



TASK 2: QUALITY ASSURANCE

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Exhibits

See CRP web site for QAPP Shell and related documents

www.tceq.state.tx.us/compliance/monitoring/crp/ga/index.html

TASK 2: QUALITY ASSURANCE

Introduction

Quality assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure a process is of the type and quality needed and expected by the customer. The focus on this definition provides this task's rationale as it relates to project planning, oversight, and corrective action.

Systematic project planning is central to an integrated quality assurance approach and is fundamental to the success of water quality monitoring projects conducted under the Clean Rivers Program (CRP). It is a process that considers:

- project objectives
- measurement performance specifications
- appropriate methods
- field and laboratory quality control
- data management
- verification and validation of data
- oversight
- corrective action

Quality Assurance Project Plans (QAPPs) will continue to be used by the CRP to plan, organize, and define its quality assurance process in order for data to be collected with the level of reliability needed for decision-making. Although QAPPs for the CRP do not require Environmental Protection Agency (EPA) approval, the Texas Commission on Environmental Quality (TCEQ) requires that data collection under the CRP be comparable to other data collected by the TCEQ and be consistent with EPA requirements.

Oversight of data collection activities is a key component of quality assurance. Appropriate and well-timed oversight of projects -in the form of on-site visits - is essential to ensure that all elements of the quality system and the QAPP are conducted as prescribed. Also paramount to success is ensuring that corrective actions are identified, implemented in a timely manner, documented, monitored, and verified. Also, very important, is a good and effective system for data review. These activities will continue to be emphasized during the FY 2008-2009 biennium.

Implementation of the National Environmental Laboratory Accreditation Program (NELAP) in Texas will have an impact on the CRP as environmental testing laboratories become accredited during the FY 2008-2009 biennium. The FY 2006-2007 guidance specified that the due date for application was August 31, 2007. All laboratories will need to be compliant with the National Environmental Laboratory Accreditation Conference (NELAC) standards during the FY2008-2009 contract period and all Quality Assurance Documents should reflect that. CRP laboratories will need to be accredited by July 1, 2008. Many of the laboratory requirements specified in the NELAC standards have been incorporated under past contracts. So, CRP laboratories should be well on their way to becoming accredited.

The TCEQ recognizes that the NELAC accreditation process will be labor and resource intensive. Additional costs associated with NELAC as they relate to the CRP may be charged directly or indirectly to the program, but must be fully explained and justified in the workplan and include deliverables. Laboratories should be working towards incorporating costs associated with



accreditation into their rate schedules, so that in future contracts, additional costs to the CRP may be reflected in a per-analysis rate.

Contract Shell Provisions

Certain key components related to quality assurance are essential to the collection of valid data and ensure, to the greatest extent possible, that data produced by the CRP will be of the type and quality necessary for its intended use. These critical components represent the three key aspects of quality assurance: planning, implementation, and oversight. Due to the significance of these factors, the following provisions have been incorporated into the CRP contract shell:

- All work funded by this Agreement that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be planned in consultation with the TCEQ and be documented in a fully approved TCEQ Quality Assurance Project Plan (QAPP) before data collection can be implemented.
- The GRANTEE shall ensure laboratory data analyzed on or after July 1, 2008, is produced by laboratories (and subcontract laboratories) that are accredited according to Texas Water Code Chapter 5, Subchapter R (TWC §5.801 *et seq*) and Title 30 Texas Administrative Code Chapter 25, Subchapters A and B.
- The GRANTEE shall ensure laboratory data analyzed from the date of this agreement to July 1, 2008, is produced by laboratories (and subcontract laboratories) that conform to the NELAC Standards.
- If this Agreement is funded pursuant to the Texas Clean Rivers Program, the GRANTEE must perform on-site assessments of field monitoring activities for all sub-participants and/or subcontractors at least once during the Contract Term, for on-going projects, or once during the project's lifetime, for short-lived projects.

Project Planning

A formal project planning process has many benefits:

- It optimizes data collection efforts by promoting communication and input from all involved parties.
- It ensures that data collected are of the type and quality appropriate to their intended use; and therefore, support decision making.
- It maximizes the use of existing data.
- Conditions for data management will be specified, such as data coding, verification and validation, manipulation, and transfer.
- Agreements reached during the process will determine the information to be documented in the QAPP appendix, expediting review and approval so projects can begin in a timely manner.

Special study and permit support monitoring projects to be conducted during FY 2008-2009 should be thoroughly discussed with TCEQ staff and all applicable parties before the work plan is finalized. If Basin Planning Agencies intend to conduct multiple special projects under subcontract, they should carefully consider staggering projects over the biennium, with consideration of variable funding.



Sufficient time should be allocated to properly plan and execute the QAPP prior to data collection and reporting. Certain projects (or components of projects such as report writing) can be carried into the subsequent biennium to allow for adequate data collection. This should be determined prior to the execution of the work plan.

