Review of Program-funded Quality Assurance Project Plans

April 13, 2011

Approved by Beverly H. van Buuren, Surface Water Ambient Monitoring Program Quality Assurance Officer, on April 13, 2011

1. Purpose

This document describes the process used by the Surface Water Ambient Monitoring Program (SWAMP) Quality Assurance (QA) Team (QAT) to review the QA project plans (QAPPs) associated with SWAMP-funded projects. The review may include consultation with the QAT, and produces a completed checklist and narrative that may be used to make QAPP updates prior to the approval process.

All QAPP reviews performed through the SWAMP QA Help Desk must follow the separate process document *Help Desk Review of Quality Assurance Project Plans*.

The QAPP-creation process is detailed in the SWAMP guidance document *Creation and Approval of Quality Assurance Project Plans for SWAMP-funded Projects*.

2. Responsibilities

Responsibility for the QAPP review process is shared by project management, the SWAMP QA Officer, the QAT, and the SWAMP Bioassessment Coordinator (if applicable).

Project Management is responsible for:

- Creating a QAPP according to the SWAMP guidance document *Creation and Approval of Quality Assurance Project Plans for SWAMP-funded Projects*;
- Consulting with the QAT as necessary;
- Obtaining expert technical review when appropriate or when requested by the SWAMP QA Officer;
- Submitting a QAPP for review;
- Obtaining QAPP approval according to the SWAMP guidance document *Creation and Approval of Quality Assurance Project Plans for SWAMP-funded Projects*; and

- Distributing the approved QAPP according to the document's Element 3: *Distribution List*.

The QAT is responsible for:

- Providing consultation during QAPP development and approval;
- Reviewing QAPPs;
- Summarizing reviews in narrative and checklist formats;
- Forwarding the resulting QAPP checklist and supporting narrative to project management; and
- Cataloging QAPP reviews.

The SWAMP Quality Assurance (QA) Officer is responsible for:

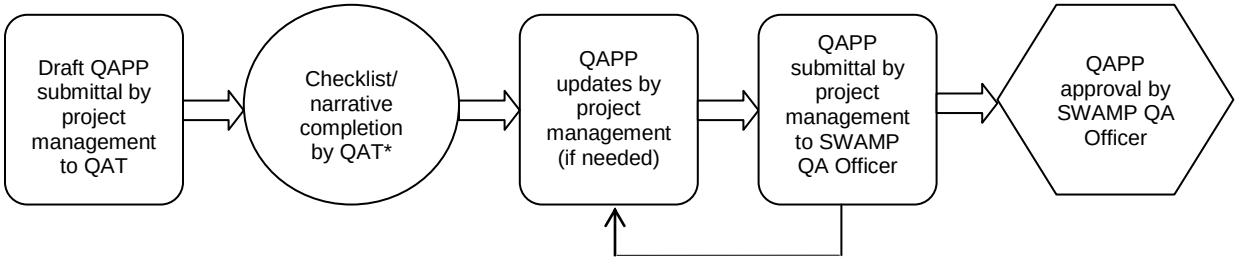
- Informing project management when expert technical review is required prior to QAT QAPP review; and
- Approving new or revised QAPPs according to the SWAMP guidance document *Creation and Approval of Quality Assurance Project Plans for SWAMP-funded Projects*.

The SWAMP Bioassessment Coordinator is responsible for:

- Providing technical review and approval of all bioassessment- and algae-related QAPPs prior to SWAMP QA Officer approval.

3. Procedure

The SWAMP QAPP review process is summarized in the diagram below.



* Preceded by SWAMP Bioassessment Coordinator's technical review (if applicable), or other technical review if required by the SWAMP QA Officer

Consultation by the QAT may be utilized at any point in the above process.

3.1 Quality Assurance Project Plan Consultation

At the discretion of project management, the QAT may be consulted during the QAPP development and review process. This consultation has no time limit and may include:

- QAPP-writing tools and assistance;
- Assembly of focus groups made up of subject matter experts;
- Establishment of non-SWAMP parameters; and
- Re-review following initial QAPP updates.

3.2 Quality Assurance Project Plan Submittal

A draft QAPP is submitted to the QAT by project management. At this time, the project is provided with a projected completion date for the QAPP review. Typically, this is within 2-4 weeks of QAPP receipt. However, the timeline varies depending on the size and complexity of the involved QAPP and the current QAT workload.

3.3 Quality Assurance Project Plan Review

SWAMP-funded QAPPs are comprehensively reviewed by the QAT against Environmental Protection Agency (EPA) guidelines and the *Surface Water Ambient Monitoring Program Quality Assurance Program Plan* (QAPrP).

