QUALITY MANAGEMENT PLAN

for the

OHIO RIVER VALLEY

WATER SANITATION COMMISSION

February 23, 2015

Prepared by:

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COMMISSION APPROVAL

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Peter A. Tennant

Quality Assurance Officer_____ Date:_____
Lila Xepoleas Ziolkowski

USEPA APPROVAL

Tinka Hyde_____ Date:_____
USEPA Director, Water Division Region 5

Andrew Tschampa _____ Date:_____
Quality Assurance Manager, Water Division, Region 5

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Region V Quality Assurance Manager, Andrew Tschampa has conditionally approved ORSANCO's Quality Management Plan (v.2.1), originally submitted and approved by Terry Simpson USEPA Region III Quality Assurance Manager offices on May 26, 2010. This QMP is valid until June 15, 2015 under Region III.

Minor issues with QMP (v.2.1) are being addressed to satisfy USEPA Region V conditional approval. Conditional approval of v.2.1 of ORSANCO's Quality Management Plan allows for full review and consideration by USEPA Region V Quality Assurance Managers and staff since USEPA oversight for ORSANCO has been transferred from Region III to Region V for Grant Administration purposes.

Prior to June 15, 2015, an updated and revised Quality Management Plan will be submitted to USEPA Region V for review and approval in accordance with 106 Grant requirements.

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QUALITY MANAGEMENT PLAN BACKGROUND

A structured system that describes the policies and procedures for ensuring that work processes, products or services satisfy stated expectations or specifications is called a **Quality System.** All organizations conducting environmental programs funded by EPA are required t o establish and implement a quality system.

EPA order 5360.1 A2 describes the mandatory quality system that applies to all EPA organizations and any non-EPA organizations funded by EPA through contracts, assistance agreements, grants or interagency agreements. Non-EPA organizations and Agencies are required to document their quality system in a **Quality Management Plan** as stated in:

48 CFR 46, (for contractors)
40 CFR 30, 31, and 35 (for assistance agreement recipients and grants);
other mechanisms such as consent agreements in enforcement actions

The U.S. Environmental Protection Agency (USEPA) has developed the Quality Management Plan (QMP) as a means of documenting how an organization will plan, implement and assess the effectiveness of its quality assurance and quality control operations as applied to environmental programs. This plan requires all organizations performing work for EPA to develop and operate management processes and structures for assuring that data or information collected are of needed and expected quality for their desired use.

The Quality Management Plan described herein has been developed for the Ohio River Valley Water Sanitation Commission and is in accordance to the requirements outlined in the March 2001 edition of **EPA QA/R-2: *EPA Requirements for Quality Management Plans***.

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ORSANCO QUALITY MANAGEMENT PLAN

1.0 COMMISSION BACKGROUND AND MISSION

1.1 Commission Background

The Ohio River Valley Water Sanitation Commission is an interstate water pollution control organization created in 1948 by the signing of a Compact by the states of Illinois, Indiana, Kentucky, New York, Ohio, Pennsylvania, Virginia, and West Virginia with the approval of the United States government. The Commission is made up of three representatives from each state, appointed by their respective Governors, and three representatives of the U.S. government who are appointed by the President. The Commission is headquartered in Cincinnati, Ohio where a small staff (currently 23 persons) is involved with a number of programs and special projects that includes monitoring and assessment of the water quality of the Ohio River and its tributaries.

1.2 Mission Statement

The mission of the Ohio River Valley Water Sanitation Commission (ORSANCO) is to coordinate and supplement efforts of the signatory states and to take whatever action that is within its authority to place and maintain the interstate waters of the Ohio River Basin in a condition that is satisfactory for use as a source of public and industrial water supplies, suitable for recreational and agricultural usage, favorable for maintaining fish and other aquatic life, free from unsightly or malodorous nuisances due to floating solids, debris or sludge deposits, and is acceptable for other beneficial uses.

2.0 QUALITY SYSTEM MANAGEMENT AND AGENCY ORGANIZATION

2.1 Quality System Management Goals and Objectives

The Commission's Quality Management Plan describes policies required for carrying out Quality Assurance and Quality Control measures as well as providing a framework for program planning, implementation, documentation, assessment, and improvement. The QMP is a written record that serves to document the Commission's quality system and assess the effectiveness of activities that support environmental monitoring programs.

2.2 Commission's Statement of Policy on Quality Assurance

The Commission's "Statement of Policies" provides guidance in maintaining the articles of the Compact. As stated in policy Item 8:

"…In all data collection activities, it is the Commission' s intent to provide procedures that ensure the highest level of quality assurance that is appropriate to the intended use of the data..."

Therefore, in accord with Item 8, for activities resulting in the generation and collection of environmental data and information, ORSANCO will establish and implement written procedures and protocols that meet quality assurance objectives and are appropriate for the intended use of data. Furthermore, acquired data and information shall be found to be scientifically valid, legally defensible, and an accurate and true representation of river conditions at that point in time.

2.2.1 All programs and projects supported by a federal grant under Section 106 of the Clean Water Act will have a Quality Assurance Program Plan (QAPP) and other essential, related documents developed and implemented per ORSANCO's Quality Management Plan.

2.2.2 Likewise, other monitoring programs and projects undertaken by the Commission, and unsupported by 106 federal grant monies, shall have a QAPP and other related documents developed.

2.3 Maintaining Quality System Integrity

The integrity of ORSANCO's quality system is maintained throughout each phase of a program and/or project, from planning, implementation, data analysis and review, to final report and publication, storage, retrieval, and archiving.

2.3.1 Data or information generated or gathered from the use of EPA funds is subject to requirements in accordance with EPA order 5360.1 A2 or other applicable federal regulations as cited in 48 CFR 46 and 40 CFR 30, 31, and 35. This includes all EPA 106 programs and special projects under the Clean Water Act.

2.3.2 Data generated or gathered without benefit of EPA funds is not subject to requirements under EPA order 5360.1 A2 or related subsequent federal regulations, and, therefore, may have different QA/QC parameters. However, all activities that relate to the collection, generation or assessment of data from such programs and projects is subject to the same standard and level of quality assurance as is outlined in Item 8 of the Commission's Statement of Policies. Data and information from such programs/projects shall be maintained separately and independently from EPA funded 106 projects and programs.

2.3.3 Any products, services, or other deliverables provided to the EPA or an EPA designated recipient that were developed using EPA funds will adhere to the protocols outlined in the Quality Management Plan and its supporting documents.

2.3.4 QA/QC activities shall be carried out in a cost effective manner, but not so as to compromise the integrity of the Quality System or the reliability of information and data collected.

2.3.5 All personnel involved in EPA funded programs and projects will receive proper training to adequately perform assigned duties and tasks and will adhere to the requirements and specifications in the program QAPP and QMP.

2.3.6 All programs that use a third party for sample collection, processing, or interpretation of data will stipulate, in writing, to said party, all applicable QA/QC requirements from the Commission's Quality System.

2.3.7 Similarly, any program(s) or activities that accept externally generated environmental data shall ensure that the party supplying the data has followed the Commission's quality management practices.

2.3.9 An ongoing system of evaluation of the Commission's Quality System and QA efforts will be done by the QAO to ensure that the Quality System is meeting the needs and expectations of data users and that Quality System goals and objectives are met.

2.3.10 Acquisition of goods and services for EPA funded programs will be in accordance with ORSANCO's Procurement Procedures. When possible, MBE/WBE vendors will be utilized. Procurement procedure guidelines are available from the Commission's Comptroller or Director of Administrative Programs.

2.4 Importance of QA/QC to the Commission

Pollution control and abatement to improve the quality of surface water of the Ohio River and tributaries for over 20 million residents in the Ohio River Valley Basin is the cornerstone of our Agency's mission. Decisions made by the Commission and its member state and federal counterparts depend heavily on the caliber of the information used, so it is imperative that data and information collected accurately characterize the conditions of the river at that point in time. Valid data and information is achieved when an active Quality Assurance and Quality Control program is an integral part of Commission programs and projects.

2.5 Resource Allocation

Funds, resources and personnel are allocated for the Quality Assurance/Quality Control Program within the organization. This program operates independently and without influence from any other programs, projects and data generating activities. The QA/QC Program functions to verify that quality assurance goals are met and maintained and is involved in all aspects of a monitoring program, from planning and development, implementation, data validation and use, publication, and data storage.

2.5.1 Quality assurance (QA) practices and quality control (QC) procedures are carried out in a cost-effective manner without compromise to data quality objectives and goals.

2.6 Organizational Structure

The structural hierarchy of the Commission and of the Commission Staff is depicted in Organizational Charts. These Charts can be found as Figures 1 and 2 of the Appendix.

2.7 Description of Commission Structure

The Ohio River Valley Water Sanitation Commission operates through five types of committees as described below:

2.7.1 Standing Committees are comprised entirely of Commissioners and/or their designees; they are the means through which the Commission maintains oversight of the organization's operations. Standing Committees also communicate and coordinate with state and federal environmental agencies as needed.

2.7.2 Technical Committee (TEC) membership consists of representatives from each states' environmental department, US Army Corp of Engineers, US Coast Guard, US EPA, and US Geological Survey. A single Commissioner serves as the Committee Chair by nomination. In addition, the Deputy Director resides as staff liaison to the committee. TEC provides the Commission with advice and counsel from the perspective of the state and national government.

2.7.2.1 Subcommittees are standing committees developed to address specific areas of concern and to bring specific issues to the Technical Committee. Subcommittee members are state agency personnel and are usually appointed or directly under their state's Technical Committee member.

2.7.2.2 Workgroups also address specific areas of concern and bring issues to the Technical Committee, but workgroup members can be personnel from sources outside state agencies and are often interested parties from industry or related companies.

2.7.3 Special Committees are appointed on an ad hoc basis to address particular concerns or issues; membership may include Commissioners and other individuals as appropriate.

2.7.4 Program Advisory Committees function to oversee specific commission programs where coordination with certain entities is required. Membership usually includes one or more Commissioners plus representatives of the entities involved.

2.7.5 Advisory Committees are made up of representatives from specific river-related interests. They provide advice and counsel the Commission from the perspective of the interests they represent.

2.7.5.1 Water Users (potable water facilities)
2.7.5.2 Public Interest
2.7.5.3 Publicly Owned Treatment Works
2.7.5.4 Power Industry
2.7.5.5 Chemical Industry

All committees report to the Commission. Committees, subcommittees, work groups or task groups are not authorized to act or to speak on behalf of the Commission unless directed to.

2.8 Commission Staff Positions

Commission staff are responsible for carrying out day to day operations of the Commission, as well as, developing and implementing monitoring programs,, conducting research projects, promoting education and awareness, and resolving inter- and intra-state issues.

Current Commission staff holds the following positions, as depicted on the Commission Staff Organizational Chart (figure 2, Appendix). Job descriptions are provided electronically within ORSANCO's Intranet Human Resources webpage (staff and Commissioner access only) and with the Director of Human Resources and Administrative Programs. ORSANCO's website, provides general roles and responsibilities of current staff members at www.orsanco.org/about us/staff.

2.8.1 Executive Director and Chief Engineer
2.8.2 Deputy Executive Director
2.8.3 Director of Administration & Human Resources
2.8.4 Quality Assurance Officer (QAO)
2.8.5 Manager of Technical Programs
2.8.6 Manager of Source Water Protection & Emergency Response
2.8.7 Manager of Biological Programs
2.8.8 Manager of Water Resources Assessment
2.8.9 Manager of Public Information
2.8.10 Analytical Chemist/Environmental Chemist
2.8.11 Environmental Specialist (ODS)
2.8.12 Environmental Specialist
2.8.13 Senior Biologist
2.8.14 Aquatic Biologist
2.8.15 Public Information Specialist
2.8.16 Comptroller/Grants Administrator
2.8.17 Computer Systems Administrator

2.8.18 Data Processing Specialist
2.8.19 Administrative Assistant
2.8.20 Maintenance and Facilities Specialist

2.9 Quality Assurance/Quality Control Management

The Deputy Executive Director has overall responsibility for the implementation of US EPA's quality assurance requirements. QA/QC responsibilities of Technical Staff are listed below:

2.9.1 Quality Assurance Officer (QAO): The QAO is a full time position with the Commission and is an independent yet integral component of all Commission programs and projects. The QAO is a supervisory/programmatic role under administrative management.