Basin Planning Agency Project Managers should contact their CRP Project Managers to indicate their intent and desire to conduct a planning meeting. After a date has been agreed upon, the CRP Project Manager will make the Agency contacts.

The objective of the project planning meeting is to implement a systematic planning process based on the elements of the QAPP. The information developed during the planning meeting will be incorporated into a QAPP.

The Basin Planning Agency Project Manager will play the lead role in respect to planning projects and will:

- establish the planning team in consultation with the TCEQ
- schedule meetings
- distribute meeting materials in advance of the meeting
- facilitate the meetings
- prepare meeting minutes

Meeting preparation materials should include a proposed scope of work rather than a draft QAPP. Meetings may be conducted in Austin, at the Basin Planning Agency, or via conference call, and will usually take 1-2 hours. The detailed meeting minutes serve as the deliverable for this task. The meeting minutes should be submitted with the progress report.

Approval to Conduct Work

As stated in the contract, all work funded by the contract that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QAPP except under two limited conditions.

1. Lapses in Basin-wide QAPP coverage sometimes occur due to time constraints in getting updated QAPPs fully approved and distributed at the beginning of a new two-year contract cycle. When a QAPP is due to expire, if no changes are being made to the next QAPP other than to the monitoring schedule, and the new monitoring schedule has already been approved, then the Basin Planning Agency may request authorization to proceed with the monitoring plan conditionally under the existing QAPP until the new QAPP is approved and distributed.

To obtain conditional approval, the Basin Planning Agency Project Manager must submit an e-mail request to the CRP Project Manager prior to the expiration date of the existing QAPP. The CRP Project Manager, with the concurrence of the TCEQ CRP Program Manager and the Lead Quality Assurance Specialist (QAS) may grant approval for a maximum of 90 days beyond the expiration date of the existing QAPP.

2. Special projects which are documented in QAPP appendices may be approved conditionally by the CRP Program Manager on a case-by-case basis. Under all circumstances, these



projects must have been planned in accordance with the requirements for project planning, and a first draft of the QAPP appendix must have been submitted to the TCEQ for review. The CRP Program Manager in concurrence with the CRP Project Manager and the Lead QAS, may permit some work to begin while noncritical deficiencies are being resolved.

To obtain conditional approval to begin work on special projects, the Basin Planning Agency Project Manager must submit an e-mail request to the CRP Project Manager outlining the reasons why a conditional approval is being requested, what work will begin conditionally, and when. The CRP Program Manager will send a response to the Basin Planning Agency Project Manager by e-mail.

Specific CRP Laboratory Requirements

Ambient Water Reporting Limits (AWRLs) For surface water to be evaluated for compliance with Texas Surface Water Quality Standards (TSWQS) (30 TAC §307.1 - 307.10) and screening levels, data must be reported at or below specified levels. To ensure data are collected at or below these levels, required reporting specifications (now known as AWRLs, but previously known as minimum analytical levels, or MALs) were established early in the CRP.

Many of the MALs were originally based on widely available analytical techniques and not necessarily on the data needs of the TCEQ's surface water quality programs. A workgroup was established in the summer of 2001 to review the MALs to ensure reporting limit requirements were properly aligned with the TCEQ's data needs. The term MAL was confusing for a variety of reasons so, as a first step, the workgroup adopted the term AWRL to more accurately reflect the process.

To set AWRLs appropriately, the workgroup first looked at how data would be compared against the TSWQSs. Ultimately, the lowest standard or screening level was used to set each AWRL. The parameters for which AWRLs have been established are available electronically (see Web Page Resources for Task 2).

While the AWRL is the program-defined reporting specification for each analyte, most laboratories report data based on the concept of a limit of quantitation (LOQ). A limit of quantitation (formerly known as Reporting Limit) is the minimum level, concentration, or quantity of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. The following requirements must be met in order to report results to the CRP:

- **The laboratory's LOQ for each analyte must be at or below the AWRL as a matter of routine practice**
- **The laboratory must demonstrate its ability to quantitate at its LOQ for each analyte by running an LOQ check standard each time that CRP Samples are analyzed. The requirements for lab control check standards are described in Section B5 of the QAPP shell.**

The laboratory should be instructed to analyze a calibration standard (if applicable) at the LOQ on each day CRP samples are analyzed. Two acceptance criteria **must** be met. 1) Calibrations (including the standard at the LOQ) must meet the calibration requirements of the analytical method. 2) The laboratory will analyze an LOQ check standard on each day that CRP samples are analyzed.



For certain parameters that are routinely reported close to the LOQ, LCS should be run at the LOQ. These parameters include nutrients and metals.

Authorized Laboratory Methods

Analytical methodologies under the CRP are specified in the TSWQS. The TSWQS mandate that procedures for laboratory analysis will be in accordance with:

- the most recently published edition of the book entitled *Standard Methods for the Examination of Water and Wastewater*
- the latest version of the *Surface Water Quality Monitoring Procedures (RG 415 and RG 416)*
- 40 Code of Federal Regulations (CFR) Part 136
- other reliable procedures acceptable to the Agency

Changes to 40 CFR §136 became effective March 12, 2007. These changes allow the use of 189 updated methods from the 19th and 20th editions of *Standard Methods* in addition to the methods approved earlier for use. Requirements for analytical methodologies are specified in the QAPP shell document.

