to ensure conformance to *EPA QA/R-2, EPA Requirements for Quality Management Plans* prior to performing activities that include the generation & use of environmental data. |

Once the QMP or QMP/QAPP is deemed compliant with *EPA QA/R-2*, the RQAM will sign and submit an approval memo to the DPM or directly to the requesting organization, or both. No environmental data operations may be conducted until approval is received. EPA approval of a QMP or QMP/QAPP is valid up to five years with annual reviews to ensure revisions are not required. The recipient shall report minor organizational and policy changes in its annual report to R3, as applicable. When there are material changes (defined in Section F.1.c) that impact the recipient's Quality System, the recipient shall notify the RQAM within 45 days of the material change; the timeframe for the submission for the revised QMP will be coordinated with the RQAM for their subsequent review and approval.

Each quarter, ASQAB will update the R3 QMP Status Report, post it on the R3 QA intranet site, and notify internal stakeholders. DPMs shall use this information to ensure that extramural agreement recipients under their purview have fulfilled their EPA QA requirements.

## F.1.e QMP Reciprocity

If an external organization has a QMP or QMP/QAPP that has been approved by another EPA organization (i.e., Region, Office), that document can be accepted reciprocally by R3 as an approved QMP under certain conditions.

ASQAB Quality staff must verify the approval period or expiration date of the QMP and confirm approval by the original EPA organization. The decision to accept a QMP or QMP/QAPP under reciprocity requires a recommendation from the applicable Division QAC and managers of the applicable programmatic organization and approval by the RQAM. The Division's recommendation is essential to ensure the document adequately covers the type of work being performed. The external organization seeking reciprocity shall provide a signed copy of the QMP or QMP/QAPP for R3's files. The name of the original EPA approver, their organization, date of approval. and length of approval shall be obtained and recorded on the R3 QMP Status

Report. The approval period of a reciprocally approved QMP or QMP/QAPP shall not exceed its approval period from the approving EPA organization.

## F.2 PROGRAM-LEVEL PLANNING

Programs are functional areas of work authorized by statute (e.g., the Air Toxics Program), Executive Order, or Agency directive (e.g., the Volunteer Monitoring Program). Regional environmental data operations conducted in support of these programs are covered by this QMP, although not all require the same level of QA. When initiating a new program or incorporating major statutory changes, the program shall establish minimum Quality System components required to achieve program compliance.

For many ongoing environmental monitoring programs, the National Programs at EPA Headquarters have established standard QA/QC requirements. In these cases, R3 shall defer to these national program documents. The program-specific QA/QC requirements will be documented in the appropriate and applicable QA document (e.g., QMP, QAPrP, QAPP, SOP). Any modifications and deviations from the national program documents shall be documented.

### F.2.a Quality Assurance Program Plans (QAPrPs)

R3 accepts the use of QAPrPs whenever practicable and where an overarching QMP exists. QAPrPs define and document type and quality of data and methods required for collecting, analyzing, and assessing data to support decisions across recurring or like activities within a single program. QAPrPs shall describe the QA elements that remain constant among the different projects, activities, or sites. Most QAPrPs shall be supported by project-specific, activity-specific, or site-specific documentation (e.g., FSPs, SAPs, Work Plans, inspection checklists, or equivalent). These documents shall address specific QA elements articulated in EPA's QA/R-5 (QAPP requirements) and QA/G-5 (QAPP guidance) documents and are unique to each project, activity, or site. QAPrPs and supporting documents undergo technical reviews for accuracy, completeness, and compliance with programmatic guidance. Discussion of QAPP preparation, reviews, etc. in the following sections also apply to QAPrPs and supporting documents. Appendix 1 lists additional guidance for QAPrP preparation.

External state & tribal programs with new or continuing grants, assistance contracts or IAs may use QAPrPs as part of their QA system and under an overarching QMP. The appropriateness of a QAPrP is determined on a case-by-case basis by the DPM to ensure alignment with the program guidance and in consultation with ASQAB Quality staff, the RQAM, and Division/Office QAC. The QAPrP shall include the elements that remain constant in the grant, contract, or IA, and will be supported by project-specific, activity-specific, or site-specific documentation (e.g., FSPs, SAPs, Work Plans, inspection checklists, or equivalent).

## F.3 PROJECT-SPECIFIC PLANNING

Project-level planning ensures efficient appropriation of resources (avoids rework and re-sampling) and maximum quality, objectivity, utility, and integrity of data.

## F.3.a Systematic Planning Process

A systematic planning process shall be used for environmental data operations conducted by or on behalf of R3 and is a mechanism for balancing conflicting demands and data quality needs to ensure that environmental data operations will effectively support decision-making. EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4)* (Appendix 1) describes one such process (see Figure F.1) but any other systematic planning process may be used as long as it is based on the scientific method and complies with Chapter 3 of CIO Procedure 2105-P-01.0.


**Figure F.2. Overview of a DQO process**
(as outlined in EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4*)

Elements of a systematic planning approach shall include the following:

- Identifying and involving DPMs, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (i.e., relevant customers and suppliers);
- Describing the project goal, objectives and questions/issues to be addressed;
- Identifying project schedule, time and resource constraints, milestones, and any applicable requirements (e.g., regulatory or contractual requirements);
- Identifying the type of data needed and how the data will be used to support the project's objectives;
- Determining the quantity of data needed and specifying performance criteria for measuring quality, i.e. data quality indicators (Table F.2);

- Describing how, when, and where the data will be obtained including existing data and identification of any constraints on data collection;
- Specifying needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.); and
- Describing how acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review, validation, verification), and assessed (e.g., data quality assessment) against its intended use and quality performance criteria.

The DPMs are responsible for ensuring a systematic planning process is used and documented and that organizations and parties who contribute to the quality of the environmental project or use the results are identified and participate in the planning process. Guidance and technical support for using a systematic planning process are available from the RQAM and ASQAB Quality Staff.

**Table F.2. Data Quality Indicators**

| Data Quality Indicator | Description |
|---|---|
| Precision | measure of agreement among repeated measurements of the same property under identical or substantially similar conditions. |
| Accuracy (and Bias) | measure of the correctness of data, as given by the difference between the measured value & the true or standard value. (Bias is a systematic or persistent distortion of a measurement process that causes errors in one direction.) |
| Representativeness | degree to which a sample accurately and precisely represents the larger context. |
| Completeness | a measure of the amount of valid data needed to be obtained from a measurement system. |
| Comparability | measure of confidence that the underlying assumptions behind two data sets are similar enough that the data sets can be compared and combined to inform decisions. |
| Sensitivity | a measurement of the capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest. |

## F.3.b Quality Assurance Project Plans (QAPPs)

The systematic planning process described in Section F.3.a results in development of a sampling design, generation of appropriate data quality indicators, selection of measurement and analytical methodologies and procedures, etc. R3 policy requires results of the systematic planning process be documented in a QAPP or equivalent QA document approved by authorized personnel (see Section F.3.b.2) prior to implementation. QAPP requirements apply to all environmental data operations, including secondary data, conducted by Regional staff or through grants, cooperative agreements, contracts, IAs, and compliance orders. QAPPs must be approved prior to any data collection work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

All grant recipients, IA participants, and contractors conducting projects that involve environmental data operations must submit a QMP documenting their Quality System, as

appropriate, and a QAPP for each project, per the *National Programmatic Terms and Conditions* (updated annually by Office of Grants and Debarment- Appendix 4). The terms and conditions may require submittal of the QMP and QAPP within a specified timeframe. Environmental data operations may not commence until the QMP and QAPP have been approved by R3.

### F.3.b.1 QAPP Preparation

DPMs shall ensure QAPPs are developed and approved for all data-related projects under their purview. QAPPs shall be prepared in accordance with a "graded approach" as defined in Section 2.4.2 of *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations, EPA QA/R-5* (Appendix 1). Additional guidance is found in *Guidance for Quality Assurance Project Plans, EPA QA/G-5* (Appendix 1). Both documents describe required elements of a QAPP (Table F.3). The level of detail found in the QAPP shall be commensurate with the nature of the work being performed and intended use of the data. If a particular QAPP element does not apply to the project, the element must be included and an explanation describing why it does not apply. The R3 Quality Assurance Project Plans webpage (Appendix 1) provides additional resources for QAPP preparation.

EPA's Office of Land and Emergency Management (OLEM) has issued Directive 9272.0-17, requiring the *Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), EPA-505-B-04-900A* (Appendix 1) be used in Federal facility projects where environmental data are collected (e.g., CERCLA, RCRA, Brownfields). Superfund Remedial Acquisition Framework (RAF) contracts also require use of the UFP-QAPP. Thus, R3 will use the UFP-QAPP format for RAF contracts, federal facilities, and other hazardous waste projects (See Appendices 11 and 14 for LCRD and SEMD information).

### Table F.3. Required QAPP Elements

The required elements should be structured in the QAPP in an organized fashion, e.g. alpha-numerically, numerical order, UFP-QAPP style, etc.

| Major Groups with Elements |
|---|
| Group A: **Project Management** |
| A1 Title and Approval Sheet |
| A2 Table of Contents |
| A3 Distribution List |
| A4 Project/ Task Organization |
| A5 Problem Definition/ Background |
| A6 Project/ Task Description |
| A7 Quality Objectives and Criteria |
| A8 Special Training/Certification |
| A9 Documents and Records |
| Group B: **Data Generation & Acquisition Elements** |
| B1 Sampling Process Design (Experimental Design) |
| B2 Sampling Methods |
| B3 Sample Handling and Custody |
| B4 Analytical Methods |
| B5 Quality Control |
| B6 Instrument/Equipment Testing, Inspection, and Maintenance |
| B7 Instrument/Equipment Calibration and Frequency |
| B8 Inspection/Acceptance of Supplies and Consumables |
| B9 Non-direct Measurements |
| B10 Data Management |
| Group C: **Assessment & Oversight Elements** |
| C1 Assessments and Response Actions |
| C2 Reports to Management |
| Group D: **Data Validation & Usability Elements** |
| D1 Data Review, Verification, and Validation |
| D2 Verification and Validation Methods |
| D3 Reconciliation with User Requirements |

## F.3.b.2 Review & Approval of QAPPs

The roles/steps to prepare, review, approve, issue, revise, revoke, distribute, and archive controlled documents, including QAPPs, are shown in Table D.1 (Section D.2). The R3 QAPP Checklist (Appendix 3) should be used when reviewing QAPPs (or a UFP checklist for those QAPP types).

QAPP approval status shall be formally documented and classified as one of the options listed in Table F.4. Following review of the QAPP, the reviewer/approving authority shall prepare a written decision memo that addresses QAPP status, comments, and recommendations, and submit it to the DPM(s). Once all documented issues are addressed, the reviewer/approving authority shall issue final approval through a written decision memo and an approval signature in the document.

**Table F.4. QAPP Status Descriptions**

| QAPP Status | Description |
|---|---|
| **Approved** | Document was found to address key QA requirements satisfactorily. |
| **Conditionally Approved** | Document satisfactorily addressed most key elements; however, minor deficiencies were noted, which do not affect quality of the data collected/used. Sampling & analyses may begin while these minor deficiencies are being resolved. Resubmittal required. |
| **Resubmission Required** | Document found to be deficient in describing key elements. Further clarification of specific issues is required. Modification to specific procedures that may influence data quality should be accomplished prior to approval of plan and initiation of data collection activity. |

For continuous projects, the QAPP must be reviewed annually at a minimum by the authoring organization to ensure that no material changes are needed. If changes are significant and affect scope and objectives of the project, data use, or data quality, revisions to the approved QAPP shall be documented in a second or subsequent revision or an addendum. This submission shall be reviewed and approved in the same manner as the original QAPP. The authoring organization is responsible for ensuring appropriate personnel receive a copy of the revised QAPP or addendum once it is approved. For external organizations, annual review shall be documented in the organization's annual report to the DPM.

### F.3.b.3 QAPPs & Existing Data

Existing data (i.e., secondary data, non-direct measurements) is defined as data that is collected for other purposes or from other existing internal or external sources, such as literature, surveys, databases, geospatial information and analyses, and models. Because of the key role existing data has in decision-making or in new study design at EPA, existing data is also subject to QA principles and requirements, just as is required for collection of primary data. The quality of needed existing data must be included as part of a QAPP or QAPrP, or as a standalone QAPP or QAPrP for existing data. Prior to its use, existing environmental data collected from secondary sources shall be evaluated to ensure a level of quality that is commensurate with its intended use(s). The DPM is responsible for ensuring that such data collection is addressed in the QAPP, if applicable. The project QAPP shall:

- Identify types of existing data needed for project implementation or decision making;
- Specify steps to find or choose a data source, if the location of a certain type of data is unknown or if multiple sources are available;
- Describe intended uses of existing data;
- Define acceptance criteria for use of existing data (see Section J.3 for assessment factors that should be considered);
- Specify any limitations on use of the data; and

- Identify individual(s) responsible for evaluating and qualifying the data.

For those projects that involve compilation and use of existing environmental data from secondary sources exclusively (i.e., there are no direct environmental data generation performed to accomplish the project), a project-specific QAPP is still required. Per the graded approach, the level of detail for this QAPP will differ from that for a direct environmental data generation project.

More information on appropriate elements for a secondary data project QAPP are available on the R3 Quality Assurance Project Plans webpage (Appendix 1). Other resources (Appendix 1) include the following:

1. Guidance for Geospatial Data Quality Assurance Project Plans (G-5G);
2. Guidance for Quality Assurance Project Plans for Modeling (G-5M); and
3. Guidance on Quality Assurance Project Plans for Secondary Research Data.

### F.3.b.4 QAPPs for Projects Not Funded by EPA

New technologies for environmental monitoring and tools for sharing information have given citizens more opportunities to collect environmental data and as a result, many environmental agencies are using these data. A major challenge, however, is that data users, such as federal, state, tribal and local agencies, are sometimes skeptical about the quality of data collected by citizen science organizations. QAPPs are a key to overcoming that barrier. By writing and applying a QAPP, an organization builds data quality procedures into the project from the beginning and will be more confident that the data will meet the specific needs of the project.

However, EPA's quality-related regulations only apply to EPA contracts, cooperative agreements, grants, interagency agreements and Agency mandates. EPA personnel do not have authority to approve documentation of an organization's quality system for work involving collection or use of environmental information when that work is not funded by EPA. This documentation includes but is not limited to Quality Management Plans, Quality Assurance Project Plans, etc. Should EPA choose to use data collected by a non-funded entity or project, EPA personnel will ensure a QAPP is prepared for the secondary use of this data.

EPA provides QAPP preparation information and templates for voluntary, non-EPA funded projects/collection of environmental data solely as a public service. Use of this information or templates neither represents nor implies endorsement by EPA or EPA's intent to use the data generated. For example, guidance for QAPPs for citizen science can be found in EPA's "Handbook for Citizen Science: Quality Assurance and Documentation" (EPA 206-B-18-001) (Appendix 1). The Handbook and companion documents are applicable to the collection and use of environmental data for three broad categories of citizen science projects: increasing public understanding; scientific studies and research; and legal and policy action.

# SECTION G: IMPLEMENTATION OF WORK PROCESSES

Implementation of procedures specified in this section shall ensure environmental data operations conform to requirements found in this QMP. Proper implementation of the R3 QMP, extramural agreements, QAPrPs, QAPPs, SOPs, field operations, and laboratory services are critical to ensuring the Region and its stakeholders produce data of known and sufficient quality.

## G.1 R3 ORGANIZATION-WIDE IMPLEMENTATION

The RQAM is responsible for overseeing implementation of the Regional Quality System. To ensure documented QA policies and procedures are current and accurate, the R3 QMP will be developed, reviewed, and managed as outlined in Section F.1.c.– reviewed at least annually, whenever there is a major reorganization or significant policy and procedural changes that impact the Region's Quality System, and every five years, based upon the original approval date, for a more in-depth review. After final approval, a copy of the QMP will be posted on the R3 Quality internet site (Appendix 1). Announcement(s) about the newly approved R3 QMP will be communicated internally to R3 personnel and externally to states, tribes, grantees, contractors, and others receiving EPA funding.

### G.1.a Extramural Agreements

R3 ensures its contractors, grantees, and other partners implement sufficient Quality Systems to fulfill environmental data operations and R3 QA requirements and needs. In order to assure implementation of QA requirements by extramural agreement holders, DPMs shall verify the following:

- For contracts, the QARF or RAF QARF (Appendix 3) is completed and submitted for approval by the RQAM (or designee); and
- For grants and assistance agreements, the funding recommendation form in the Integrated Grants Management System (IGMS) indicates whether QA terms and conditions apply.

The Region's policy is that submitted QMPs must conform to *EPA Requirements for Quality Management Plans, EPA QA/R-2* (Section F.1.d). Extramural agreement holders' QMPs or QMP/QAPPs are valid for up to 5 years with annual reviews to ensure revisions are not required. If revisions are required, the revised QMP or QMP/QAPP shall be resubmitted to R3 for review and approval in accordance with procedures specified in Section F.1.d. The QMP Status Report is prepared on a quarterly basis and documents the approval status of QMPs and QMP/QAPPs for extramural projects.

### G.1.b Quality Assurance Annual Report & Work Plan

To assess implementation efficacy of the R3 quality system, R3 shall annually submit a Quality Assurance Annual Report and Work Plan (QAARWP) to the Director of EQMD. The QAARWP summarizes QA-related resources, training, accomplishments (i.e., innovative practices, technical assessments, QMP revisions, QA guidance, technical assistance, etc.) and Quality System assessments/audits that were conducted the previous fiscal year. The QAARWP

includes a list of QA activities planned for the upcoming fiscal year. The QAARWP will also be used to identify needed changes and updates to R3's QMP.

The RQAM and ASQAB quality staff, in coordination with the RQC, shall prepare and review the QAARWP according to Chapter 4 of the most current version of the CIO Procedure 2105-P-01.0. The QAARWP will be approved by the Regional Administrator or designee prior to its submittal to the Director of EQMD.

## G.2 PROGRAM-LEVEL IMPLEMENTATION

R3 personnel who are directly or indirectly involved with environmental data operations in work authorized by statute (e.g., the Air Toxics Program), Executive Order, or Agency directive (e.g., the Volunteer Monitoring Program) have responsibility for ensuring data quality as outlined in this QMP, their group's QA procedures (including QAPrPs), and applicable national program documents.

QAPrPs follow the same implementation guidelines as QAPPs, detailed in Section G.3. Each Regional organization's QAC shall annually coordinate review of their organization's QA procedures and documentation, including QAPrPs, or per the prescribed schedule. Changes to QA procedures will be documented in the QAARWP and in any relevant QA documentation, and communicated to staff.

## G.3 PROJECT-SPECIFIC IMPLEMENTATION

Once a QAPP is approved, the DPM(s) or lead organization for the QAPP shall ensure all project personnel have a copy and ensure the QAPP is available during project work. If applicable, the DPM, or other responsible party as outlined in the QAPP, shall ensure obsolete versions of the QAPP are removed from work areas. The approved QAPP must be implemented as prescribed; however, the QAPP may be modified and amended at any time to ensure project objectives are met. A QAPP is not just a document, but rather a dynamic tool used by project personnel. If deviation from the QAPP or equivalent QA document occurs during implementation, the deviations should be documented and distributed to everyone involved. Modifications and amendments to QAPP(s) must follow appropriate submission and approval procedures outlined in Section F.3.b. Verification of changes to the QAPP shall be determined during a project's technical system audit.

QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under law enforcement authority. In these circumstances, existing Standard Operating Procedures (SOPs) will be followed.

During project implementation, R3 personnel are responsible for the following:

- Adhering to established sampling practices and procedures as described in approved QA planning documents (e.g., QAPPs, QAPrPs, SOPs, etc.);
- Documenting any deviations from established methodologies, SOPs, and QC protocols, and reporting deviations to the DPM;

- Identifying possible data quality problems and potential quality improvements and reporting these to the DPM (and divisional QAC if applicable); and
- Identifying to the DPM (and divisional QAC if applicable) any defective, outdated, or deficient SOPs and suggesting routine operations that need SOPs.

## G.4 STANDARD OPERATING PROCEDURES

Use of SOPs serves as a mechanism to ensure comparability and consistency across programs and individual environmental data operations.

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*A Standard Operating Procedure is a set of written instructions that document a routine or repetitive activity that shall be followed.*

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SOP use ensures routine and repetitive activities, processes, and procedures are performed consistently within acceptable timeframes and quality. SOPs can describe both technical and administrative operational elements. SOPs will thoroughly describe steps and techniques, and will be sufficiently clear to be understood by a person with knowledge in the general concept of the procedure or process without interpretation or assumption. Any limitation on use or applicability of a specific SOP will be documented in the SOP itself. SOPs are needed even when published methods (e.g., standard analytical method) are being used so details can be specified on differences and options for the organization. Table G.1. outlines the process for QA SOP development.

**Table G.1. QA SOP Lifecycle**

| Step | Description |
|---|---|
| **Identifying Need** | Need for an SOP for a specific activity or operation can be identified by any R3 staff member. The RQAM, FQM, QAOs, QACs, FACs, & ASQAB Quality staff may also identify need for standardized procedures through Quality System assessments & technical system audits, which identify areas of inconsistency that would benefit from standardized procedures. When this occurs, development of SOPs as a corrective action is recommended. |
| **Preparing** | The SOP can be written by any R3 staff member knowledgeable of the activity, equipment, procedure, or process to be addressed. The primary guidance document for preparation of QA SOPs is *Guidance for the Preparation of Standard Operating Procedure, EPA QA/G-6* (Appendix 1). |
| **Reviewing & Approving** | SOPs shall be reviewed, approved, & controlled by the appropriate personnel as outlined in Section D.2. SOPs shall be reviewed periodically (EPA QA/G-6 recommends 1-2 years) & at a minimum of every five years. |

| Step | Description |
|---|---|
| **Implementing** | DPMs, managers, or other personnel notify relevant staff of new or revised SOPs & verify that any changes are made as prescribed. Training on new or revised procedures should be offered within 45 days of SOP approval or as deemed pertinent. Current electronic or hardcopy versions of SOPs need to be readily accessible for reference in work areas of those individuals who perform the activity. Managers may also verify implementation by staff demonstration of capability & comparability of work products between staff. Individual users of an SOP are responsible for following procedures or documenting & justifying any deviations. |
| **Managing** | DPMs, managers, or other personnel responsible for routine use of specific procedure are responsible for updating, controlling, withdrawing, and archiving SOPs in coordination with the QAC. Outdated & obsolete SOPs & related documentation will be withdrawn from work areas & archived when no longer relevant. |

## G.5 FIELD ACTIVITIES

As part of the overall Agency quality system, the EPA QA Field Activities Procedure (QAFAP) (CIO 2105-P-02.0) promotes national consistency among the Agency's field activities. Field activities are defined as activities requiring the collection of observations, samples, or data in support of EPA programs, Executive Orders, regulations, or environmental laws, at a site or location (facility, water body, wetland, etc.). Field Activities include, but are not limited to, the following:

- Planning and conducting on-site inspections of such activities as facility permit operations, maintenance practices, self-monitoring practices, field recordkeeping practices, and field sampling/measurement practices for gathering data and potential evidence for all EPA programs; and
- Planning and carrying out field studies, investigations, and evaluations for gathering and developing data and potential evidence, including, but not limited to, field observations (including photographs), field measurements, sample collection, and field engineering evaluations for EPA program activities that include ambient and compliance monitoring and other comprehensive studies and evaluations (both short and long term).

The QAFAP requirements are based on best practices for field activities as determined by EPA field groups, EPA quality requirements, and concepts of quality management systems established by the International Organization for Standardization (ISO, 17025). The QAFAP provides a consistent, coordinated approach for conducting field activities, and describes formal procedural requirements that are a part of *EPA's Policy and Program Requirements for the Mandatory Agencywide Quality System (EPA Order CIO 2105)*.

The QAFAP is comprised of ten elements that establish a quality management system for field activities:

1. personnel training;
2. document control;
3. records management;
4. sample and environmental data management;
5. field documentation;
6. field equipment;
7. planning field inspections & investigations;
8. reports;
9. internal audits; and
10. corrective actions.

Each element of the QAFAP is an important and integral component of the whole, which when used together, provides the foundation for the R3 Field Operations Management System (FOMS) and helps ensure the scientific integrity of data collection.

## G.5.a R3 Field Operations Management System

As a component of the overall R3 Quality System, the R3 FOMS provides a framework to implement, where necessary & appropriate, the minimum requirements set forth in the national QAFAP. All R3 personnel who are involved in field activities shall implement and comply with the QAFAP as outlined in the FOMS.