2.9.1.1 The QAO is one of the staff managers and is under the direct supervision of the Deputy Executive Director. The QAO reports directly to the Deputy Executive Director and/or the Executive Director.

2.9.1.2 The QAO is the official contact for all Commission quality assurance matters and coordinates Commission activities with the USEPA or other state and federal agencies.

2.9.1.3 Authority and responsibility for administering quality assurance activities within the Commission are delegated to the Quality Assurance Officer and includes all areas covered in the Quality Management Plan.

2.9.1.4 The QAO will provide technical assistance as necessary and work with technical program and project managers in preparation of QMP supporting documents, such as the Quality Assurance Program Plan, (QAPP) and Standard Operating Procedures (SOP's). Assistance with grants, contracts, extramural procurement packages, contractual laboratory services and development of QA protocols for new programs and projects is also within the purview of the Quality Assurance Officer.

2.9.1.5 Annually, SOP's, QAPP's and other QMP supporting documents should be reviewed and approved by the QAO.

2.9.1.6 Submission of an updated and current copy of the Commission Quality Management Plan to USEPA annually (or as necessary) is the responsibility of the

QAO; likewise, it is the responsibility of the QAO to provide the Commission with a current, updated, USEPA approved Quality Management Plan annually.

2.9.1.7 The QAO works with Technical Program Managers to ensure that all technical staff/field personnel are adequately trained and capable of performing duties related to safety, sample preparation, collection, analyses, data entry and peer review for the intended program/project in accordance with SOP and QAPP guidelines. Any review and training procedures are documented and retained by Technical Manager and are audited by the QAO.

2.9.1.8 The QAO conducts Field Performance Audits on programs and project to assure that data integrity is maintained and records are up to date. These audits are performed in areas such as: field reconnaissance, sampling, data assessment, and analytical activities, whether these are performed in-house or through contractual services.

2.9.1.10 The QAO works with Technical Managers and other Commission staff to take appropriate corrective actions when necessary. All corrective action measures shouldbe documented and approved by the QAO. There may be instances where a follow up audit is necessary to verify and document that a situation has been remedied.

2.9.1.11 The Quality Assurance Officer will prepare for the Commission, three quarterly and one Annual QA Summary Report, describing Commission Quality Assurance activities and accomplishments.

2.9.2 Technical Program or Project Managers (also referred to as Program Manager or Technical Manager) coordinate with the QAO on quality assurance requirements to satisfy data quality needs of the program/project.

2.9.2.1 A Program Manager defines the intended uses of data for a particular program or project prior to any field sampling and data generation events. The Program Manager identifies the DQO's.

2.9.2.2 The Program Manager is responsible developing and annually reviewing and updating the program/project QAPP. All QAPP's are forwarded to the QAO for review and approval.

2.9.2.3 The Program Manager ensures that SOP's are written, revised as necessary, and current. The PM will include all aspects of a monitoring program, including, instrument setup and calibration, field reconnaissance, sampling techniques, outsourcing analyses, safety, data generation, and the like. All necessary QA/QC needed to satisfy program requirements must be included in an SOP.

2.9.2.4 The responsibility for ensuring all field staff receive adequate training in safety and sampling procedures and are knowledgeable in the program and project goals lies with the Program Manager. Any training provided should be thoroughly documented.

2.9.2.5 With concurrence of the QAO, a Technical manager performs audits to verify that SOP procedures are followed and data quality objectives are being met. The Program Manager reports any failures to the QAO and appropriate corrective action measures undertaken.

2.9.2.6 It is the responsibility of a Technical Program Manager to review QA/QC protocols undertaken for all contracted services used within the program. Any failures in QA/QC protocols are reported to the QAO and appropriate corrective action measures are undertaken.

2.9.2.7 Data collected and generated will be evaluated and validated by the program manager. All data shall be reviewed to verify that DQO's have been met as stated in the Program QAPP.

2.9.2.8 Data entered into a database or publication is verified by the Technical Manager to be an accurate true reflection of conditions at that point in time.

2.9.2.9 For purchases of goods and services related to a specific program or project, the designated Program Manager will verify that these items are a necessary component needed to accomplish program goals and tasks and that product specifications adequately meet data quality objectives stipulated.

2.9.2.10 The Technical Manager is responsible for operating within the designated budget for the program and will approve and sign all purchase orders relating to specified program.

2.9.3 Project Leaders/Project Coordinators oversee a specific project and have similar responsibilities of managing the project as those of a program manager; however, they usually work directly under the supervision of a

program manager and have the ability to carry out QA functions within the specified project.

2.9.4 Field Monitoring Personnel & Technical Staff Field Monitoring Personnel and other technical staff work under the supervision of a Program Manager or Project Coordinator and are an essential part of a program, performing assigned tasks necessary for successful for data acquisition and executing the protocols detailed in the Program SOP.

2.9.4.1 Each person involved with an EPA funded monitoring program is responsible for being familiar with the most current edition of an approved Program SOP, for adhering to procedures outlined in said SOP, and for maintaining all QA/QC requirements.

2.9.4.2 Each person will be trained in accordance with approved SOPs to maintain uniformity, consistency and reproducibility for all monitoring events and between individual field personnel. Field personnel will be trained in the following areas: Commission and specific program QA/QC policies, Program Operating Procedures, instrument & equipment setup, repair and maintenance, and safety.

2.9.4.3 Each person should report any deviations from established protocols to their immediate supervisor to determine if corrective actions to protocols and procedures are in order.

2.9.4.4 Field personnel are responsible for properly preparing, and, if necessary, transporting samples for to a contract laboratory for further analysis.

2.10 Applicability of QMP to CWA Section 106 grant Technical Programs

The Commission's Quality System applies to all technical programs and projects involving reconnaissance, collection, evaluation, and use of environmental data for characterization, investigation, demonstration and/or publication. The Quality Management Plan functions to verify that quality assurance goals are met and maintained; it is involved in all phases of a monitoring program.

Quality Assurance is an integral part of every program and activity within the Commission. The level of QA resources needed for any given program or project is initially determined by the Program Manager with input from the Quality Assurance Officer. When QA parameters are determined for a particular program, they are included in the QAPP for that particular program.

2.10.1 Water Pollution Control Programs of the Commission are developed and designed to carry out the Ohio River Valley Water Sanitation Commission Compact, the Commission's Strategic Plan and directives of the member

states. These programs are funded by the States' contributions and by a federal grant pursuant to Section 106 of the Clean Water Act.

2.10.2 Below are current programs to which Section 106 grant monies are applied:

2.10.2.1 Public Information and Education
2.10.2.2 Water Quality Monitoring
2.10.2.3 Macroinvertebrate Sampling
2.10.2.4 Fish Population Studies
2.10.2.5 Fish Tissue Analysis for Contaminants
2.10.2.6 Monitoring Strategy Development
2.10.2.7 Integrated Monitoring for Aquatic Life Use
2.10.2.8 USGS Comparison Study
2.10.2.9 Bacterial Monitoring
2.10.2.10 Watershed Protection
2.10.2.11 TMDLs for PCB's Dioxin and Pathogens
2.10.2.12 Pollution Control Standards Development and Administration
2.10.2.13 Work Groups Development
2.10.2.14 Source Water Assessment and Protection
2.10.2.15 Water Quality Data Assessment & Distribution
2.10.2.16 Bi-Monthly Sampling
2.10.2.17 Dissolved/Clean Metals Analyses
2.10.2.18 Quality Assurance & Quality Control

Detailed descriptions of listed Programs are located on the Commission's website.

2.10.3 Special Projects include all Commission activities funded by sources other than the combination of states' contributions and federal water pollution control grants. Funding sources for special projects may include grants from state and federal agencies, penalties directed to the Commission by states from enforcement settlements and contributions from industry.

2.11 Communication

The Quality Assurance Officer reports to the Deputy Executive Director and the Executive Director and provides information regarding quality system status. This ensures that QA programs are effectively coordinated and aligned with Commission objectives and program needs as well as to communicate issues that may need upper management intervention or resolution.

The QAO maintains communications with both regional EPA and USEPA personnel and is responsible for forwarding revised, updated and current QA documentation to them.

Changes within the Quality System and to the Commission's Quality Management plan shall be documented and available to all Commission staff. It is the responsibility of all Technical & Program Managers to document and verify that QA/QC updates have been discussed and are understood by technical staff and field personnel.

2.12 Resolution of Quality System Related Conflicts, Discrepancies, and Disputes

Within the workforce there may be several different personality types, viewpoints, and opinions on how, what, where, when, and why to accomplish certain tasks and goals. Fortunately, most often these issues are readily resolved with little or no impact to the quality system. A project leader or program manager may also assist in finding an equitable solution if the situation warrants. In instances where resolution is at an impasse, or of a more serious or egregious nature, the Director of Human Resources may be asked to step in.

The QAO has final decision authority pertaining to significant disputes regarding quality system related matters.

2.12.1 The first step in the overall resolution process is to document an accurate accounting of events. This will allow for a systematic approach to assess the issues, maintain integrity within the quality system, provide a solution and prevent repeat situations.

2.12.1.1 Procedural, method related, and QA/QC issues should be documented on a corrective action form. The form should indicate a proposed course of action to bring the situation back under control. A Corrective Action Report (CAR) can be initiated by any staff member.

2.12.1.2 Other issues are clearly and concisely written in case narrative form to describe the situation and issues of concern.

2.12.2 The second step involves an evaluation of the situation by involved party or parties to determine what level of management involvement is warranted.

2.12.3 Discussion(s) occur to actively move towards a remedy. Depending on the nature of the situation, a decision is made on the course of action to pursue, a CAR or other forms should reflect any decisions.

2.12.4 Implementation of the final decision occurs. Implementation outcomes are documented.

2.12.5 Follow up by the QAO and/or management may be necessary to ensure that quality system integrity is maintained.

2.13 Quality Management Plan Review and Revision

The Quality Management Plan shall be reviewed annually to incorporate and update information and to evaluate feedback regarding the effectiveness of established quality management practices. At least every five years the QMP is to be wholly revised and resubmitted to EPA for review and approval.

2.14 Quality Management Plan Approval

An approved Quality Management Plan has signatures from the following EPA and staff representatives: Acknowledgement by signature indicates that the plan has been reviewed by designated parties and found acceptable. The QMP approval page is located in the front of the document.

2.14.1 Executive Director and Chief Engineer
2.14.2. Deputy Executive Director
2.14.3 Quality Assurance Officer
2.14.4 EPA Quality Management Officer
2.14.5 USEPA Project Officer

3.0 QUALITY SYSTEM ASSESSMENT TOOLS

ORSANCO's Quality System is designed to avoid occasions where data and information collected falls short of meeting established requirements for the use of the data. Since the primary goal of the Commission's Quality System is to ensure that all data is of verifiable quality and can be used with a high degree of certainty to support specific decisions or actions, the mechanisms to provide successful generation, collection, and processing rely on certain tools within the quality system to ascertain how well these activities are performed.

3.1 Key Components of ORSANCO's Quality System

Described below are the documents and procedures that ORSANCO uses to evaluate the Quality System.

3.1.1 The Quality Management Plan (QMP) details the Commission's Quality System regarding organizational structure, roles and responsibilities of staff members, QA/QC policies and procedures for planning, implementing producing and assessing data. The Quality Management Plan is updated and maintained by the Quality Assurance Officer annually or as needed.

3.1.2 Management System Reviews (MSR) look at sampling and data collection procedures to evaluate whether or not related quality management practices are adequate for the type and quality of data produced. The Quality Assurance Officer and Project Manager perform Management System Reviews annually or as needed.

3.1.3 Data Quality Objectives (DQOs) clarify program objectives, specify data format and type, determine what the data acceptance/rejection criteria are,

and establish what data and information is needed and how it is applied in decision making processes. DQOs are established by the Program Manager and the Quality Assurance Officer and are reviewed semi-annually. DQOs should be compared with program activity to corroborate parity between objectives and data output.