Laboratory Data Review

The laboratory's role in the review of CRP data is very important. At a minimum, all laboratory data must be reviewed (as described under "**Data Review**" in this Task). Laboratories should have SOPs in place to ensure data are free from transcription and calculation errors, all quality control measures are reviewed and evaluated, and project specifications are met. Laboratory data review records must be signed and dated by the analyst reviewer(s) and/or the Laboratory QA Officer.

The use of data review checklists by the laboratory is encouraged. If any requirements or specifications are not met, based on the data review, the laboratory should document the nonconforming activities and submit the information in the report narrative to the Basin Planning Agency with the data. In turn, this information must be communicated to the TCEQ by the Basin Planning Agency in the Data Summary.

Statistical Control of Precision and Bias

Analytical laboratories must have a statistical process in place to review results as applicable to control on-going performance. To generate data for the CRP, the laboratories' control limits must be set and controlled within the bounds set by the measurement performance specifications for laboratory control samples (LCS) and LCS/LCS duplicates as defined in Table A7 of the QAPP.

The most common method of statistical process control involves the use of control charts as described in *Standard Methods for the Examination of Water and Wastewater* or the EPA *Handbook for Analytical Quality Control in Water and Wastewater Laboratories*. (Computer-generated lists or databases with values, limits, and trends may be used as an alternative to control charts.)

Laboratory Test Reports

Laboratory test reports (if applicable for routine water quality data analysis) should be clear, unambiguous and, at a minimum, contain the information specified in the NELAC Standards. The information required by NELAC with test results is required even if the data are transmitted from the laboratories in event result format unless the laboratory has valid reasons for not doing so. In addition to the specified information, test reports for the CRP should include project-specific quality control results such as results of equipment, trip, and field blank results, as applicable. It is important for



laboratories to provide narrative information about why results were not compliant with specifications as stated in a previous section under "Laboratory Data Review." Without this information, Basin Planning Agency data management staff cannot verify and validate data and provide required information on the Data Summary when data are submitted to the TCEQ. Copies of test reports will be reviewed during monitoring systems audits. Information regarding standard test report format is contained in the QAPP shell document. Additional information may be requested.

Project Oversight

In order to ensure that data collection is conducted as planned and environmental monitoring projects are successful, a process of oversight and evaluation is necessary. Adequate oversight and evaluation of projects ensure that:

- work is accomplished as planned
- data quality is adequate
- corrective actions, when needed, are implemented effectively

Basin Planning Agency Oversight Requirements

Basin Planning Agencies are required to oversee the activities addressed in their QAPPs and must conduct formal oversight of all sub-participants who conduct field monitoring.

Two types of field monitoring oversight are acceptable: 1) readiness reviews and 2) monitoring systems audits. Both of these activities should be performed on-site at least once during the contract cycle in the case of on-going projects, or once during a project's lifetime in the case of short-lived special studies. (This requirement does not apply if all work is performed by the Basin Planning Agency.) The type and timing of oversight activities will be negotiated during project planning and will be documented in the QAPP.

Basin Planning Agencies are also tasked with conducting status monitoring which involves the continual evaluation of programs or projects to ensure they are being conducted as planned and documented. Oversight activities are described in the following sections.

Readiness Review

A readiness review involves an evaluation to determine if all components of the project are in place so that work can begin. Readiness reviews are the preferred type of assessment activity to detect deficiencies so that corrective actions can be taken prior to initiation of data collection activities. The process is designed to evaluate the performance or effectiveness of the sampling process from collection through final reporting of the results, including (as applicable):

- required documentation
- adequacy of facilities and equipment
- instrument calibration procedures and logs
- field measurement protocols
- sample collection protocols
- biological sampling protocols
- sample handling and analysis protocols
- data verification and validation protocols and records
- data management protocols



The Monitoring Systems Audit Checklist is available electronically (see Web Page Resources for Task 2). The checklist should be modified to accommodate a readiness review. To conduct a readiness review, the reviewer must be familiar with the QAPP, field standard operating procedures, and data management protocols.

Monitoring Systems Audit

A monitoring systems audit is a thorough and systematic technical systems audit which involves an on-site qualitative review of activities related to monitoring and during which facilities, equipment, personnel, training procedures, and record keeping are examined for conformance to the requirements of the QAPP. The goal of a monitoring systems audit is to detect deficiencies and/or nonconformances so that corrective actions can be taken. The audit process is designed to evaluate the sampling process from collection through final reporting of the results to include the same types of activities/processes looked at during a readiness review and can be performed at any time during the lifetime of a monitoring program or project.

The Monitoring Systems Audit Checklist is accessible electronically (see Web Page Resources for Task 2). The checklist should be adapted as necessary based on the audit scope.