As part of the FOMS implementation, R3 has nine Field Standard Operating Procedures (SOPs) that cover the ten QAFAP elements. The SOPs are available on the R3 FOMS intranet site (Appendix 1). Field personnel should be familiar with the SOPs and quick reference guides available for each SOP. The Regional field SOPs are living documents and represent the current best approaches for implementation of the QAFAP. R3 field SOPs shall be revised and approved at a minimum of every 5 years but can be revised sooner to reflect any system or procedural changes. FOMS implementation will be evaluated through internal and external assessments on a biennial schedule.

Successful implementation and sustainability of the FOMS rely on commitment from senior management of each affected R3 Division or organization. Effective and regular communications are essential in implementing and maintaining FOMS and will occur as outlined in Section A.6. The roles listed in table G.1 are involved in implementation of the R3 FOMS.

**Table G.2. FOMS Implementation by Role**

*Additional details of role located in Section A.4.

| Role | Action |
|---|---|
| **R3 Field Quality Manager (FQM)*** | The FQM has the responsibility and authority for ensuring the R3 FOMS is implemented and followed. The FQM is the approving authority for Regionwide QAFAP controlled field documents such as document templates, technical R3 SOPs, checklists, forms, etc. |
| **Field Activities Coordination Team (FACT)*** | The FACT assists the RFQM in implementing the FOMS. The FACT is led by the RFQM and includes Field Activities Coordinators representing regional divisions and ad hoc members from other offices who are involved in field activities. |
| **Field Activities Coordinators (FACs)*** | FACs work with staff in their organization (i.e., field personnel, subject matter experts) and assist in reviewing and implementing activities to ensure consistent regional field operations. |
| **Subject Matter Experts (SME)** | SMEs are experienced and knowledgeable staff who may be tasked to assist on document review, procedures, standards, guidance, or other field activities subject matters. |
| **Field Personnel** | R3 personnel involved in field sampling and data collection are responsible for ensuring that work follows procedures set in place to comply with QAFAP and approved QA planning documents (e.g., QAPPs, QAPrPs, SOPs, etc.).[2] |

## G.5.b Competency for Field Activities

R3 managers and staff involved in field activities shall be trained on the FOMS on a biennial basis, either Tier 1 Field Operations Management System awareness training or Tier 2 Field Operations, depending on their roles (Section B). In addition to documenting training as outlined in Section B.5., individuals are responsible for being familiar with R3 field SOPs and any field programmatic SOPs within their respective programs. For additional information about field training requirements, refer to the R3 field SOP: *Personnel & Training* (R3FAP001, most current version) (R3 FOMS intranet site).

## G.6 LABORATORY SERVICES

LSASD's Laboratory & Technical Services Branch (LTSB) serves as the Regional Sample Control Center to coordinate analytical support for regional programs and acquisition and delivery of routine and specialized analytical services conducted by external providers.

LTSB's Sample Submission Procedures (Appendix 1) specify procedures to be followed when submitting samples to LTSB, which help ensure field and laboratory aspects of the sampling are linked to produce reliable data of known quality. Analytical services provided by LTSB are documented in the Laboratory Quality Manual (Appendix 1). This manual describes the

[2] For sampling conducted to support criminal investigations, the Criminal Investigation Division (CID) investigator in charge of the case manages sampling activities following national enforcement SOPs and approved procedures. CID investigators often rely on technical expertise of R3 field inspectors to help determine location, quantity, and type of samples to be collected.

Laboratory's quality procedures, which are ISO 17025 accredited by A2LA accreditation body. The Laboratory also holds Drinking Water certification from the EPA Office of Water-Cincinnati in inorganics, organics, and microbiology. LTSB personnel and laboratory QAO (Section A.4.i) are responsible for ensuring QA/QC is implemented during laboratory activities. LTSB also oversees laboratory audits (Section H.2.b.2), including the state chemistry and microbiological laboratory certification program.

## G.6.a Laboratory Competency

EPA's Policy to Assure Competency of Laboratories, Field Sampling and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions (Section C.1.a) requires organizations (e.g. laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions submit documentation of their competency, which may include participation in applicable certification and accreditation programs. Organizations performing environmental analyses for the Agency shall demonstrate their qualifications in the analyses to be conducted, prior to performing such analyses. For the analysis of samples using non-CLP methods, the Region acquires commercial laboratory capability and capacity via small purchase orders or regional contracts. Whenever possible, the Region will use accredited or certified laboratories. Use of accredited laboratories provides the Region with access to information about the laboratory's performance (i.e., Proficiency Testing sample results, on-site audit reports, etc). Prior to contract award, laboratories not accredited must provide documentation to be reviewed as outlined in Section H.2.b.2, Table H.5.

## G.6.b Alternate Test Procedures

The RQAM serves as the Regional Alternate Test Procedure (ATP) Coordinator supporting the CWA NPDES and SDWA programs. EPA's regulations at 40 CFR 136.4 and 136.5 establish procedures for EPA to review and approve use of an ATP in place of an EPA-approved method for CWA methods. In cases where an ATP limited use request is made in a state or tribe that has not been granted authority to administer the NPDES permit program or in cases where the state or tribe is the applicant, the request is submitted directly to the Regional ATP Coordinator who has the final authority to approve or reject applications for use of an ATP. The Regional ATP Coordinator will forward a copy of every approval and rejection notification to the National ATP Coordinator. Additional information on this process can be found on EPA's ATP web page (Appendix 1).

# SECTION H: ASSESSMENT & RESPONSE

To verify the effectiveness of the regional Quality System, R3 uses management, technical, and data assessments, outlined in Table H.1, which evaluate if procedures documented in this QMP and other QA documents (e.g., QAPPs, QAPrPs, etc.) are being implemented. The RQAM (or designee) shall ensure that a description of applicable management, technical, and data assessments is included in the R3 QMP and relevant external QMPs, including titles and roles of responsible personnel conducting the assessments.

QAPPs and QAPrPs shall include information on technical and data assessments (Table F.3. Required QAPP Elements), including the scope and frequency of assessments to be conducted, the titles and roles of responsible personnel conducting the assessments, and procedures used to implement corrective actions.

**Table H.1 Assessment Types**

| Type | Purpose | Responsible Entity | Expected Frequency | Guidance Documentation (links in Appendix 1) |
|---|---|---|---|---|
| Management | To determine conformance with an approved QMP or equivalent QA document & to assess efficacy of its implementation | EPA Managers, RQAM, RQC, FQM or FACT | Annually or as outlined in QA documents | Guidance on Assessing Quality Systems (G-3)<br><br>EPA Region 3 Quality System Audit Checklist (Appendix 3) |
| Technical | To evaluate the implementation of a project or activity against its defined technical or quality procedures or criteria | DPMs or technical personnel with assistance from relevant EPA Manager(s), ASQAB quality staff, QAC, or FAC | As outlined in QA documents (i.e., QAPP, QAPrP, Quality Manual, SOPs, etc.), usually per project or per organizational unit as applicable | *Guidance on Technical Audits and Related Assessments for Environmental Data Operations (EPA QA/G-7)*<br><br>Program-specific checklists |
| Data | To assess type, quantity, & quality of data | DPMs & appropriate technical personnel | As outlined in QA documents (i.e., QAPP, QAPrP, Quality Manual, SOPs, etc.), usually per project or per organizational unit as applicable | *Guidance on Environmental Data Verification & Data Validation (EPA QA/G-8)*<br><br>*Guidance for DQA: Practical Methods for Data Analysis (EPA QA/G-9)* |

## H.1 ASSESSMENT PLANNING

Initial planning steps are the following:

- Gain knowledge and understanding of the assessee organization;
- Consider available resources;
- Select the appropriate assessment tool;
- Determine assessment scope and objectives;
- Determine criteria for the assessment; and
- Select the assessment team.

For assessment planning, selection of appropriate assessment tools depends upon whether the assessment is occurring at the management, technical, or data level. Technical and data assessment tools are also dependent upon the stage of the project being assessed. Table H.2 outlines the types of assessment tools that may be used in R3.

Assessment scope is the area or the extent to be covered, defining the limits of the time period and subject matter or organizational "boundaries". The scope guides the detailed planning process for the assessment and can be affected by assessor time and resource constraints. The scope must be clearly articulated to the assessment team and to the assessee.

Roles involved in the assessment process are listed in Table H.3 with examples of how roles apply in R3 in Table H.4. Personnel participating in the assessment should be deemed competent by the Authorizing Entity and Assessment Team Leader based on training and qualifications. Members of the assessment teams shall be familiar with the QA requirements found in this QMP. The individuals should also have professional knowledge of any related scientific principles, theories, practices, and established methods.

Personnel should have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed. The Authorizing Entity, the Assessment Team Leader, and the Assessee shall ensure personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom.

## Table H.2. Assessment Tools

| Tool | Stage | Description |
|---|---|---|
| **Management Assessments** | | |
| Quality System Audits (QSA) | Organization-wide Implementation | Assesses conformance/compliance to a documented Quality System through collection of information & documented evidence of implementation. Uses a quantitative approach & findings are based on objective evidence. |
| Management Systems Review (MSR) | Organization-wide Implementation | Qualitatively assesses QA/QC practices to establish consistency with policies & requirements & are adequately implemented to satisfy needs & expectations (e.g., QAFAP internal assessments). Less quantitative than a QSA since interviewing is the primary data collection method. Applies best to situations where the quality system is not well-documented or developed & seeks to determine actual activities. |
| **Technical Assessments** | | |
| Readiness Review | Planning | Conducted before specific technical activities (e.g., sample collection, field work, & laboratory analysis) are initiated to assess if procedures, personnel, equipment, & facilities are ready for environmental data to be collected according to the QAPP or QAPrP (e.g., QAPP Review; Site Scoping Meeting & Visit, etc.) |
| Technical Systems Audit (TSA) | Implementation | Qualitatively documents the degree to which procedures & processes specified in the approved QAPP, QAPrP, program requirements, & other relevant QA documents are being implemented. (e.g., Field Sampling Audit, Lab Audit, etc.) |
| Surveillance | Implementation | Used to continuously or periodically assess real-time implementation of activities to determine conformance with established procedures & protocols. |
| Performance evaluation (PE) | Implementation | Quantitatively tests the ability of a measurement system to obtain acceptable results (e.g., Proficiency Testing Sample). |
| Peer Reviews | Implementation | Intended to uncover any technical problems or unresolved issues in a preliminary work product through use of independent experts. This information is then used to revise the draft product so that the final work product will reflect sound technical information & analyses. |
| **Data Assessments** | | |
| Data Validation & Verification | Data Assessment | Data verification is an evaluation of performance against pre-determined (& often generic) requirements in a document such as an analytical method procedure or a contract. Data validation focuses on particular data needs for a project, as stated in a project-specific document such as a QAPP. |
| Audit of data quality (ADQ) | Data Assessment | Conducted on verified data to document the capability of a project's data management system (hardcopy or electronic) to collect, analyze, interpret, & report data as specified in the QAPP or QAPrP. (e.g., Data Audit Inspection) |
| Data Quality Assessment (DQA) | Data Assessment | Scientific & statistical evaluations of validated data to determine if the data are of the right type, quality, & quantity to support their intended use (e.g., Usability Report) |

## Table H.3 Assessment Roles & Responsibilities

| Role | Responsibilities |
|---|---|
| Authorizing Entity | • Authorize & provide resources for the assessment<br>• May set the scope of the assessment<br>• Approve the assessment plan<br>• Review assessment results & ensure corrective actions |
| Assessee | • Acknowledge the communications<br>• Review the assessment plan<br>• Provide preliminary documentation & scheduling assistance<br>• Work with the assessor to accomplish the assessment |
| Assessment Team Leader | • Understand the need, authority, & resources for the assessment<br>• Select team members<br>• Prepare written & oral communication, including assessment plan<br>• Prepare interview/document review checklists<br>• Complete & submit the assessment report<br>• Address comments to the report |
| Assessors | • Understand the purpose of the assessment & assigned areas<br>• Review relevant documentation<br>• Assist with assessment plan & checklists, etc.<br>• Identify & accurately document non-compliance & noteworthy practices<br>• Review & comment on draft reports to ensure accuracy |

## Table H.4 Examples of Assessment Roles

| Assessment Type | Assessee | Authorizing Entity | Assessment Team Leader & Assessors |
|---|---|---|---|
| **Management Assessments** | | | |
| R3 Quality System (internal) | R3 & major Offices & Divisions | Assistant/ Regional Administrator | RQAM (or designee) & at least one member of the RQC; may also include a representative from a major office/ division that is not part of the RQC. |
| Assistance agreement recipient/ contractor | State or tribal environmental agency, nonprofit organization, or other assistance agreement recipient/contractor | RQAM or major Offices & Divisions | RQAM or R3 Offices & Divisions & R3 QA staff & technical experts as needed |
| R3 Quality System (independent) | R3 & major Offices & Divisions | OMS EQMD | EQMD staff & technical experts as needed |
| R3 FOMS | R3 & major Offices & Divisions | FQM or major Offices & Divisions | FQM (or designee) & at least one member of the FACT or R3 Offices & Divisions & R3 QA staff & technical experts as needed |
| **Technical & Data Assessments** | | | |
| R3 Quality System components (internal) | R3 programs or projects personnel | R3 Offices & Divisions management | Management & QAO, QA staff & technical experts as needed |
| Assistance agreement recipient/ contractor | Program & project personnel from state or tribal environmental agency, nonprofit organization, or other assistance agreement recipient/contractor | R3 Offices & Divisions, R3 Laboratory | R3 DPMs, R3 QA staff & technical experts as needed |

## H.2 ASSESSMENT IMPLEMENTATION

Details on implementation of assessment tools more commonly used by R3 are discussed below.

### H.2.a Management Assessments

R3 conducts internal management assessments of its quality system, which can also be assessed independently by EQMD or other authorizing entities. In addition, R3 may perform management assessments of external entities as needed. Extramural organizations may also conduct periodic internal management assessments of their own quality systems.

For an assessment team to assess adequacy and effectiveness of a quality system in an objective manner, comparisons of the quality system's characteristics should be made with objective and written reference standards rather than with subjective, unwritten expectations of assessors or other individuals. Assessments can be guided by the Guidance on Assessing Quality Systems (G-3) and the R3 QSA checklist.

Management assessment criteria generally include: (1) the external policies, procedures, and specifications applicable to the assessee; and (2) the assessee's internal policies, procedures, specifications, and quality system planning documents. Specific policies and requirements relevant to the quality systems of EPA organizations and recipients of R3 financial assistance (i.e., grants, cooperative agreements, contracts and interagency agreements) may include the following:

- CIO Quality Policy 2105;
- CIO Procedure 2105 P-01.0;
- R3 QMP;
- EPA specifications for QMPs (EPA/R-2);
- Assessee's approved QMP or combined QMP/QAPP;
- Assessee's reports [e.g., quarterly progress reports or QA Annual Report & Work Plan (QAARWP)];
- Terms & Conditions for Grants in IGMS (if applicable); and
- Any other relevant QA and QC specifications in regulations.

#### H.2.a.1 Internal R3 Quality System Assessment

To annually assess adequacy of the quality management system and conformance with CIO Quality Policy 2105 and CIO Procedure 2105-P-01.0, the RQAM with assistance from the RQC and ASQAB quality staff, shall annually summarize QA-related information in the QAARWP (Section G.1.b), including: 1) quality management resources; 2) QA/QC training; 3) Quality System-related accomplishments; and 4) assessments of quality and technical systems. This assessment will evaluate the Region's environmental program activities to determine adequacy of the number and type of QA resources. The assessment will also evaluate adequacy of intramural and extramural funding to determine if adequate funding is provided for QA-related activities. The QAAWRP will summarize findings and corrective actions of each QSA conducted during the fiscal year. The RQAM and RQC will use the QAARWP to identify needed changes and updates to R3's QMP and quality system and to inform decisions on QA priorities for

the following year. A corrective action plan will be developed which includes findings identified.

Every 3 years, the RQAM leads the regional QSA, assembling the assessment team, and coordinating assessment-related activities. At a minimum, the team shall consist of the RQAM (or designee) and at least one member of the RQC. The team may also include a member of the ASQAB quality staff and a representative from a major office/division who is not a member of the RQC . Relevant QACs shall assist the assessment team in handling logistics of the assessment, scheduling interviews, and providing preliminary documentation. During the QSA, managers and staff involved in the quality system are interviewed. Project files, previous audit reports, and corrective action plans are also reviewed.

Upon completion of the assessment, preliminary results of the QSA shall be shared with senior management during an exit briefing. Approximately 60 days following the QSA, the assessment team shall complete a draft findings report documenting results of the QSA. Findings may include objective evidence of non-conformance with the organization's Quality System and noteworthy accomplishments. Senior managers and the RQC shall review the draft report to ensure accuracy of findings. The assessment team will then revise as applicable and finalize the report. The assessment team shall submit the final report to Senior Management and the RQC. If concurrence with the formal findings cannot be achieved, dispute resolution specified in Section H.5 shall be used to achieve consensus on the content of the final findings report.

Upon receipt of the final findings report, the RQC shall complete the corrective action plan (Section H.4) with assistance from the RQAM. The Corrective Action Plan must identify the corrective action, responsible officials, and projected completion date for each finding requiring corrective action. Upon acceptance by the RQC, implementation of corrective actions may begin. The RQC shall periodically review the status of the Corrective Action Plan.

### H.2.a.2 Independent R3 Quality System Assessments

Independent assessments of the R3 Quality System can be conducted by the EQMD staff, the Office of Inspector General, the Government Accountability Office, or Headquarters' Office personnel. The frequency of these assessments is determined by the office conducting the QSA. Every three years, the EQMD staff conducts a QSA of the Region's Quality System. The QSA Team typically consists of EQMD staff and at least one person from another Region or EPA Headquarters Office. The scope of their assessment is determined by the EQMD QSA Team. The RQAM and RQC shall assist the EQMD QSA team by handling logistics and scheduling interviews.

Findings of the EQMD QSA are documented in a draft Findings Report. After the Region's Senior Management and EQMD QSA Team reach consensus on the accuracy of observations, the draft QSA Findings Report is finalized. If corrective actions are required, the RQC with input from Senior managers shall develop the Region's Corrective Action Plan. Milestones will be developed so that progress on corrective actions can be measured. This information will be included in the assessment file, which

is maintained by the RQAM or designee. R3 managers are responsible for ensuring compliance with the approved corrective actions. The RQC will periodically provide Senior managers with information about the Region's progress on implementation of the Corrective Action Plan.

#### H.2.a.3 Quality System Assessments of External Organizations

Federal regulations governing extramural agreements (addressed in 48 CFR Part 1546 and 40 CFR Parts 30, 31, and 35) mention the assessment of external organizations by EPA. Assessments will be implemented in accordance and in conjunction with extramural agreement regulations and the organization's approved QMP or combined QMP/QAPP. New, undeveloped quality systems generally undergo an MSR with broader review criteria, instead of a QSA.

External assessments tend toward more formality than internal assessments. After an initial verbal contact, it may be appropriate for the assessment team leader or the authorizing entity to send a written notification of the upcoming assessment to the assessed organization's senior management and QA manager, as appropriate. Regardless of how the initial contact is made, the assessed organization's senior management should be aware that an assessment will be occurring.

Confidentiality should be considered when conducting these assessments. The assessment plan should clearly state rules for dissemination of findings and confidentiality for the particular assessment. Generally, assessment findings are disseminated only to involved parties. If the assessment will involve CBI, the assessee should notify the assessment team leader so that the documents containing CBI can be handled in accordance with applicable regulations. Assessors may also have access to enforcement/compliance-sensitive information, which should be treated with appropriate confidentiality.

### H.2.b Technical Assessments

The goal of technical assessments is to determine whether implemented environmental data operations and related results comply with documented activity as outlined in planning documents (e.g., QAPP, QAPrP, SOPs, manuals, methods, etc.) and are suitable to achieve data quality goals Technical assessments may also be used as an investigative tool when problems are suspected. Because they accomplish different objectives, different types of technical assessments can often be integrated into one effort, depending on needs. Planning for technical assessments will occur as outlined in Section H.1 and results and corrective actions will be handled as addressed in H.3 and H.4 (unless detailed differently in the following sections).

DPMs are responsible for ensuring technical assessments are accomplished as outlined in the QAPP, QAPrP, grant terms and conditions, contract SOW, SOPs, or equivalent document. EPA remedial and field investigation team contractors are required to conduct technical assessments of their own environmental data operations. Grantees and other recipients of financial assistance (e.g., cooperative agreements and interagency agreements) with approved QMPs or combined QMP/QAPPs may conduct technical assessments of their own environmental data operations.

Some technical assessment tools include readiness reviews, Technical Systems Audits (TSA), surveillance, performance evaluations (PE), and peer reviews. More information on these tools is found in Table H.2. TSAs, laboratory audits, proficiency testing (a type of PE), and peer reviews are further discussed in the following sections.

### H.2.b.1 Technical System Audits

Technical systems audits (TSAs) are thorough, systematic, and qualitative audits of the measurement system used in environmental data operations. The two main purposes of a TSA are to determine that:

1. Project personnel and equipment are functioning and
2. All procedures are being implemented as prescribed in relevant QA documents.

The Assessment Team may examine facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and analysis, and reporting aspects of a measurement system in a TSA. A TSA is often conducted shortly after a project starts to allow for early corrective action. For longer projects, TSAs should be performed on a regular schedule throughout the project's life. Typically, the approved QAPP, QAPrP, program requirements, or equivalent QA documents provide performance criteria for the TSA, which can then be used to prepare a checklist. Objective evidence is gathered by interviewing personnel, examining records, and observing project activities.

In some instances, R3 is required by regulation to conduct TSAs of certain delegated program activities (e.g., state drinking water analysis laboratories and state ambient air quality monitoring networks (Appendix 7).

### H.2.b.2 Laboratory Audits

LSASD staff coordinate and conduct assessments of laboratories for various purposes and programs, as outlined in Appendix 10-Table 10.2. During laboratory assessments, reviews are made of analytical procedures, sampling procedures, equipment, instrumentation, record keeping, documentation, analytical data, and P/T sample results. A Data Audit Inspection (DAI) may also be conducted. A DAI consists of recalculating the results from unprocessed instrument results and comparing them to results reported on the Discharge Monitoring Reports (DMRs). If routine problems are found in the P/T sample results, a more extensive tracking of P/T sample results will occur until successful performance is achieved. Laboratory assessment reports are completed within 30 days of the assessment and follow-up corrective actions are tracked (corrective action reports are required within 45 days of the assessment through the issuance of a Deficiency Notice).

Additionally, EPA's Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions (Section C.1.a) requires organizations (e.g. laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions submit documentation of their competency, which may include participation in applicable certification and or accreditation programs. Organizations performing environmental analyses for the Agency shall demonstrate their qualifications in the fields of analyses to be conducted, prior to performing such analyses.

### H.2.b.3 Proficiency Testing

A Proficiency Testing (P/T) sample is used as a quantitative audit of analytical results generated by a measurement system. Whenever possible, the proficiency testing sample shall mimic the matrix of the routine field sample. The concentration of the P/T sample shall be unknown to the analyst. Results of the P/T sample are used to determine if a measurement system's results are within measurement quality objectives specified by the program (i.e., Superfund, CLP, Drinking Water, etc.) or found in the QAPP. The procedures used for acquisition and evaluation of proficiency testing samples shall be included in the Laboratory Quality Manual, program SOP, QAPP, or QAPrP. LTSB also coordinates P/Ts for PRPs or contracted laboratories from QATS (Appendix 10-Table 10.2).

### H.2.b.4 Peer Review

An important element in ensuring that the Agency's decisions are based on sound and defensible science is to have an open and transparent peer review process. EPA conducts peer reviews of major scientifically and technically based work products used to support its decisions. Peer review is intended to uncover any technical problems or unresolved issues in a preliminary work product through review by independent experts . This information is then used to revise the draft product so that the final work product will reflect sound technical information and analyses. Peer review is a process for enhancing a scientific or technical work product so that the decision or position taken by the Agency, based on that product, has a sound, credible basis. To be most effective, peer review of a scientific and technical work product should be incorporated into the up-front planning, including obtaining the proper resource commitments and establishing realistic schedules. Peer review takes many different forms depending on the nature of the work product, relevant statutory requirements, and office-specific policies and practices.

It is R3's practice that DPMs, in consultation with their first line supervisors, senior managers, and technical staff, will determine whether the product should be peer reviewed and to what extent. R3 staff may also consult with the Regional Peer Review Coordinator (PRC) for assistance. The role of the PRC is to coordinate and monitor peer review activities related to EPA scientific and technical work products in an organization and is the main contact for information about peer review activities. When applicable, R3 follows the procedures and guidance found in EPA's Peer Review Handbook (Appendix 1). The Handbook provides a roadmap to peer review at EPA and guidance on performing peer review.