3.1.4 A Quality Assurance Program Plan (QAPP) is a written document that defines and specifies the necessary quality control and quality assurance parameters for a particular program or data acquisition event. The QAPP ensures that the results obtained will satisfy established performance criteria and meet any data quality objectives. QAPPs must be approved prior to any program data collection and analyses. The Quality Assurance Officer is responsible for reviewing and approving each of the Commission's Quality Assurance Program Plans. Program Leaders and Project Coordinators are responsible for ensuring that QAPP's are updated annually, prior to the start of field season. For year-round, continuing programs, QAPP's should be updated prior to the start of the next fiscal year (July 1st).

3.1.5 Standard Operating Procedures (SOPs) are written documents that *clearly detail* each step in the data acquisition process. These are the analytical methodologies that field personnel and analysts must follow. SOPs must include protocols for equipment set up, calibration and maintenance; sample collection, preservation, storage and delivery; data collection, review and interpretation; and quality control and corrective action measures. Technical Program Managers and field personnel are responsible for preparing and revising SOPs on an annual and as needed basis. SOPs provide consistency and comparability between field personnel, ensuring that routine and repetitive tasks are performed in the same manner. SOPs must be approved before any data collection or analyses can be undertaken. SOPs must be incorporated in their entirety or referenced in the Commission's QMP or the Program QAPP. The QAO reviews and approves all SOPs annually.

3.1.6 Technical Assessments involve the review of sampling locale, facilities, equipment, sampling and analytical procedures, documentation, data validation, training procedures, reporting and data archiving protocols. For in-house audits, the QAO performs technical Assessments. EPA's QA team may elect to perform a Technical Assessment on a particular program.

3.1.7 Data Quality Assessments are statistical and scientific evaluations of a data set. Common data quality indicators include precision, accuracy, representativeness, comparability, and completeness. These parameters aid in determining the statistical validity of the data and measure the adequacy of the program methodology. The Technical Manager or Project Leader performs a DQA as necessary.

3.1.8 Quality Assurance Status Reports (QASR) are provided to the Deputy Executive Director and/or the Executive Director and aid in tracking the progress of a particular program or project. A Program QAPP must discuss in detail the frequency, content, and format of Quality Assurance Status Reports. Elements of the QASR should include the following:

3.1.8.1 Status of Project
3.1.8.2 Changes in Program Activities
3.1.8.3 Project Organizational Changes
3.1.8.4 Results of Data Quality Indicator Assessments
3.1.8.5 Results of Technical Assessments
3.1.8.6 Corrective Actions taken

3.2 Roles and Responsibilities of Commission Staff Utilizing Quality System Tools

Commission personnel who are involved with environmental data collection or analyses, either directly or indirectly, have responsibility to provide quality data. This may include staff level personnel, supervisors, project officers, program managers, senior managers, and personnel specifically assigned to perform QA functions. The following is an overview of the QA responsibilities of *some* of the Commission Staff: A more comprehensive listing of QA/QC roles and responsibilities can be found in Section 2.8 of the Quality Management Plan.

3.2.1 The **Executive Director** has overall authority for the Commission's Quality System. The Executive Director is responsible for ensuring that quality assurance is an active and identifiable activity with adequate resources allocated for the accomplishment of QA program goals for all in house and extramural activities.

3.2.2 The **Deputy Executive Director** also has authority over the Commission's Quality System. The Deputy Executive Director is responsible for ensuring that the implementation of USEPA QA requirements occur within Commission Programs and the QA Program has adequate resources to accomplish all necessary tasks in order to maintain the integrity of this program. Likewise, the Deputy Executive Director conducts management of the Commission's Quality Assurance Program. The Quality Assurance Officer reports to the Deputy Executive Director.

3.2.3 The **Quality Assurance Officer** has QA/QC oversight of all monitoring programs and can designate and assign QA/QC activities to any program or project in order to comply with the Commission's Quality Management Plan. The QAO is not directly involved in data acquisition or raw data evaluation activities but has the authority to provide remedy to situations involving corrective action.

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3.2.4 **Technical Program Managers** are directly responsible for supervising QA activities within their designated program areas. They coordinate efforts with the Quality Assurance Officer and provide the necessary training for field personnel.

A Technical Manager is assigned to each of the following program areas:

3.2.4.1 Water Quality Standards, Monitoring and Assessment
3.2.4.2 Source Water Protection and Emergency Response
3.2.4.3 Biological Programs and Special Research Projects
3.2.4.4 Water Resources

3.2.5 **Program Leaders and Project Coordinators** are also responsible for managing QA activities within their assigned program or project area. They report directly to Technical Program Managers.

3.2.6 **Technical Staff and Field Personnel** are responsible for understanding and complying with all QAPP and SOP requirements pertinent to their program or project affiliation and will report situations and conditions that do not meet QA/QC standards to their Technical Manager and/or the designated QAO for review, so that appropriate corrective action measures can be implemented.

3.3 Preparation and Approval of the Commission's Quality Management Plan

The Quality Management Plan is prepared and maintained by the Quality Assurance Officer. Once developed, the QMP is reviewed internally by Commission staff and approved by the Deputy Executive Director. The QMP is then submitted to the Regional EPA Quality Assurance Officer for review and approval.

The Quality Management Plan is to be reviewed and updated annually. Revisions to the QMP will be approved by Commission management prior to submission and approval to the Regional EPA Quality Assurance Officer.

4.0 Personnel Qualifications and Training

4.1 Policy for Quality Assurance Training

It is the Commission's intent to retain staff working with environmental programs that are qualified and capable of adequately performing tasks and functions commensurate with program needs. Prior to carrying out duties related to any environmental program, staff must have adequate education, training, experience, and demonstrate proficiency for specified program/project needs. Commission staff participates in training events germane to program needs.

Furthermore, any staff member working within an environmental program must have a fundamental understanding of the Commission's QA/QC concepts and implement these QA/QC processes where appropriate.

All QA personnel should have experience in quality assurance and quality control matters prior to assuming any quality system responsibilities, especially in areas pertaining to USEPA requirements for Quality Systems.

The appointed Quality Assurance Officer will routinely attend QA/QC training sessions and workshops offered by the USEPA and/or state agencies to keep apprised of changes and revisions to QA/QC policies. The QAO shall participate in other QA/QC workshops as necessary to maintain required skill set.

4.2 Identification and Implementation of Training Needs

The Quality Assurance Officer is in charge of assessing quality assurance and quality control training needs for the Commission based on the level of QA related responsibilities and QA function each staff member has for a given program. The QAO is responsible for providing the necessary QA training to staff.

Technical Program Managers are responsible for providing proper training to technical staff and field personnel as related to specific program needs. This can be achieved through in-house training, formal training sessions, workshops, conferences, and other courses. On-going training and/ or re-training is necessary in order to keep up with changes to methodologies, technologies and/or EPA requirements. All Training events are documented by a Technical Manager or Project Leader.

While Technical Program Managers and the QAO determine the training regimen for specific programs, Commission staff is encouraged to seek opportunities to expand their professional development by participating in additional training, courses, workshops and seminars related to the environmental field and their area of expertise and interest. The Technical Manager must approve such courses, workshops, and the like prior to attendance.

4.3 Assurances for Grants and Contracts

Technical Program Managers and the QAO are responsible for ensuring that all contractual personnel and/or services involved with EPA funded programs or projects for the Commission have the necessary QA training to successfully complete their stipulated duties and functions *prior* to any data collection, generation or assessments. Minimum QA training requirements for contractual services should be comprehensively described in Requests for Proposals (RFPs), Statements of Work (SOW), or similar documents.

Technical Program Managers should regularly receive information regarding QA training and on-going proof of proficiency (demonstration of capability) from

contracted parties. A summary review and status update of QA proficiency of contracted/analytical services should be provided to the QAO semi-annually.

4.4 Documentation and Recordkeeping

The QAO will maintain a record of all QA training taken by staff and managers involved in environmental data generation and operations. Plans for upcoming QA training is included in the annual Program Plan and QA Report.

Documentation pertaining to education and experience should reside within Human Resources and the appropriate Technical Manager. Training and proficiency documentation should be kept with the Program Manager and/or the after review by the QAO. Copies of certifications, licenses, and accreditations should be retained by the Program Manager and/or the Quality Assurance Officer.

5.0 Extramural Agreements and Procurement of Goods and Services

5.1 Commission Policy Pertaining to Extramural Agreements

It is the Commission's practice that all Extramural Agreements entered into between the EPA and ORSANCO for the purposes of environmental data generation, collection, or assessment will comply with the policies and guidelines for procurement of goods and services in accordance with the most recent version of QA/R-2: *EPA Requirements for Quality Management Plans* and the most recent version of the EPA Procurement Policy *Notice: Guidance for Use of Higher-level Contract Quality Requirements in Acquisitions*.

Prior to formal execution of any EPA funded program/project, including purchases for goods and services for said program/project, ORSANCO will provide the EPA Regional Quality Assurance Manager with a current Commission approved Quality Assurance Management Plan for RQAM review and approval.

5.2 General Policy on Procurement Procedures for Goods and Services

Procedures for acquisition of goods and services through vendors and contractors have been established by the Commission through the Manager of Administrative Programs and/or the Comptroller. These procedures are federally approved and available to authorized staff through the Human Resources website under "Administrative Policies and Procedures, Appendix I." A copy of the Current Procurement Procedures policy is found in the Appendix.

5.2.1 ORSANCO follows the protocols for Quality Assurance requirements relating to acquisition of goods and services are contained in 40 CFR Part 30.54, 40 CFR Part 31.45, Regional Order 5360.50: Quality Assurance Program Policy and Responsibilities and Regional Order 5361.5: Location Identification Policy and Responsibilities.

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5.2.2 Procurement of services involving Federal Information Processing Standards resources will meet the requirements of the FAR, the Federal Information Resources Management Regulations (FIRMR), Delegation 1-84 (1200 TN310).

5.2.3 The Director of Administrative Programs & Human Resources revises and updates procurement policies as necessary, under the direction or with advisement of Commission committees.

5.2.4 Each Technical Manager or the Director of Administrative Programs and Human Resources is responsible for familiarizing staff with appropriate acquisition procedures and ensuring these procedures are followed.

5.2.5 For procurement of items and services where QA for an environmental program is required or may be affected, the QAO will be consulted to ensure that appropriate QA/QC measures are included and accounted for in the acquisition.

5.2.6 The use of purchase orders is mandatory for all items, goods and services utilized for an environmental program. Authorized personnel may access the purchase order database to generate a purchase order requisition. All purchase orders must be approved and signed by a Technical Manager and the Comptroller, who verifies program funds are available.

5.2.7 All items ordered are to be checked against the packing slip (if attached) or shipping invoice and matched to the corresponding purchase order. Items should be thoroughly inspected. The date and receiver's initials should be noted on the packing slip/invoice to indicate that all items have been received and are in good condition. Problems/special notes should be noted on the packing slip with any corrective action measures undertaken.

5.2.8 Invoices must be reviewed and authorized as "OK to pay" by the orderee with an indication of date, reviewer's initials, and amount payable. Invoice totals should match the purchase order totals; discrepancies are to be reconciled, and, if necessary, a new signed purchase order submitted.

5.3 Small Purchases

Small purchases are considered such when the item cost is under $5,000.00 and a bidding process does not need to be initiated. Generally, consumables such as parts & supplies, minor repairs, certain field and laboratory instrumentation and support services qualify as small purchases.

5.3.1 All small purchases must meet any QA/QC program criteria as determined by the program's QAPP.

5.3.2 Policies set forth in Section 5.2 of the Quality Management Plan shall apply.

5.4 Analytical Services

It may be necessary to use services outside the Commission in order to fulfill terms and conditions stipulated through an EPA funded program or project. Each contractor or subcontractor must demonstrate the following:

5.4.1 Laboratories performing analytical work and generating environmental data for an EPA funded project must have a documented quality system in place and a current Laboratory QA/QC manual. This QA/QC plan is reviewed and approved by the Commission's QAO prior to any analyses for the EPA funded project.

5.4.2 Laboratories currently USEPA certified using EPA approved methodologies should be employed whenever available for EPA funded projects. Laboratories must show an initial demonstration of capability for all applicable analyses that is subject to review by the Commission's QAO. All analyses must be performed "in-house" and may not be contracted out to another laboratory without prior authorization or approval by the project leader, technical manager or QAO.