Report and Response

Following either a readiness review or a monitoring systems audit, the auditor must provide the audited organization with a report within 30 days. If no deficiencies are identified, then the report should state such. If deficiencies are identified, they must be reported as "findings" in the report. Audit reports should reference specific requirement(s) in the QAPP or in SOP and should not be general in nature. Additional information regarding the justification of findings may be included. The audited organization should be asked to respond to the report in writing within 30 days regarding:

- the root cause of the deficiency
- the effect, if any, on any previously completed or current work
- proposed corrective action(s) to correct the deficiency
- action(s) planned to prevent recurrence of the deficiency
- date that each action will be, or was completed

A copy of the audit report and the response must be submitted as a deliverable to the CRP Project Manager with the progress report no later than the quarter following the one in which the audit was conducted.

Status Monitoring

Status monitoring involves the continual evaluation of programs or projects to ensure they are being conducted as planned and documented in the QAPP. This type of oversight is specified in the QAPP to ensure that CRP Project Managers perform a continual review of quality assurance activities over the course of the biennium. This type of monitoring may be a formal management review or a less formal review of QA activities. At a minimum, the Basin Planning Agency Project Manager should request a written status of QA activities from staff on a quarterly basis.

TCEQ Laboratory Inspections and Monitoring Systems Audits

The TCEQ will continue to oversee Basin Planning Agency activities by performing laboratory and monitoring systems audits of Planning Agencies as determined by a risk-based assessment.



The TCEQ may inspect laboratories that provide data to the CRP. These inspections are planned annually and conducted throughout the year. Basin Planning Agencies may contact the CRP Project Manager to request a laboratory inspection. The TCEQ Laboratory Inspector will accommodate requests for inspections as time and resources permit. Regulations, standards, procedures, and other documents that specify requirements by which laboratory activities may be evaluated/assessed include:

- Contracts and QAPPs
- SOPs
- Laboratory Quality Manuals
- the NELAC Standards
- EPA's *Handbook for Analytical Quality Control in Water and Wastewater Laboratories* EPA's *Methods for the Chemical Analysis of Water and Waste*
- APHA's *Standard Methods for the Examination of Water and Wastewater*
- 40 Code of Federal Regulation, Part 136

These documents include requirements concerning laboratory audits; analyst training; systems for calibration of weights, thermometers, and other instruments; traceability of standards; limit of detection (LOD) (formerly method detection limit) studies; etc.

Quality Assurance Project Plans

The development and implementation of a QAPP help to ensure:

- all projects use a planned approach, and that objectives, roles, and responsibilities of the participants are defined
- all aspects of measurement systems are defined and appropriate
- project oversight is adequate
- data verification and validation procedures are specified, thus enabling reconciliation with data quality objectives

Shells have been provided for all CRP QAPP documents and can be accessed electronically (www.tceq.state.tx.us/compliance/monitoring/crp/ga/index.html). The use of shell documents has streamlined the CRP QAPP preparation, review, and approval processes.

Much of the shell language represents CRP and/or TCEQ requirements. Language in standard text format is provided as an example. The language should be modified to reflect actual activities. Please discuss changes with the CRP Project Manager. Information to be provided by the Basin Planning Agency is provided in shaded text. Italicized instructions are provided for the various sections and should be deleted from the document before it is submitted to the TCEQ.

The first draft of the QAPP should be submitted electronically. The TCEQ will send the first round of comments in a table. Responses to each TCEQ comment should be submitted noting how the comment was addressed in the column marked "Response". The review and approval of proposed revisions to the QAPP may be expedited if two versions of the document are submitted. One version should include highlights and strike-outs to show changes to the document, the other should have the highlights and strike-outs removed.

Web Site Deliverable

Certain sections of QAPPs should be posted on the Basin Planning Agency's CRP Web page to enable the public to know and understand the water quality monitoring that is being conducted in their basin. These sections include the monitoring program or project objectives, measurement performance specifications (i.e., Table A7), link to the coordinated monitoring schedule (CMS) website with disclaimer that states that the CMS includes stations monitored by other entities, and special study appendices. You may also include monitoring schedule and maps of sampling sites.

Biennial Submittal of Basin-Wide QAPPs

Draft basin-wide QAPPs should be sent electronically to the CRP Project Manager on June 15 prior to the start of the new biennium. Review comments will be sent to the Basin Planning Agency Project Manager within approximately 30 days of QAPP receipt. The Basin Planning Agency must modify and resubmit the document within 30 days. The final basin-wide QAPP is due by August 15, 2007 for FY 2008/2009 and August 15, 2009 for FY 2010/2011.