## H.2.c Data Assessments

Environmental data shall be reviewed to ensure the criteria specified in the approved QAPP, QAPrP, or equivalent document have been met. Planning for data assessments will occur as outlined in Section H.1 and results and corrective actions will be handled as addressed in H.3 and H.4. DPMs are responsible for ensuring data assessments are accomplished as outlined in the QAPP, QAPrP, grant terms and conditions, contract SOW, or equivalent document.

Data verification and validation do not concentrate on decisions, but on specific data processes and results. Conversely, Audits of Data Quality (project implementation phase) and Data Quality Assessments (project assessment phase) focus on environmental decision making, and whether data sets generated can effectively and credibly support those decisions.

### H.2.C.1 Data Verification & Validation

Data verification and validation are related but reflect two separate data assessment processes with two separate purposes, as outlined in Table H.5. Data verification is performed during or at the culmination of data collection activities; data validation begins with outputs from data verification, mostly by a party independent of both the data collector and user. Personnel performing data verification and validation should have knowledge of scientific principles and established methods, statistical techniques commonly used in quality control, data assessments, data management practices, and project-specific data quality indicators. R3 adheres to EPA's *Guidance on Environmental Data Verification and Data Validation (EPA QA/G-8)* (Appendix 1).

**Table H.5. Data Verification & Validation Processes**

| Data Process | Purpose | Process | Performed by | Other Details |
|---|---|---|---|---|
| Verification | To ensure & document that reported results reflect what was actually done | Evaluating completeness, correctness, & conformance/ compliance of a specific data set against the method, procedural, or contractual requirements. | Personnel involved with collection of samples or data, generation of analytical data, or by an external data verifier. | Data verification is incorporated into most, if not all, environmental data operation projects. Some programs may require external data verification upon receipt of data packages to confirm completeness of the data package & to permit authorization of payment for work. |
| Validation | To assess achievement of data quality goals established in planning phase | Extending evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine analytical quality of a specific data set. | Typically, person(s) independent of project activity. The appropriate degree of independence is determined on a program specific basis. At a minimum, the validator(s) should not belong to the same organizational unit with immediate responsibility for producing the data set. | DQIs (e.g., precision, accuracy, etc.) are typically used as expressions of quality of data. Data validation includes a determination, where possible, of the reasons for any failure to meet method, procedural, or contractual requirements, & an evaluation of impact of such failure on overall quality of the data set. |

When performing data verification and validation of laboratory data (regardless of the program), R3 follows a tiered data evaluation system, in which the level of effort of the review increases with successive levels, is appropriate to project DQOs, and adheres to U.S. EPA's Contract Laboratory Program (CLP) National Functional Guidelines (Appendix 1).

- Level 1 is a relatively streamlined review of quality control (QC) information. Data review may be limited to reviewing reported QC results against acceptance limits, possibly using a software program, with no review of raw data. The inherent risk of mischaracterizing data quality must be assumed to be acceptable for project needs.

- Level 2 is a full data review, including but not limited to method details, instrument printouts and logs, including calculation checks. Level 2 reviews are intended to evaluate the legal defensibility of the data. For Superfund projects, Level 2 validation is performed using the National Functional Guidelines for organic and inorganic analyses generated through the CLP. Although the guidance is used principally to validate Superfund data, it may be used in other programs.

Table H.6 visually represents R3 validation level nomenclature consistent with the National CLP's Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use.

**Table H.6. R3 Laboratory Data Validation Level Nomenclature**

(applies to all programs but follows Superfund guidance documents as discussed in this section)

| Name | Summary | Superfund Stage | Stage Abbreviation |
|---|---|---|---|
| **Inorganic Level 1** | QC, false negatives, detection limits | Stage 2B Validation Electronic & Manual | S2BVEM |
| **Inorganic Level 2** | CLP National Functional Guidelines w/R3 Modification (Use of 'B' qualifier) | Stage 4 Validation Electronic & Manual | S4VEM |
| **Organic Level 1** | QC, false negatives, detection limits | Stage 3 Validation Electronic & Manual | S3VEM |
| **Organic Level 2** | CLP National Functional Guidelines w/R3 Modification (Use of 'B' qualifier) | Stage 4 Validation Electronic & Manual | S4VEM |

### H.2.c.2 Audits of Data Quality

An ADQ examines data after collection and is verified by project personnel to document the capability of a project's data management system to collect, analyze, interpret, and report data as specified in the QAPP, QAPrP, or other equivalent document. Usually occuring in the project implementation phase, an ADQ documents and evaluates methods by which decisions were made during treatment of data. Primary questions to be answered in an ADQ are as follows:

- Is there sufficient documentation of all procedures used in the data collection effort to allow for repetition of effort by a person or team with technical qualifications similar to those of the original data collector?
- Can the data be replicated by the original data collector?
- Is there sufficient documentation to verify the data have been collected and reported according to these procedures?
- Is enough information provided to allow a potential user to determine quality and limitations of the data and whether intended use of the data is appropriate?
- Are the data of sufficient quality with respect to DQI goals and other performance criteria for their intended use?

A typical ADQ begins by reviewing available data from a project, by determining needed missing data, and by devising a plan for the assessment. The plan usually includes steps involving pursuing all available needed data, collecting them, and conducting an extensive review of the entire collection.

### H.2.c.3 Data Quality Assessment

A Data Quality Assessment (DQA) is the scientific and statistical evaluation of validated data sets to determine if the data are of the right type, quality, and quantity to support their intended use as defined by the DQO process. DQAs, which occur during the assessment phase of a project, are more comprehensive than ADQs, which typically occur during the implementation phase. The scope of the DQA should be commensurate with the project objectives and intended use of the data.

Relevant guidance documents (Appendix 1) are the following:

- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (EPA QA/G-9);*
- *Data Quality Assessment: A Reviewer's Guide (EPA QA/G-9R)*; and
- *Data Quality Assessment: Statistical Methods for Practitioners (EPA QA/G-9S)*.

Generally, the 5 steps of a DQA are:

1. review the DQOs or performance criteria and sampling design;
2. conduct a preliminary data review;
3. select the statistical test;
4. verify the assumptions of the statistical test; and
5. draw conclusions from the data.

R3 personnel who may perform DQAs include:

- Data users (such as DPMs or risk assessors who are responsible for making decisions or producing estimates regarding environmental characteristics based on environmental data);
- Data analysts (such as QA specialists, or any technical professional who is responsible for evaluating the quality of environmental data); and

- Data generators (such as analytical chemists, field sampling specialists, or technical support staff responsible for collecting and analyzing environmental samples and reporting the resulting data values).

## H.3 ASSESSMENT REPORTING & RESPONSE

Assessments must be documented and reports to management must be completed in a timely manner, including with appropriate level of review and approval.

Assessments must, by definition, produce a written report that includes the following:

1. Summarizes the assessment
    a) Assessee;
    b) Assessment location and date;
    c) Purpose and objectives of the assessment;
    d) Type of assessments performed; and
    e) List of assessment team.
2. States findings and their bases, including those requiring corrective action. Commonly used tiers for categorizing findings – from most severe to least severe – include: Major Findings, Minor Findings, Concerns, and Observations (Table H.7).
3. Provides conclusions and recommendations, and, for certain types of assessments, lists suggested corrective actions (if it is appropriate for the assessment team to formulate these items)

**Table H.7 Example Findings Categorization**

| Category | Description |
|---|---|
| **Finding** | Nonconformance with or absence of a specified requirement (regulatory, QMP, QAPP, SOP, etc.) or guidance deviation that could significantly impact data quality. |
| **Concern** | Practices with the potential detrimental effect on program/projects operational effectiveness or quality of sampling or measurement results. |
| **Observation** | An infrequent deviation, error, or omission that does not impact output or quality of the work product but may impact the record for future reference. |

Without documentation in a final report, a site visit, evaluation, or other review, is not considered an assessment. The objective of the report is to communicate assessment results to the responsible level of management. Efficient communication of results allows management to implement timely and effective actions so that quality objectives can be met. Assessment findings affecting data quality should (on case-by-case basis) halt additional data collection.

The draft assessment report shall be reviewed by the assessment team. The team lead and authorizing entity (if applicable) will approve and transmit the report to the assessee in a timely manner. When the report is sent to the assessee for comment, a specific date for receiving comments is often stated in the transmittal memorandum or letter. Management assessments are typically reported to senior managers of the organization responsible for the work. Technical and data assessments of project activities are reported to the DPM and relevant management.

The DPM or management may request a review of an assessment report by the ASQAB Quality Staff.

Senior managers of the assessee organization are responsible for ensuring that any deficiencies found in Management Assessments are appropriately addressed, while DPMs and relevant management shall address findings from technical and data assessments. The assessee should provide any comments on the report, and if applicable, submit a corrective action plan for approval. To finalize the report, the assessment team should incorporate any relevant comments from the assessee when appropriate, correct any factual errors, and if necessary, resolve any disputes (Section H.5). After final approval is received from the authorizing entity, the report should be distributed as previously agreed in the assessment plan. Assessment reports are entered in the QA tracking database by the relevant RQAM or ASQAB quality staff.

## H.4 CORRECTIVE ACTION

The assessed organization is responsible for implementing corrective actions. The assessee shall provide a written response for all assessment findings with objective evidence of the effectiveness of the corrective action and with specific timeframes. If mutually agreed, the assessee can send the corrective action plan (which may be a pre-approved template) separate from the assessment report within a specified timeframe. The authority and responsibility for verifying timeliness of corrective action resides with management and DPM, who are ultimately responsible for the work that was assessed. Implementation and effectiveness of corrective actions can be verified in several ways, including:

- reassessing the deficient areas;
- reviewing new or revised quality-affecting documents such as manuals, procedures, and training records;
- confirming actions during the next scheduled assessment; and
- conducting surveillance covering areas of concern.

Closeout of an assessment is the last formal action of the process and occurs after all corrective actions have been implemented and confirmed as effective. Assessment and corrective action follow-up is documented and reported using the same process as the original assessment (as detailed in Section H.3).

## H.5 ASSESSMENT DISPUTE RESOLUTION

Any assessment disputes are usually resolved at the lowest administrative level possible. Taking good, organized notes during the assessment will substantiate findings in the event of disputes. Disputes over confidentiality issues should be resolved with involved organizations prior to start of the assessment. The authorizing entity may need to mediate disputes, and may monitor responses to and implementation of any corrective actions. If necessary, the dispute resolution processes discussed in the assessing organization's QMP should be followed, unless there is an overriding legal constraint. If disputes arise as a result of R3 assessments and related responses, the dispute resolution process as defined in Section A.7 of this QMP shall apply.

# SECTION I: QUALITY IMPROVEMENT

One of the goals of the R3 Quality System is to incorporate quality assurance in all regional environmental data and information work functions. Quality assurance procedures described in this QMP establish a foundation and processes for ensuring that conditions adverse to quality and scientific integrity are prevented or promptly identified and corrected, and that any actions taken are documented and tracked to avoid reoccurrences.

## SECTION I.1 ADDRESSING QUALITY ISSUES

Regional personnel are encouraged to raise issues that impact quality of data and information, establish QA communications (including between customers and suppliers), identify process improvement opportunities, and suggest solutions for problems. Quality improvement issues and suggestions should be raised to the relevant QAC or FAC. If issues impact more than one division or office, the QAC or FAC will facilitate a discussion of the issue during the scheduled RQC meeting or FACT meeting respectively. Based on these discussions, the RQC or FAC will make a recommendation to Senior Management about remedies and ideas to improve the Region's Quality System. If the issue requires immediate action, the RQAM or FQM will coordinate with the RQC or FAC and respective Senior Management to determine an appropriate remedy. Whenever possible, the RQC will be involved in discussions about issues that impact the Region's Quality System.

## SECTION I.2 SCIENTIFIC INTEGRITY

EPA's Scientific Integrity Policy (Appendix 1) ensures that sound science is the foundation of Agency decision making. This policy provides a framework intended to ensure scientific integrity throughout EPA and promote scientific and ethical standards, including quality standards, communications with the public, use of peer review and advisory committees, and professional development. To promote scientific integrity throughout the Agency, EPA's Scientific Integrity Policy addresses four specific areas:

1. culture of scientific integrity at the EPA;
2. public communications;
3. use of peer review and Federal Advisory Committees; and
4. professional development of government scientists and engineers.

Agency employees, regardless of grade, position, or duties, and including scientists, engineers, managers, and political appointees, are required to follow this policy when:

1. engaging in, supervising, managing, or influencing scientific activities;
2. communicating information in an official capacity about Agency scientific activities; and
3. utilizing scientific information in making Agency policy or management decisions.

In addition, contractors, grantees, collaborators and student volunteers of the Agency who engage in scientific activities are expected to uphold the standards established by this policy and may be required to do so as part of their respective agreements with the EPA.

The Agency's Scientific Integrity Official chairs a standing committee of Deputy Scientific Integrity Officials representing each EPA Program Office and Region. These senior level employees provide oversight for the implementation of the Scientific Integrity Policy at EPA, act as liaisons for their respective Programs and Regions, and annually provide a brief, high-level discussion of their program's efforts. R3's Deputy Scientific Integrity Official (Appendix 2) can be contacted about scientific integrity concerns, questions, and areas of improvement.

# SECTION J: INFORMATION QUALITY GUIDELINES

The EPA Quality Program also covers implementation of the Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, or more commonly known as the Information Quality Guidelines (IQG) (Appendix 1). The IQG contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates. EPA's quality system serves as a framework to ensure that information products meet specifications of the IQG. EPA's IQG comply with OMB's governmentwide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information, including statistical information, disseminated by Federal Agencies" (Section 515 of the "Treasury and General Government Appropriations Act for FY 2001 [Public Law 106-554]).

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*"Information" generally includes any communication or representation of knowledge, position or policy such as facts or data, in any medium, or form. This includes "preliminary" information endorsed or adopted by EPA, and also conclusions or facts drawn from or based upon other existing information.*

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Although information can be disseminated to the public through various media, most information is disseminated from an EPA web page. However, not all web content is considered "information" under the IQG (e.g., certain information from outside sources that is not adopted, endorsed, or used by EPA to support an Agency decision or position)." Six broad categories of EPA information likely to be disseminated include the following (additional details in Appendix 5):

1. Tools (models, mapping/GIS-related programs, etc.);
2. Reports (studies, public reports to Congress, strategic plans, etc.);
3. Data (maps, databases, spreadsheets, etc.);
4. Information contained in EPA policy and guidance documents;
5. Outreach or communication products or broad audience information resources (brochures, flyers, videotapes, educational aids, etc.); and
6. Information disseminated in support of an EPA rulemaking (proposed rules, final rules, regulatory impact analyses, etc.).

R3 will ensure that EPA-disseminated information products will comply with IQGs and that the integrity of EPA websites will be protected from unauthorized access and revision. The Regional Product Review Officer and Information Quality Guidelines Officer (Appendix 2) are at the core of the process to assist EPA staff with communications.

## J.1 PRE-DISSEMINATION REVIEW

Pre-Dissemination Reviews (PDRs) ensure that information disseminated by or on behalf of EPA is consistent with EPA's IQGs which maximizes quality of those products. PDR procedures for

information products should begin at the planning stage and may include peer and quality reviews that occur at many steps in the development of information, not only at the point immediately prior to dissemination.

R3 has established PDR procedures for complying with IQGs, with emphasis on using existing Regional processes and procedures wherever possible. R3 programs may use one or more review processes to satisfy PDR as specified by EPA's IQGs. The R3 IQG Officer works with communications and web coordinators in each division for proposed dissemination of information products. As detailed in Appendix 5, major R3 PDR areas include R3 Geospatial Information Products, QAPPs, Peer Review, R3 Office of Public Affairs reviews, Open Source Code, and Qlik Applications.

## J.2 REQUESTS FOR CORRECTION OR RECONSIDERATION

The IQGs create a mechanism that enables the public to seek and obtain, where appropriate, corrections of information disseminated by the Agency that does not comply with EPA or OMB IQGs. EQMD staff will receive requests for correction (RFC) (Appendix 1) and forward them to the R3 IQG Officer when the information in question belongs to or involves R3. The IQG Officer will then collaborate with EQMD staff and appropriate R3 information owner to formulate a response.

The public may appeal EPA responses to RFC's under a formal Request for Reconsideration (RFR) (Appendix 1). When an RFR is received for a R3 product, the R3 IQG Officer will work on the response with the R3 information owner and EQMD staff.

## J.3 ASSESSMENT FACTORS

Following promulgation of the Data Quality Act of 2001 and issuance of EPA's IQGs in October 2002, the EPA Science Policy Council developed a summary of Agency practice to evaluate the quality and relevance of scientific and technical information, entitled A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information (Appendix 1). The intent of the assessment factors is to enhance transparency of EPA's quality expectations for information that is voluntarily submitted, gathered, generated, or used by EPA. The five assessment factors are the following:

1. Soundness - Based on valid reasoning. The information is founded on thorough knowledge or experience; and marked by showing common sense and good judgment;
2. Applicability and Utility - The extent to which information is relevant and useful for the Agency's intended use;
3. Clarity and Completeness - Having all necessary and normal parts;
4. Uncertainty and Variability - Uncertainty refers to the inability to know for sure and is often due to incomplete data. Variability is the amount of fluctuation; having no fixed quantitative value; and
5. Evaluation and Review - Evaluation is the act of examining and determining the value. Review is the consideration, inspection, or reexamination of a subject or thing.

EPA published an addendum to the Assessment Factors- Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information (Appendix 1). QAPPs for existing data should take into consideration the assessment factors when documenting the data/information review and analysis process.

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# APPENDICES

# Appendix 1 References & Links to QA Resources

## Table 1.1. Main R3 & Quality Websites

| Site | Location |
|---|---|
| R3 Internet Site | http://www.epa.gov/aboutepa/epa-region-3-mid-atlantic |
| R3 Quality System Internet Site: Managing the Quality of Environmental Data at EPA Region 3 | https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-3 |
| R3 Quality System Intranet Site | http://intranet.epa.gov/r3intran/qa |
| R3 Field Operations Management System Intranet Site | http://intranet.epa.gov/r3intran/FOMS |
| EPA Quality Internet Site | https://www.epa.gov/quality |

## Table 1.2. References & Links to QA Resources

Listed in order of mention in main body of QMP

| Title | Location |
|---|---|
| Terms & Acronyms | http://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do |
| **Section A** | **Quality System Management, Organization, and Components** |
| CIO 2105.0<br>Policy and Program Requirements for the Mandatory Agencywide Quality System, May 2000 | https://www.epa.gov/sites/production/files/2013-10/documents/21050.pdf |
| CIO 2105-P-01.0<br>EPA Quality Manual for Environmental Programs, May 2000 | https://www.epa.gov/sites/production/files/2013-10/documents/2105p010.pdf |
| CIO 2105-P-02.0<br>EPA QA Field Activities Procedures, September 2014 | https://www.epa.gov/irmpoli8/epa-qa-field-activities-procedures |
| CIO 2105-P-03.0<br>CIO Notification Procedure for Environmental Data Quality Issues, April 2018 | https://www.epa.gov/sites/production/files/2018-04/documents/cio_notification_procedure.final_electronic_signature_508.pdf |
| Guidance for Developing Quality Systems for Environmental Programs, EPA QA/G-1, November 2002 | https://www.epa.gov/quality/guidance-developing-quality-systems-environmental-programs-epa-qag-1 |
| Determining the Quality Specifications for Your Agreement with EPA | https://www.epa.gov/quality/quality-specifications-non-epa-organizations-do-business-epa#your-reqts |
| EPA General terms and conditions applicable to 40 CFR part 30 and 31 recipients effective October 1, 2014 | https://www.epa.gov/grants/epa-general-terms-and-conditions-applicable-40-cfr-part-30-and-31-recipients-effective-0 |
| CFR Title 40 Part 31.45 | https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol1/xml/CFR-2014-title40-vol1-sec31-45.xml |
| EPA Conflict Prevention and Resolution Center (CPRC) | https://www.epa.gov/adr/about-cprc |
| EPA Alternative Dispute Resolution (ADR) Policy | https://www.epa.gov/adr/alternative-dispute-resolution-epa |
| Chesapeake Bay Program Office (CBPO) Executive Council (EC) Agreements | https://www.chesapeakebay.net/what/what_guides_us/watershed_agreement |
| **Section B** | **Personnel Qualifications and Training** |
| Guidance for Developing a Training Program for Quality Systems, EPA QA/G-10, December 2000 | https://www.epa.gov/quality/guidance-developing-training-program-quality-systems-epa-qag-10 |
| **Section C** | **Procurement of Items and Services** |

| Title | Location |
|---|---|
| EPA Acquisition Guide (EPAAG) Subsection 46.2.1 and appendix 46.2.1-D | https://contracts.epa.gov/EPAAG (EPA intranet) |
| Federal Acquisition Regulation (FAR) 46.202-4 and 52.246-01 | https://www.acquisition.gov/content/part-46-quality-assurance and https://www.acquisition.gov/content/part-52-solicitation-provisions-and-contract-clauses |
| Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions (Agency Policy Directive #FEM-2011-01), November 14, 2016 | https://www.epa.gov/sites/production/files/2016-11/documents/fem-lab-competency-policy_policy_updated_nov2016.pdf |
| Frequently Asked Questions: Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Acquisitions, February 21, 2011 | https://www.epa.gov/sites/production/files/2015-10/documents/faqs-for-acquisitions.pdf |
| Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency Funded Assistance Agreements (Agency Policy Directive # FEM-2012-02), December 21, 2016 | https://www.epa.gov/sites/production/files/2017-05/documents/policy_to_assure_the_competency_of_organizations.pdf |
| Frequently Asked Questions: Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency Funded Assistance Agreements, September 12, 2013 | https://www.epa.gov/sites/production/files/2015-03/documents/faqs-competency-policy-091213.pdf |
| **Section D** | **Documents and Records** |
| CIO 2155.4 Records Management Policy, August 22, 2018 | https://www.epa.gov/sites/production/files/2018-09/documents/interim-records-mgmt-policy-20180822.pdf |
| EPA National Records Management Program web site | https://www.epa.gov/records |
| **Section E** | **Computer Hardware and Software** |
| Information Directives | https://www.epa.gov/irmpoli8/current-information-directives |
| System Life Cycle Management (SLCM) Requirements Guidance, the System Life Cycle Management Policy, and the System Life Cycle Management Procedure, December 2017 | https://www.epa.gov/irmpoli8/policy-procedures-and-guidance-system-life-cycle-management-slcm |
| National Institute of Standards and Technology standards and guidelines | https://www.nist.gov/standardsgov |
| Federal Information Processing Standards Publications (FIPS PUBS) | https://www.nist.gov/topics/federal-information-standards-fips |
| Policy and Procedures for EPA's Data Standards | https://www.epa.gov/irmpoli8/policy-and-procedures-epas-data-standards |
| **Section F** | **Planning- Organization-wide** |
| EPA Requirements for Quality Management Plans, EPA QA/R-2, March 2001 | https://www.epa.gov/quality/epa-qar-2-epa-requirements-quality-management-plans |
| | **Planning- Program-level** |
| EPA Region 9 Guidance for Quality Assurance Program Plans, R9QA/03.2, March 2012 | https://www.epa.gov/sites/production/files/2016-05/documents/mngmt-plan_guidance_2012.pdf |
| Additional Program Guidance for QAPrPs (and QAPPs) for Air Monitoring and Air Pollution Measurement: | Appendix 7 ARD, Table 7.1 |
| Additional Program Guidance for QAPrPs (and QAPPs) for Brownfields, Lead Monitoring, FIFRA, and State RCRA Subtitle C or LUST or UST Program: | Appendix 11 LCRD, Table 11.1 |
| Additional Program Guidance for QAPrPs (and QAPPs) for Water Quality Modeling | Appendix 15 WD, Table 15.1 |
| | **Planning- Project-specific** |

| Title | Location |
|---|---|
| Guidance on Systematic Planning using the Data Quality Objectives Process, EPA QA/G-4, February 2006 | https://www.epa.gov/quality/guidance-systematic-planning-using-data-quality-objectives-process-epa-qag-4 |
| EPA Requirements for QA Project Plans, EPA QA/R-5, March 2001 | https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans |
| Guidance for Quality Assurance Project Plans, EPAQA/G-5 | https://www.epa.gov/quality/guidance-quality-assurance-project-plans-epa-qag-5 |
| R3 Quality Assurance Project Plans webpage- Resources for Preparing QAPPs, Templates, and Guidance for Secondary Data Use | https://www.epa.gov/quality/epa-region-3-quality-assurance-project-plans |
| Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP)<br>(Manual, Worksheets, QA/QC Compendium, Sample QAPP, FAQs, and Training Materials) | https://www.epa.gov/fedfac/assuring-quality-federal-cleanups#ufp-qapp |
| Guidance for Geospatial Data Quality Assurance Project Plans, EPA QA/G-5G, March 2003 | https://www.epa.gov/quality/guidance-geospatial-data-quality-assurance-project-plans-epa-qag-5g |
| Guidance for Quality Assurance Project Plans for Modeling, EPA QA/G-5M, December 2002 | https://www.epa.gov/quality/guidance-quality-assurance-project-plans-modeling-epa-qag-5m |
| Quality Assurance Project Plan Requirements for Secondary Data Research Projects, July 1, 1999 | https://www.epa.gov/quality/quality-assurance-project-plan-requirements-secondary-data-research-projects |
| Handbook for Citizen Science: Quality Assurance and Documentation, March 2019 (EPA 206-B-18-001) | https://go.usa.gov/xEw43 |
| **Section G** | **Implementation** |
| Guidance for the Preparation of Standard Operating Procedure, EPA QA/G-6, April 2007 | https://www.epa.gov/quality/guidance-preparing-standard-operating-procedures-epa-qag-6-march-2001 |
| R3 Field Operations Management System | http://intranet.epa.gov/r3intran/FOMS |
| R3 Laboratory Sample Submission Procedures | https://www.epa.gov/regionallabs/epa-region-3-laboratory-sample-submission-process-0 |
| R3 Laboratory Quality Manual | R3 Network Drive- I:\LTSB Quality System |
| Alternate Test Procedures | https://www.epa.gov/cwa-methods/alternate-test-procedures |
| **Section H** | **Assessment** |
| Guidance on Assessing Quality Systems, QA/G-3, March 2003 | https://www.epa.gov/quality/guidance-assessing-quality-systems-epa-gag-3 |
| Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7, January 2000 | https://www.epa.gov/quality/guidance-technical-audits-and-related-assessments-environmental-data-operations-epa-qag-7 |
| Guidance on Environmental Data Verification and Data Validation, EPA QA/G-8, November 2002 | https://www.epa.gov/quality/guidance-environmental-data-verification-and-data-validation |
| Guidance for Data Quality Assessments:<br>Practical Methods for Data Analysis, EPA QA/G-9, July 2000<br>A Reviewer's Guide, QA/G-9R, February 2006<br>Statistical Methods for Practitioners, EPA QA/G-9S, February 2006 | https://www.epa.gov/quality/guidance-data-quality-assessment |
| Peer Review Handbook, 4th edition, October 2015 | https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015 |
| National Functional Guidelines | https://www.epa.gov/clp/superfund-clp-national-functional-guidelines-data-review |
| **Section I** | **Quality Improvement** |
| EPA Scientific Integrity | https://www.epa.gov/osa/basic-information-about-scientific-integrity |
| **Section J** | **Information Quality Guidelines** |

| Title | Location |
|---|---|
| Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, or more commonly known as the Information Quality Guidelines (IQGs), October 2002 | https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information |
| EPA IQG - Requests for Correction and Requests for Reconsideration | https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration |
| A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, June 2003 | https://www.epa.gov/risk/summary-general-assessment-factors-evaluating-quality-scientific-and-technical-information |
| Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information, December 2012 | https://www.epa.gov/risk/guidance-evaluating-and-documenting-quality-existing-scientific-and-technical-information |

# Appendix 2 Contact Names

Contact names and information in tables 2.1, 2.2, and 2.3 are current as of March 2020.