5.4.3 Any instrumentation, tools, supplies, and data management systems that are capable of performing required analyses and tasks and are acceptable for required methodologies can be used for ORSANCO projects as long as they are well maintained and operating within manufacturer's specifications.

5.4.4 The QAO will assign QA/QC parameters and may use "check" samples to validate laboratory results in accordance with program QAPP specifications.

5.4.5 The Technical Manager and QAO are responsible for verifying that all analytical data submitted by the laboratory meets all QA requirements stipulated.

5.5 QA Guidelines for Procurements through Contracts, Grants, and Interagency and Cooperative Agreements

5.5.1 For any EPA funded projects, the Executive Director and/or the Deputy Executive Director, Quality Assurance Officer, and appropriate Technical Manager shall be involved in the development and execution of any contracts, grants, interagency agreements and other pertinent documents between the Commission and the USEPA.

Documents needing QAO oversight include, but are not limited to, the following:

5.5.1.1 **Statement of Work**-QAO reviews statement of work and provides QA tasks where required.

5.5.1.2 **Sample Analysis Plan**-the QAO and Project leader will propose and provide a sampling and analytical schedule.

5.5.1.3 **Acquisition Plan**-QAO and Project Officer define QA oversight role in acquisition process.

5.5.1.4 **RFP Development**-QAO incorporates QA activities into evaluation as needed, including QA in sample work assignment, Quality Management Plan, and Quality Assurance Project Plan.

5.5.1.5 **RFP Evaluation**-QAO assists the Technical Manager or Project Leader in selection as needed. The QAO will review specified QA submissions.

5.5.1.6 **Contract Award**-The QAO participates in debriefing as needed.

5.5.1.7 **Work Assignments and Delivery Orders**- The QAO reviews work assignments which require a QAPP and monitors QA activities with the Technical Manager or Project Leader.

5.5.1.8 **Quality Assurance Review-** A QA review is conducted by Technical Program Managers and the QAO for each new contract, or modification thereof, Work Assignment, or Delivery Order. Where measurements and data are collected, the QAR stipulates QA requirements and addresses functions such as (1) procurement source evaluation and selection, (2) evaluation of objective evidence of quality (furnished by the supplier), (3) source inspections, (4) supplier audits, and (5) examination of deliverables.

5.5.1.9 **Professional Services Agreement (PSA)-** The Technical Manager and QAO will determine what QA requirements are applicable. The PSA shall include a statement regarding the status of the QAPP and any stipulations that apply prior to sample collection and analysis.

6.0 Documents and Records Management

Quality Assurance measures have been established so that *any* data collected, generated, manipulated and/or stored on behalf of the EPA, relating to an EPA funded project, whether in raw or final output form, will follow applicable document and records policies outlined in EPA Policy 2161: Records Management Policy; EPA 2160: Records Management Manual (currently under revision); and Chapter 10 of the EPA IRM Policy Manual. These policies will aid in avoiding introduction of errors, loss of data, misinterpretation of information, and storage, retrieval and archival problems relating to documents and records.

The document and records management process serves as a vehicle for identifying quality-related documents and records requiring management control and assures that documents and

records are accessible and protected in storage against damage or deterioration. Finally, these quality assurance practices ensure compliance with statutory, contractual, and assistance agreement requirements for records.

6.0.1 Data collected, generated, manipulated, or stored not relating to EPA funded 106 projects follows quality assurance and quality control guidelines aligned with objectives in Item 8 of the Commission's *Statement of Policies* to uphold the requirements in the Articles of the Compact.

Quality Assurance documents and records are maintained as outlined in the following sections:

6.1 Roles and Responsibilities of Management and staff for Document Control of QA Related Documents

Each commission staff member has a responsibility to adhere to practices in order to maintain effective control of the Quality System. Document, records, and information management is managed by the individual staff member and overseen by the technical Manager and QAO.

6.1.1 The **Deputy Executive Director** oversees the entire Quality System for the Commission. The Deputy Executive Director will also:

6.1.1.1 Review and approve Commission Quality Management Plan annually.

6.1.1.2 Allocate funding and program resources for adequate document and recordkeeping practices, which may include provisions for training, software, database use, and management.

6.1.2 The **Quality Assurance Officer** has the responsibility of ensuring that documents and records have the appropriate level of QA/QC and that necessary information is properly recorded, readily accessible and available, and proper storage and archival procedures are in place. Additional duties of the QAO pertaining to document and records management include:

6.1.2.1 Issuance of a document control number on all QA/QC related documents

6.1.2.2 Maintaining a record log of all document control numbers.

6.1.2.3 Updating and revising the Commission's Quality Management Plan and related supporting documents.

6.1.2.4 Reviews and approves other quality assurance documents and such as individual program and project QAPPs, SOPs and training related training documents an annual basis.

6.1.2.5 Maintains a system for tracking corrective actions for QA/QC related matters for all EPA funded programs and projects.

6.1.2.6 Reviews supporting QA/QC documents and bench forms used in data collection, generation and assessment.

6.1.2.7 Determines QA/QC protocols for databases are appropriate and in use.

6.1.2.8 Verifies that documents and records from contractual and analytical services contain the required QA/QC information.

6.1.3 **Technical Program Managers and Project Leaders** review and verify that data and report generation from paper and electronic formats are accurate and program related databases are reliable and consistent in data storage and manipulation. These staff members provide current SOP and QAPP documents for the QAO, technical staff and field personnel. Technical Program Managers shall also:

6.1.3.1 Provide bench forms and documents for program recordkeeping and data entry by technical staff

6.1.3.2 Provide documentation of corrective action measures for out of control situations.

6.1.3.3 Review of QA/QC and data from analytical contracted services or other extramural sources

6.1.3.4 Ensure that database entry users have had an acceptable level of training prior to use of database.

6.1.3.5 Verify that database calculations and formulas are routinely checked within the database, data input fields are valid, and the output generates correct values and information. A record of database entry is kept.

6.1.3.6 Maintain overall database control to protect integrity of data.

6.1.4 **Technical Staff/Field Personnel** maintain day- to-day documentation and accurately record data and information in real time as events occur. Technical staff may be responsible for data conversion from paper to electronic format and preparing report summaries and database queries. Additional duties include:

6.1.4.1 SOP protocols are followed as written; any modifications or recommendations to amend current SOP are reported to the Project Coordinator or Technical Programs Manager

6.1.4.2 Field notebooks, bench forms and other data collection materials are legible and clear.

6.1.4.3 Transfer of information from paper to electronic format is accurate, error free, has been peer reviewed, and has enterer's initials and date entered on data sheet used for database input.

6.1.4.4 Database entry and values generated from database calculations are accurate and all data entered into database is noted and logged with date and enterer's initials on hard copy records and worksheets.

6.1.4.5 Performs peer review of data and database entries.

6.1.4.6 Completes Chain of Custody document for every sample submitted for outside analytical services and retains a legible copy for project documentation.

6.1.4.7 Notify Project Leader, Technical Manager, or QAO of events/situations that warrant corrective action measures or changes to current SOP protocols.

6.1.5 The **Data Processing Specialist** maintains USEPA's STORET database for the organization and is responsible for updating records into STORET. The data processing specialist may also have access to other organizational databases and generate records and other pertinent documents as needed.

6.1.5.1 The data processing specialist overseeing the STORET database must be adequately trained on STORET database use and function through the USEPA and continues to receive training in order to maintain competency and compatibility with the current version of STORET.

6.1.5.2 All data input into a database should be checked for accuracy. Data entry person should record on documents the date information was entered, database(s) used and entry person's initials.

6.1.5.3 Formulas should be frequently checked to verify that calculations are correctly determined.

6.1.5.4 The data processing specialist will peer review data entered into STORET and any other organizational database as necessary.

6.1.5.5 The data processing specialist may also assist IT staff in maintaining security and archival protocols for the organization as it relates to database management and recordkeeping.

6.1.5.6 Access and storage to records and documents used for database input should be kept in accordance with program/project specifications.

6.1.5.7 Corrective actions and problems relating to database and data entry should be reported to the IT Specialist and the Technical Programs Manager as appropriate.

6.1.6 The **Data Systems Administrator (DSA)** oversees the organization's computer hardware, software, and networking systems and serves to maintain the security and integrity of data and information. System

functions related to network security, internet access, web site infrastructure and integrity, email, remote access, electronic bulletin boards and file server maintenance duties are under the purview of the Data Systems Administrator.

The Data Systems Administrator implements data processing operating protocols and quality assurance procedures and reviews and revises all information systems quality assurance procedures on an annual basis.

The Data Systems Specialist must be proficient with Windows operating systems and TCIP/IP networking protocols and provides assistance and support to staff as needed.

6.1.7 **Public Information- ORSANCO's** public information department serves the Ohio River Basin community and functions to provide a thorough and accurate representation of Commission activities to the public. It is imperative that data and information communicated to the public is reliable and valid.

ORSANCO'S public information department is tasked with effectively communicating the Commission's mission and directives in a clear and concise manner that is appropriate for the intended audience. Information may be provided in the form of fact sheets, brochures, reports, posters, publications, or live event coverage. Two key documents produced by the Public Information department are ORSANCO's *Annual Report* and *Quality Monitor*.

6.1.7.1 Information obtained for these reports come from a variety of sources; all material should be proofread and reviewed for accuracy before final printing.

6.1.7.2 Requests for data and information go through the Public Information Department; all requests are recorded and logged into a database.

6.1.7.3 To prevent conveying misinformation during a public or media coverage event, the organization's spokesperson should defer requests for information and data to the appropriate technical staff representative, if available, or provide a contact with whom they can speak with at a later date.

6.2 Printed Documents and Records

A hard copy of documents that support the validity of environmental data, such as field sheets, chains of custody records, laboratory notes, instrument readings, maintenance and calibration logs, etc. are kept with the Program Manager or

Project Coordinator. These documents should have the project name included on them.

Quality Assurance and Quality Control documents reside with the Quality Assurance Officer. QA/QC documents are also stored on the Commission network server and Commission staff has access to these policies and guidance documents on line; they are also available in printer friendly format.

Copies of documents and records generated through USEPA funded projects are available to the public upon request. Requests for information and data is recorded, routed, and processed through the Public Information Department.

6.2.1 **E-Mail Correspondence** and communications sent electronically are considered official documents. Any pertinent emails should be printed out and stored in the program/project folder.

6.2.1.1 Currently, Microsoft Outlook is the default E-mail system. Items stored in under "Saved" Messages are not backed up with the Network Server back up. Only messages held in the user's "Inbox" are backed up routinely with the Server. It is the user's responsibility to back up "Saved" emails.

6.2.2 **Document Revisions**-Revisions to quality assurance documents will be clearly marked with the word "REVISION" and include the revision date and reviser's initials. The document version number should be included and have the following format:(v.X.XX).

6.2.2.1 A minor revision to a document should be annotated with an increment of the extension (.XX) after the decimal point. Minor revisions include such things as grammatical, spelling, phrasing, formatting, etc. and do not include major procedural changes. (Revison: 1.02 to 1.03)

6.2.2.2 A major revision to a document would involve a change in a procedure, goal, data output, assessment strategy, policy, timeline, etc. This is annotated by increment in the number preceding the decimal (X.)

6.2.2.2 A copy of the original document should be retained in permanent program file and all other copies disposed of as soon as a revised document has been issued.

6.2.3 **Document Retention and Storage-**All documents and records are to be kept in a safe, dry place to prevent damage, loss or deterioration. They are to be kept for a period of time that is no less than what is required by the applicable agency. This includes, field notes, printed email correspondence and laboratory notes.

6.2.3.1 Documents and records stored in containers will have the contents legibly noted on the outside of the container in permanent ink.

6.2.4 **Disposition of Documents and Records**-Documents and records may be discarded only after the length of time specified in the agreement has passed. If no timeframe is specified, QA/QC records will be maintained for a minimum of 5 years or at the discretion of the Deputy Executive Director.

6.3 Electronic Records and Databases

The Data Systems Administrator and the IT Specialist have the responsibility for maintaining the integrity of all databases, spreadsheets, reports, and other electronic records related to access, security, hardware compatibility, data back up, retrieval and archival processes, and network and server management.