Approval, Signature, and Distribution of Basin-Wide QAPPs

After the TCEQ has given verbal approval of the QAPP, **three** copies of the document should be signed by the Basin Planning Agency based on the designated signatures on the QAPP shell and sent to the TCEQ for signature. An electronic copy of the QAPP should be submitted to the CRP Project Manager in addition to the hard copies. The TCEQ will retain two signed copies of the QAPP. The Basin Planning Agency may send additional signature pages it would like to be signed by the TCEQ, if necessary. [we ask that you provide an electronic copy of the QAPP in case changes need to be made during sign off]

Required signatures are designated on the Basin-wide QAPP shell document. The Basin Planning Agency must distribute the QAPP to all participants and sub-participants. (Note: The TCEQ Lead QA Specialist will distribute copies to the TCEQ personnel indicated on the distribution list.) The Basin Planning Agency will secure a receipt and commitment letter from sub-participants of its QAPP stating the sub-participants' receipt of the document and commitment to requirements contained in the QAPP. An example letter is provided in the QAPP shell document. This QAPP documentation should be maintained as part of the project's quality assurance records. **Copies of all commitment letters must be forwarded to the TCEQ within 60 days of TCEQ approval of the QAPP.**

QAPP Amendments

Project changes (including changes to analytical procedures/changes to Table A.7, sampling sites and/or schedule, changes that would affect the data generated by the project, project organization, etc.) require amendments to the QAPP. QAPP amendments are contract deliverables and will be submitted to the TCEQ on an "as needed" basis. The Basin Planning Agency must provide a justification and summary of the changes as specified in the QAPP amendment shell, as well as specific details related to the required QAPP elements. The changes should not be implemented until the amendment is fully executed.

It is recognized that many QAPP amendments involve changes to address existing activities which have been consistent with program requirements all along and therefore correct information that was not included or was incorrect in the original QAPP. These amendments should not be "backdated."

To streamline the amendment process, there is a procedure for electronic review and approval of QAPP amendments and revisions to appendices. The steps for the process are as follows:



- 1) The Basin Planning Agency sends the TCEQ CRP Project Manager an e-mailed amendment.
- 2) TCEQ Project and Lead QA Specialists review the amendment and provide comments to the TCEQ CRP Project Manager or indicate that amendment can be approved.
- 3) If an amendment is ready to be approved, the TCEQ Lead QA Specialist initiates an e-mail "signature page" and sends the e-mail to all signatories: Basin Planning Agency Project Manager and QAO, TCEQ CRP Project Manager and Project QA Specialist.
- 4) The first signatory indicates approval by checking the box by his/her name and replying "in order" to the person who sent the e-mail, and cc-ing" all other signatories.
- 5) Each subsequent signatory follows the steps in item #5, in the order of the list of names on the signature page.

When the TCEQ Lead QA Specialist receives the final signatures, s/he will put the TCEQ approval date on the cover of the final amendment and e-mail the completed signature page and amendment to the Basin Planning Agency Project Manager or QAO, TCEQ Project Manager, and TCEQ DM&QA.

As in the past, the Basin Planning Agency will secure a commitment letter from sub-participants of its QAPP stating the sub-participants' commitment to requirements contained in the QAPP amendment. An example letter is provided in the QAPP shell document. QAPP commitment documentation should be maintained as part of the project's quality assurance records. **Copies of all commitment letters must be forwarded to the TCEQ within 60 days of TCEQ approval of the QAPP amendment.**

QAPP Amendments must be distributed to all personnel on the distribution list maintained by the Basin Planning Agency. (Note: The TCEQ Quality Assurance work group (QAWG) will distribute copies to TCEQ project participants, including but not limited to the CRP project Manager, DM&QA staff, and the Houston Laboratory as appropriate).

QAPP Appendices

Appendices are prepared to itemize additional work or projects not initially described in the original QAPP. The appendices are planned by PA Project Managers in coordination with CRP project managers, the Project QA Specialist, the Lead QA Specialist and other technical specialists (laboratories, consultants, other agency water programs, etc.) as appropriate.

Appendix B: Monitoring Schedule Update

Because the basin-wide QAPP has a two-year effective date, the monitoring schedule in Appendix B of the basin-wide QAPP will need to be updated for the second year of the biennium after the annual coordinated monitoring meeting. Revisions to Appendix B should be submitted for review and approval by July 31, 2008, in the first year of the contract period for the second year of the contract period.

Special Study or Permit Support Monitoring

QAPP appendices are designed to incorporate special study or permit support monitoring projects into the QAPP as they are planned. Although QAPP appendices are designed to be attachments to the basin-wide QAPP and reference applicable parts, they do need to have specific information addressed that is unique to a project such as: problem definition, task description, project objective, measurement performance specifications, sample design rationale, sampling methods requirements, data management, etc. There should be enough information provided in the QAPP appendix that it functions, for easy reference, like a stand-alone document. This information will be addressed during the project planning meeting.



QAPP appendices will be sent to the TCEQ through the CRP Project Manager, who will track the deliverables and forward them to the Lead QA Specialist for review. After the document has been reviewed by the TCEQ, comments will be compiled and sent to the Basin Planning Agency through the CRP Project Manager. The TCEQ is committed to an expeditious review and approval of these documents. Generally, they can be reviewed and approved within a short time frame if all issues discussed in the planning meeting are addressed properly.