The QAPP review is documented using the SWAMP QAPP review checklist (see Appendix A of this SOP). This checklist is based on EPA's 24-element guidelines as described in EPA QA/G-5: *Guidance for Quality Assurance Project Plans*, and EPA QA/R-5: *Requirements for Quality Assurance Project Plans*. These elements include:

<u>Group A: Project Management</u>

- A1 – Title and Approval Sheet
- A2 – Table of Contents
- A3 – Distribution List
- A4 – Project/Task Organization
- A5 – Problem Definition and Background

- A6 – Project/Task Description
- A7 – Quality Objectives and Criteria
- A8 – Special Training/Certifications
- A9 – Documentations and Records

Group B: Data Generation and Acquisition

- B1 – Sampling Process Design (Experimental Design)
- B2 – Sampling Methods
- B3 – Sample Handling and Custody
- B4 – Analytical Methods
- B5 – Quality Control
- B6 – Instrument/Equipment Testing, Inspection, and Maintenance
- B7 – Instrument/Equipment Calibration and Frequency
- B8 – Inspection/Acceptance of Supplies and Consumables
- B9 – Non-direct Measurements
- B10 – Data Management

Group C: Assessment and Oversight

- C1 – Assessment and Response Actions
- C2 – Reports to Management

Group D: Data Validation and Usability

- D1 – Data Review, Verification, and Validation
- D2 – Verification and Validation Methods
- D3 – Reconciliation with User Requirements

During review, checklist items relating to each element are assigned one of the following ratings:

- Acceptable – The item is completely addressed in the QAPP or its attachments
- Unacceptable – The item is present in the QAPP or its attachments, but is somehow incomplete

- Not Included – The item is not included in the QAPP or its attachments
- Not Applicable – The item is not applicable to the project

For all checklist items rated “Acceptable” or “Unacceptable”, QAPP section and page number references are noted. For all items, a “Notes” section is available to the reviewer.

The completed QAPP review checklist is then used as the basis for the accompanying narrative. This narrative details and provides recommendations for checklist items that were rated “Unacceptable” or “Not Included” during review. Narrated items contain specific reference to the QAPP element and checklist item that they describe. The narrative is intended for use during a QAPP’s update or revision.

Upon completion of the QAPP review, the QAT forwards a completed QAPP review checklist and supporting narrative to project management.

3.4 Quality Assurance Project Plan Submittal

Following the QAT’s QAPP review, project management revises the document based on the items specified in the QAPP review checklist and narrative. If needed, the QAT may again be consulted before the revised QAPP is finalized. The document is then electronically submitted for the SWAMP QA Officer’s review and approval according to the guidance document *Creation and Approval of Quality Assurance Project Plans for SWAMP-funded Projects*.

4. Documentation

All QAPP reviews and consultations performed by the QAT are cataloged in a spreadsheet. Reviews are also summarized in each QAT annual report.

5. References

Creation and Approval of Quality Assurance Project Plans for SWAMP-funded Projects; Moss Landing Marine Laboratories, Moss Landing, CA, 2011.

Environmental Protection Agency Requirements for Quality Assurance Project Plans; EPA QA/R-5; U.S. Environmental Protection Agency, U.S. Government Printing Office: Washington, DC, 2001.

Guidance for Preparing Standard Operating Procedures; EPA QA/G-6; U.S. Environmental Protection Agency, U.S. Government Printing Office: Washington, DC, 2001.

Guidance for Quality Assurance Project Plans; EPA QA/G-5; U.S. Environmental Protection Agency, U.S. Government Printing Office: Washington, DC, 2002.

Help Desk Review of Quality Assurance Project Plans; Moss Landing Marine Laboratories, Moss Landing, CA, 2011.

Surface Water Ambient Monitoring Program Quality Assurance Program Plan; Moss Landing Marine Laboratories, Moss Landing, CA, 2008.

Appendix A: Quality Assurance Project Plan Review Checklist

SWAMP Element Number	Element	Element Name and Review Aspect	A Acceptable	U Unacceptable	NI Not Included	NA Not Applicable	Page # (Section #)	Notes
A		**PROJECT MANAGEMENT**						
A1	1	**Title and Approval Sheet (s)**						
A1.1	1	Contains project title						
A1.2	1	Indicates revision number, if applicable						
A1.3	1	Indicates organization's name						
A1.4	1	Dated signature of organization's project manager present						
A1.5	1	Signature block for Organization's Project Manager						
A1.6	1	Signature block for Organization's QA Officer						
A1.7	1	Signature block for Contract Manager						
A1.8	1	Signature block for Board QA Officer						
A2.	2	**Table of Contents**						
A2.1	2	Lists QA Project Plan information sections						
A2.2	2	Document control information indicated						
A2.3	2	Provides lists of tables and figures,						
A2.4	2	Provides contents of each Appendix						
A2.5	2	Lists all attached SOPs (with names, not just numbers)						
A3.	3	**Distribution List**						
A3.1	3	Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization.						