6.3.1 Microsoft SQL Server is used manage and protect electronic databases and other records; the IT Specialist ensures that the SQL server functions properly and is able to identify and troubleshoot problem areas.

6.3.2 When automatic data entry tracking is not available within the database, a manual record log must be used to document data entry events. Each in-house database is documented using a Microsoft Access documentation tool, which records changes to tables, fields, and relationships within each Access or SQL database. The Data Systems Administrator is available to provide this information.

6.3.3 The Data Systems Administrator or IT specialist may assign certain administrative rights or privileges to trained data processing specialists or technical staff to support management of databases.

6.3.4 The use of multiple copies of the same database, spreadsheet or records should be avoided because this could lead to data entry into the wrong database and inconsistencies within the data table. Any unused databases should be removed from the active Server Network and protected so information cannot be inadvertently entered into it or altered.

6.3.5 ORSANCO manages several databases and spreadsheets that process and store raw data. These databases and spreadsheet records are regularly backed up and stored on an alternate media in the event there is a system failure or a database becomes corrupted. Listed below are databases currently in use:

6.3.5.1 **STORET** Legacy Data Center database: This is a USEPA national database that tracks water quality data. The Legacy Data Center contains data of undocumented quality and the data is static so there can be no updates or changes to the database over time.

6.3.5.2 *Active Biological Databases*

- 6.3.5.2.1 Fish Tissue
- 6.3.5.2.2 Fish Population
- 6.3.5.2.3 Macroinvertabrae

6.3.5.3 *Active Watershed Databases*

- 6.3.5.3.1 Clean Metals
- 6.3.5.3.2 Algae*
- 6.3.5.3.3 Nutrients
- 6.3.5.3.4 PCB's and Dioxin
- 6.3.5.3.5 NPDES Permits/Dockets
- 6.3.5.3.7 Bacteria Database

6.3.5.4 *Information Systems and Technology Databases*

- 6.3.5.4.1 Computer & Peripherals Hardware Inventory
- 6.3.5.4.2 Windows Update Services Database
- 6.3.5.4.3 Web/Internet Issues Database

6.3.5.5 *Other Active Databases*

- 6.3.5.5.1 River Watchers
- 6.3.5.5.2 River Velocity and Flow
- 6.3.5.5.3 Spills Database*****
- 6.3.5.5.4 Purchase Orders Database

Databases that are marked with an * have an external user that has limited and controlled use of database functions. These are secure data collection sites controlled by ORSANCO's Data Systems Administrator. These connections are behind the server firewall.

6.4 Storage formats

Magnetic tapes and disks are alternative media storage formats used to protect data and information in the event of loss or corruption to the network. The Data Systems Administrator is responsible for converting all relevant data and information from its servers to a physical format.

6.5 Developing and Identifying Quality Related Documents

Documents developed for and through a project or program that describes and contains information relating to the collection, generation, assessment, storage and use of data from an EPA funded project are identified with the project name and a document control number (DCN). The document control number is issued by the QAO who records and tracks each document control number.

6.5.1 Both electronic and paper forms of the same document shall have the same DCN.

6.5.2 Electronic records are stored on a secure server. Final copies of documents of QA related documents are to be password protected and are designated as "Read Only".

Quality related documents are drafted by technical staff and are reviewed by peers and by a Technical Manager. Any comments are addressed by the draft writer and incorporated as appropriate. The QAO shall review the document as well. Any additional comments are incorporated into draft document. Once approval by the QAO is received, the document will receive a DCN. The final document is stored electronically in the project folder and in a QA/QC folder. A hard copy printout is maintained in the project folder.

The procedures described in Section 8.4 discuss the development of SOPs in detail; this is the standard protocol used for the development of quality related documents.

Sections 6.2 and 6.3 of the Quality Management Plan address procedures for document revision and disposition.

7.0 Computer Hardware and Software

7.1 Role of the Data Systems Administrator

The Commission's Information Technology & Data Systems department handles all computer hardware and software issues. This department maintains, upgrades and replaces equipment and software on a regular basis.

The Data Systems Administrator (DSA) is responsible for overseeing the day-to-day information systems operations and has knowledge and experience pertaining to computers, computer applications, programming, networking, and database and webpage management. The DSA is required to maintain any certifications necessary and is provided training and continuing education opportunities in order keep current with industry standards and meet the needs of the organization.

IT staff also provide support to end users and serve to identify and troubleshoot problems as necessary.

Annually, the DSA will evaluate and address hardware and software needs to ensure that technologies in are compatible with data processing requirements. Recommendations are prepared for upper management for review and approval. The ability to identify, troubleshoot and repair system and server problems is required.

The DSA has the authority to limit access to hardware/software functions as deemed necessary in order to maintain a secure environment for data and information.

7.2 Computer Hardware Standards

Computer hardware requirements and technical specifications are determined by the IT department. Managers and end users also have input, but responsibility for compatibility with existing systems and networking specifications lies with the IT staff. The Executive Director has final approval on all computer hardware decisions.

Each staff member is assigned a computer approved for use by the Data Systems Administrator with which to conduct business related matters for the Commission.

7.2.1 Guidelines on proper use of computer equipment is stated in the Commissions Electronic Systems Policy. This document is found on the ORSANCO Intranet page under *Policies and Procedures/Internal Policies* folder.

7.2.2 The IT staff is responsible for maintenance, upgrade, and system replacement of all computer systems and related equipment. Each system and the network are to be reviewed and analyzed annually to determine what will be required to maintain industry standards over the next fiscal year. Upgrades and system replacement is scheduled accordingly.

7.2.3 Each computer system within the organization is identified with a unique code. These ID codes are documented and kept by the IT department in a database. Peripheral hardware such as printers, scanners, projectors and cameras are also inventoried.

7.2.4 To log onto the organization's network, a user must input his/her username and password. Passwords expire after ninety (90) days and a new password must be generated. Passwords are chosen by the user and must be at least 8 characters in length and must be an alphanumeric string. The same password cannot be used again for at least 270 days.

7.2.5 Only the IT department or other authorized party is allowed to configure computer systems and load software. This is to prevent misuse of computer as well as protect against damage from viruses, hackers or other things that may destroy the system or network.

7.2.6 Any configurations or system changes are documented by the IT specialist or Data Systems Administrator and kept on record. Configurations and system changes should be tested before implementation to ensure that the

change will not corrupt or permanently damage system files or cause irretrievable data loss.

7.2.7 A file is maintained on each piece of equipment and contains information regarding location, user privileges, repair/maintenance, upgrade, and software licenses. This information is kept in individual files in the Data Systems Administrators office.

7.2.8 The IT specialist sets up administrative rights and privileges on each computer. Access is limited to prevent damage of system files or installation of unauthorized software.

7.2.9 All end users must adhere to the practices and protocols developed by the IT department regarding use of computers, software and related equipment. Protocols are documented and kept by the Data Systems Administrator.

7.2.10 Proposals for computer equipment upgrades/replacement are submitted to management for budgetary consideration for the upcoming fiscal year.

7.2.11 The Data Systems Administrator is the only staff employee that has complete access all network and server activities; he has VPN capabilities for remote access to the server and networked system

7.2.12 Problems with hardware and software should be reported to the IT Specialist so that a proper course of action can be determined.

7.3 *Data Backup Protocols*

Each backup event is documented and maintained by the Data Systems Administrator. Network and server backup procedures are on file with the Data Systems Administrator. These procedures are updated as necessary and reviewed and approved by the Director of Administrative Programs and Human Resources and the QAO.

Nightly, data and information from the network server is backed up onto an external magnetic tape drive that is stored on site.

Quarterly, information is transferred to disk and stored off site in a fireproof safe deposit box.

The following servers are backed up nightly:

7.3.1 Hulkstor (data storage and printers)
7.3.2 Deathstar (SQL)
7.3.3 ORSANCO webserver
7.3.4 Morpheus (Exchange server for email, DNS)
7.3.5 MIP (Accounting)

Users who have data stored on the c:\ are responsible for backing up and preserving that information. *Data and information residing on the c:\ backed up in accordance to the data back up protocols referenced in 7.3.* The onus is on the user to back up in a consistent and routine manner to prevent loss of data and information. Procedures for backing up and storing data from individual terminals are located on the ORSANCO intranet page.

E-mails saved in personal folders within the user's Inbox are not backed up since they reside on the c:\. However, items in the main inbox are stored on the exchange server that is backed up nightly.

7.4 Computer Software Standards

Computer software requirements for the organization's network are determined by the IT department. Furthermore, it is the responsibility of the IT department to provide upgrades as necessary in order to conform to current industry standards and practices.

The network operates on a combination of Windows NT and Windows peer-to-peer networking. All internal IP addresses are masqueraded from the public Internet. All web browsing and other Internet access is accomplished through a firewall/proxy server.

Microsoft Office is the ORSANCO standard for word processing, spreadsheet, presentations, and database management. MS Office offers superior integration between the applications, advanced features where needed, and is widely accepted by other technical organizations for the purpose of information sharing between organizations.

Data and information is written in a format that is Adobe Acrobat compatible. Adobe Acrobat portable document format is easily viewed in either a Windows or Macintosh operating system and has become and industry standard for document viewing.

Computer software purchased for a specific technical program or project must be evaluated first by the Technical Manager and users to verify that program needs will be adequately met. Where custom software may be required, the Technical Manager will work closely with a programmer to ensure that the final product meets all project specifications.

7.4.1 All computer software that resides on the Commission network or on Commission owned laptops must be installed by a member of the IT department. Likewise, computer software that is to be removed is done by the IT department to prevent accidental deletion or corruption of system files.

7.4.2 All software loaded onto the Commission owned computer equipment must be licensed. The IT department maintains a log of all licensed

software and where software is loaded. Unauthorized, unlicensed software is not permitted.

7.4.3 Software that is no longer in used is removed from the network or individual computer and the original software disk is physically destroyed and disposed of.

7.5 *Information Security*

Proactive measures are taken to protect any information that is generated, processed or stored within Commission Headquarters. This includes transferring pertinent information onto different media formats, storing information off-site, using firewall and antiviral software and controlling administrative privileges and password securities on many applications.

7.5.1 In-house databases utilize MS SQL Server, a client/server database system which offers superior manageability and informational security. Each database has a primary administrator who is a trained member of the data processing or technical staff. Any changes or modifications made to information within a database are tracked and recorded.

7.5.2 The Data Systems Administrator is responsible for the deployment, maintenance, troubleshooting, and upgrading of staff computers and servers. Data systems staff members are also responsible for the deployment and maintenance of application software and licensing issues. Nightly backups are conducted on servers and a full backup procedure is done weekly with the information stored in a fireproof safety deposit box.

7.6 *Email Correspondence*

A common and frequent mode of communication is accomplished via email which is now an accepted practice. Microsoft Outlook is the default email service for the organization.

7.6.1 Emails are considered official records and any email containing pertinent information should be printed and stored in the program or project folder.

7.6.2 Emails that are stored in the user's inbox reside on the computer's hard drive and, are therefore, not backed up.

7.6.3 Emails can be accessed remotely through the exchange server.

7.6.4 Additionally, the organization has a secure email account through yahoo.

7.7 Disposal of Computers, Peripherals and Software

Before computers and peripheral hardware are disposed of, all software is removed. Internally each computer contains a degaussing function which erases the memory and removes all programs and information from the computer. Computers are then recycled. Obsolete software is physically destroyed and disposed of.

7.7.1 ORSANCO collects and disposes of computers and peripheral equipment no longer in service to BYTES, an organization that refurbishes computers and donates them to public schools and other low income or non-profit agencies.

7.8 Internet and Web Access

Cincinnati Bell is the host for ORSANCO's website. The lease on the domain name **orsanco.org** is valid for 15 years. The server resides at ORSANCO and is firewall protected.

ORSANCO's web page is accessible to the public and is maintained by the Web Team. The Web team is comprised of staff members from Information Technology, Public Information and Human Resources. Accuracy in the content posted onto the public web page is the responsibility of the submitting party and should be proofed and reviewed with the web team prior to it's posting on the web page.