Revisions to Appendices

Revisions to the Appendices may be necessary to address incorrectly documented information or to reflect changes in project organization, tasks, schedules, objectives, and methods. Requests for revisions will be directed from the Basin Planning Agency Project Manager to the CRP Project Manager electronically. Revisions are effective immediately upon approval by the Basin Planning Agency Project Manager, the Basin Planning Agency QAO, the CRP Project Manager, the CRP Lead QA Specialist, and the CRP Project QA Specialist. They will be incorporated into the QAPP by way of attachment and distributed to personnel on the distribution list by the Basin Planning Agency Project Manager.

Quality Assurance Project Plans - Additional Information

Project Management

The *Project Management* section of a QAPP defines roles and responsibilities of CRP program and project participants. The roles of subcontractors and monitoring participants should be clearly explained and should reflect roles in respect to the CRP not to the Basin Planning Agency in general. The *Organizational Chart* in the QAPP is intended to show lines of authority and communication for the exchange of information and notification of problems.

The CRP encourages the Basin Planning Agencies to assign project management and QA functions to separate personnel within their organization. Ideally, the QA Officer should not be functionally involved in data generation, data use, or decision-making; however, the availability of CRP resources does not make this a feasible option in certain situations.

The CRP also encourages the Basin Planning Agencies to assign project management, QA, and data management roles and responsibilities to sub-participant group staff. This helps to more clearly define roles and responsibilities and assists in the delegation of responsibilities to sub-participating staff.

Laboratories that provide data to the CRP must have a "Quality Manager" who has responsibility for the quality system and its implementation and maintenance. In small laboratories, the Quality Manager may also be the technical manager or deputy technical manager.

TCEQ Quality Assurance Organization

The TCEQ Quality Assurance Work Group of the Compliance Support Division is the lead quality assurance organization within the TCEQ. The Lead CRP QA specialist is part of the QAWG.

The QA organization also includes a Project QA Specialist. The CRP Project QA Specialist serves as a liaison with the TCEQ QAWG and is the point-of-contact within the TCEQ CRP staff on issues related to quality assurance.



Together, the CRP Lead and Project QA Specialist are responsible for developing and implementing the CRP quality assurance program. Their roles and responsibilities are defined in the CRP QAPP shell.

Measurement Performance Specifications

Measurement performance specifications define the data quality needed to satisfy project objectives. To this end, measurement performance specifications are qualitative and quantitative statements that:

- clarify the intended use of the data
- define the type of data needed to support the end use
- identify the conditions under which the data should be collected

Element A7 of the QAPP addresses measurement performance specifications, including:

- analytical methodologies
- AWRLs
- limits of quantitation
- bias limits for laboratory control samples
- precision limits for laboratory control sample duplicates
- completeness goals
- qualitative statements regarding representativeness and comparability

The items identified above need to be considered for each type of monitoring activity. The CRP emphasizes that data should be collected to address multiple objectives, if possible, thereby maximizing the expenditure of resources. Caution should be applied when attempting to collect data for multiple purposes because measurement performance specifications may vary according to the purpose. For example, limits of quantitation may differ for data used to assess standards attainment and for trend analysis. When planning projects, first priority should be given to the main use of the project data and the data quality needed to support that use, then secondary goals should be considered.

The measurement performance criteria for routine data collection are specified in the basin-wide QAPP shell. Further information is provided in the following sections. The final QAPP statements regarding project objectives and measurement performance criteria should be posted on the Basin Planning Agency's Web page as defined in this task under "**Web Site Deliverable.**"

Precision

Precision is the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. It is a measure of agreement among replicate measurements of the same property, under prescribed similar conditions, and is an indication of random error. Measurement performance specifications for laboratory precision (as measured by the agreement of laboratory control duplicates pair results) have been established for the CRP and are calculated by relative percent difference. Lack of precision in laboratory duplicate pair results stem from analytical system variability introduced at each step during sample preparation and analysis. Detail is provided in the QAPP shell regarding the implementation of the laboratory precision requirement, including the formula for evaluating the acceptability of LCS/LCS duplicate pairs.

Field Splits

A field split is a single sample subdivided in the field, preserved and analyzed separately as two separate samples. Field splits are used to assess the variability of sample handling, preservation, and storage along with the variability of the analytical process. The QAPP shell, Element B5, contains information on how to implement the field split requirement and evaluate the results. Field duplicates are defined as two samples sequentially taken one after the other.

Bias

Bias is the systematic or persistent distortion in a measurement process that causes error in one direction. Measurement criteria for bias (as measured by the recovery of LCSs and LOQ Check Standards) have been established and are calculated by percent recovery of a measured value compared to a true value. The analysis of laboratory control sample recovery (as a replacement for matrix spike recovery) can be used to measure the analytical bias in the measurement system. The QAPP shell, Element B5, contains information regarding the implementation of this requirement and the evaluation of results.