SWAMP Element Number	Element	Element Name and Review Aspect	A Acceptable	U Unacceptable	NI Not Included	NA Not Applicable	Page # (Section #)	Notes
A4.	4	**Project/Task Organization**						
A4.1	4	Identifies key individuals involved in all major aspects of the project, including contractors						
A4.2	4	Discuss their responsibilities						
A4.3	4	Project QA Manager position indicates independence from unit generating data						
A4.4	4	Identifies individual responsible for maintaining the official, approved QA Project Plan						
A4.5	4	Organizational chart shows lines of authority and reporting responsibilities						
A4.6	4	Clearly identifies who is part of the Project Team and who is related to the Project in an advisory role (but is not responsible for delivery of any product)						
A5.	5	**Problem Definition/Background**						
A5.1	5	States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained						
A5.2	5	Clearly explains the reason (site background or historical context) for initiating this project						
A5.3	5	Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project						
A6.	6	**Project/Task Description**						
A6.1	6	Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project's goals						
A6.2	6	Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments						
A6.3	6	Details geographical locations to be studied, including maps where possible						
A6.4	6	Discuss resource and time constraints, if applicable						

SWAMP Element Number	Element	Element Name and Review Aspect	A Acceptable	U Unacceptable	NI Not Included	NA Not Applicable	Page # (Section #)	Notes
A7.	7	**Quality Objectives and Criteria**						
A7.1	7	Provides parameter lists with data quality objectives for all field measurements and lab analyses, including laboratory target detection limits, which are as good as the SWAMP DQOs or better.						
A7.2	7	Identifies project action limits for all parameters of interest						
A7.3	7	Identifies acceptance criteria for all previously collected information						
A7.4	7	Discuss precision						
A7.5	7	Addresses bias						
A7.6	7	Discuss representativeness and how it will be assessed and controlled						
A7.7	7	Identifies the need for completeness						
A8.	8	**Special Training/Certifications**						
A8.1	8	Identifies any project personnel specialized training or certifications						
A8.2	8	States that the Contractor's QA Officer is responsible for overseeing training						
A8.3	8	Discusses how this training will be provided						
A8.4	8	Indicates personnel responsible for assuring these are satisfied						
A8.5	8	Identifies where this information is documented						
A9.	9	**Documentation and Records**						
A9.1	9	Identifies report format and summarizes all data report package information						
A9.2	9	Lists all other project documents, record, and electronic files that will be produced						
A9.3	9	Identifies where project information should be kept and for how long						
A9.4	9	Discusses back up plans for records stored electronically						

SWAMP Element Number	Element	Element Name and Review Aspect	A Acceptable	U Unacceptable	NI Not Included	NA Not Applicable	Page # (Section #)	Notes
A9.5	9	States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individuals responsible for this						
B	10	**DATA GENERATION AND ACQUISITION**						
B01.	10	**Sampling Process Design (Sampling Design and Logistics)**						
B01.1	10	Provides the design information, or a reference to a specific document that contains it, at the required level of detail to enable the reader to tell whether the data will achieve the objective.						
B01.2	10	Describes and justifies design strategy, indicating size of the area, or time period to be represented by a sample						
B01.3	10	Details the type and total number of sample types/matrix or test runs/trials expected and needed						
B01.4	10	Indicates where samples should be taken, how sites will be identified located						
B01.5	10	Discusses what to do if sampling sites become inaccessible [logistics]						
B01.6	10	Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc. [logistics]						
B01.7	10	Specifies what information is critical and what is for informational purposes only						
B01.8	10	Identifies sources of natural variability and how this variability should be reconciled with project information						
B01.9	10	Identifies potential sources of bias or misrepresentation and how their contribution can be minimized						
B02.	11	**Sampling (sample collection) Methods**						
B02.1	11	Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken. SOPs for sample collection should be attached, unless they are the original SWAMP SOPs.						
B02.2	11	Indicates how each kind of matrix and each sample type should be collected						