ORSANCO has an *Intranet* page accessible to all staff employees. The intranet page is also maintained by the Web Team.

7.9 *Ergonomics*

In order to prevent injury and reduce stress while working at the computer, ORSANCO participates in OSHA's Ergonomic Practices program and can provide the following to staff upon request:

7.9.1 Monitor stands
7.9.2 Mouse wrist guards and pads
7.9.3 Keyboard wrist guards
7.9.4 Ergonomically designed keyboards
7.9.5 Ergonomically designed mouse
7.9.6 Low glare monitor screens
7.9.7 Appropriately designed desks and chairs

8.0 PROGRAMMATIC AND STRATEGIC PLANNING

8.1 Program Plan

The annual Program Plan describes the monitoring agenda for the upcoming fiscal year. It prioritizes what the Commission will focus on given available funding, budget allocations, and other resources. The annual Program Plan is reviewed and approved by the Technical Committee and the Commission prior to the upcoming fiscal year.

8.2 Overview of Program Plan Elements

Key Elements used in developing an annual Program Plan include: input and guidance from various subcommittees, workgroups, and Commission staff; The Commission's *Strategic Plan, Monitoring Network and Assessment Strategy,* and *Quality Management Plan;* sound QA/QC practices, and a proposed annual budget from the Program and Finance Committee. Technical Committee and Commission meetings throughout the year focus on the development, approval, and implementation of the annual Program Plan.

The annual Program Plan should contain the following elements for each approved monitoring and assessment activity. These items are described in detail in supporting documents used in the development of the annual Program Plan, and, therefore, only a brief narrative may appear in the final Program Plan.

8.2.1 Identification of Technical Manager and/or Project Leader
8.2.2 Description of monitoring objectives and goals
8.2.3 Specify QA/QC monitoring activities
8.2.4 Proposed projected timeline & schedule
8.2.5 Identify type and quantity of data desired,
8.2.6 Description of how data will be obtained and analyzed
8.2.7 Evaluation tools for data from external sources

8.3 Key Committees and Groups involved in Program and Strategic Planning

The following committees of the Commission are involved in the development of monitoring activities for the annual Program Plan:

8.3.1 **Technical Committee** decides on system wide monitoring and assessment activities for the upcoming fiscal year through approval of the Program Plan by the Commission.
8.3.2 **Biological Water Quality Subcommittee** develops biological activities and then makes recommendations to the Technical Committee.
8.3.3 **Monitoring Strategy Subcommittee** develops the protocols for monitoring activities and suggests the types of monitoring activities to

take place; those recommendations are proposed to the Technical Committee.

8.3.4 **Program and Finance Committee** makes recommendations for funding for each of the programs the Technical Committee endorses prior to approval by the Commission.

8.3.5 **Advisory Committees to the Commission** such as WUAC and PCS make recommendations for monitoring and data information and data generation activities to support their needs.

8.4 Core Documents Involved in the Program Planning Process

Environmental monitoring and assessment initiatives are developed for each project by Technical Managers, Commission staff, Subcommittees, or work groups as part of the Program Plan. These initiatives describe the goals and objectives, type of data produced, its intended use, and what the performance criteria are. These initiatives are submitted to the Technical Committee for review, recommendation, and prioritization.

Technical Committee and Commission meetings are the forum through which Program Plan recommendations are proposed, reviewed and accepted for implementation in the upcoming Fiscal year. Program Plan updates and status reports on current activities are presented to committee members and provide the opportunity for comments and feedback. These reports serve to specify future monitoring and assessment activities and their criteria, provide a basis for future action, and address any quality assurance and quality control issues.

The following are developed as a result of communications between staff and committees and serve to align the monitoring needs, Agency requests, Compact Directives and the Commission's vision. These records state the intent of the Commission to implement environmental data operations in accordance with the Compact.

8.4.1 The Commission's *Strategic Plan* is the foundation upon which all programmatic priorities and corresponding environmentally related data collection and use activities is based. The Strategic Plan is developed by the Commission and focuses on the directives in the Compact and aligns those objectives to the current needs of the member states in the Ohio River Basin.

8.4.2 The *Monitoring Network and Assessment Strategy* is developed through the Monitoring Strategy Subcommittee with input from other subcommittees, work groups, and advisory committees. This document details how individual programs and projects are designed and how they will operate. It specifies water quality indicators; QA/QC parameters; data analysis, assessment, management and reporting; and program evaluation.

8.4.3 The *Quality Management Plan* and supporting documents provide the framework for QA/QC practices used in environmental monitoring and data assessments in the program plan.

8.5 Role of Commission Staff in Program Planning

Development of a detailed, well-organized, comprehensible, achievable Program Plan relies on the information provided by Commission Staff and sound quality assurance and quality control protocols. Commission staff contributes to an annual Program Plan in the following ways:

8.5.1 The Staff Liason(s) to advisory committees, subcommittees, and work groups is responsible for accurately recording and maintaining pertinent documents in the course during the strategic planning and program development process. This includes all correspondence by telephone, letter, email, as well as, transcribing meeting minutes.

8.5.2 Technical Program Managers identify the needs and expectations of their programs/projects, in terms of technical and quality goals and translate those expectations into specific criteria to meet project requirements for the Program Plan.

8.5.3 At least quarterly, Technical Program Managers are responsible for preparing reports to executive management describing the status and progress of the program/project. Details of the report include: sampling status, percent completion, budgetary expenditures, unusual findings, and any corrective actions undertaken.

8.5.4 Project Leaders document the data operations process and are responsible for organizing, maintaining, reviewing, and archiving generated data and information. The Project Leader is responsible for ensuring that any data quality objectives (DQO's) are met.

8.6 Quality Assurance Components of the Program Plan

Establishing sound quality assurance and quality control practices are an integral part of program planning. The *Quality Management Plan* provides the framework for QA/QC characteristics that each program utilizes and sets performance criteria standards. Each monitoring and assessment project within the program operates with these guidelines:

8.6.1 All technical and field staff have read and understand applicable QAPP and SOPs and are thoroughly trained in routine procedures, safety, and QA/QC protocols prior to any sampling or analyses and all training events are properly documented and recorded. All personnel connected with project are required to follow protocols outlined in the associated QAPP and SOP(s) and implement monitoring strategies outlined the Program Plan.

8.6.2 Standard Operating Procedures (SOP) are the cornerstone of a QAPP. SOPs provide the steps that are followed in order to accomplish a certain task, procedure, or goal to yield a predicted outcome. They must be written to provide enough information such that any layperson could read and follow with little or no problem. SOP's are created using a combination hands-on, trial-and-error experience, reliable references and citations, and vendor information.

The SOP should address areas pertaining to safety, hazardous waste disposal, equipment lists, reagent and chemical identification and concentration, data and results entry, corrective action procedures, QA/QC and performance criteria.

8.6.2.1 For all EPA funded projects, SOPs are developed using an EPA approved or accepted method. In cases where no approved or accepted method exists, a statement must be included in the introduction or overview section that there is currently no approved or accepted method.

8.6.2.2 The current version number must be included on the SOP. Revised documents must have the reviser's initials and date.

8.6.2.3 SOP's are drafted by technical staff, the project coordinator, program manager or QAO. The Technical Program Manager reviews the document and provides recommendations, revisions and feedback to staff to implement in the final SOP draft.

8.6.2.4 After the Technical Program Manger has reviewed the SOP, it is given to the QAO for review and approval. Pending any recommendations and revisions, the SOP is approved. The QAO issues a Document Control Number (DCN) and this is the approved SOP. A copy of this is maintained electronically for staff access as well as a paper copy.

8.6.2.5 The SOP should be listed and referenced in the appropriate QAPP.

8.6.2.6 The Project Leader distributes a copy of the active SOP to applicable staff.

8.6.2.6.1 Each SOP recipient indicating that a new/revised copy of SOP has been provided which has been read and understood; the protocols described will be followed; and, this version replaces any and all previous versions of the SOP.

8.6.2.7 Previous acknowledgement is to be signed and dated by SOP's are removed from circulation and destroyed. One copy may remain, but should be clearly marked "for reference use only" or "historical copy, do not use, refer to (v.X.XX)".

8.6.2.8 Technical and field staff should review sOPs annually. Comments and corrections should be submitted to reviser for inclusion in next SOP iteration.

8.6.3 All methods are approved by the QAO prior to analyses. Methods may not be substituted without prior notice and authorization from the QAO. When sampling procedures or analyses must be modified (location, technique, equipment) or DQOs shift, the project officer must show justification and provide adequate documentation for the change. This documentation is included as an addendum attachment to the QAPP or SOP.

8.6.4 A USEPA certified laboratory is used when available. A site visit to the laboratory may performed by the QAO or project leader to review and document the primary analyst's ability to process and analyze samples. Once the contract laboratory has been approved, samples may be delivered for analyses (assuming the QAPP is approved).

8.6.5 A copy of recent Performance Evaluation testing and QA/QC documentation must be reviewed for all analytical services employed prior to the start of any sampling or analyses.

8.6.6 Data received from outside sources must have quality control and quality assurance documentation to validate all results and each batch of samples must be processed with quality control samples

8.6.7 The Technical Manager and/or Project leader will maintain continued oversight of all contracted services performing environmentally related tasks. The Project leader reviews the data submitted by the contract lab and checks for errors and verifies that correct formulas and procedures were used in determining results.

8.6.8 Performance criteria is established and used for data validation and assessment to determine if project requirements have been satisfied and the end users needs are met. Performance criteria are included in detail in each program/project QAPP. Performance criteria may be method dependent; it is the responsibility of the Technical Manager to determine which statistical measurements meet end the DQO's for the project. Likewise, the QAO may request certain statistical calculations to support data validation.

8.6.8.1 **Accuracy**-Indicate the acceptable range, how accuracy is measured, and how well the data fit within this criteria

8.6.8.2 **Precision-**Indicate the acceptable parameters, how precision is determined, and how well the data fit within this criteria

8.6.8.3 **Completeness-** Determine if the amount of data collected is sufficient to accurately characterize the situation or event.

8.6.8.4 **Representativeness-**Indicate how well the data corresponds to the actual conditions at sampling location and whether sampling methods were appropriate.

8.6.8.5 **Comparability**-what are the similarities or differences between individual sampling events, samplers and analysts.

8.7 Systematic Program Planning Process for Environmental Data Operations

The timeframe between planning and implementation of a commission project typically occurs within a 12 month cycle. Each quarterly TEC/Commission meeting focuses on an element to move the process along. The Systematic Program planning cycle coincides with ORSANCO's fiscal year, which starts July 1. Projects and programs typically start at the beginning of ORSANCO's fiscal year; however, some projects and programs may coincide with the federal fiscal year to align funding with project costs. Projects funded from other sources may start at any time. TEC/Commission meetings occur in February, June and October of each year.

The planning process is recorded through minutes of meetings, conference calls, and the exchange of e-mails and letters. The staff liaison is responsible for maintaining this information. The frequency of meetings and conference calls is determined by the chairman of the committee (or lead person for other work groups). Correspondence electronically, by phone or via mail may occur at any time.

Two primary outputs of the planning process and annual Program Plan include the Monitoring Assessment Strategy and Strategic Plan. These documents are developed by the Deputy Executive Director.

8.7.1 At any time, ideas and propositions for environmental projects may come to the commission through a variety of sources: State or federal agencies, private enterprise, staff, workgroups, subcommittees, and committees. Further input, research, and collaboration from staff and involved parties and stakeholders is used to develop the scope of work, data quality objectives, timelines, schedules, costs, and goals.

8.7.2 A primary purpose of the February TEC/Commission meeting is to present proposed ideas for a desired area of study for the upcoming fiscal year to the Technical Committee and the Commission. Status updates of current projects are also given.

8.7.2.1 The TEC Committee and the Commission decide which projects are carried forward for the next fiscal year. Recommendations and support for proposed projects are put forth as a motion and voted on. Regardless of number of votes, the majority vote carries the motion.

8.7.2.2 Appropriate workgroups, subcommittees and commission committees work with staff during Feb-March to field/technical staffing to further develop Project Plan and Monitoring Strategy elements.