## Table 2.1. Regional Quality Council Membership/ Divisional QACs

(QAC= Quality Assurance Coordinator)

| Organization or Responsibility | Representative | Phone | Email |
|---|---|---|---|
| RQAM/ Chair of RQC | Kia Long | 215-814-2111 | long.kia@epa.gov |
| Field Quality Manager | Norman Rodriguez | 215-814-5274 | rodriguez.norman@epa.gov |
| ASQAB Chief | John Forren | 215-814-2705 | forren.john@epa.gov |
| LSASD Sr. Mgmt Representative | Cynthia Caporale | 410-305-2732 | caporale.cynthia@epa.gov |
| ORA QAC | Humberto Monsalvo | 215-814-2163 | monsalvo.humberto@epa.gov |
| ARD QAC | Verena Joerger | 215-814-2218 | joerger.verena@epa.gov |
| CBPO QAC | Durga Ghosh | 410-267-5750 | dghosh@chesapeakebay.net |
| ECAD QAC | Zelma Maldonado | 215-814-3448 | maldonado.zelma@epa.gov |
| LCRD QAC | Debra Forman | 215-814-2073 | forman.debra@epa.gov |
| LSASD QAC (annually rotated) | Kelly Krock | 304-234-0242 | krock.kelly@epa.gov |
| SEMD QAC | Laura Mohollen | 215-814-3295 | mohollen.laura@epa.gov |
| MSD QAC | Jackie Guerry | 215-814-2184 | guerry.jacquelineB@epa.gov |
| WD QAC | Jillian Adair | 215-814-5713 | adair.jillian@epa.gov |
| **Ad hoc members** | | | |
| ASQAB Quality Staff | R3 QAOs (e.g., Laboratory, FSB, CBPO, etc.) | Regional Counsel Representative, as appropriate | |

## Table 2.2. Other QA-Related Positions

(QAO=Quality Assurance Officer)

| Responsibility | Name | Phone | Email |
|---|---|---|---|
| Regional Laboratory (LSASD LTSB) QAO | Pepa Sassin | 410-305-3021 | sassin.pepa@epa.gov |
| CBPO QAO | Lee McDonnell | 410-267-5731 | mcdonnell.lee@epa.gov |
| LSASD FSB QAO | Kelly Krock | 304-234-0242 | krock.kelly@epa.gov |
| IQG Officer | John Graves | 215-814-5710 | graves.john@epa.gov |
| Records Liaison Officer | Mike Klotz | 215-814-5382 | klotz.michaelk@epa.gov |
| Regional Peer Review Coordinator | Bill Jenkins | 215-814-2911 | jenkins.bill@epa.gov |
| Deputy Scientific Integrity Official | Bill Jenkins | 215-814-2911 | jenkins.bill@epa.gov |
| Regional GIS Coordinator | Don Evans | 215-814-5370 | evans.don@epa.gov |
| Regional Science Liaison | Regina Poeske | 215-814-2725 | poeske.regina@epa.gov |

## Table 2.3. Field Activities Coordination Team

(FAC= Field Activities Coordinator)

| Organization or Responsibility | Representative Alternate Rep | Phone | Email |
|---|---|---|---|
| FQM / Chair of FACT | Norman Rodriguez | 215-814-5274 | rodriguez.norman@epa.gov |
| ARD FAC | TBD | | |
| CBPO FAC | TBD | | |
| ECAD FAC | Zelma Maldonado | 215-814-3448 | maldonado.zelma@epa.gov |
| LCRD FAC | TBD | | |
| LSASD FAC | Kelly Krock | 304-234-0242 | krock.kelly@epa.gov |
| ORA FAC | TBD | | |
| SEMD FAC | TBD | | |
| WD FAC | TBD | | |
| Ad Hoc Members | | | |
| RQAM | Human Resources | Regional Counsel Representative, as appropriate | |

# Appendix 3 Region 3 Forms & Checklists

## Table 3.1. Region 3 Forms and Checklists

The following R3 forms and checklists are available at the following links:
https://www.epa.gov/quality/region-3-forms-and-checklists.
http://intranet.epa.gov/r3intran/qa

| Title | Purpose |
|---|---|
| R3 QA Document Review Request | Submittal of QA documents for review |
| Quality Management Plan (QMP) Review Checklist | Ensure compliance with QMP requirements |
| Quality Assurance Project Plan (QAPP) Review Checklist | Ensure compliance with QAPP requirements |
| Quality Assurance Review Form (QARF) | As applicable for extramural agreements (i.e., contracts), determines what, if any, QA documentation is needed |
| Remedial Acquisition Framework (RAF) Contracts Task Order Quality Assurance Review Form (QARF) | As applicable for extramural agreements (i.e., RAF-contracts), determines what, if any, QA documentation is needed |
| EPA Region 3 Quality System Audit (QSA) Checklist | Conduct QSA according to QA requirements |
| PO QAPP Checklist | Cursory review of QAPPs by PO |

# Appendix 4 National Programmatic Terms and Conditions for Grants in Integrated Grants Management System (IGMS)

## J. QUALITY ASSURANCE *Updated 10/1/19*

**Quality Assurance System Terms and Condition Instructions for Project Officers:**
**If the award will include potential environmental data use or collection activities:**

1. **Insert the Scope, Authorities and Communications sections; then**
2. **Insert one of the two Quality Management Plan (QMP) conditions and one of the two Quality Assurance Project Plan (QAPP) conditions. *The QMP and QAPP conditions can be replaced by language that is provided by the national program sponsoring the work.***

**Note: In most instances, there is a QMP supported by at least one project-specific QAPP.**

- **Criteria for combining quality documents is in *EPA QA/R-2: EPA Requirements for Quality Management Plans*, Section 1.2 paragraph 3.**
- **Criteria for QAPP approval by other than authorized EPA reviewer is in *EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans*, Section 2.5.**

**Note: Program may insert Authorities in addition to or more specific than the provided list (for example: additional regulatory citation, requirements document or standard, or a specific section of 40 CFR 35).**
**Justification for removal must be approved by the Quality Assurance Manager (QAM) for the organization sponsoring the work.**

**Quality Assurance System Mandatory for All Agreements Requiring QA**

**Scope:**
Quality assurance (QA) applies to all agreements that involve environmental data operations, including environmental or scientific data and information collection, production or use. Environmental data operations include the acquisition, generation, compilation or use of environmental data and technology. These terms and conditions apply to all environmental programs included in the agreement's workplan that contain environmental data operations.

Sub-awards will include appropriate quality requirements for the work conducted through sub-agreements with other organizations. The prime recipient is accountable for all work performed on the project or program award including any portion of the external agreement work that the recipient awards to a sub-recipient.

Definitions applicable to these terms and conditions are in the following locations: *EPA Requirements for Quality Management Plans, EPA QA/R-2* and *EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5* (Appendix 1).

Examples are included in the definitions of Environmental Data, Environmental Programs, and Environmental Technology and on the internet at: Quality Specifications for non-EPA Organizations to do business with EPA in the Example Activities Section.

Authorities, in accordance with:

- 2 CFR §1500.11;
- 40 CFR 35;
- Policy and Program Requirements for the Mandatory Agencywide Quality System, May 2000 CIO 2105.0;
- EPA Quality Manual for Environmental Programs, May 2000 CIO 2105-P-01-0;
- EPA QA/R-2: EPA Requirements for Quality Management Plans;
- EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans; and
- and as described by the Office of Grants and Debarment Quality Assurance Requirements

Communications:
The EPA Project Officer will provide the recipient with the EPA QA contact upon EPA's award issuance or upon request by recipient for pre-submittal questions and other communications regarding QA system document(s). A list of QA managers is posted on EPA's Quality Program website.

The recipient agrees to include the EPA Project Officer on all written communications with the EPA QA contact.

Quality Assurance System Terms and Condition Selection Options (if programmatic T&Cs not supplied)

**QUALITY MANAGEMENT PLAN**
**Insert one of the two QMP terms and conditions below:**

1. **Quality Management Plan** Insert if recipient does not have a currently approved QMP.

Recipient agrees to prepare a Quality Management Plan (QMP) that documents its organization's quality system for planning, implementing, documenting, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs to which it is applied, and must include in the QMP definitions of appropriate authorities and responsibilities for managers and staff. The QMP documents policies and practices, including quality assurance (QA) and quality control (QC) activities that the recipient will use to ensure that the results of technical work are of the type and quality needed for their intended use and sufficient to produce data of adequate quality to meet program objectives.

The recipient agrees to prepare the QMP in accordance with (IAW) *EPA QA/R-2: EPA Requirements for Quality Management Plans*. IAW EPA QA/R-2 Section 2.7: Recipient must review its QMP at least annually to reconfirm the suitability and effectiveness of the approved quality management practices. QMP review results and/or revisions must be submitted to EPA Project Officer and QA contact at least annually but may be submitted when any changes occur. Significant changes made to the quality system that affect the performance of work for the Agency requiring the revision of an approved QMP are listed in EPA QA/R-2 Section 2.6.

If there are multiple programs involved in an assistance agreement, the recipient must submit one of the following:

A. A single QMP covering all the programs in the agreement; or
B. A separate QMP for each program receiving the agreement funds.

The QMP must be submitted to the EPA Project Officer at least *[Insert 60/90/120]* days prior to the initiation of data collection or data compilation and no later than *[Insert 60/90/120]* days after award.

The recipient cannot begin work involving environmental data operations until the QMP has been approved by the authorized EPA reviewer.

2. **Quality Management Plan** **Insert if recipient already has an approved QMP.**

The recipient shall continue to implement and adhere to the Quality Management Plan (QMP), based on the *EPA QA/R-2: EPA Requirements for Quality Management Plans*, submitted to EPA.

_____ Approval Date

_____Version

In accordance with EPA QA/R-2 Section 2.7: Recipient must review its QMP at least annually to reconfirm the suitability and effectiveness of the approved quality management practices. QMP review results and/or revisions made must be submitted to EPA Project Officer and QA contact at least annually but may be submitted when the changes occur.

Significant changes made to the quality system that affect the performance of work for the Agency requiring the revision of an approved QMP are listed in EPA QA/R-2 Section 2.6.

**QUALITY ASSURANCE PROJECT PLAN**
**Use one of the two QAPP terms and conditions below:**

1. **Quality Assurance Project Plan** **Insert if recipient does not have a currently approved QAPP.**

A Quality Assurance Project Plan (QAPP) is a record of determinations made during planning by the organization of the data type, quality, and quantity necessary to meet project objectives and the quality assurance and quality control procedures, specifications and documentation that the recipient will use to ensure the desired results.

The recipient agrees to comprehensively document in a QAPP the quality assurance (QA), quality control (QC), and technical activities that must be implemented to ensure that project objectives are met. Recipients implementing environmental programs within the scope of the assistance agreement must submit a QAPP to the EPA Project Officer at least ***[Insert 60/90/120]*** days prior to the initiation of data collection or data compilation and no later than ***[Insert 60/90/120]***days after award.

The recipient agrees to ensure that no environmental data collection, production, or use occurs without a QAPP approved by the EPA authorized reviewer except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

The QAPP should be prepared in accordance with (IAW) *EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans*. Recipient must review its QAPP at least annually to reconfirm its suitability and effectiveness. QAPP review results and/or revisions made must be submitted to EPA Project Officer and QA contact at least annually but may be submitted when any changes occur.

IAW EPA QA/R-5 Section 2.7: When substantive change is warranted, the recipient must modify the QAPP and submit the revision for EPA approval. Only after the revision has been received and approved shall the change be implemented.

2. **Quality Assurance Project Plan** **Insert if recipient already has an approved QAPP.**
The recipient shall continue to implement and adhere to the approved Quality Assurance Project Plan (QAPP) based on the *EPA QA/R-5: EPA Requirements for Quality Assurance Project Plans*, submitted to EPA.

_____ Approval Date

_____Version

Recipient must review its QAPP at least annually to reconfirm its suitability and effectiveness. QAPP review results and/or revisions made must be submitted to EPA Project Officer and QA contact at least annually but may be submitted when the changes occur.

In accordance with EPA QA/R-5 Section 2.7: When substantive change is warranted, the recipient must modify the QAPP and submit the revision for EPA approval. Only after the revision has been received and approved shall the change be implemented.

# Appendix 5 EPA R3 Information Quality Guidelines Pre-Dissemination Review

***Background***

EPA developed its Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency (IQG) in response to guidelines issued by the Office of Management and Budget (OMB)1 under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658). The IQG contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information it disseminates. The IQG also outline administrative mechanisms for EPA pre-dissemination review of information products and describe some new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB guidelines. This document provides guidance on the review of information products prior to their dissemination to ensure maximum quality.

In 2006, EPA's OMS issued Review Guidelines to Ensure That Disseminated Information is Consistent with EPA Information Quality Guidelines. OMS issued the guidelines to help Agency National Program and Regional Offices to develop their own procedures to provide consistent cross-Agency pre-dissemination reviews (PDR) while meeting each office's needs. OMS's guidelines provide non-binding internal policy and procedural guidance intended solely for EPA management and staff. Similarly, these R3 PDR guidelines are non-binding and intended for R3 management and staff.

Wherever possible existing standards and procedures should be employed in pre-dissemination review. R3 offices may expand upon the reviews listed in this document.

***Products covered by Pre-dissemination Review***

Pre-dissemination review is a review of an information product prior to its distribution by EPA as explained below.

Ideally quality is considered and addressed starting from the concept stage of an information product for example, by using guidance documents outlining "best practices." Given the wide variety of activities within EPA that generate information, EPA's challenge is to identify this information as early as possible so that systematic planning can be integrated into the development process, and quality incorporated during development.

Information is defined under the IQG "generally includes any communication or representation of knowledge such as facts or data, in any medium or form. Preliminary information EPA disseminates to the public is also considered "information" for the purposes of the Guidelines. Information generally includes material that EPA disseminates from a web page. However not all web content is considered "information" under these Guidelines (e.g., certain information from outside sources that is not adopted, endorsed, or used by EPA to support an Agency decision or position)."

Six broad categories of EPA information likely to be disseminated include:

1. Tools – data query tools, models, estimator tools, mapping/GIS-related programs, products from these tools, and software used to analyze or evaluate data;

2. Reports – analytical products that involve scientific, economic and technical information and that are endorsed or adopted by EPA (e.g., some journal articles, studies, trends analyses, public reports to Congress, strategic plans, annual reports, criteria documents, assessment documents, Integrated Risk Information System summaries, EPA published reports);
3. Data – results from models, scientific data, maps (including GIS coverage), databases, spreadsheets, and flat files generated by EPA or data from a third party that EPA adopts or endorses; the disseminated products in this category do NOT include all public filings, such as adverse health effects information or Toxics Release Inventory data;
4. Information contained in EPA policy and guidance documents – policies and guidance that are disseminated to the public, subsequent guidance on implementing policies, training materials, user guides/manuals, methodology documents such as test methods;
5. Outreach or communication products or broad audience information resources – brochures, bulletins, flyers, videotapes, action plans, strategic plans, citizen guides, handbooks, newsletters, conference summaries posted on the EPA Web site, educational aids, and similar products; and
6. Information that is disseminated in support of an EPA rulemaking – information used to support regulatory actions, such as advance notices of proposed rulemaking, proposed rules, final rules, regulatory impact analyses, risk assessments, responses to public comments, Federal Register notices.

Dissemination means that EPA distributes information in one of several ways:

- To support or represent EPA's viewpoint or to formulate, or support a regulation, guidance or other Agency decision of position;
- Uses the information to suggest EPA endorses or agrees with it; supports EPA's viewpoint or the information to formulate or to support a regulation, guidance, policy, or other Agency decision or position;
- Comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

Dissemination does not include distributions of information that EPA does not initiate or sponsor. Examples of these types of distributions includes those to government employees only, recipients of government contracts, grants or cooperative agreements, EPA's responses to requests for information under the Freedom of Information Act (FOIA), correspondence directed to individuals or persons. Additional examples of information distributions not considered to be dissemination under the IGQ can be found in the IQG pages 16 – 17 and in "US EPA Information Quality Guidelines Frequent Questions Regarding When the Guidelines Apply".

EPA sometimes provides a service to the public and the regulated community by distributing information from non-EPA sources. EPA has stated that disclaimers and other notifications should be used to explain the status of such information. An example of a disclaimer for general content follows:

> *EPA is distributing this information solely as a public service. [Insert name of information source] is responsible for the quality of this information. EPA's distribution of this information does not represent or imply endorsement by EPA.*

Examples of disclaimers for other types of content may be found on the EPA intranet site.

### *IQG Review Criteria*

R3 pre-dissemination reviews should aim to meet the performance goals of objectivity, utility and integrity for disseminated information that EPA articulated as part of the IQG. Disseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity, and the principles of information quality should be integrated into each step of R3's development of information, including its creation, collection, maintenance, and dissemination. These performance goals reflect EPA's expectation that the information it creates will conform to applicable quality standards and will adhere to applicable approved quality criteria. In addition, under EPA's quality policy all information R3 distributes should be transparent regarding data sources and data limitation and meet a basic standard of information quality and that the utility, objectivity, and integrity of that information should be appropriate to the nature and timeliness of the planned and anticipated uses.

"Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. "Utility" refers to the usefulness of the information to the intended users. The utility, objectivity, and integrity of information should be scaled and appropriate to the nature and timeliness of the planned and anticipated uses. EPA recognizes that some of the information it disseminates includes influential scientific, financial, or statistical information, and that this category should meet a higher standard of quality. Classes of influential information that must meet more rigorous reviews are listed in the IQG p. 20.

### *Implementation of Review Procedures in R3*

During the planning process and prior to release, staff should notify their direct supervisor that information products that are being developed for dissemination as described in the IQG. Questions regarding applicability of the IQG to an information product can be directed to the regional IQG officer. Supervisors are responsible for ensuring that information subject to the IQG is identified before it is disseminated by their group. Supervisors should also determine what mechanism for reviewing the information is appropriate before it is disseminated. The supervisor should determine what level of review is appropriate.

EPA's IQG provide guidance regarding the documentation of the quality reviews conducted for disseminated information. When the Agency responds to an external request for correction of information under the IQG, the documentation provides evidence of the adequacy of the Agency pre-dissemination review process. Under the IQG, managers and staff are encouraged to practice sound documentation practices so that review documentation is readily retrievable. For example, it is advisable to create an electronic or a hard copy folder in which review records are maintained.

The following is a list of some of the key review guidances, policies and procedures which can be used to meet pre-dissemination reviews in R3.

**Quality Assurance Project Plans**

A Quality Assurance Project Plan (QAPP) can be used to ensure information products have built in quality from the conceptual stage. The level of detail found in the QAPP shall be commensurate with the nature of the work being performed and the intended use of the data. QAPPs can be written for projects which generate data and for projects which use existing data exclusively (such as GIS). The Regional Quality Assurance Manager should be consulted on when a QAPP is required. QAPPs which involve geospatial information will also be reviewed by the Regional GIS Coordinator as a technical reviewer (R3 QMP Section D.2).

**Peer Review**

Scientific products may need to undergo an internal technical review, a journal-convened external peer review or other external peer review.[3] EPA's Peer Review Handbook provides information on how peer reviews are conducted. Managers should decision whether to employ peer review in particular instances and, if so, its character, scope, and timing.

**R3 Geospatial Information Products**

Products created using geospatial technology in all divisions except for the Chesapeake Bay Program will be reviewed using R3 GIS guidance documents and SOPs. Geospatial products produced by the Chesapeake Bay Program will be reviewed under their own CBPO geospatial data quality plan. Other EPA geospatial policies will apply by reference. To ensure sufficient quality review of geospatial systems and analyses, and the data and information on which they are based, coordination with and concurrence from the Regional GIS Coordinator are also required for GIS and GIS-related project design and new mapping documents.

**R3 Office of Public Affairs reviews**

The Office of Public Affairs should be contacted about review of videos, print materials, new web areas, Story Maps and social media content. Videos and print material reviews are facilitated using EPA's PROTRAC system. PROTRAC and other requirements are described on the Development and Review of EPA Communications Products on the EPA website.

**Open Source Code**

Regional code developers who wish to share their code as open source should follow the EPA Interim Open Source Software (OSS) Policy and EPA GitHub Guidance.

**Qlik Applications**

Deployment of Qlik applications on the EPA NCC server should follow the processes listed on the EPA Qlik Public Access Process and List of Public Applications intranet page. The R3 Office of Public Affairs should also be contacted about any additional reviews for web content.

[3] EPA. 2018. Best Practices for Clearance of Scientific Products at EPA.

**Assessment Factors**

The Assessment Factors can be used to evaluate information submitted from organizations to EPA. It is also an additional resource for EPA staff as they evaluate the quality and relevance of information, regardless of source. It is available on the A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information page on the EPA website with an addendum, Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information.

**Environmental Indicators**

Environmental indicators can be used to summarize pollution sources, ecosystem conditions and trends toward meeting specific restoration goals. The Chesapeake Bay Program's template for CBP Indicator Analysis and Methods Document may be used to evaluate environmental indicators. It is available in the Chesapeake Bay Program Quality Manual.