Data Comparability

When collecting water quality data within a river basin, the conditions under which the data are collected and analyzed must be consistent if data are to be compared from one site to another. The degree to which sampling conditions, analytical procedures, and reporting units are consistent from one data set to another is a measure of comparability. Caution must be applied in mingling data collected under different sampling regimes. General language regarding the comparability requirement is incorporated into the QAPP shell, Element A7.

Blanks

The SWQM Program requires field equipment blanks for metals-in-water samples, trip blanks for VOA samples, and project-specific field blanks. The basin-wide QAPP shell and the *Surface Water Quality Monitoring Procedures (RG-415)* include details regarding these requirements and criteria for evaluation.

Quality-Related Documents and Records Retention

Quality-related documents are those that the CRP uses for specifying requirements and instructions concerning data quality, such as QAPPs, Quality Manuals, and SOPs. Quality-related records are items that furnish objective evidence of the quality of items that have been verified as correct, complete, or compliant with CRP requirements, such as test reports and forms.

At a minimum, the CRP Quality Management Plan requires Basin Planning Agencies to maintain documents for 5 years after the close of a project for a total of 7 years and records for 2 years after the close of a project for a total of 4 years. Therefore, the documents and records retention schedule in the QAPP must specify that documents will be held in accordance with this requirement. In addition, the QAPP must provide specific locations where documents will be kept.

Laboratory records associated with accreditation parameters shall meet the requirements of Chapter 5, Section 5.12 of the NELAC Standards and shall be maintained for a minimum of five years unless otherwise designated for a longer period in another regulation or authority. In the case of data used in litigation, the laboratory is required to store such records for a longer period upon written notification from the accrediting authority.

Data Collection Procedures

The TCEQ *Surface Water Quality Monitoring Procedures (RG-415 and RG-416)* (www.tceq.state.tx.us/compliance/monitoring/water/quality/data/wqm/mtr/swqm_procedures.html)

describe field procedures used for surface water sampling and biological collection for the purpose of submitting data to TCEQ. The QAPP states that the most recent version of the *Surface Water Quality Monitoring Procedures* must be used, including any updates made between revisions. If other SOPs apply, they should be referenced in the QAPP, as appropriate. SOPs should not be submitted with the QAPP for TCEQ review (unless specifically requested) but should be available to sampling staff and accessible for review by TCEQ staff during an audit.

QAPP Maps

QAPP maps need to include and label: sampling sites covered under the QAPP, stream/reservoirs, major roads, and cities.

Use and Qualification of Non-Measurement Data

Data which are not newly generated as part of a project are called "existing," "historical," or "non-measurement" data. For the purpose of routine data, Element B9 of the basin-wide QAPP shell document addresses non-measurement data and specifies, "this QAPP does not include the use of routine monitoring data obtained from non-measurement sources." Therefore, Basin Planning Agencies should not request that historical routine data be submitted through the CRP.

However, in some cases, non-measurement data will be co-mingled with new data collected under a special project or permit support QAPP appendix. Acquiring non-measurement data can allow data needs to be met despite time and resource constraints. The use of non-measurement data may also provide more detailed and exhaustive information than the project could produce otherwise, allowing for a better understanding of the situation. Sources of non-measurement data include: other projects, databases, reports, etc. These non-measurement data must be qualified in Element B9 of the QAPP.

To qualify non-measurement data, the Basin Planning Agency must consider and describe the following elements of data collection:

- Quality Objectives and Criteria - The original purpose of the data and what QAPP the data were collected under (if applicable) and measurement performance specifications.
- Sampling and Process Design - Sampling locations, dates and times; limitations associated with the data and how these may impact their intended use relative to the project objectives
- Sampling Methods, Handling and Custody - Chain-of-custody procedures, sample preservation, holding times.
- Analytical Methods- Type of analytical equipment, maintenance, and calibration procedures; laboratory analyst training and capability; sample preparation and methods of analysis.

For the purpose of CRP projects, it is important to verify that data are consistent with TCEQ requirements and; therefore, comparable to other data, allowing for comparisons. To qualify non-measurement data, the Basin Planning Agency must use whatever metadata are available and consider and describe all elements of the QAPP, as applicable in Element B9. The EPA Guidance document *EPA QA/G-5* (See Web Resources for Task 2) provides information regarding the qualification and use of existing data.

Deficiencies, Nonconformances, and Corrective Action



Basin Planning Agencies are asked to address issues that may affect data quality. Definitions are in place to help Basin Planning Agencies track, address, and report issues effectively without imposing unnecessary requirements.

For the purpose of the CRP, **deficiencies** are defined as unauthorized deviations from procedures or documentation specified in the QAPP and referenced documents. (Note: Deficiencies do not normally include things for which there is an established procedure to address.) **Nonconformances** are deficiencies which affect the quality and/or quantity of data generated by the CRP. Action must be taken to eliminate the causes and effects of deficiencies. Basin Planning Agencies must address deficiencies in response to deviations associated with:

- sampling activities
- chain-of-custody
- analytical method requirements
- quality control
- data management

Deficiencies are documented in logbooks, field data sheets, etc. by field or laboratory staff and are reported to the cognizant field or laboratory supervisor who will notify the Basin Planning Agency Project Manager. The Basin Planning Agency Project Manager will notify the Basin Planning Agency Quality Assurance Officer (QAO) of the deficiency. The Basin Planning Agency QAO will initiate a nonconformance report (NCR) to document the activity or item which may be nonconforming.