8.7.2.3 The Deputy Executive Director, who oversees all technical projects and programs prioritizes and ranks each upcoming project. The DED prepares key document outputs for the new fiscal year, including the Commission Monitoring Strategy and Program Plan. Key elements of proposed projects are incorporated into these documents.

8.7.2.4 The Program & Finance Committee evaluates each project in April-May to balance funding, estimated costs, matching contributions, etc., within the Commisson's annual budget. The Program and Finance Committee decides what can be allocated for a given project.

8.7.2.4.1 In situations where funding resources and options are limited and all proposed projects couldn't be financed, the Deputy Executive Director decides which projects will move forward.

8.7.2.5 After the Program & Finance allocations are given, project is given back to group for any cost adjustments. Technical Managers determine what modifications are necessary and determine the impact on any related DQO's. The project is modified accordingly.

8.7.2.5.1 In cases where DQO's would be negatively impacted significantly, the project would not progress. The project may be re-proposed if funding changes.

8.8.3 The Commission's Program Plan and Monitoring Strategy documents are finalized and presented to TEC/Commission member for recommendation and approval at the June meeting. With Commission approval, projects are ready for implementation as long as all QA/QC and quality system components are satisfied.

8.8.3.1 Each program/project specific QAPP (or document referenced in the QAPP) shall describe the details of the program/project specific systematic planning results.

8.8.3.2 8.5.3.2 Program/Project work shall not begin until the Technical Manager, QAO and State/Federal Agency officials, have approved the QAPP.

8.8.3.3 Any action items the commission recommends are addressed before project implementation.

8.8.3.4 The field season for projects involving watercraft and on river access usually begins in late spring, and as soon as weather permits. Logistical planning, recon missions, safe boating practices, and trial runs take place prior to any actual field events. The field season typically ends in late October, weather permitting. On river data collection events are dependent on factors such as weather, flow, velocity, and other river conditions.

8.8.4 At the October TEC/Commission meeting, a status update of all current projects is presented. The Commission Chairman also presents his vision for his term. The Chairman's term also coincides with ORSANCO's fiscal year and begins on July 1st of every year.

8.8.5 For on river data collection operations, particularly biological related activities, the winter months focus on data assessment and analysis.

8.8.6 Data assessment and analysis for other programs not dependent on watercraft occurs after the data is collected.

9.0 IMPLEMENTATION OF WORK PROCESSES AND QA PROTOCOLS

This chapter of the QMP describes the processes used by the Commission for ensuring that quality assurance plans and procedures, which comprise the Quality System, are effectively implemented for each monitoring initiative. As with the QA planning described in the previous chapter, implementation of QA procedures takes place at commission staff program and project levels.

9.1 All technical staff members are involved in performing tasks associated with work processes. Technical staff assigned to a project are required to follow procedures as outlined in the current, approved SOP. The SOP provides clearly defined steps the user follows so that the resulting data/information generated meets all QA and performance criteria. The SOP development, revision and execution process is outlined in Section 8.6.2 of the Quality Management Plan.

9.2 Technical Program Managers and Project Leaders are responsible for ensuring that all work performed is in accordance to the Quality Assurance Program Plan.

9.3. Each QAPP will address the process for implementing environmental data operations according to the approved planning documents.

9.4 Additionally, each program and or project coordinator will identify those specific activities that will ensure the generation of quality data by:

9.4.1 Identifying mission elements and/or programs generating or using data for environmental decisions;
9.4.2 Identifying criteria for collecting or selecting data sufficient to support environmental decisions;
9.4.3 Outlining procedures to ensure that the work described in the QAPP is being performed according to the Program Plan, including evaluation activities;
9.4.4 Ensuring that individuals with QA responsibilities have been properly trained and continue training,
9.4.5 Defining the level of management oversight and inspection to be provided that will be commensurate with the importance of the particular project task and the intended use of the project results.

9.5 Once an environmental activity has been endorsed by the Technical Committee or a Commission Advisory Committee and approved by the Commission, staff proceeds to the logistics involved in acquiring, scheduling, and utilizing resources to accomplish the goals described in the Program Plan. This includes instrument and equipment procurement, training, calibration, maintenance; allocation of staff and estimated man hours required; surveillance and reconnaissance trips to determine sample locations; acquisition of appropriate document and recordkeeping tools by hard copy or electronic means; and coordination between sample collection and analyses to maintain sample integrity.

9.6 The Project Leader is responsible for any field activities and ensures field personnel complete the assigned task(s). Field-personnel are responsible for the completion of work as described in the specified QAPP. The Project Leader confers with the QAO prior to and during field activity to provide updates with respect to QA/QC issues for sample collection and analyses.

9.7 As soon as data collection begins, the Project Leader and field staff should evaluate the entire process for accuracy, consistency, reproducibility, efficiency; any necessary changes to improve the process should be discussed, approved, and implemented. Minor deficiencies can be corrected immediately. Addendums to the SOP and corrective actions are drafted by the respective Technical Manager.

9.8 Maintaining direct communication with upper level management and USEPA Region offices provides the opportunity for regular QA status updates and promotes feedback opportunities to aid in resolving programmatic issues and needs.

9.9 Documents that become obsolete or have been superseded can be removed from service by a program manager, QAO, or executive management. A notice should be attached to a copy current document with instructions to remove previous copies from

circulation and destroy them. Sections 6.2-6.4 address document revisions, archiving and storage issues.

9.9.1 Some documents and information are retained for historical purposes. These records should be clearly labeled and identified so they cannot be used as working copies, but may be reviewed for reference purposes.

9.9.2 Electronic records and documents should be stored in archiving folder. The document should contain a statement that it is for reference/historical purposes only and not for active use.

9.9.3 Hard copy records should be stored in boxes that are clearly labeled. A master list of the content of each box should be posted on the front of the box or on top of all records. Program Managers are responsible for maintaining storage of program related documents.

10.0 ASSESSMENT AND RESPONSE

The suitability and effectiveness of a quality system and the performance of environmental programs is monitored through analytical assessments. Experienced personnel perform assessments at least annually and as needed. Continued review and on-going training isrecommended for any quality assurance and quality control related tasks an assessor is involved in. Depending on the type of assessment needed, the assessor may be a Project Leader, Technical Manager, or Quality Assurance Officer.

10.1 Responsibilities of an Assessor

10.1.1 The trained assessor has authority, understands the scope of the project; DQO's, goals, and outputs; has access to managers, documents and records; and can freely discuss and share findings with management, staff, and any designated committees within the organization.

10.1.2 Assessments identify problems and recognize noteworthy practices. Corrective actions cite deficiencies and contain recommendations for resolving the situation. Section 11.1 of this document details records and forms used in the assessment process

10.1.3.1 Corrective actions document the process of identifying the problem, providing a remedy, implementing changes, and verifying the effectiveness through follow up. Corrective action procedures are detailed in project SOP's.

10.1.3.2 The Technical manager is responsible for verifying that appropriate actions are taken to remedy the issue stated in the corrective action. A technical manager shall keep a record of all corrective actions, a copy of which is forwarded to the QAO for review.

10.2 Assessment Findings

Once assessments have been completed, the information is compiled and a report is issued to the appropriate committee. Upon review, any actions are discussed, and, if necessary, a recommendation will be placed before the Technical Committee and/or the Commission. These meetings are recorded and transcribed into meeting minutes. Reports are attached and become part of the official record.

10.2.1 Assessment results and reported findings are available for review and comment by staff. Feedback from staff can augment the assessment process by providing alternate solutions.

10.2.2 Special recognition and other noteworthy events found through assessments are featured at Technical Committee Meetings in the Chief Engineer's Report.

11.0 QUALITY IMPROVEMENT

Effective management of the Quality System includes recognizing and implementing those changes which will bring forth a valid, more efficient, streamlined process for generating, processing, evaluating, verifying, and archiving data and information. Quality system improvements are made whenever necessary; it is the responsibility of the Quality Assurance Officer to facilitate changes and fulfill program needs accordingly. The QAO is tasked with overseeing all aspects of quality assurance activities within the Commission and depends upon support from upper management and staff to enforce actions as necessary to resolve QA issues or programmatic conflicts.

The quality improvement process at ORSASNCO intends to be a dynamic, on-going process and all staff members are expected to promptly identify and communicate any QA/QC issues or instances where data quality falls below required acceptable limits to the QAO so that a remedy and proper course of action can be implemented.

Commission staff is also encouraged to offer feedback, suggestions, and comments that would better improve the Quality System or any part of the QA/QC management process.

The QAO, with assistance from Technical Program Managers and/or Project Leaders evaluates the current status of QA/QC activities for each program. In order to accomplish this, there are several quality system checks that are used in the evaluation process. These include:

11.1 **Quality System Review**-An annual review of the organization's Quality System and supporting documents including the QMP, program QAPPs, and program SOPs. Documents are amended and revised as necessary. Revisions should be discussed with appropriate managers and field personnel to ensure that modifications are clearly understood and implemented.

11.2 **Quality System Reports**-The QAO and/or Technical Manager will maintain a record of all quality system checks made, any unusual findings and any corrective actions implemented as a result thereof.

11.3 **Field Performance Audit**-To verify that QAPP and SOP protocols are followed, a field performance audit is conducted. Any variances should be documented and discussed with individual(s). Instruction on proper technique and additional training may be necessary and an audit follow up may occur.

11.4 **External Audits**-The Quality Assurance Office and Project Leader should perform an external audit for any contracted or other analytical services, along with a physical site inspection to observe that contractual obligations are met and method protocols are followed. An unannounced visit is ideal, but may not be possible. For analytical laboratories, performance evaluation results are to be forwarded for review and serve as part of the permanent record for QA/QC. Blind and "split" QA/QC samples should be sent to the laboratory for additional performance evaluation testing.

11.5 **Equipment Malfunction-**Any equipment or instrument problems should be reported to the project Leader. Because there may be an impact to scheduling, sample collection or deadlines, any problems should be reported promptly so that measures can be taken to prevent deviations. The Project Leader will report findings to the QAO and prepare the corrective action as the situation warrants.

11.6 **Corrective Action Reports-**Corrective actions are a necessary component of the maintaining a Quality System. They serve to document out-of-control situations and provide a course of action to correct the situation. An out-of-control situation may be minor and have no significant effect on the out come of data, or it may be extreme, warranting further action or consideration by the Commission. In any case, each instance must be documented.

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12.0 COMMON TERMS AND DEFINITIONS

Listed below are terms associated with a Quality System and may be contained within the Quality Management Plan. These terms are herein described using EPA definitions found within EPA Quality System and related QA/QC documents.

ASSESSMENT - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

AUDIT(quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

BIAS – the systematic or persistant distortion of a measurement process which causes errors in one direction (the expected sample measurement is different from the sample's true value).

CALIBRATION –comparison of a measurement, standard, instrument, or item with a known and validated reference. The reference is usually of higher accuracy that what is being measured.

DATA QUALITY ASSESSMENT (DQA) - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use. design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

DATA QUALITY OBJECTIVES –qualitative and quantitative statements derived from the DQS process that clarify study objectives, defines the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity needed to support decisions.

DATA QUALITY OBJECTIVES PROCESS –a systematic planning tool to facilitate the planning of environmental data collection activities. DQO's are the qualitative and quantitative outputs of the DQO process.

DOCUMENT –any compliation of information which describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to environmental programs.

ENVIRONMENTAL CONDITIONS - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

ENVIRONMENTAL DATA- any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

ENVIRONMENTAL DATA OPERATIONS- work performed to obtain, use, or report information pertaining to environmental processes and conditions.

ENVIRONMENTAL PROCESSES – manufactured or natural processes that produce discharges to or that impact the ambient environment.

ENVIRONMENTAL PROGRAMS- work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

ENVIRONMENTAL TECHNOLOGY- an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for
pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

EXTRAMURAL AGREEMENT – a legal agreement between the EPA and an organization outside EPA for goods, items or services. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, and governmental interagency agreements.

GRADED APPROACH - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

INDEPENDENT ASSESSMENT - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

INSPECTION - examination or measurement of an item or activity to verify conformance to specific requirements.

MANAGEMENT - those individuals directly responsible and accountable for planning, implementing, and assessing work.