# Appendix 6 Office of the Regional Administrator (ORA)

A general description of the ORA's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 6.1. More details are provided at:

- Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#ora
- Intranet site- https://intranet.epa.gov/r3intran/ora/

ORA for R3 is responsible for leading the environmental protection efforts for the five (5) Mid-Atlantic States of Delaware, Maryland, Pennsylvania, Virginia, West Virginia and the District of Columbia along with seven (7) federally-recognized Native American Indian Tribes. ORA provides the overall supervision of the Region, with all Division Directors reporting to the RA. Among many other things, the ORA is responsible for planning, programming, implementation, control and direction of technical and administrative aspects of R3 programs. By exercising responsibility for developing plans, the ORA establishes internal operating policies and procedures and resolves operational challenges. Through its continuous evaluation of R3 programs and activities, the ORA is responsible for total resources management in the Region. By resolving conflicts of proposals and interest among Regional program activities, the ORA selects, assigns, and provides critical direction and guidance to EPA staff, as needed, to attain program objectives. Additionally, the ORA serves as the primary representative for R3 to Headquarters' Senior Leadership and external stakeholders. Moreover, the ORA provides expert advice to R3 Senior leaders on national initiatives and Administration priorities. The ORA also provides technical oversight of the Region's Equal Employment Opportunity (EEO) and Special Emphasis Programs (SEPs). R3 is organized to promote efficiency in resource allocation, positive relations with State, tribal, and local partners, and produce needed outcomes to protect human health and the environment. In order to fulfill EPA's mission of protecting human health and the environment, the ORA ensures that R3 works closely with State and local governments. The ORA also oversees close and effective interaction with the Region's seven (7) federally recognized Native American Indian Tribes located in Virginia which include the Pamunkey, the Chickahominy, the Eastern Chickahominy, the Upper Mattaponi, the Rappahannock, the Monacan and the Nansemond Tribes.

ORA is comprised of the Immediate Office, Office of Civil Rights (OCR), Office of Public Affairs (OPA), and Office of Communities, Tribes, and Environmental Assessments (OCTEA).

*Office of Civil Rights (OCR)*

OCR enables R3 to have a diverse and inclusive workforce, advances equal employment opportunity for employees and applicants, provides fair and impartial processing of discrimination complaints, affords maximum practicable prime and sub-contracting opportunities for small businesses, and allows for meaningful and equal access to Agency-conducted and financially-assisted programs and activities including partnerships with Minority Serving Institutions.

*Office of Public Affairs (OPA)*

OPA is responsible for communications, congressional and intergovernmental relations, and community involvement. Liaisons use a network of relationships to gather information to create a comprehensive view of the environmental and political landscape in designated States and

Tribes while sharing that information with key decision makers within EPA. OPA performs the following external and internal communication functions:

- Community Involvement and Outreach (Superfund Remedial / Removal / Emergency Response focus);
- Digital Engagement (Social Media, Website Management, Video and Photography);
- Congressional and Intergovernmental Relations;
- Internal Communication (Develop and implement internal communication strategies to support management priorities, employee interests and engagement);

OPA is comprised of two branches:

- OPA's Communications Branch
  - Manages an overall strategy for internal and external communications
  - Advises the RA on releasing information to the public
  - Writes news releases, speeches, and other outreach materials
- Manages the R3 web and social media content
  OPA's Community Involvement Branch
  - Ensures R3 meets the public involvement requirements of the Superfund Program
  - Assists with Site Assessment outreach / communication efforts
  - Supports execution of emergency response communication actions (Public Information Officers)
  - Facilitates Superfund website updates
  - Prepares and provides community involvement training for the region
  - Participates in Regional Superfund Technical Assistance Grants (TAG) process and Superfund contracts management

*Office of Communities, Tribes, & Environmental Assessment (OCTEA)*

OCTEA is tasked to build relationships, gather information, and identify the environmental and public concerns of R3 communities and Tribes. This objective facilitates OCTEA's ability to incorporate such principles into the media specific priorities, goals and measures that EPA implements nationwide. Additionally, OCTEA supports nationally identified efforts to advance U.S. national interests through international collaboration while sharing the knowledge that EPA has gathered during the past 50+ years. OCTEA programs may be subject to QA requirements set forth by the R3 QMP. OCTEA administers environmental justice, Indian Environmental General Assistance Program (GAP), environmental education, and children's environmental health grants within all applicable EPA policies, rules, standards and regulations.

OCTEA manages the following programs and performs the following functions:

- Environmental Justice
- Tribal Affairs
- International Affairs
- Children's Health
- Environmental Education
- National Environmental Policy Act (NEPA)
- National Historic Preservation Act (NHPA) (R3 compliance)
- Endangered Species Act (R3 compliance)
- Opportunity Zone Program
- Smart Sectors Program (SSP)

## Table 6.1. QA documents & resources for ORA

| Office/ Branch | Program | Resource Type | Title | Location |
|---|---|---|---|---|
| OCTEA | NEPA | Guidance | EPA National Environmental Policy Act Web site | https://www.epa.gov/nepa |
| OCTEA | Env. Justice | Tool | EJSCREEN: Environmental Justice Screening and Mapping Tool | https://www.epa.gov/ejscreen |
| OCTEA | Tribal Affairs | Guidance | Environmental Protection in Indian Country; All Environmental Programs in Indian Country | https://www.epa.gov/tribal; https://www.epa.gov/tribal/all-environmental-programs-indian-country-0 |
| OCTEA | International Affairs | Guidance | International Cooperation | https://www.epa.gov/international-cooperation |
| OCTEA | Children's Health | Guidance | Protecting Children's Environmental Health | https://www.epa.gov/children |
| OCTEA | Children's Health; Environmental Education | Guidance | Environmental Information Exchange Network | https://www.epa.gov/exchangenetwork |
| OCTEA | Environmental Education | Guidance | Environmental Education | https://www.epa.gov/education |
| OCTEA | Environmental Education | Guidance | Learning and Teaching about the Environment | https://www.epa.gov/students |
| OCTEA | Environmental Education | Guidance | People, Prosperity and the Planet (P3) Student Design Competition | https://www.epa.gov/P3 |
| OCTEA | NHPA | Regulation | National Historic Preservation Act of 1966 as amended through 1992 | https://www.nps.gov/history/local-law/nhpa1966.htm |
| OCTEA | NHPA | Guidance | Section 106: National Historic Preservation Act of 1966 | https://www.gsa.gov/real-estate/historic-preservation/historic-preservation-policy-tools/legislation-policy-and-reports/section-106-national-historic-preservation-act-of-1966 |
| OCTEA | Endangered Species Act | Regulation | Summary of the Endangered Species Act | https://www.epa.gov/laws-regulations/summary-endangered-species-act |
| OCTEA | Endangered Species Act | Guidance | About the Endangered Species Protection Program | https://www.epa.gov/endangered-species/about-endangered-species-protection-program |
| OCTEA | Opportunity Zone | Guidance | Opportunity Zones | https://www.epa.gov/opportunity-zones |
| OCTEA | Smart Sectors | Guidance | EPA Smart Sectors Program | https://www.epa.gov/smartsectors |

# Appendix 7 Air & Radiation Division (ARD)

A general description of the ARD's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 7.1. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#ard
Intranet site- https://intranet.epa.gov/r3inaird/

ARD implements the programmatic aspects of Clean Air Act (CAA) within the geographic boundaries of R3, except for inspections and enforcement, which are principally managed by ECAD. Under this statute and in accordance with implementing regulations and Agency guidelines, ARD conducts activities to reduce emissions so that air pollution does not constitute a threat to public health, safety, well-being and the environment. To carry out its mission, ARD works with other federal agencies, state, tribes, and local agencies, tribal governments, the public, and the private sector. ARD coordinates with the Office of Air and Radiation to ensure national consistency and strives to meet legal deadlines imposed by the CAA.

In accordance with the requirements of the CAA, and to advance implementation of both regulatory and nonregulatory programs to improve air quality, ARD performs a wide variety of functions and consists of the Immediate Office of the Division Director and the following four branches: Permits Branch (PB), Partnership Programs & Grants Branch (PPGB), Planning & Implementation Branch (PIB), and Air Quality Analysis Branch (AQAB).

*Permits Branch (PB)*

The PB is responsible for issuing delegations, equivalencies, and plan approvals for New Source Performance Standards (NSPS), National Emission Standards for Hazardous Air Pollutants (NESHAP), and Maximum Attainable Control Technology (MACT) standards. The PB evaluates state, tribal, and local permit programs, performs oversight of state and local Title V permits, and provides technical and program guidance to state and local air pollution control agencies regarding the requirements of New Source Review/Prevention of Significant Deterioration (NSR/PSD). The PB is also tasked with implementing the Prevention of Significant Deterioration (PSD) permit program for the District of Columbia and issuing permits in areas where state/local/tribal agencies have not been given authority. Some of the PB's responsibilities involve using secondary data—including modeling results (evaluated by AQAB), and evaluating facility data stored in the ICIS-AIR database.

*Partnership Programs & Grants Branch (PPGB)*

The PPGB represents voluntary programs (Energy Star, Radon & Radiation, Indoor Environments, Clean Diesel Initiative, Burnwise) to improve ambient and indoor air quality and increase energy efficiency within R3. PPGB staff provide public information, training, and technical advice and support relating to these voluntary programs. The branch is also responsible for administering and overseeing all grants in the ARD: Clean Diesel state and competitive grants, State Indoor Radon Grants (SIRG), Indoor Environment grants, Multi-Purpose grants, CAA Section 105 grants supporting state/tribal/local air pollution control programs, and CAA Section 103 grants relating to regulatory ambient air monitoring.

*Planning & Implementation Branch (PIB)*

The PIB is responsible for implementing CAA programs related to the six criteria pollutants (ozone, particulate matter, sulfur dioxide, lead, nitrogen dioxide, and carbon monoxide). The Branch works with R3 state, tribal, and local agencies to help build each state's federally-enforceable state implementation plan (SIP). A SIP is a living collection of regulations and documents used by a state or local air district to meet the national ambient air quality standards (NAAQS) which are established for each of the criteria pollutants. The PIB is involved in planning programs such as transportation conformity, general conformity, reasonably available control technology (RACT), and regional haze, as well as mobile source programs like vehicle inspection and maintenance.

*Air Quality Analysis Branch (AQAB)*

The AQAB is responsible for the oversight of state, local and tribal agencies' CAA programs. Specifically, administering and overseeing regulatory and congressionally mandated programs for ambient air quality monitoring, air toxics monitoring and National Air Toxics Assessment (NATA), air quality modeling (photochemical and dispersion), emissions inventories and quality assurance. Data collected from these various programs are often analyzed for trends, special projects, and suitability for regulatory decision making. AQAB supports regulatory actions by providing air quality data analysis, quality assurance and modeling for the other branches within ARD and the ECAD's air enforcement section. The PIB's SIPs (designations, redesignations, clean data determinations, etc.) are supported by AQAB through technical support documents for modeling, inventories, design value/data completeness determinations, and exceptional events reviews. AQAB provides PSD/NSR modeling reviews for the APB and supports PPGB staff who administer and oversee the CAA Section 103/105, air toxics and special purpose grants. The ECAD's air enforcement section receives technical monitoring support for consent decrees, special projects, and data packages for enforcement targeting.

The main QA responsibilities for AQAB are approving QAPPs, reviewing SOPs, conducting TSAs, implementing the National Performance Evaluation Program (NPEP) programs, distributing technical QA information and related training to monitoring organizations and elevating QA needs of state, tribal, and local monitoring organizations to EPA Headquarters that are national in scope.

*ARD State, Local & Tribal (S/L/T) Quality Documents Review & Approval*

Monitoring organizations are state, local or tribal air agencies responsible for meeting the monitoring requirements of 40 CFR Part 58. Under Part 58 monitoring organizations must fully implement satisfactory monitoring and QA programs. Each organization must operate under approved QMPs, QAPrPs, QAPPs and SOPs. All phases of the data collection process (including laboratory analysis) conducted by the organization or contractors must have appropriate and sufficiently documented QA. Monitoring organizations can consolidate under a set of commonly shared QA activities and form a Primary Quality Assurance Organization (PQAO). 40 CFR Part 58 requirements of PQAOs:

a) Operation by a common team of field operators according to a common set of procedures;
b) Use of a common QAPP or SOP(s);
c) Common calibration facilities and standards;
d) Oversight by a common QA organization; and

e) Support by a common management organization (*i.e.* state agency) or laboratory.

R3 has eight state and local air monitoring agencies (Figure 7.1.) who individually function as their own PQAOs. Each PQAO submits QAPrPs to AQAB every five years (or sooner if revision is needed) for review and approval as outlined in R3 QMP Section D.2. DAOs review the QAPrPs and QAPPs with monitoring staff performing technical reviews, based on the criteria set forth in the regulations, data validation templates, consent decrees, technical assistance and guidance documents (see Table 7.1 below for the list of QA documents). Final versions of approved QAPrPs and QAPPs are signed by the AQAB chief, DAO, and PPGB grants coordinator. PQAOs approve their SOPs; DAOs review them for technical accuracy. Additionally, DAOs review and approve QAPPs and sampling plans for special projects using the same criteria and approval process described for S/L/T QAPrPs. The status of QAPPs and QAPrPs are tracked both in ARD's internal GRANTRAX database, EPA's national Air Quality System (AQS) database, and the R3 QA database. AQAB QA staff are responsible for updating the QAPP status in AQS. AQAB staff and the PPBG grants coordinator regularly update GRANTRAX.

AQAB is also responsible for reviewing and approving air monitoring agencies' Annual Monitoring Network Plans (AMNP). The plan describes an agency's entire monitoring network and provides an opportunity to request changes to the network for EPA approval. Agencies are required to submit AMNPs, to the RA, annually on July 1st per the requirements of 40 CFR Part §58.10. The AMNP must be made available for public inspection and comment for at least 30 days prior to submission to the EPA and the submitted plan must include and address, as appropriate, any received comments. AQAB staff use a checklist (see Table 7.1 below) to review and approve AMNPs. The checklist can be revised and modified by AQAB monitoring staff as needed. AMNPs and related review documents and letters are stored in folders in ARD/AQAB LAN drive.

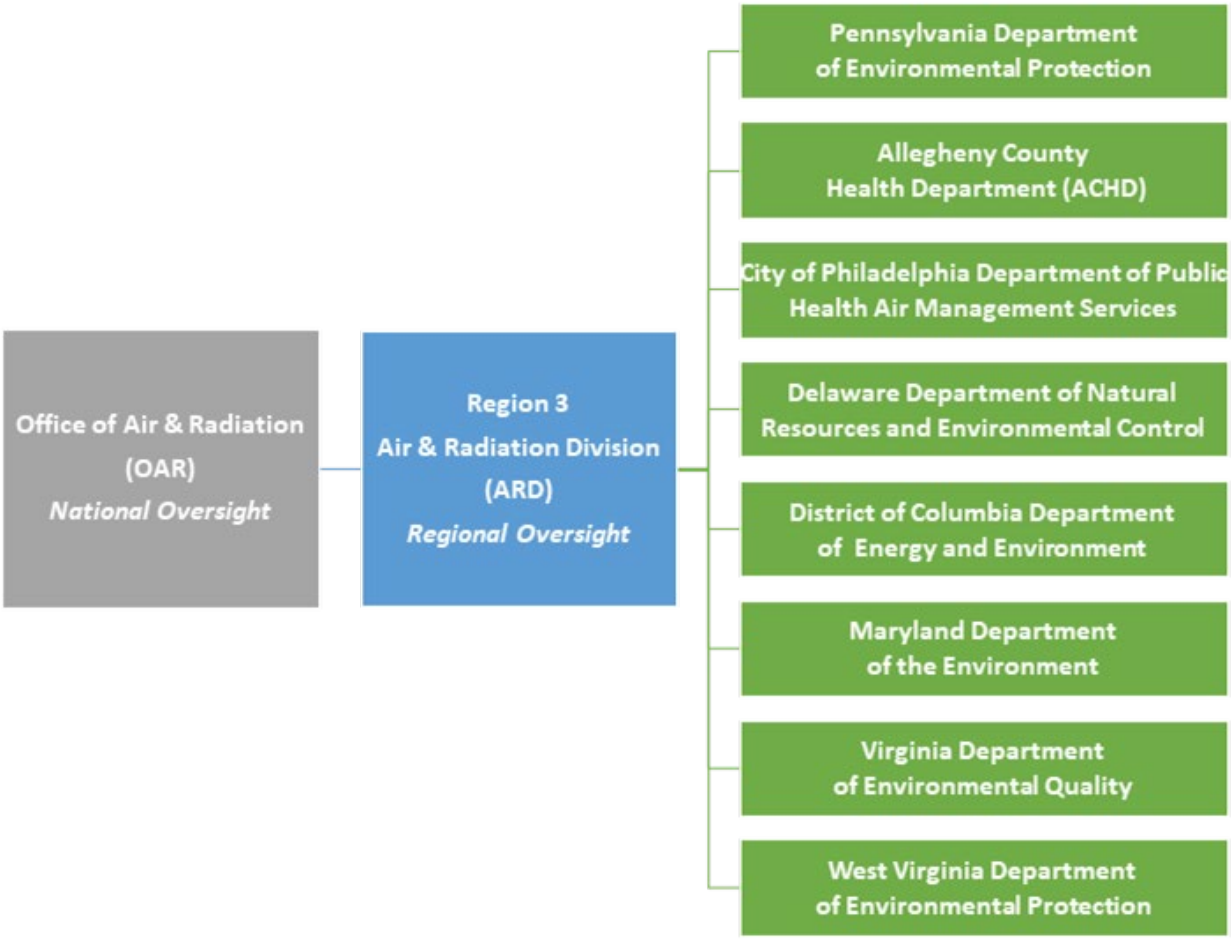


**Figure 7.1. R3 Air Program Organization**

*ARD Technical Systems Audits (TSAs)*

A TSA is an on-site review and inspection of a state or local agency's ambient air monitoring program to assess its compliance with established regulations governing the collection, analysis, validation, and reporting of ambient air quality data. It includes (but is not limited to) on-site interviews with key program personnel, evaluations of ambient air monitoring sites operated by the state or local, laboratory inspections and a review of QA and data processing procedures.

As required by 40 CFR Part 58 Appendix A, R3 AQAB conducts TSAs for each PQAO at least every three years. AQAB monitoring and QA staff use the *Quality Assurance Guidance Document Conducting Technical Systems Audits of Ambient Air Monitoring Programs EPA-454/B-17-004 November 2017* as a framework for performing audits. AQAB QA staff serve as the lead auditor on the audit team and are responsible for the audit coordination, audit plan development, site scheduling, laboratory and office visits, initial summary write-up, final report issuance, and correct action plan development and maintenance. An initial summary of the audit findings is submitted to the PQAO within 30 days after the conclusion of onsite audit activities. PQAOs are given a comment period (not exceed 45 days) to fact-check the written information in the findings summary such as staff names/titles, spellings, site names, and other typographical/minor errors made by the audit team. A final TSA report and a corrective action plan is submitted to the PQAO within 60 days following the receipt of the PQAO's findings summary comments. AQAB staff continue to work with PQAOs to track the status and resolve

findings post audit. Documents and photographs related to TSA are stored on ARD's M: drive in the TSA folder. Furthermore, AQAB QA staff input TSA start and completion dates EPA's national AQS database. Assessments are also entered in the R3 QA database.

*ARD Data Certification*

EPA uses the ambient air monitoring data collected by S/L/Ts agencies to: assess the extent of pollution; provide air pollution data to the public ; support implementation of air quality goals or standards; evaluate the effectiveness of emissions control strategies; provide information on air quality trends; provide data for air quality models; and support research (e.g., long-term studies of the health effects of air pollution). Per 40 CFR §58.16 state and local agencies must report all ambient air quality data and associated QA data to the Administrator via AQS based on the schedule and criteria outlined in Section 58.16. Therefore, monitoring agencies and PQAOs must perform QA (i.e. data verification and data validation) on all data submitted to AQS. Per 40 CFR §58.15, the senior official in each monitoring agency, or designee, shall certify that the previous year of ambient concentration and QA data are completely submitted to AQS and that the ambient concentration data are accurate to the best of their knowledge, taking into consideration the QA findings. The annual data certification letter is due by May 1st of each year. AQAB staff review all submitted materials in the data certification package and set appropriate concurrence flags based on 40 CFR Part 58 Appendix A criteria. Guidance on the Data Certification Process and Q&A on Ambient Air Monitoring Data Certification can be found at https://www.epa.gov/amtic/data-certificationvalidation.

*ARD Training*

In addition to QA training requirements set forth in Section B of the R3 QMP, specific training to ARD staff may include: courses provided by EPA's Air Pollution Training Institute (APTI-Learn), Mid-Atlantic Regional Air Management Association, Inc. (MARAMA) and EPA OAR; regular conferences and workshops organized by MARAMA and EPA; internal, hands-on training provided by colleagues through mentorship, brown-bag lunches, etc.. Training requirements for state and local air programs are described in their QAPrPs and QAPPs.

**Table 7.1. QA documents & resources for ARD**

| Branch | Program | Resource Type | Title | Location |
|---|---|---|---|---|
| PB | All | Website (regulations, guidance and databases) | Clean Air Act Permitting Tools & Related Resources | https://www.epa.gov/caa-permitting/caa-permitting-tools-related-resources |
| PB | All | Training Manual | New EPA Employee Toolkit for the Air Permitting Program | M:\Group\3AD10 |
| PB | PSD | Checklist | PSD Application/Permit Review Summary Document | M:\Group\3AD10 |
| PB | Title V | Checklist | Title V Permit Review Checklist | M:\Group\3AD10 |
| PPGB | SIRG | QAPrP | Pennsylvania Department of Environmental Protection (DEP) Bureau of Radiation Protection Radon Division Quality Assurance Project Plan | GRANTRAX |

| Branch | Program | Resource Type | Title | Location |
|---|---|---|---|---|
| PPGB | SIRG | QAPrP | DOEE Quality Management Program/Quality Assurance Project Plan 2019 | GRANTRAX |
| PPGB | SIRG | QAPrP | Delaware Radon Program Combined Quality Management and Quality Assurance Project Plan-2019 | GRANTRAX |
| PPGB | SIRG | QAPrP | West Virginia State Indoor Radon Grant Program Quality Management and Quality Assurance Project Plan-2017 | GRANTRAX |
| PPGB | SIRG | QAPrP | Virginia Radon Program Combined Quality Management and Quality Assurance Project Plan-2015 | GRANTRAX |
| PPGB | SIRG | QAPrP | Pennsylvania Department of Environmental Protection Bureau of Radiation Protection Radon Division Quality Assurance Project Plan-2014 | GRANTRAX |
| PPGB | SIRG | QAPrP | Delaware Radon Program Combined Quality Management and Quality Assurance Project Plan-2014 | GRANTRAX |
| PPGB | SIRG | QAPrP | DOEE Quality Management Program/Quality Assurance Project Plan 2014 | GRANTRAX |
| PIB | Sulfur Dioxide NAAQS | Guidance | Supplemental guidance for round 4 designations for the 2010 primary sulfur dioxide NAAQS | https://www.epa.gov/sulfur-dioxide-designations/area-designations-2010-primary-sulfur-dioxide-national-ambient-air-0 |
| PIB | Sulfur Dioxide NAAQS | Guidance | Guidance for 1-hour sulfur dioxide nonattainment SIP submissions | https://www.epa.gov/so2-pollution/guidance-1-hour-sulfur-dioxide-so2-nonattainment-area-state-implementation-plans-sip |
| PIB | Ozone NAAQS | Guidance | Resource Document for 197 Ozone NAAQS Areas: Supporting Information for States Developing Maintenance Plans | https://www.epa.gov/sites/production/files/2018-11/documents/ozone_1997_naaqs_1mp_resource_document_nov_20_2018.pdf |
| PIB | Ozone RACT | Guidance | 82 CTG and ACT guidance documents | https://www.epa.gov/ground-level-ozone-pollution/control-techniques-guidelines-and-alternative-control-techniques |
| PIB | Ozone RACT | Guidance | Cost Control Manual | https://www.epa.gov/economic-and-cost-analysis-air-pollution-regulations/cost-reports-and-guidance-air-pollution |
| PIB | Ozone RACT | Guidance | Guidance on cost-effective NOx RACT (issued 3/16/94) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | De Minimis Values for NOx RACT (issued 1/1/95) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | NOx Substitution Guidance (issued Dec 93) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | NOX RACT for the Repowering of Utility Boilers (issued 3/9/94) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | RACT and Innovative Control Technology Projects (issued 7/5/94) | M:\Group\3AD30 |