Some examples of deficiencies that should be documented and tracked in a report include the following:

- hold times for bacteria samples expired
- post calibrations not performed
- samples not preserved in the field
- incubator temperature out-of-range
- bacteria samples not collected in sterile bottles
- field blank contamination

The Basin Planning Agency Project Manager, in consultation with the Basin Planning Agency QAO, will determine if a deficiency is a nonconformance. If the answer is “yes” to any of the following questions, the deficiency is considered to be a nonconformance and corrective action is required.

1. Is the deficiency a recurring issue?
2. Could the deficiency affect data currently residing in the database?
3. Could the deficiency affect the availability of data for decision making?

If the deficiency does not constitute a nonconformance, the NCR will be completed accordingly and the report entry closed. If it is determined a nonconformance does exist, the Basin Planning Agency Project Manager, in consultation with Basin Planning Agency QAO, will determine the disposition of the nonconforming activity or item and necessary corrective action(s).

If corrective action is needed, documentation should include:



- root cause of the nonconformance
- programmatic impact
- specific corrective action(s) to correct the nonconformance and to prevent recurrence
- individual(s) responsible for each action
- timetable for completion of each action
- means by which completed corrective action(s) will be documented and verified

NCRs will be included with quarterly progress reports. A form has been developed for the Basin Planning Agencies to document deficiencies, nonconformances, and corrective action. The forms can be accessed electronically at (www.tceq.state.tx.us/compliance/monitoring/crp/qa/index.html). Planning Agencies may choose to use the forms provided or devise their own system and set of forms.

CRP Data Review

A good, well-defined, documented system of data review is very important to ensure the validity of data that are submitted to the TCEQ. This activity has been emphasized in past Guidance documents and will continue to be emphasized during the FY 2008-2009 biennium. For the purpose of reviewing data, the CRP will continue to define and recognize the two terms **verification** and **validation** as they are part of NELAC terminology. Verification is confirmation by examination and provision of evidence that specified requirements have been met. It refers to the data review processes used to determine data completeness, correctness, and compliance with technical specifications contained in applicable documents (e.g. QAPPs, SOPs, QAMs, analytical methods). Validation is the confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use is fulfilled. It refers to a specific review process that extends the evaluation of a data set beyond method and procedural compliance (i.e., data verification) to determine the quality of a data set specific to its intended use.

Beyond the assignment of "final validation" (i.e., data meet conditions of end use and are reportable) to the Basin Planning Agency Project Manager, the terms are not particularly helpful. The terminology is not well-delineated and; therefore, not helpful in defining a data review process or assigning roles and responsibilities. What is helpful; though, is the list of review tasks (whether part of verification or validation) that need to be performed in order to say that data have been reviewed sufficiently and are acceptable for reporting.

The Basin Planning Agency will delineate the specifics of data review in the QAPP and specify responsible parties. Generally speaking, there are levels of review to be performed by field staff and by laboratory staff. The field data review tasks are usually performed by field staff and the laboratory data review tasks are usually performed by laboratory staff. The rest of the tasks are performed after the field and laboratory data are combined into a data set and depending on the situation are performed initially by sub-participant Data Managers or QAOs, and then by the Basin Planning Agency Data Managers or QAOs.

To facilitate the review of data by the various parties, it may be helpful to develop and use checklists that address the various levels of review. Checklists should be developed for the review of field data that incorporate the various requirements defined in the *Surface Water Quality Monitoring Procedures (RG-415)* and in the QAPP so that the data review tasks associated with field data can be accomplished. Likewise, checklists should be developed for the review of lab data. Similarly, the Basin Planning Agency should prepare a checklist for use in reviewing the data after the data set is assembled that speaks to the usability of the data.



If any requirements or specifications of the CRP are not met, based on any part of the data review, the responsible party should document the nonconforming activities and submit the information to the Basin Planning Agency with the data. In turn, this information must be communicated to the TCEQ by the Basin Planning Agency in the Data Summary.

Quality Assurance Training

The CRP encourages all applicable Basin Planning Agency personnel and in-kind contributors to obtain training on topics associated with those outlined in this task. This is especially critical to ensuring data is collected using TCEQ-approved policies and procedures. Special accommodations may need to be made to ensure in-kind contributors get an appropriate level and amount of training. All non-CRP training events require prior approval to be considered for reimbursement. All training will be itemized in Task 1 of the progress report and charged accordingly.





Task 2 Exhibits

See CRP web site for QAPP Shell and related documents

www.tceq.state.tx.us/compliance/monitoring/crp/qa/index.html