MANAGEMENT SYSTEM - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

MANAGEMENT SYSTEMS REVIEW (MSR)- the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

MBE - a business organization which is beneficially owned and controlled 51% or more by one or more Minority Group Members and is certified as such by the Massachusetts State Office of Minority and Women's Business Affairs.

MEASUREMENT AND TESTING EQUIPMENT –tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test or inspect in order to control or qcquire data to verify conformance to specified requirements.

METHOD –a body of procedures and techniques for performing an activity (e.g., sampling, analysis, quantification) systematically presented in the order in which they are to be executed.

MINORITY GROUP MEMBER -a person who is of one of the following groups:

(a) Native American or Alaskan Native - A person having origins in any of the original peoples of North America, and who maintains cultural identifications through tribal affiliations or community recognition.

(b) Asian or Pacific Islander - A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian Sub-continent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands and Samoa.

(c) Black - A person having origins in any of the black racial groups of Africa.

(d) Hispanic - A person of Mexican, Puerto Rican, Cuban, Dominican, Central, or South American origin.

(e) Cape Verdean - A person having origins in the Cape Verde Islands.

NON RECORD (MATERIALS)-U.S. Government owed informational materials excluded from the legal definition of records. This includes extra copies of documents kept only for convenience or reference, such as stocks of publications and processed materials and library materials intended soley for reference or exhibition.

OBSERVATION - an assessment conclusion that identifies a condition (either positive or negative) and does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

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OBJECTIVE EVIDENCE - any documented statement of fact, other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

ORGANIZATION - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

PEER REVIEW - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

PERFORMANCE EVALUATION - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

PRECISION –a measure of mutual agreement among individual measurements of the same property, usually under a prescribed set of similar conditions; this measurement is typically expressed in terms of the standard deviation.

PROCESS- a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

QUALITY - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

QUALITY ASSURANCE (QA) - an integrated to ensure that a process, item, or service is of the type and quality needed and expected by the client system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement.

QUALITY ASSURANCE OFFICER (QAO)-the individual designated as the principal person within the organization of having management oversight and responsibilities for planning, documenting, coordinating and assessing the effectiveness of the quality system.

QUALITY ASSURANCE PROGRAM PLAN (QAPP) - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

QUALITY CONTROL (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

QUALITY IMPROVEMENT - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

QUALITY MANAGEMENT - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.

QUALITY MANAGEMENT PLAN - a document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

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

READINESS REVIEW - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

RECORD- A completed document that provides objective evidence and information of an item or process. Records include information documented on paper, photographs, drawings, microfilm, audio tape, portable drives, magnetic tape, machine readable materials, data recording media or any other background materials, regardless of physical form or characteristics, resulting from specific transactions, operations, processes which are accumulated and maintained in a filing system.

RECORDKEEPING REQUIREMENTS-are statements in statutes, regulations or directives that provide general and specific information on particular records to be created and maintained by the EPA. EPA directive 2161 (04/06) and EPA 2100 Ch10, Records Management. (Records Management Manual currently under revision.)

RECORDS MANAGEMENT-The planning, controlling, directing, organizing, training, promoting, and other management activities involved with records creation, maintenance, use and disposition in order to achieve adequate and proper documentation.

SAMPLE ANALYSIS PLAN (SAS) –ensures that sample collection and analytical activities are conducted in accordance with technology, protocols are acceptable and that the data meets intended DQO's. Included in an SAS is: sampling objectives, sampling location and frequency, equipment, procedures, sample handling and preservation, acceptable method(s) and analyses.

SCIENTIFIC METHOD –the principles and processes regarded as necessary for scientific investigation, including rules for concept or hypotheses formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

SELF-ASSESSMENT - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

SPECIFICATION - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

STANDARD DEVIATION –a statistical measurement that each individual value is compared by distance by its from the mean (average value) of all samples in

STANDARD OPERATING PROCEDURE (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

SUPPLIER - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

SURVEILLANCE (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

TECHNICAL ASSESSMENT the evaluation process used to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations.

TECHNICAL REVIEW - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

TECHNICAL SYSTEMS AUDIT (TSA)- a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

USER-an organization group or individual that utilizes the results or products from environmental programs or a customer for whom the results or products were collected or created.

VALIDATION –confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

VERIFICATION –confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of given activity to determine conformance to the stated requirements for that activity.

WBE - means a business organization which is beneficially owned and controlled 51% or more by one or more women and is certified as such by the Massachusetts State Office of Minority and Women's Business Affairs.

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REFERENCES

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EPA Order 5360.1 A2 EPA Quality Manual for Environmental Programs

USEPA Region III *Quality Management Plan*, September 1996

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APPENDICES

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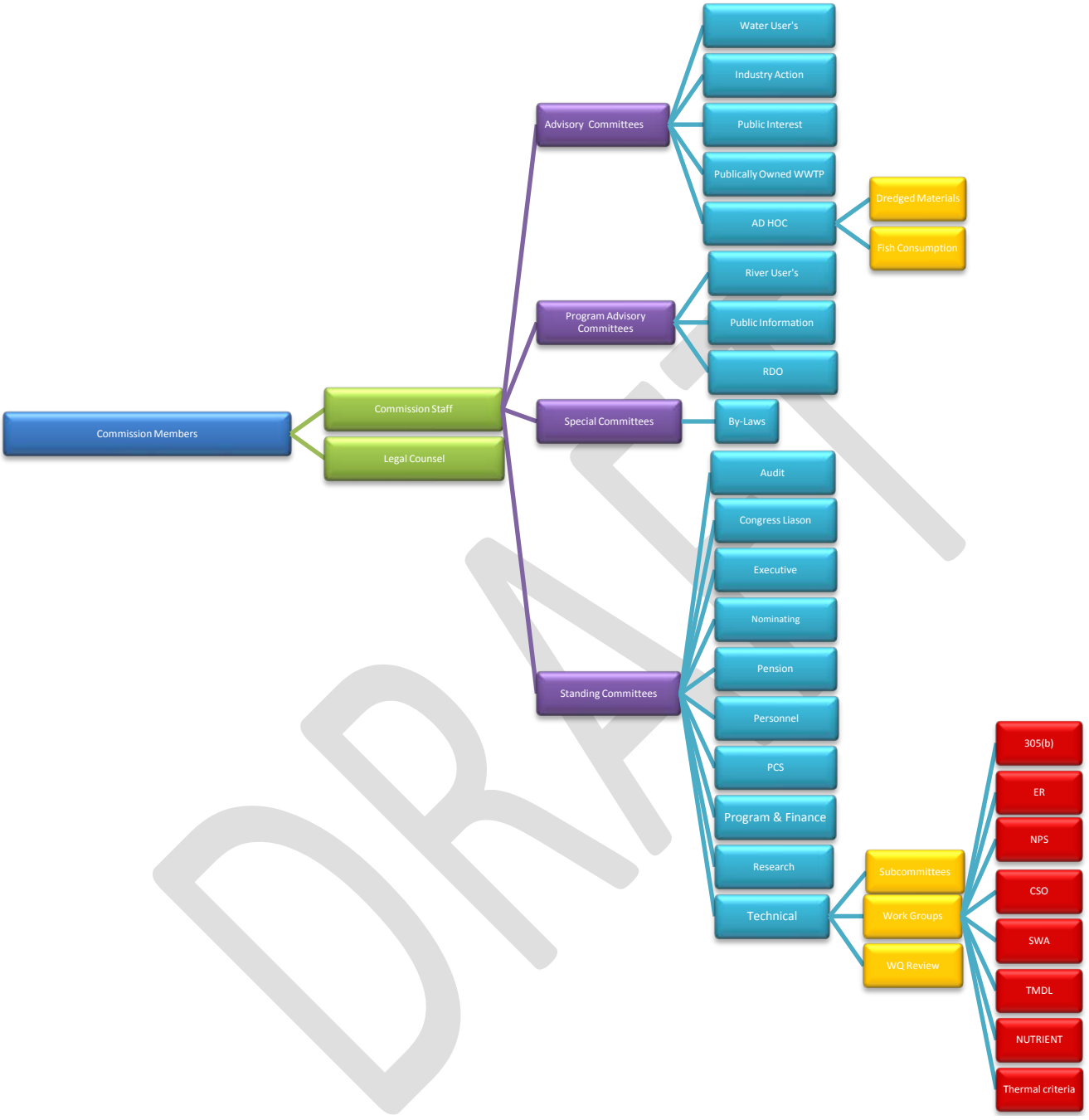

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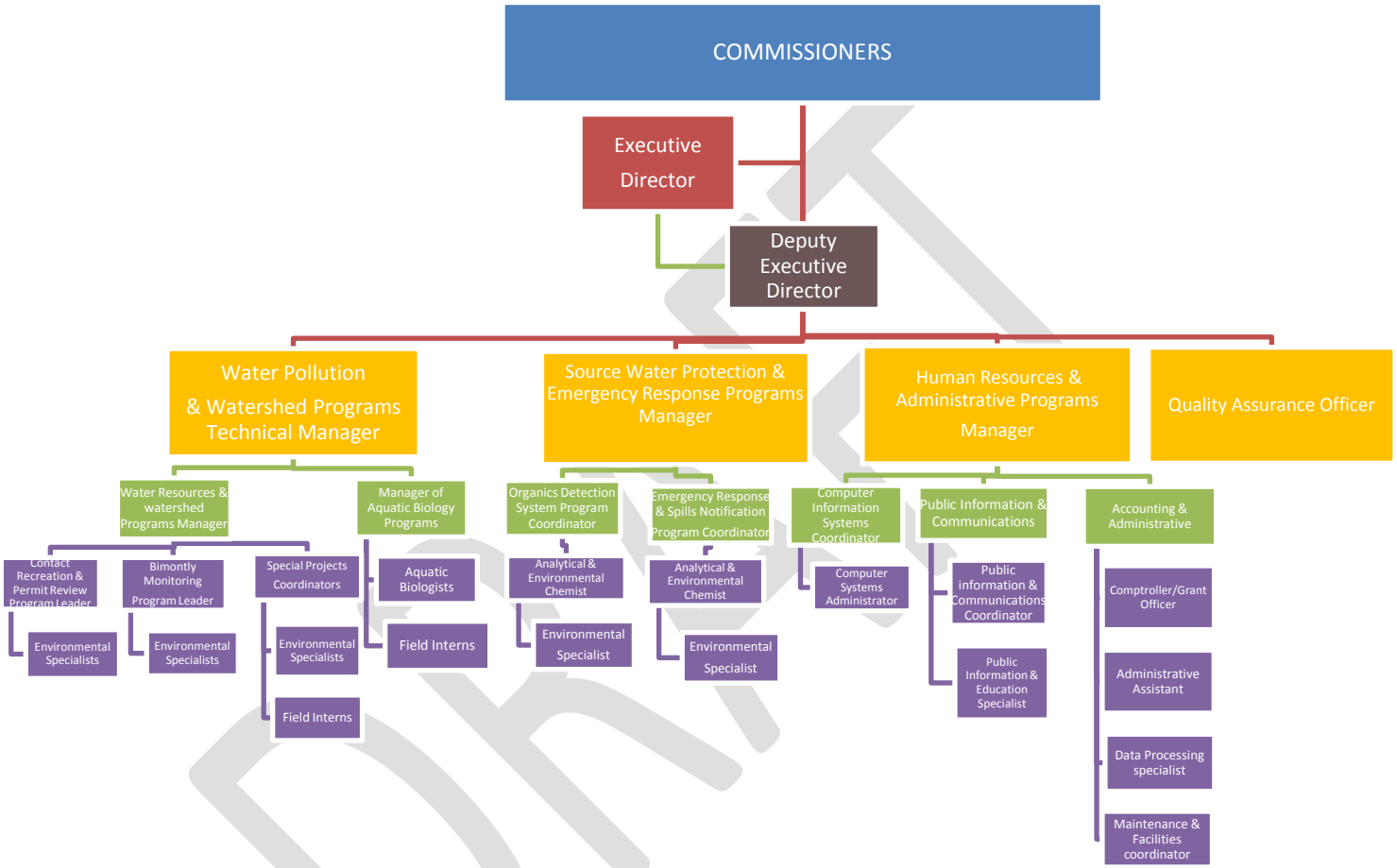

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