| Branch | Program | Resource Type | Title | Location |
|---|---|---|---|---|
| PIB | Ozone RACT | Guidance | Scope of Nox Exemptions (issued 1/12/95) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Questions and Answers on NOx Emissions Policy (issued 2/2/93) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Approaches to Creating Federally-Enforceable Emission Limits, Seitz (issued 11/3/1993) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Approval Options for Generic RACT Rules Submitted to Meet the non-CTG VOC RACT Requirement and Certain NOx RACT Requirements (issued 11/7/96) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Major Source Determinations for Military Installations under the Air Toxics, New Source Review, and Title V Operating Permit Programs of the CAA (issued 8/2/96) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Second Extension of January 25, 1995 Potential to Emit Transition Policy and Clarification of Interim Policy (issued 7/10/98) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Recommended Policy on Control of Volatile Organic Compounds (42 FR 35313) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Technical Bulletin: Choosing and Adsorption System for VOC: Carbon, Zeolite, or Polymers? (EPA 456/F-99-004, May 1999) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Release of Interim Policy on Federal Enforceability of Limitations on Potential to Emit (issued 1/22/96) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | VOC Blue Book (5/25/88) | M:\Group\3AD30 |
| PIB | Ozone RACT | Guidance | Guidance for State Rules for Optional Federally-Enforceable Emissions Limits Based on VOC Use (issued 10/15/93) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | Fuel Switching to Meet the RACT Requirements for NOx (7/30/93) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | Once-In/Always-In Requirement for RACT Applicability, Helms (issued 8/23/1990) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | General Preamble for Proposed Rulemaking on Approval of Plan Revisions for Nonattainment Areas (44 FR 20372) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | NOx Supplement to the General Preamble (issued 11/25/92 (57 FR 55620)) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | SIP Requirements for Areas Submitting Requests for Redesignation to Attainment of Ozone and CO NAAQS on or after Nov 15, 1992 (issued 9/17/93) | M:\Group\3AD30 |

| | | | | |
|---|---|---|---|---|
| PIB | Ozone RACT | Regulation | Guideline for Determining the Applicability of NOx Requirements Under Section 182(f) (issued 12/16/93) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | Section 182(f) NOx Exemptions revised process and criteria (issued 2/8/95) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | General Preamble for Proposed Rulemaking on Approval of Plan Revisions for Nonattainment Areas-Supplement (on Control Techniques Guidelines) (44 FR 53761) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | 2008 ozone NAAQS SIP Requirements Rule (80 FR 12264) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | Approval of Post-1987 Ozone and Carbon Monoxide Plan Revisions for Areas Not Attaining the National Ambient Air Quality Standards (52 FR 45044) | M:\Group\3AD30 |
| PIB | Ozone RACT | Regulation | Control Techniques for Volatile Organic Emissions from Stationary Sources (EPA-450/2-78-022, May 1978) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | Harnett Memo (aka the RACT Q&As) (issued 5/18/06) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | Nitrogen Oxides Questions from the Ohio EPA (issued 3/30/94) – seasonal NOx RACT rules, 30-day rolling averages, NOx emissions trading, fuel switching, NOx compliance schedules | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | Clarification of Policy for NOx Substitution (issued 8/5/94) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | September 12, 1995 letter from Seitz to MARAMA, NESCAUM, and OTR (issued 9/12/95) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | November 2, 1994 letter from Seitz to NESCAUM (issued 11/2/1994) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | Criteria for Proposing Approval of Revisions for Nonattainment Plans Memo (issued 2/24/1978, see 43 FR 21673) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | Determinations of Economic Feasibility, Helms Memo (issued 1/20/87) | M:\Group\3AD30 |
| PIB | Ozone RACT | Technical Memo | March 31, 1999 letter from Seitz to CAPCOA (issued 3/31/99) | M:\Group\3AD30 |
| PIB | Regional Haze | Regulation | CAA citation for regional haze 40 CRF Part 51.308 | https://www.ecfr.gov/cgi-bin/text-idx?SID=1113e021e54eaefc9436b379ea4752cd&mc=true&node=se40.2.51_1308&rgn=div8 |
| PIB | Regional Haze | Guidance | August 2019 Regional Haze Guidance | https://www.epa.gov/sites/production/files/2019-08/documents/8-20-2019_-_regional_haze_guidance_final_guidance.pdf |

| Branch | Program | Resource Type | Title | Location |
|---|---|---|---|---|
| PIB | SIP | Checklist | Final rule action citation within which the Clean Data Policy was articulated 81 FR 58010 (August 24, 2016) | M:\Group\3AD30 |
| PIB | SIP | Checklist | Consolidated guidance for processing requests to redesignate areas to attainment for ozone, carbon monoxide, particulate matter, sulfur dioxide, nitrogen dioxide, and lead | M:\Group\3AD30 |
| PIB | SIP | Checklist | SIP Submittal Completeness Criteria Checklist for 40 CFR Part 51 - App. V | M:\Group\3AD30 |
| AQAB | Quality Assurance | QAPrP | Chemical Speciation Network national QAPP | https://www.epa.gov/amtic/csn-shipping-and-handling-quality-assurance-project-plans-qapps-and-standard-operating |
| AQAB | Quality Assurance | Technical Assistance Document | PAMS National Model QAPP | https://www3.epa.gov/ttnamti1/pamsguidance.html |
| AQAB | Quality Assurance | Technical Assistance Document | NATIONAL AIR TOXICS TRENDS STATIONS PROGRAM Revision 3 | https://www3.epa.gov/ttn/amtic/files/ambient/airtox/NATTS%20TAD%20Revision%203_FINAL%20October%202016.pdf |
| AQAB | Quality Assurance | Technical Assistance Document | SAMPLING AND ANALYSIS OF OZONE PRECURSORS FOR THE PHOTOCHEMICAL ASSESSMENT MONITORING STATIONS PROGRAM - Revision 2 - April 2019 | https://www3.epa.gov/ttnamti1/files/ambient/pams/PAMS%20Technical%20Assistance%20Document%20Revision%202%20April%202019.pdf |
| AQAB | Quality Assurance | QAPP/ QAPrP | R3 State and Local Air Monitoring Agency QAPPs for all grant funded programs and projects | Grantrax |
| AQAB | Quality Assurance | Reports | Final Reports for Technical Systems Audits | M:\Group\3AD40\TSA |
| AQAB | Quality Assurance | Form | Technical Systems Audit Forms (Field Sites and Laboratories) | M:\Group\3AD40\TSA |
| AQAB | Quality Assurance | Guidance | Technical Systems Audit Guidance Document | M:\Group\3AD40\TSA |
| AQAB | PEP | SOPs | Field Standard Operating Procedures for the Federal PM2.5 Performance Evaluation Program | https://www3.epa.gov/ttn/amtic/files/ambient/pm25/qa/PEP_Field_SOP.pdf |
| AQAB | NPEP | SOPs | National Performance Audit Program for O3, NO2, SO2, and CO | https://www3.epa.gov/ttn/amtic/npepqa.html |
| AQAB | Air Monitoring | Website (regulations, QA guidance and databases) | Ambient Monitoring Technology Information Center (AMTIC) | https://www.epa.gov/amtic |
| AQAB | Air Monitoring | Guidance | Guide to Writing Quality Assurance Project Plans for Ambient Air Monitoring Networks | https://www3.epa.gov/ttn/amtic/files/ambient/qaqc/Air%20Monitoring%20QAPP%20Guide%20-%20FINAL.pdf |
| AQAB | Air Monitoring | Checklist | Air Monitoring QAPP Review Checklist October 2018 | https://www3.epa.gov/ttn/amtic/qalist.html |
| AQAB | Air Monitoring | QA Handbook | Quality Assurance Handbook for Air Pollution Measurement Systems Volume II Ambient Air Quality Monitoring Program 2017 | https://www3.epa.gov/ttn/amtic/files/ambient/pm25/qa/Final%20Handbook%20Document%201_17.pdf |

| Branch | Program | Resource Type | Title | Location |
|---|---|---|---|---|
| AQAB | Air Monitoring | QA Handbook | Quality Assurance Handbook for Air Pollution Measurement Systems Volume IV: Meteorological Measurements Version 2.0 (Final) | https://www3.epa.gov/ttn/amtic/files/ambient/met/Volume_IV_Meteorological_Measurements.pdf |
| AQAB | Air Monitoring | Template | Appendix D: Measurement Quality Objectives and Validation Templates | https://www3.epa.gov/ttn/amtic/files/ambient/pm25/qa/APP_D%20validation%20template%20version%2003_2017_for%20AMTIC%20Rev_1.pdf |
| AQAB | Modeling | Website (tools, applications and guidance) | Support Center for Regulatory Atmospheric Modeling (SCRAM) | https://www.epa.gov/scram/air-quality-dispersion-modeling |
| AQAB | Emissions Inventory | Website (tools, database and guidance) | National Emissions Inventory (NEI) | https://www.epa.gov/air-emissions-inventories/national-emissions-inventory-nei |

# Appendix 8 Chesapeake Bay Program Office (CBPO)

A general description of the CPBO's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 8.1. More details are provided at: Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#cbpo; https://www.epa.gov/chesapeake-bay-tmdl

CBPO has a QAO responsible for the management of the organizations' QA procedures to ensure compliance and consistency with the Regional QMP. The CBPO is organized into two Branches with responsibilities listed below:

*Partnerships & Accountability Branch*

- Oversees and manages policies, programs, and strategies to implement CBP's mission; assists in budget formulation; develops goal-related economic and financial reports/mechanisms, including analyzing and evaluating how CBPO grants are distributed to support Chesapeake Bay Watershed Agreement (CBWA) goals; coordinates responses to external audits and evaluations
- Coordinates development and implementation of federal and state joint goals, outcomes and priorities established under the CBWA; effective governance partnership structures; a strategy review system using adaptive management principles; programs and tools to directly engage Bay watershed local stakeholders, such as local governments and community groups
- Provides coordination, facilitation, and staff support to the CBP partnership's various workgroups, Goal Implementation Teams, advisory committees, action teams, Management Board, Principals' Staff Committee, and Executive Council, which are formed to implement the CBWA and CWA Section 117
- Develops, coordinates and presents program related measures and indicators to be used in public reporting, EPA strategic planning, and program accountability
- Tracks EPA and other Federal agency water quality 2-year milestones in coordination with other R3, Region 2 and Headquarters offices and the partnership
- Implements, develops, and enhances the Chesapeake Bay suite of accountability products to support partnership accountability transparency and decision making. Ensures design, development, and maintenance of the partnership's websites

*Science, Analysis & Implementation Branch*

- Directs the technical and policy resources of the CBP partnership and the CBPO to support and actively promote continued adaptation in the face of new information, geographical and source sector targeting, and accelerated implementation of the most cost effective and efficient pollution reduction practices and technologies
- Develops, calibrates, and applies the evolving suite of science models and analysis tools in support of management decision making and application in support of the goals and outcomes under the CBWA. Provides federal, state, regional, and local partners and stakeholders with innovative technical solutions while providing advice on scientific and technical challenges
- Leads the oversight and implementation of the Chesapeake Bay's 2010 Total Maximum Daily Load (Bay TMDL), in coordination with the Water Division. Provides ongoing

coordination and enhanced oversight of the jurisdictions' Watershed Implementation Plans (WIPs); support implementation of the WIP Outcomes and the Water Quality Standards Attainment and Monitoring Outcome under the CBWA
- Coordinates the ongoing operation of and analysis of data generated by the tidal and watershed monitoring networks
- Integrates the development of CBP partnership's information systems with national information systems including the EPA's National Environmental Information Exchange Network
- Develops and fosters multi-organizational coordination to integrate and improve access to data, tools, and methodologies for analysis, with the goal of eliminating duplicative efforts and realizing cost savings. Works with CBP partners to develop policies, guidelines, and standards to support data sharing
- Identifies opportunities to expand the full suite of CBP partnership models to find management applications for other Goal Implementation Teams beyond water quality.
- Provides geographic information system, land data acquisition, analysis and projection, and web development and application support to the CBPO, the Annapolis campus, and the CBP partnership

**Table 8.1. QA documents & resources for CBPO**

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| All CPBO | Manual | Chesapeake Bay Program Office Quality Manual | https://www.chesapeakebay.net/what/programs/chesapeake_bay_quality_assurance_program |

Some specific QA requirements from the CBPO manual include:
- All grant recipients are required to submit semi-annual or quarterly progress reports (Section 1.3). These reports include any project-level changes to QAPPs or SOPs.
- The objectives and priorities for Chesapeake Bay Program (CBP) monitoring activities are described in Section 3.1. These specifications ensure consistent and comparable data from multiple agencies across the Chesapeake Bay watershed.
- All Best Management Practice data (i.e. secondary data) generated by state and county agencies needs to be accompanied by approved QAPPs (Section 2.3). The Chesapeake Bay Basin-wide BMP Verification Framework provides an additional resource for the Bay Program to ensure accurate reporting of BMP treatments (section 2.3).
- Technical systems audits for the CBP are performed by the QAC and reports are submitted to appropriate State Project Manager and CBP workgroup coordinators or POs (section 3.3.2 and § 3.3.3). All monitoring data submitted to the CBP are run through a series of automated computer verification programs, called the Data Upload and Evaluation Tool (DUET) as detailed in Section 3.3.1 Data Management.

# Appendix 9 Enforcement & Compliance Assurance Division (ECAD)

A general description of the ECAD's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 9.1. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#ecad
Intranet site- https://intranet.epa.gov/r3intran/ecad/

ECAD is responsible for developing and implementing R3 enforcement and compliance assurance programs for the statutes that EPA administers in Pennsylvania, Delaware, Maryland, Virginia, West Virginia, and the District of Columbia, as well as, any tribal governments if and when they establish enforcement programs.

ECAD works in collaboration with the Mid-Atlantic States and local governments utilizing the entire spectrum of compliance assurance tools available to the region. ECAD has a wide range of activities that may generate data including compliance monitoring inspections and investigations and environmental sampling in support of enforcement activities. ECAD maintains required training records and credentials for inspectors. ECAD has 3 branches: Data, Support & Prevention Branch (DSPB), Air, RCRA and Toxics Branch (ARTB), and Water Branch (WB).

*Data, Support & Prevention Branch (DSPB)*

DSPB - Data Support Section (DSPB-DSS)

This Section supports the Region's enforcement program by performing the following functions:

- Provides data systems support, analysis and reporting of enforcement data using systems such as ICIS, ICIS-NPDES, ICIS-Air, SDWIS, RCRAInfo, ECAD's Pipeline Case tracking system, etc.;
- Coordinates oversight of State and local governments' compliance assurance and enforcement programs as part of the State Review Framework (SRF); and
- Provides technical and program support to CID, as appropriate.

DSPB - Oil & Prevention Enforcement Section (DSPB-OPES)

DSPB-OPES ensures facilities' compliance through inspections, enforcement actions, compliance determinations and compliance assistance. This Section oversees compliance and implements the enforcement program for the following regulations:

- Clean Air Act (CAA) 112(r)
- Clean Water Act (CWA) – Oil Pollution Act (311)
- EPCRA Non-313 (EPCRA 311/312) / CERCLA / 103
- Marine Protection, Research, and Sanctuaries Act (MPRSA)

DSPB - Enforcement Support Section (DSPB-ESS)

The Enforcement Support Section provides support to some of ECAD's enforcement programs by performing single media inspections in such areas as RCRA Hazardous Waste and Underground Storage Tank (UST) programs, EPCRA 313, CWA 311, , TSCA PCB program, and the SDWA program. The Enforcement Support Sections is also responsible for providing sampling support to ECAD and provides multi-media

inspections at federal facilities across the Region. This includes field and laboratory data-generated activities used for investigations.

*Air, RCRA and Toxics Branch (ARTB)*

ARTB - Air Section (ARTB-AS)

This Section oversees compliance and implements the enforcement program for the CAA for stationary sources as well as mobile sources. ARTB-AS ensures facilities' compliance through inspections, enforcement actions, compliance determinations and compliance assistance.

ARTB - RCRA Section (ARTB-RS)

ARTB-RS ensures facilities' compliance through inspections, enforcement actions, compliance determinations and compliance assistance. This Section oversees compliance and implements the enforcement program for the following regulations:

- RCRA C – Hazardous Wastes (with exception of Corrective Action)
- RCRA I – UST (with exception of Corrective Action)

ARTB - Toxics Section (ARTB-TS)

ARTB-TS ensures facilities' compliance through inspections, enforcement actions, compliance determinations and compliance assistance. This Section oversees compliance and implements the enforcement program for the following regulations:

- FIFRA
- TSCA – Core (includes Asbestos Hazard Emergency Response Act – AHERA)
- TSCA - Lead Paint
- TSCA – Polychlorinated Biphenyl (PCBs)
- EPCRA 313

*Water Branch*

WB - SDWA & Wetlands Section (WB-SWS)

WB-SWS ensures facilities' compliance through inspections, enforcement actions, compliance determinations and compliance assistance. This Section oversees compliance and implements the enforcement program for the following regulations:

- SDWA – Underground Injection Control
- SDWA – Public Water Systems
- CWA – Wetlands (404)

WB - NPDES Section (WB-NS)

WB-NS ensures facilities' compliance through inspections, enforcement actions, compliance determinations and compliance assistance. WB-NS oversees compliance and implements the enforcement program for the:

- CWA – NPDES

## Table 9.1. QA documents & resources for ECAD

| Branch-Section | Resource Type | Title | Location |
|---|---|---|---|
| ARTB-TS | Checklist | Asbestos AHERA Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Checklist | Asbestos Removal Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Form | Asbestos sampling Chain of Custody | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-AS | Template | CAA Inspection Report | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-AS | Template | CAA Mobile Cover Letter | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-AS | Template | CAA Photo log for inspections | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-AS | SOP | CAA-SOP for FLIR Temperature Calibration | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-AS | SOP | Organic Vapor Analyzers (TVA-1000B and COSMOS) | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Template | CERCLA-EPCRA Contractor Inspection Template | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ALL ECAD | Checklist | ECAD H&S Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-ESS | SOP | ECAD Sampling and Data Management | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | SOP | EPCRA 313 desk top inspections | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Checklist | EPCRA Section 313 Inspection Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Checklist | EPCRA Section 313 Inspection Checklist-Data Quality | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Guidelines | FIFRA_NOA Submission Guidelines | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB - OPES | Checklist | FRP Checklists workbook approach | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB - OPES | Checklist | FRP Inspection Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| HQ-OECA | Guidance | ICIS User Guide August_2002 | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Template | OIL GIUE Certificate Fill-in Form | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Template | OIL GIUE Drill - Failed Sample Letter | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Template | OIL GIUE Drill - Pass Sample Letter | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-RS | Template | RCRA C-Inspection Report Template | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Checklist | SPCC Inspection & Plan Review Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Template | SPCC-FRP Post Inspection Cover letter | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| DSPB-OPES | Template | SPCC-Inspection Report | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Template | TSCA LEAD RRP Job Description Template | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |

| Branch-Section | Resource Type | Title | Location |
|---|---|---|---|
| ARTB-TS | Template | TSCA LEAD RRP Records Inspection Report | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Template | TSCA LEAD RRP Site Inspection Report | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Template | TSCA LEAD RRP Tip Complaint Template | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Template | TSCA New & Existing Chemicals Inspection Report Template | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Template | TSCA SECTION 6(a) WORKER PROTECTION RULE INSPECTION REPORT | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Checklist | TSCA-Core Inspection Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |
| ARTB-TS | Checklist | TSCA-LEAD-Contract Review Checklist | G:\ G- -ECAD-Share/ECAD QA/ECAD SOPs |

# Appendix 10 Laboratory Services & Applied Science Division (LSASD)

A general description of the LSASD's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 10.1. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#lsasd
Intranet site- https://intranet.epa.gov/r3intran/lsasd/

LSASD integrates the region's analytical science activities to support regional programs and provides a center of technical expertise in quality assurance and the collection, review, and communication of environmental data. LSASD coordinates with regional programs to ensure the effective collection and analysis of environmental data in support of programmatic priorities. LSASD staff may also coordinate and conduct management, technical, and data assessments (e.g. laboratories- Table 10.2, QSAs, field quality, etc.). The Division consists of the Immediate Office and three branches: Applied Science & Quality Assurance Branch (ASQAB), Laboratory & Technical Services Branch (LTSB) and Field Services Branch (FSB). LTSB and FSB each have a Quality Assurance Officer (QAO) responsible for the management of their organizations' QA procedures to ensure compliance and consistency with the Regional QMP.

*Immediate Office*

- Houses the Deputy Scientific Integrity Official who is responsible for ensuring the integrity of technical products, peer review, science inventory, science hub services, and general regional scientific integrity issues
- Through the Regional Science Liaison, collaborates with the Office of Research and Development (ORD) and delivers technical and programmatic assistance to all regional programs and staff on their applied research goals and objectives and champions and manages the Regional Science Council

*Applied Science & Quality Assurance Branch (ASQAB)*

- Provides leadership and oversight of the Quality System in R3 through the RQAM and ASQAB Quality Staff, including the R3 FOMS through the FQM
- Ensures that the environmental data collected, reported and used in the Region is properly documented, sufficiently accurate and precise to meet the data quality objectives of regional program needs
- Analyzes, evaluates, and displays environmental information, including geospatial, in support of all regional programs and staff and cross-cutting and emerging environmental issues
- Builds scientific and technical capacity of regional staff, state/local partners, and community stakeholders and facilitates the application of environmental tools, such as geographic information systems, to a broad array of environmental issues and programmatic priorities

*Laboratory & Technical Services Branch (LTSB)*

- Provides laboratory analyses, data management, quality control, and associated tasks to support regional programs, emergencies, compliance assurance, criminal investigations research-related studies, and other work by external entities

- Acts as Regional Sample Control Center to coordinate the acquisition and delivery of routine and specialized analytical services (Section G.6)
- Oversees the state Safe Drinking Water Act (SDWA) chemistry and microbiological laboratory certification program and administers the SDWA and NPDES Proficiency Testing (P/T) studies and Provides P/Ts upon request for extramural projects (contracted laboratories);
- Provides technical assistance and training to state/local partners regarding laboratory practices, techniques, and management
- Performs state/local laboratory inspections and conducts related certification programs for the Superfund Contract Laboratory Program (CLP), and other contract laboratories;
- Provides technical assistance to RQAM on Alternate Testing Procedures requests

LTSB has a QA program which is ISO 17025 accredited by A2LA, an approved Accrediting Body. Quality procedures are documented in the most recent version of the LTSB Laboratory Quality Manual. Certificates for accreditation and each accredited analytical method is available from the Lab QAO. LTSB maintains QA system documents and functions including SOPs, demonstration of capability files for personnel, assigned equipment notebooks, and records management.

*Field Services Branch (FSB)*

The FSB is responsible for the following:

- Collecting & analyzing environmental data to evaluate condition of aquatic resources, and leading and coordinating aquatic monitoring initiatives
- Developing and reviewing scientifically defensible bioassessment tools & methods and biological criteria and methods to interpret narrative standards
- Training and providing technical expertise to state and federal partners
- Providing field support for regional programs, which includes field sampling, investigations and the field activities associated with studies in support of Superfund remediation, hazardous waste determinations, air quality assessment, water quality assessment, ecological condition assessment, and enforcement activities

The FSB maintains QA system documents and functions including SOPs, demonstration of capability files for personnel, assigned equipment notebooks, records management, and authoring and reviewing project QAPPs. When appropriate and in accordance with QA standards, the FSB follows state/tribal or programmatic sampling procedures.

**Table 10.1. QA documents & resources for LSASD**

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| LTSB | Quality Manual | R3 Laboratory Quality Manual (includes listing of SOPs) | I:\LTSB Quality System |
| FSB | SOP | Management of Quality System and Project Records | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Macroinvertebrate Sample Receiving and Handling | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Macroinvertebrate Subsampling and Sorting | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Identification of Macroinvertebrates | H:(LSASD 3LS30)\QAQC |

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| FSB | SOP | Field Bioassessments | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Continuous Monitoring | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Toxicity Testing Data Review | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Sampling of Fish for Bioassessment | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Transporting and Operating Boats | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Identification of Fishes in the Laboratory | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Collection of Fish Tissue Contaminant Samples | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Fish Sample Receiving and Handling | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Marine Sediment Sample Collection | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Marine Water Nutrient Sample Collection | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Hydrographic Sampling | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Marine Benthic Macroinvertebrate Sample Collection | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Sample Shipment and Chain of Custody | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Marine Benthic Macroinvertebrate Tissue Collection | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Ocean Acidification Sample Collection | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Storage and Handling of Sample Fixative | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Echosounder Monitoring | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Submerged Aquatic Vegetation Raking and Documentation | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Quadrat Sampling of Submerged Aquatic Vegetation for Biomass Measurements | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Submerged Aquatic Vegetation Percent Cover and Species Determination Dive Survey | H:(LSASD 3LS30)\QAQC |
| FSB | SOP | Shoreline Characteristic Data Generation | H:(LSASD 3LS30)\QAQC |
| FSB | Manual | Regional Supplement to the Corps of Engineers Wetland Delineation Manual: Northcentral and Northeast Region | https://www.usace.army.mil/Missions/Civil-Works/Regulatory-Program-and-Permits/reg_supp/ |
| FSB | Manual | Regional Supplement to the Corps of Engineers Wetland Delineation Manual: Atlantic and Gulf Coastal Plain Region (Version 2.0) | https://www.usace.army.mil/Missions/Civil-Works/Regulatory-Program-and-Permits/reg_supp/ |
| FSB | Manual | Regional Supplement to the Corps of Engineers Wetland Delineation Manual: Eastern Mountains and Piedmont Region (Version 2.0) | https://www.usace.army.mil/Missions/Civil-Works/Regulatory-Program-and-Permits/reg_supp/ |
| FSB | Manual | National Aquatic Resource Surveys Manuals and QAPPs | https://www.epa.gov/national-aquatic-resource-surveys/manuals-used-national-aquatic-resource-surveys |

## Table 10.2. Laboratory Audits

| Audit Type or Subject | Assessee | Details | Guidance Documents |
|---|---|---|---|
| National Pollutant Discharge Elimination System (NPDES) | NPDES permittees' and commercial laboratories analyzing compliance samples, as requested by the NPDES program in WD. | Inspections are performed in partnership with the State Authority and may be announced or unannounced to the facility. LSASD staff are responsible for tracking resulting corrective actions for NPDES permittee laboratories and commercial laboratories analyzing compliance samples. The goals are to improve Discharge Monitoring Reports Quality Assurance (DMRQA) performance; provide technical assistance to States that have limited expertise in certain analytical methodology; and improve analytical QA/QC and documentation procedures. | NPDES Self-Monitoring Data and Data Inspections DAIs, EPA-903-R-94-043. |
| Safe Drinking Water Act/ Drinking water Laboratory Certification | R3 State Laboratories | On-site assessments are conducted every three years and LTSB extends an invitation to WD to attend. LTSB staff track resulting corrective actions and also performs reviews of the R3 State SDWA Laboratory Certification Programs. Every three years, the assessments and program are reviewed by the Office of Ground Water and Drinking Water through yearly questionnaires and on-site inspection. | EPA's Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance, EPA 815-R-05-004.<br>LTSB SOP, On-site Laboratory Assessments in the Drinking Water Laboratory Certification Program, R3-QA801 (most current version).<br>DAIs as discussed above. |
| Laboratories Used by Potentially Responsible Parties | Laboratories used by R3 Superfund Potentially Responsible Parties (PRPs). | LSASD personnel and the Laboratory QAO may conduct limited inspections. SEMD and LCRD selects the PRP laboratories to be inspected, as needed. The PRP laboratory inspections include the review of P/T sample results; the site's QAPP and SAP; and the site's third-party data validation reports. Prior to distribution of the laboratory inspection findings report to the appropriate SEMD or LCRD PO, the report shall be reviewed by the LSASD Staff. LSASD Staff are responsible for tracking the resulting corrective actions for PRP laboratories. | LTSB SOP, On-site Inspection of Superfund PRP Monitoring Procedures, (most current version).<br>DAIs as discussed above. |
| National Environmental Laboratory Accreditation Program | Accrediting Bodies (AB) | The results of the inspections are documented in a checklist. Findings are resolved with the ABs and the final reports are sent to the NELAP Board for final review and approval. The program's procedures, assessments and accreditation are reviewed annually by the NELAP Board as described in Chapter 6 of the NELAC standards. | Chapter 6 of the National Environmental Laboratory Accreditation Conference (NELAC) standards |

| Audit Type or Subject | Assessee | Details | Guidance Documents |
|---|---|---|---|
| Contract Laboratory Program (CLP) | CLP laboratories located in R3 | The CLP PO conducts an annual on-site audit, which can include routine P/T samples, to assess a CLP laboratory's overall performance. The national CLP processes the data through EXES[4]. In addition to the EXES reports, the CLP labs are provided with a data assessment report that documents the instances of non-compliance. The CLP Quality Assurance and Technical Support (QATS) contractor performs data evaluation and review services. This three-step review process provides the CLP customer with data of known and documented quality. When the data package is delivered to the Regional Sample Control Center, the package is subject to an evidentiary review to ensure the documentation for COC and sample handling procedures are present and also undergoes a data validation process to further assess the quality and usability of the data. Corrective actions from these lab checks are monitored by the R3 CLP PO. Significant contract non-conformances are forwarded to the National CLP Program Manager and COR for appropriate action, which may include the rejection of data and a reduction in payment. | Applicable CLP Statement of Work (SOW)<br><br>National Functional Guidelines (most current version) (Appendix 1) |
| Non-CLP methods | Non-accredited or non-certified laboratories | Prior to contract award, labs not accredited must provide a copy of their quality manual and applicable SOPs, which should include the lab's quality policy, description of the lab facilities, a list of personnel with qualifications, and procedures for measurement, calibration, data review and corrective action. For non-routine methods, the lab must also submit an initial DOC and method detection limit study for the non-routine method, which LSASD evaluates to determine the laboratory's competency and capability to conduct the requested analyses, in accordance with EPA's Competency Policy discussed above. LSASD personnel and the Laboratory QAO will conduct on-site audits of the regionally contracted labs where R3 has reason to believe data quality is suspect, using the procedures identified above and contained in the applicable SOW. The regionally contracted lab data is subject to the same evidentiary review and data validation procedures as CLP data. Corrective actions are monitored by the R3 PO. If significant contract non-conformance is found, the R3 PO may recommend rejection of the data and reduction in payment. | Applicable SOW<br><br>If applicable, the CLP on-site audit checklist may also be used for specific analytical fractions (i.e., volatiles, semi-volatiles, pesticides, metals, cyanide, etc.). |

[4] The Electronic Data Exchange and Evaluation System (EXES) is an automated data assessment tool that incorporates Contract Compliance Screening (CCS) and data usability reviews to provide EPA Regions with electronic data usability and compliance reports, spreadsheets, and files within 24 to 48 hours from the receipt of data from laboratories. This automated tool facilitates the transfer of analytical data into Regional databases.

# Appendix 11 Land, Chemicals, & Redevelopment Division (LCRD)

A general description of the LCRD's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 11.1. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#lcrd
Intranet site- https://intranet.epa.gov/r3intran/LCRD/

LCRD implements the following statutory programs:

- RCRA, Subtitle C (Hazardous Waste)
- RCRA Subtitle D (Solid Waste)
- RCRA Subtitle I (UST and Leaking UST (LUST))
- RCRA Hazardous and Solid Waste Amendments (1984)
- The Brownfields provisions of the CERCLA as created by the Small Business Liability Relief and Brownfields Revitalization Act (2002) and amended by the Better Utilization of Investments Leading to Development (BUILD) Act of 2018
- FIFRA
- Residential Lead Based Paint Hazard Reduction Act
- TSCA
- Asbestos Hazard Abatement Act (ASHAA) of 1984
- AHERA of 1986
- PPA of 1990
- EPCRA TRI Program

The following programs have been delegated to some or all of R3 Mid-Atlantic States - Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia:

- RCRA Subtitle C (hazardous waste)
- RCRA Subtitle I (UST)
- Pesticides

LCRD implements these programs through oversight and assistance related to State and tribal delegated programs, direct program implementation, issuing permits, tribal projects, grants management, oversight of trust fund, partnership efforts, program approvals, technical assistance, community engagement and outreach, and projects to promote sustainable environmental results.

*Immediate Office*

The Immediate Office is responsible for overall program management, strategic planning, budgeting, information management, communications, and all managerial, administrative, and programmatic functions.

*RCRA Corrective Action Branches 1 & 2*

RCRA Corrective Action Branch 1 (Virginia, West Virginia, Delaware, Maryland, and the District of Columbia) and RCRA Corrective Action Branch 2 (Pennsylvania) are responsible for the following activities:

- Ensuring that hazardous wastes, chemicals, and pesticides do not constitute a threat to human health, safety, well-being, and the environment;

- Remediating hazardous waste at sites where human health or the environment are threatened;
- Helping States develop State RCRA programs and supporting the authorization of State RCRA programs;
- Issuing permits under the statutes referenced above;
- Issuing corrective action permits and orders under Subtitle C of RCRA;
- Ensuring community involvement in areas managed by the RCRA program

*RCRA Programs Branch*

RCRA Programs Branch is responsible for the following activities:

- Developing and coordinating the implementation of joint EPA/State/tribal multi-media plans and recommending the award of program grants to States and tribes to support implementation of these plans
- Working with States and tribes to develop and manage the hazardous waste storage, treatment and disposal permitting and corrective action programs under Subtitle C of RCRA
- Assisting the States and tribes in implementing programs under Subtitle D and Subtitle I of RCRA and in implementing corrective actions performed under the RCRA Hazardous and Solid Waste Amendments (1984)
- Working with other federal agencies, States, tribes, local governments, and public and private sector partners to develop an integrated sustainability program that incorporates materials management and waste reduction

*Chemicals Safety Program Branch*

Chemicals Safety Program Branch is responsible for the following activities:

- Ensuring that hazardous wastes, chemicals, and pesticides do not constitute a threat to human health, safety, well-being, and the environment
- Assist states in the development and subsequent authorization and approval of state programs
- Developing and coordinating the implementation of joint EPA/State/tribal multi-media plans and recommendation of program grant awards to States and tribes to support these plans
- Ensuring community involvement in impacted areas

*Brownfields & Revitalization Branch*

The Brownfields and Revitalization Branch is responsible for the following activities:

- Implementing the Brownfields program, which addresses the expansion, redevelopment or reuse of properties, which may be complicated by the presence or potential presence of a hazardous substance, pollutant or contaminant.
- Providing funds and technical assistance to tribes, States, communities and other stakeholders in economic development to work together to assess, safely clean up, and sustainably reuse brownfields.
- Ensuring community involvement in impacted areas

Brownfields grant recipients are required to have an approved QAPP and PO-reviewed site-specific sampling plans as a standard condition of their funding agreement and before

environmental samples are collected. Brownfields grant recipients use R3's Brownfields QAPP template (Interim Final, March 2001) and Site-Specific SAP template (Draft Interim Final August 1999). ASQAB's Quality staff or DAO assist the POs in evaluating and approving the grant recipient's QAPP.

*LCRD- START Contractor*
LCRD uses the Superfund Technical Assistance and Response Team (START) program, that was developed under EPA's Long-Term Contracting Strategy (LTCS) and combines the previously separate support activities of the Field Investigation Team and Technical Assistance Team into a single contract. The START contracts are managed by SEMD and provide technical support to EPA's site assessment, response, prevention, and preparedness activities. EPA's START contractors are used to collect samples as part of CERCLA site assessments, removal assessments, fund-lead removal actions (post-removal confirmation sampling) and targeted Brownfields assessments. The START contractors have prepared QAPPs that are intended to be sufficiently broad-based to address collection/analysis of samples in support of these activities. QAPPs must meet the requirements outlined in Section F.2.a of the Regional QMP.

*LCRD- State-Prepared QAPrPs*
R3 has cooperative agreements with several states in R3. Under these Agreements, these states perform the majority of program-specific environmental sampling related to site assessments in all LCRD programs. According to programmatic guidance from the National Program Offices, including OLEM, Office of Chemical Safety and Pollution Prevention (OCSPP), and Office of Brownfields and Land Revitalization (OBLR), QAPrPs are prepared by each of the states to cover the work they are performing and to provide program and project level QA requirements. These QAPrPs are reviewed by EPA annually and revised, as necessary, with approval not to exceed the length of the agreement. R3's Brownfields program maintains cooperative agreements with DNREC in DE, DOEE in District of Columbia (DC), MDE in MD, PADPEP in PA, VADEQ in VA, WVDEP in WV.

LCRD relies on both the R3 QMP as well as HQ guidance to determine the requirements for its programmatic QAPrP reviews. As part of the review process outlined in R3 QMP Figure D.1 and LCRD Grants and QA/QC SOP, LCRD divides DPM, i.e., PO, responsibilities into two roles, Technical and Administrative. The Administrative PO is responsible for maintaining the Grant File according to grant requirements (e.g., Baseline monitoring). The Technical PO confers with the Administrative PO to determine QA documentation requirements, completes PO checklist and R3 QA Document Review Request, and shares these forms and QA documentation through LCRD's SharePoint site with ASQAB Quality Staff for review/approval assignment. Consistent with the R3 QMP, LCRD requires POs to be certified in both Tier 1 and the following Tier 2 training courses: QAPPs, Secondary Data QA, and QMPs.

**Table 11.1. QA documents & resources for LCRD**

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| Brownfields and Redevelopment Branch | Template | Generic QAPP for Brownfields 104K grants | https://www.epa.gov/land-revitalization/region-3s-quality-assurance-project-plan-qapp-template |

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| Brownfields and Redevelopment Branch | Template | Generic Sampling Plan for Brownfields 104K grants | https://www.epa.gov/brownfields/us-epa-region-iii-brownfields-site-specific-sampling-and-analysis-plan-template |
| Chemicals Safety Branch | Guidance | Asbestos Inspector's Guidance library | https://usepa.sharepoint.com/sites/R3/landchemicalsandredevelopment/lcrdfrontoffice/Asbestos%20Guidance%20Library/Forms/AllItems.aspx |
| Chemicals Safety Branch | Guidance | Get the Lead Out – EPA Region 3 Guidance for Preparing Lead-Monitoring Project Plans, May 1999 | https://www.epa.gov/sites/production/files/2015-06/documents/leadout.pdf |
| Chemicals Safety Branch | Guidance | Guidance for Quality Assurance Project Plan Development for EPA Funded Cooperative Agreements with State and Tribal Agencies for the Conduct of FIFRA Pesticide Programs, December 15, 2000, Document Control No. EC-G-2000-067 | https://www.epa.gov/sites/production/files/2015-06/documents/finalqaappver9.pdf |
| RCRA Programs Branch | Guidance | EPA Region 3 Guide for Preparing a Generic Quality Assurance Project Plan for a State RCRA Subtitle C or LUST or UST Program, October 2000 | https://usepa.sharepoint.com/sites/R3/landchemicalsandredevelopment/lcrdfrontoffice/Lists/Helpful%20QAQC%20Links/Attachments/16/GuideforGenericQAPrPforStateRCRACI.pdf |

# Appendix 12 Mission Support Division (MSD)

A general description of the MSD's functions, including QA-related information, is provided below. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#msd
Intranet site- https://intranet.epa.gov/r3intran/msd.html

MSD is responsible for providing leadership, support, communications and direction to ensure efficient operations vital to EPA and regional goals. The MSD Director is the Assistant RA (ARA), who advises the RA and Deputy Regional Administrator (DRA), senior leadership, and management on regional and national policies involving strategic planning, technical, and resource management issues.
MSD is responsible for managing the following functional areas:

- Strategic planning and coordination of EPA's process improvement systems
- Budget
- Finance
- Financial aspects of cost recovery
- Management control and integrity (Federal Manager's Financial Integrity Act (FMFIA))
- Facilities and security
- Human resources
- Information technology and information management
- Management of grants and IAs
- Contracts and acquisition
- Health and safety

MSD assures integration and coordination of programs with other divisions across the region and nationally. MSD supports, and its director performs, the following unique roles:

- Senior Resource Official (SRO) – establishes and maintains a regionwide integrated accounting and financial management system, providing accounting and fiscal services, and enforcement of internal controls policies. Responsible for the region's ethical, effective resource management, including acquisition, assistance, budget, financial management and management integrity. This applies to grants, contracts, and interagency agreements.
- Senior Information Official (SIO) – responsible for ensuring effective processes, procedures and other directives are established as needed to implement policies, procedures, controls techniques and other countermeasures identified under the EPA Information Security Program. Responsible for regional implementation of Federal IT Acquisition Reform Act (FITARA) requirements involving IT investments in hardware and software.
- Controls the audit management process, ensuring timely and effective resolution of audits, corrective actions, tracking and reporting requirements.
- Manages dispute decisions on audit of grants, cooperative agreements, and interagency agreements.
- Manages regional compliance with the FMFIA.

MSD consists of eight branches whose functions are outlined below.

*Contracts Branch*

- Develop and execute strategic acquisition solutions, milestones, and forecast
- Conduct pre-award planning negotiations, resolve funding and payment issues, address protests and claims, issue terminations, contract closeouts and provide COR training
- Manage the small and disadvantaged business utilization program
- Perform self-assessment of work processes and products in compliance with Office of Acquisition Management's (OAM) Balanced Scorecard Initiative and respond to OIG audits

*Facilities Management & Services Branch*

- Policies, procedures, and oversight for facility management in all offices and field locations
- Property management- Security, leasing support, building and facilities improvements
- Disaster preparedness- Occupant Emergency Plans (OEPs), administrative functions in support of Continuity of Operations (COOP)
- Operations support- fleet management, mailroom, graphics, supplies
- Health, safety, and wellness- occupational health, site safety, medical surveillance, worker's compensation, and industrial hygiene

*Financial Management Branch*

- Budget- full time employee (FTE) and payroll management, funds control, and budget management
- Finance- financial system administration, funds reporting, financial reports, data analytics, unliquidated obligation reviews, reconciliation, time and attendance, audits, financial policies and procedures, travel management and policies, and transit subsidy
- Financial Aspects of Cost Recovery- cost accounting requirements to support the Superfund (SF) cost recovery function, including accounting for and verifying cost data for SF obligations, expenditure, producing cost documentation as necessary to support cost recovery, and assisting program personnel in accurately accounting for SF expenditures, maintains SCORPIOS and reconciles data for accuracy and integrity, and coordinates and assists in the management of SF special accounts

*Human Resources Management Branch*

- Policies, procedures, oversight, and operational support in the areas of personnel and organization management
- Training and development activities; facilitation and coaching
- Workforce planning, recruitment strategy and hiring; drug testing
- Work schedules and telework
- Reasonable accommodation
- Performance management
- Labor and Employee Relations (LER)
- Leave Bank and Transfer coordination
- Employee Assistance Program (EAP)

- 4711 Order policy (workplace harassment) and program management; violence in the workplace
- Coordination with the Human Resources Shared Services Centers
- Special employment programs (Pathways, veterans, persons with disabilities), and Senior Environmental Employment (SEE) Program

*Information Systems Branch*

- Web and application development
- Records management, including eDiscovery
- R3 library
- Working Capital Fund
- Regional Exchange Network program

*Planning & Analysis Branch*

- Strategic planning, program evaluations, and organizational assessments
- Performance measurement/Process improvement/Accountability
- Risk management
- EPA Lean Management System (ELMS) and Lean implementation/coordination
- FMFIA
- National Environmental Performance Partnership System (NEPPS), including Performance Partnership Grants (PPGs) and Performance Partnership Agreements (PPAs)
- Regional regulatory action development process and regional directives system, including delegations of authority and orders
- Employee Viewpoint Survey
- E-Enterprise
- Management community support and facilitation

*Grants & Audit Management Branch*

- Manage and oversee administrative aspects of assistance agreements, including grants and cooperative agreements to support states, tribes, local governments, non-profit organizations, and other organizations
- Compliance assistance and enforcement related to poor performance or improper actions by grant recipients
- Training and assistance to EPA personnel, recipients and others regarding grants management requirements and procedures
- IA oversight by SRO to ensure proper expenditure of funds

*Computer Services Branch*

- Policies, procedures, and oversight of IT infrastructure, applications, and desktop services
- Regional data centers, data center performance and controls
- IT support and telecommunications
- Cyber security and privacy
- Data and network management
- Regional FITARA approval and implementation

# Appendix 13 Office of Regional Counsel (ORC)

A general description of the ORC's functions, including QA-related information, is provided below. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#orc
Intranet site- https://intranet.epa.gov/r3intran/orc/

ORC reports to the Office of General Counsel (OGC) and the Assistant Administrator for Office of Enforcement and Compliance Assurance (OECA) for technical, legal, and programmatic oversight, and to the RA for administrative oversight.

- Acts as the principal legal advisor to the RA and provides legal opinions, legal counsel, and litigation support to all regional programs, divisions, and offices, including implementation and enforcement of environmental programs, grants, contracts and general law. In providing legal counsel, ORC attorneys consult and coordinate with attorneys in OGC, OECA and other ORC offices to ensure consistency in the legal positions being taken across the Agency
- Acts as Deputy Ethics Official and provides legal advice to the RA, regional management and staff on ethics issues arising within the Region, in consultation with OGC, as needed
- ORC responsibilities also include the functions of the Regional Hearing Clerk and Regional Judicial Officer
- Represents the RA and the Agency as counsel in their relationships with representatives from other federal agencies, state and local governments, and other officials or groups having an interest in regional programs. In addition, ORC provides legal review of statutory and regulatory authorities of state or local agencies in reference to proposed delegations of administration of environmental programs of the Agency.
- Provides legal support to OGC and other regions when needed
- Provides legal support to OECA's criminal enforcement program for environmental crimes cases and activities
- Provides legal counsel with respect to information law (under the Freedom of Information Act, the Privacy Act, the Federal Records Act and other authorities)

*FOIA Branch*

- Manages the regional FOIA responsibilities
- Represents the Region in administrative litigation on regional enforcement matters. Prepares enforcement cases for referral to the Department of Justice (DOJ) for judicial action and supports DOJ in its resulting judicial actions.
- In providing legal counsel on enforcement matters, ORC attorneys consult and coordinate, as appropriate and as provided in delegations of authority, with OECA and OGC.
- Participates in policy and strategic planning discussions for the national enforcement program. Provides legal support to OECA and other regions when needed.

*CERCLA Branch 1*

- Provides legal counsel, advice and litigation support to the RA, the SEMD's Remedial and Removal Programs, and LCRD's RCRA Corrective Action Program on civil judicial and administrative enforcement matters and the remedy selection process.

*CERCLA Branch 2*

- Provides legal counsel, advice, and litigation support to the RA and SEMD on site remediation regulatory procedure, including federal facility Superfund sites and oil spill remediation, pursuant to CERCLA and CWA Section 311, and on civil judicial and administrative enforcement matters arising under CERCLA and CWA Section 311.
- Provides legal counsel, advice, and litigation support to the RA and ECAD on civil judicial and administrative enforcement of CAA Section 112(r), CWA Section 311(b)(3) and (j), EPCRA Sections 303-312 and CERCLA Section 103.

*Air & Toxics Branch*

- Provides legal counsel, advice and litigation support to the RA and R3's enforcement program on civil judicial and administrative enforcement matters arising under EPA regulatory enforcement programs, including those under the CAA, FIFRA, RCRA, EPCRA and TSCA.

*Water & Waste Branch*

- Provides legal counsel, advice and litigation support to the RA and R3's enforcement program on civil judicial and administrative enforcement matters arising under EPA regulatory enforcement programs, including those under the CWA, RCRA, and SDWA.

*Media Program Counseling Branch*

- Provides legal counsel and advice to the RA and the Directors of the ARD and LCRD on matters arising under the CAA, RCRA-C, RCRA-I, TSCA-lead, TSCA-PCBs, and FIFRA, including, but not limited to, legal review of state implementation plans, CAA permits, and authorization of state regulations under RCRA.
- Provides counseling on tribal matters, Title VI of the Civil Rights Act, environmental justice, and information law, including FOIA, CBI, and Personally Identifiable Information (PII).
- Provides e-discovery counseling to lawyers within ORC and is a liaison with the E-Discovery Division and DOJ on discovery matters in active litigation.

*Water & General Law Branch*

- Provides legal review and counsel on all regulatory issues arising under the CWA and SDWA.
- Provides legal support to regional work on contracts, grants, and ethics.
- Represents R3 as counsel in personnel actions brought against the Agency and advises the RA or responsible staff concerning legal aspects of such personnel matters as employee conduct or discipline, conflict of interest, equal employment opportunities, and union contract negotiations, interpretations and grievances.

# Appendix 14 Superfund & Emergency Management Division (SEMD)

A general description of the SEMD's functions, including QA-related information, is provided below. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#semd
Intranet site- https://intranet.epa.gov/r3intran/semd/

SEMD has overall responsibility for ensuring that R3 executes its responsibility for managing resources and personnel for emergency responses, removal and remedial response actions, hazardous substance and oil spill prevention activities, cost recovery, and contingency planning and preparedness activities involving oil and hazardous substances. SEMD consists of five branches: Federal Facilities and Site Assessment Branch, Site Remediation Branch, Preparedness and Response Branch, Administrative Program and Cost Recovery Branch, and the Technical Support Branch.

*Immediate Office*

The function of SEMD's Immediate Office is to recommend goals, priorities, and objectives for implementation of activities of the programs it administers, aligning with the EPA Headquarters' Office of Land and Emergency Management (OLEM) and the Office of Enforcement and Compliance Assurance (OECA).

*Federal Facilities & Site Assessment Branch*

This Branch consists of two Sections: Federal Facilities Section and the Site Assessment Section, both of which ensure sampling and use of secondary data meets QA requirements. The Federal Facilities Section is responsible for the development and implementation of CERCLA and SARA activities associated with compliance and cleanup of federal facilities listed on the National Priorities List (NPL); the Site Assessment Section is responsible for screening hazardous waste sites for possible listing on the NPL, as well as remedial activities at federal facilities not listed on the NPL and at formerly used defense sites.

Federal Facilities Section

- Prepares and negotiates Section 120 IAs often referred to as Federal Facility Agreements for Remedial Investigation/Feasibility Study (RI/FS) and Remedial Design/Remedial Actions at NPL sites.
- Oversees the investigation and cleanup of federal facilities listed on the NPL.

Site Assessment Section

- Responsible for hazardous waste site discovery, assessment, and investigation.
- Determines the potential for long-term risk to human health and the environment including possible ranking on the NPL, using the Hazard Ranking System (HRS), and prepares rule-making packages for sites with high risk.
- Refers sites not meeting the NPL criteria for ranking to appropriate state authorities, the Brownfields program, or other Federal programs for possible action.
- Manages the oversight of investigation and cleanup of non-NPL Federal Facilities and formerly used defense sites.

- Manages state cooperative agreements and performs oversight of State pre-remedial programs.

*Site Remediation Branch*

The Branch is responsible for the development and implementation of CERCLA and SARA remedial programs for sites (i.e., potentially responsible party (PRP) lead and fund-lead sites) throughout the Region, and manages the Superfund monetary expenditures at remedial action sites. The Branch oversees the implementation of Superfund State Contracts and cooperative agreements with the states. The Branch consists of three Sections organized geographically: Eastern Pennsylvania (PA) Remedial Section; Western PA and Maryland (MD) Remedial Section; and Delaware (DE), Virginia (VA), West Virginia (WV) Remedial Section. Each Section shares the same program and Remedial Project Manager (RPMs) responsibilities:

- Implementing the Superfund site evaluation, investigation, remediation, long-term stewardship, and revitalization programs for NPL and long-term removal sites
- Preparing and reviewing remedial investigation and feasibility studies, proposed remedial action plans, remedy decision documents, and remedial designs,
- Directing and overseeing remedial actions, including construction, performing five-year reviews, and other necessary activities.
- Overseeing contractors (e.g., Remedial Action Framework (RAF) suite of contracts), interagency agreements, and state activities (e.g., EPA state cooperative agreements and Superfund State Contracts).
- Conducting enforcement activities including negotiations with PRPs for performance of investigation, design, remedial actions, and removal actions at NPL sites and overseeing those activities.
- Ensuring data and secondary data have met all appropriate QA requirements.

*Preparedness & Response Branch*

The Branch is responsible for the development and implementation of the Regional Emergency Response and Removal Programs under CERCLA and OPA. The main functions are to provide response capability and implement emergency planning and preparedness activities for Homeland Security and natural disasters. The Branch has three Sections that provide support for:

- <u>Eastern Response Section & Western Response Section</u>
  - Managing emergency response and time critical removal actions under CERCLA/SARA and emergency response actions under Section 311 of the CWA, with specific responsibilities including:
    - Performing removal assessments, initiating emergency response operations, coordinating and directing efforts on-scene, initiating time critical removal operations at NPL and non-NPL sites; conducting and coordinating responses to oil and hazardous materials spills; and cleanup monitoring for compliance with enforcement-related conditions where PRPs have taken the lead at removal sites.
    - In the case of On-Scene Coordinators (OSCs), utilizing both the Emergency and Response Services (ERRS) contract and the Superfund Technical Assessment Response Teams (START) contract. The OSCs have the responsibility of ensuring that all data and secondary data have met all

appropriate QA requirements.

- Preparedness & Support Section
  - Manages preparedness activities for oil spills/hazardous substances incidents as specified under the NCP.
  - Maintains the readiness of the Regional Response Center (RRC) and the alternate RRC, ensuring a timely spill notification process.
  - Develops and updates the Regional Contingency Plan, and,
  - Conducts regular meetings of the R3 Regional Response Team, in cooperation with the US Coast Guard, state and Federal agencies.

*Program Support & Cost Recovery Branch*

This Branch administers the contracts, data collection and management, budget, records management, grants, IAs, training, and cost recovery functions of the Superfund program.

- Program Support Section
  - Determines the resource needs of the Superfund programs and manages the Superfund budgets, including the extramural budgets for the remedial, removal, site assessment, and federal facilities programs.
  - Manages and administers all Superfund contracts, provides the lead coordination role for Superfund State Cooperative Agreements, and administers IAs with other federal agencies.
  - Manages all Superfund data in the national data system (SEMS).
  - Operates the Superfund Records Center.

- Cost Recovery Section
  - Performs PRP search activities to identify parties to perform and reimburse EPA's costs for Superfund site cleanup work.
  - Performs ability to pay analyses to determine PRPs' ability to perform and pay for cleanup work.
  - Issues information request, general notice and demand letters and other correspondence to address PRP liability.
  - Prepares judicial pre-referrals and referrals to the U.S. Department of Justice in support of various Superfund enforcement activities and supports any resulting litigation.
  - Carries out the Region's Superfund financial assurance program to ensure PRPs maintain the finances for completing the cleanup work for which they are responsible.
  - Prepares Cost Report Packages in support of a wide range Superfund Cost Recovery activities, and support R3's Finance Office in the preparation of periodic bills issued to PRPs to recoup EPA's costs to oversee PRP cleanups at sites.
  - Administers the Region's utilization of site-specific special accounts for the performance and payment of site-specific cleanup activities.

*Technical Support Branch*

The Technical Support Branch provides authoritative scientific expertise and support on all matters pertaining to toxicology, human and ecological health risk assessment, and groundwater hydrology activities for characterizing the nature and extent of Superfund Sites and determining

appropriate response actions. The staff in the Branch perform technical reviews of a range of documents including remedial investigations, feasibility studies, records of decisions, remedial designs, site specific quality documents and five-year reviews. The Branch is responsible for SEMD's QA implementation and oversight and coordinates SEMD activities in relation to the regional laboratory. The two sections are the Hydrologic Support Section and the Risk Assessment Section.

- Hydrologic Support Section
  - Ensure groundwater is adequately characterized and sampled;
  - Ensure selected groundwater remedial technologies will be protective of human health and the environment;
  - Evaluate technologies including field sampling and analysis and management (treatment and containment) of contaminated soil and groundwater;
  - Provides advice on post construction management activities including technical assistance for 5-year review cycles and long-term remedy optimization efforts;
  - Ensures that projects adhere to all Superfund groundwater guidance and best management practices.

- Risk Assessment Section
  - Review and oversight in the development of specific site documents, ensuring data collected and used will meet QA requirements especially in the development of risk assessments;
  - Review and develop human health and ecological risk assessments;
  - Provides and coordinates appropriate technical training and presentations in support of Division programs;
  - Communicate with natural resource trustees, including the National Oceanic and Atmospheric Administration (NOAA) and the United States Fish and Wildlife Service (USFWS), and coordinates with public health agencies including the Center for Disease Control (CDC).

*SEMD DPMs*

SEMD's DPMs (i.e., RPMs, OSCs, or SAMs) ensure that site-specific QAPPs for remedial projects or FSPs for removal or site assessment projects are submitted by the EPA contractor or responsible party. The DPM is responsible for reviewing the document to ensure its appropriateness for the site work and submits the document for review as outlined in QMP Section D.2. Once reviewed and approved, the DPM has the responsibility of ensuring that site activities adhere to the approved plan and that the plan is revised as needed.

*SEMD Project & Program QAPPs*

In SEMD project specific QAPPs are used in the remedial process. The removal and site assessment programs both use QAPrPs with site specific FSPs at the project level.

*SEMD QAPP Preparation*

The Superfund Remedial Program's Remedial Action Framework (RAF), which is comprised of the Remediation Environmental Services (RES), Design and Engineering Services (DES) and Environmental Services and Operations (ESO) contracts each require the use of a UFP-QAPP, per their perspective Statements of Work, which all state:

Uniform Federal Policy Quality Assurance Project Plan (UFP-QAPP). A UFP-QAPP is a formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A UFP-QAPP integrates technical and quality control aspects of a project throughout its life cycle, including planning, implementation, assessment, and corrective actions. The UFP-QAPP will provide:

- Data quality objectives (DQO) that specify the data needed to support decisions regarding remedial response activities.
- Field sampling plan (FSP) that describes the number, type, and locations of samples and types of analyses.

*SEMD Procurement – Contracts*

A QARF is submitted each time a new Task Order is initiated under the Remedial Action Framework (RAF). QARF forms for each contracting suite are located on the Remedial Action Framework (RAF) SharePoint Site: RAF SharePoint. The form is completed by the DPM (i.e., Task Order Contracting Officer Representative (TOCOR)/ RPM for the site) and submitted to the RQAM for review and approval. If no quality related documents will be generated, then the form must be submitted to OLEM's Office of Superfund Remediation and Technology Innovation's (OSRTI) QAM for review and approval.

*SEMD Documentation & Records Management*

The Superfund program does not currently use the Enterprise Content Management System. The Superfund Enterprise Management System – Records Management (SEMS-RM) is currently the System of Record for Superfund records. Superfund is excluded for the EPA Capstone email retention requirements until a method can be added to SEMS-RM to automate the process of retaining email records. Until SEMS-RM is updated with the email-connector, Superfund email records should be submitted to the CERCLA Records Center in the same manner as all other site records for inclusion in SEMS-RM.

# Appendix 15 Water Division (WD)

A general description of the WD's functions, including QA-related information, is provided below. QA documents and resources are listed in Table 15.1. More details are provided at:
Internet site- https://www.epa.gov/aboutepa/organization-epas-region-3-office-philadelphia#wd
Intranet site- https://intranet.epa.gov/r3intran/wpd/

To carry out its mission, WD works with other federal agencies, state and local agencies, tribal governments, the public, and the private sector. WD coordinates with the Office of Water to ensure national consistency and strives to meet legal deadlines imposed by the CWA and SDWA.

Environmental data and information programs under the following statutes include:

- **Safe Drinking Water Act**: Public Water System Supervision Program; Sole Source Aquifer Program; Source Water Protection Program; Underground Injection Control Program; and Wellhead Protection Program.

- **Clean Water Act**: Ambient water monitoring (routine monitoring performed mostly through the states); Beaches; Clean Lakes Program; Dredging; Great Lakes Program; National Estuary Program; NPDES Program; Non-point Source (Section 319) Grants Program; Nutrient Criteria Program; Water Quality Management Planning (Section 604(b)) Grants Program; State Revolving Fund Program; Targeted Watershed Initiative; Integrated Reporting and TMDL Programs (Section 305(b) and 303(d)); Water Pollution Control (Surface/Groundwater Programs) (Section 106) Grants Program; Water Quality Management (Section 106) Grants Program; Water Quality Standards Program; Watershed Protection Program; and Wetlands (Section 404) permit review and grants (Section 104(b)(3)) .

*Immediate Office*

The Immediate Office of the Division Director has overall program management, strategic planning, budgeting, communications responsibilities, and coordination and support for the Chesapeake Bay Program.

WD has the following four branches: Wetlands, Drinking Water & Source Water Protection, State Assistance & Partnerships, and Clean Water.

*Wetlands Branch*

The Wetlands Branch (WB) is responsible for the implementation of the CWA Section 404 program and the Marine Protection, Research, and Sanctuaries Act (MPRSA). WB also supports NEPA projects, participates with the CBP watershed efforts, leads R3's efforts on Waters of the U.S. (WOTUS), and provides technical expertise and training in wetlands assessment and identification. Some other WB responsibilities include:

- Permit Review - technical review and comments for projects proposing impacts to aquatic resources for authorization under Section 404.
- Participation on Interagency Review Teams (IRT) – technical review and comment of proposed mitigation banks and in-lieu fee programs/projects.

- Watershed Resources Registry (WRR) leadership– convene regular webinars or meetings with state and federal partners; assist in the development of new data sources and website tools and promote the development and use of the registry nationally.
- MPRSA and Ocean Disposal programs – Evaluate the suitability of dredged material disposal in ocean locations, Burial at Sea, assist with dredged material analysis and Ocean survey.
- Enhancing State and Tribal Programs (ESTP)- Competes, awards, and monitors wetland program development grants (WPDG); approves state and tribal wetland program plans (WPP); provides state and tribal technical support through the Mid-Atlantic Wetland Workgroup (MAWWG); and supports the National Wetland Condition Assessment (NCWA) activities in R3.
- Review jurisdictional determinations (JDs) – provide comments when JDs are coordinated.
- Assessment and mitigation - participate in efforts with our State and Federal Partners to develop and use aquatic resource assessment in the protection and restoration of R3's water resources.

*Drinking Water & Source Water Protection Branch*

Drinking Water Section

The Drinking Water Section (DWS) oversees and provides financial assistance to the delegated states for the implementation of the Public Water System Supervision Program (PWSS) and activities funded by the Drinking Water State Revolving Funds (DWSRF) Set-Asides (2%, 10%, and 15%) in accordance with the requirements under SDWA.

DWS also directly implements the PWSS for DC. PWSS and DWSRF set-asides help states establish necessary programs (e.g., sanitary survey, enforcement, data reporting, technical assistance, laboratory certification, rule adoption, capacity development, source water protection) to ensure their public water systems provide safe drinking water to the citizens. As part of grant conditions, the states must have R3 approved QMPs for the PWSS and the QMP must be renewed every five years. DWS assists states with their QMP renewal and submission of complete documents in accordance with this QMP. DWS also develops and implements a drinking water security program, oversees state training and certification programs for operators of water systems, provides training for primacy agencies and drinking water systems, and develops and maintains sampling SOPs for drinking water.

DWS's functions related to QA include reviewing compliance data submitted by DC public water systems. DWS also maintains sampling equipment and sampling SOPs for common drinking water parameters. DWS and its contractors also collect water samples for laboratory analysis or field measurements of water quality parameters.

Source Water & UIC Section

The Source Water & UIC Section administers the source water protection and well head protection programs; conducts oversight of Underground Injection Control program in states that have delegated authority; and directly implements UIC program in DC, PA and VA.

*State Assistance & Partnerships Branch*

State & Watershed Partnerships Section

The State & Watershed Partnerships Section covers multiple programs that work with States and Basin Commissions towards improved waterways. These include the CWA grant programs such as Section 106, 319, and 604(b), the Mid-Atlantic National Estuary Program, Urban Waters Programs, and Green Infrastructure. Relative to the CWA, staff serve as POs and are responsible for administering and overseeing the grants to state agency grantees. Grantees implementing environmental programs including: 1) direct measurement, sampling or observation activities, 2) environmental modeling, 3) use of existing data, 4) use of survey results, or 5) calculation of environmental outcomes must prepare and implement a QMP and submit it to the PO within 45 days of receipt of the grant agreement. The PO submits the document for review as outlined in QMP section D.2. Likewise, grantees implementing environmental projects including: 1) direct measurement, sampling or observation activities, 2) environmental modeling, 3) use of existing data, 4) use of survey results, or 5) calculation of environmental outcomes must also prepare and implement a QAPP in accordance with this QMP.

Infrastructure & Assistance Section

The Infrastructure & Assistance Section oversees implementation of the Clean Water Revolving Fund and Drinking Water State Revolving Fund programs; oversees all grants management in WD; and implements programs to sustain federal investment, including energy audits, technical assistance, training, and optimization of water and wastewater utilities.

*Clean Water Branch*

The Clean Water Branch conducts oversight of the CWA where delegated, and directly implements the CWA where not delegated or authorized.

Permits Section

The Permits Section conducts oversight to states on NPDES permits where delegated; conducts audits and reviews of NPDES permit programs; directly implements NPDES permitting programs in DC; and directly implements the NPDES pre-treatment program in PA.

Standards & TMDLs Section

The Standards and TMDLs Section (STS) conducts oversight of water quality standards programs and criteria development, the TMDL program, and the 305(b) and 303(d) Integrated Reporting programs; develops guidelines and procedures for water quality monitoring and assessment; and administers the Beach Act.

STS reviews and analyzes primary and secondary data for use in: TMDL projects designed for a specific waterbody and impairment, biological evaluations as related to EPA's approval of state water quality standard submittals, integrated reporting processes in which states analyze and report all water quality data and the resulting water quality status of waters across the state, review of state submitted water quality standards, etc. STS often collects, reviews, and analyzes environmental data to determine if a water quality impairment exists that impacts applicable designated uses. These data should be

associated with QAPPs and STS will examine the QAPPs, SOPs, and other relevant QA documentation to determine if the data is appropriate for STS purposes. In many cases, data are collected using an EPA-approved or equivalent method and accompanied by detailed documentation of the associated data collection methods. Each state has developed data tier and data acceptance approaches and STS will consult state staff when utilizing data for STS functions in an effort to maintain data integrity and consistency with state methods and EPA guidance, as appropriate. Sources of environmental data include EPA's water quality exchange network, the Assessment, TMDL Tracking and Implementation System (ATTAINS), state monitoring and assessment programs, local municipality environmental programs, non-profit environmental organizations, and NPDES permittees.

**Table 15.1. QA documents & resources for WD**

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| STS | Guidance | Guidance for Quality Assurance Project Plans for Water Quality Modeling Projects. December 2016. EPA Region 10. Seattle, Washington. | https://www.epa.gov/guidance/guidance-quality-assurance-project-plans-water-quality-modeling-projects |
| STS | Guidance | Guidance for Quality Assurance Project Plans for Modeling. December 2002. EPA HQ. Washington, D.C. | https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf |
| STS | Guidance | User Guide for Water Quality Exchange Web. EPA. | https://www.epa.gov/waterdata/user-guide-version-210-water-quality-exchange-web |
| STS | Guidance | Best Practices for Submitting Nutrient Data to the Water Quality Exchange (WQX). June 2017. EPA. | https://www.epa.gov/sites/production/files/2017-06/documents/wqx_nutrient_best_practices_guide.pdf |
| STS | Guidance | Best Practices for Submitting Metals Data to the Water Quality Exchange (WQX). June 2018. EPA. | https://www.epa.gov/sites/production/files/2018-06/documents/wqx_metals_best_practices_guide_6_27_18.pdf |
| STS | Guidance | Water Quality Exchange Flow Configuration Document. October 2015. EPA. | https://www.exchangenetwork.net/schema/WQX/2/WQX_FCD_v2.1c.pdf |
| STS | Guidance | Water Quality Portal User Guide. EPA. | https://www.waterqualitydata.us/portal_userguide/ |
| STS | Guidance | Guidance for Water Quality-based Decisions: The TMDL Process. April 1991. EPA. | https://nepis.epa.gov/Exe/ZyPDF.cgi/00001KIO.PDF?Dockey=00001KIO.PDF |
| STS | Guidance | Guidelines for Reviewing TMDLs under Existing Regulations issued in 1992. May 2002. EPA. | https://www.epa.gov/sites/production/files/2015-10/documents/2002_06_04_tmdl_guidance_final52002.pdf |
| STS | Guidance | Using Microbial Source Tracking to Support TMDL Development and Implementation. April 2011. EPA. | https://www.epa.gov/sites/production/files/2015-07/documents/mst_for_tmdls_guide_04_22_11.pdf |
| STS | Guidance | Stressor Identification Guidance. December 2000. EPA. | https://nepis.epa.gov/Exe/ZyPDF.cgi/20003F6L.PDF?Dockey=20003F6L.PDF |

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| STS | Guidance | Compendium of Tools for Watershed Assessment and TMDL Development. May 1997. EPA. | https://nepis.epa.gov/Exe/ZyPDF.cgi/20004NX4.PDF?Dockey=20004NX4.PDF |
| STS | Guidance | Integrated Water Quality Monitoring and Assessment Report Guidance. November 2001. EPA. | https://www.epa.gov/sites/production/files/2015-10/documents/2002_02_13_tmdl_2002wqma.pdf |
| STS | Guidance | Guidance for 2006 Assessment, Listing and Reporting Requirements Pursuant to Sections 303(d), 305(b) and 314 of the Clean Water Act. July 2005. EPA. | https://www.epa.gov/sites/production/files/2015-10/documents/2006irg-report.pdf |
| STS | Template | TMDL Decision Rationale Template. | "DR Template_09182019.docx". M:\TMDL\Administrative\GUIDANCE\standard operating procedure. |
| STS | SOP | Drinking Water Sampling SOP, April 2019 | https://usepa.sharepoint.com/:b:/r/sites/R3/DWB/Shared%20Documents/Lab%20Sampling%20Team/FINAL_DW%20sampling%20SOP%20R3WD001-20190430.pdf?csf=1&e=5b4ACN |
| STS | Regulation | Drinking Water State Revolving Fund Program Rule (Federal Register August 2000) | http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=fr07au00-19 |
| STS | Guidance | Final Drinking Water State Revolving Fund Guidelines (Federal Register February 1997) | http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid=fr05no98-113 |
| STS | Guidance | State Implementation Guidance for the Arsenic Rule (EPA, 2002): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1009V6R.txt |
| STS | Guidance | Lead and Copper Rule 2007 Short-Term Regulatory Revisions and Clarifications State Implementation Guidance (EPA 816-R-08-009): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=60001IKR.txt |
| STS | Guidance | State Implementation Guidance for the Lead and Copper Rule Minor Revisions (EPA 816-R-01-021, October 2001): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=901R0100.txt |
| STS | Guidance | Final Implementation Guidance for Radionuclides (March 2002, EPA 816-F-00-002): | https://www.epa.gov/sites/production/files/2015-09/documents/2009_04_16_radionuclides_guide_radionuclides_stateimplementation.pdf |
| STS | Guidance | The Ground Water Rule Implementation Guidance (EPA 816-R-09-004, January 2009): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1004S1V.txt |
| STS | Guidance | Implementation Guidance for the Stage 1Disinfectants/ Disinfection Byproducts Rule ( EPA 816-R-01-012, June 2001): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000258D.txt |
| STS | Guidance | Primacy Agency Data Entry Instructions, with Examples, For Stage 1 Disinfectants and Disinfection Byproducts Rule (EPA 816-R-02-012, January 2003): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100A2EK.txt |
| STS | Guidance | Implementation Guidance for the Stage 2 Disinfectants/ Disinfection Byproducts Rule (EPA 816-R-07-007, August 2007): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=60000HO2.txt |

| Branch | Resource Type | Title | Location |
|---|---|---|---|
| STS | Guidance | Interim Enhanced Surface Water Treatment Rule Implementation Guidance (EPA 816-R-01-011): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000252R.txt |
| STS | Guidance | Long Term 1 Enhanced Surface Water Treatment Rule Implementation Guidance (EPA 816-R-04-008): | http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=30005XIJ.txt |
| STS | Guidance | Long Term 2 Enhanced Surface Water Treatment Rule Implementation Guidance (EPA 816-R07-006): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=60000HAI.txt |
| STS | Guidance | Implementation Guidance for the Filter Backwash Recycling Rule: | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=30005ZOZ.txt |
| STS | Guidance | Revised Total Coliform Rule Implementation Guidance (December 2014, EPA 816-R-14-004): | https://www.epa.gov/sites/production/files/2015-10/documents/rtcrimplementation_guidance.pdf |
| STS | Guidance | State Implementation Guidance for the CCR Rule (EPA 816-R-09-010, April 2010): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1008MWD.txt |
| STS | Guidance | Revised State Implementation Guidance for the Public Notification Rule (EPA 816-R-09-012, March 2010): | http://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1006RJ8.txt |
| WB | Guidance | Wetlands: Enhancing State and Tribal Program (ESTP) | https://www.epa.gov/wetlands/what-enhancing-state-and-tribal-programs-initiative |
| WB | Guidance | Wetlands-Core Element Framework (CEF): Monitoring and Assessment (EPA-2015) | https://www.epa.gov/sites/production/files/2015-09/documents/monitoring_and_assessment_cef.pdf |
| WB | Guidance | Wetlands-CEF: Regulation (EPA-2015) | https://www.epa.gov/sites/production/files/2015-09/documents/regulation_cef.pdf |
| WB | Guidance | Wetlands-CEF: Voluntary Restoration and Protection | https://www.epa.gov/sites/production/files/2015-09/documents/regulation_cef.pdf |
| WB | Guidance | Wetlands-CEF: Water Quality Standards for Wetlands | https://www.epa.gov/wetlands/wetland-water-quality-standards |
| WB | Guidance | Nutrient Criteria Technical Guidance Manual: Wetlands | https://www.epa.gov/nutrient-policy-data/criteria-development-guidance-wetlands |
| WB | Guidance | Application of Elements of a State Water Monitoring and Assessment Program for Wetlands (EPA, April 2006) | https://www.epa.gov/wetlands#elements |
| WB | Manuals | National Wetland Condition Assessment (Field, Lab manuals and Quality Assurance Project Plan, Site Evaluation Guidelines, 2016) | https://www.epa.gov/national-aquatic-resource-surveys/nwca |