SWAMP Element Number	Element	Element Name and Review Aspect	A Acceptable	U Unacceptable	NI Not Included	NA Not Applicable	Page # (Section #)	Notes
B02.3	11	Indicates how samples are to be homogenized, composited, split, or filtered, if needed						
B02.4	11	Indicates what sample containers and sample volumes should be used						
B02.5	11	Identifies whether samples should be preserved and indicates methods that should be followed						
B02.6	11	Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of						
B02.7	11	Identifies any equipment and support facilities needed						
B02.8	11	Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented						
B03.	12	**Sample Handling and Custody**						
B03.1	12	States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type						
B03.2	12	Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)						
B03.3	12	Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible						
B03.4	12	Identifies chain-of-custody procedures and includes form to track custody						
B04.	13	**Analytical Methods and Field Measurements**						
B04.01	13	Identifies all SOPs (field and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications; SOPs should be attached unless they are the original SWAMP SOPs.						
B04.02	13	Lists all the Instruments and Kits that will be used in the field and describes the measurement principle (e.g., nephelometric or transparency) and the major attributes (e.g., automatic temperature compensation,						

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		range and resolution, etc.)						
B04.03	13	If *in situ* monitoring, indicates how instruments should be deployed and operated to avoid fouling and ensure maintenance of proper data						
B04.04	13	If continuous monitoring, indicates how instruments should store and maintain raw data						
B04.05	13	Identifies all laboratory SOPs that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures						
B04.06	13	Identifies equipment or instrumentation needed for laboratory analyses						
B04.07	13	Specifies any specific method performance criteria						
B04.08	13	Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation						
B04.09	13	Identifies sample disposal procedures						
B04.10	13	Specifies laboratory turnaround times needed						
B04.11	13	Provides method validation and information and SOPs for nonstandard methods and PBMS						
B04.12	13	Indicates where PBMS method development records are stored and how they can be accessed						
B05.	14	**Quality Control**						
B05.1	14	For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc.						
B05.2	14	Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented						
B05.3	14	Identifies procedures and formulas for calculating Data Quality Indicators or applicable QC statistics, for						

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		example, for precision, bias, outliers and missing data						
B06.	15	**Instrument/Equipment Testing, Inspection, and Maintenance**						
B06.1	15	Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this						
B06.2	15	Identifies testing criteria [This information is instrument-specific and may be already included in the SOP for each Instrument]						
B06.3	15	Notes availability and location of spare parts						
B06.4	15	Indicates procedures in place for inspecting equipment before usage [This information is instrument-specific and may be already included in the SOP for each Instrument]						
B06.5	15	Identifies individual(s) responsible for testing, inspection and maintenance						
B06.6	15	Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented						
B07.	16	**Instrument/Equipment Calibration and Frequency**						
B07.1	16	Identifies equipment, tools, and instruments (used in the field or in the lab) that should be calibrated, and the frequency for this calibration						
B07.2	16	describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment [This information is instrument-specific and may be already included in the SOP for each Instrument]						
B07.3	16	Identifies how deficiencies should be resolved and documented						
B08.	17	**Inspection/Acceptance for supplies and Consumables**						
B08.1	17	Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials						

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B08.2	17	Identifies the individual(s) responsible for this						
B09	18	**Non-direct Measurements**						
B09.1	18	Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used						
B09.2	18	Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project						
B09.3	18	Indicates the acceptance criteria for these data sources and/or models [re-iterated or referred to Element A7)						
B09.4	18	Identifies key resources/support facilities needed						
B09.5	18	Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing						
B10.	19	**Data Management**						
B10.01	19	Describes data management scheme from field to final use and storage, for field measurements, continuous monitoring files, and lab analyses						
B10.02	19	Verifies that all continuous monitoring raw data will be kept in the original Sonde file (and stored on a PC); endpoints (e.g. Averages) can be calculated in the office after downloading and trimming records logged out of the water.						
B10.03	19	Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs						
B10.04	19	Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately						
B10.05		Describes how field measurement, continuous monitoring, and laboratory analyses data will be formatted and entered - or prepared for upload - into the SWAMP database						
B10.06	19	Identifies individual(s) responsible for each step and task						

SWAMP Element Number	Element	Element Name and Review Aspect	A Acceptable	U Unacceptable	NI Not Included	NA Not Applicable	Page # (Section #)	Notes
B10.09	19	Describes procedures to demonstrate acceptability of hardware and software configurations (??)						
B10.10	19	Attaches checklists and forms that should be used [or refers the reader to other QAPP elements where the forms are shown, or refers to SOPs]						
C	20	**ASSESSMENT AND OVERSIGHT**						
C1.	20	**Assessments and Response Actions**						
C1.1	20	Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates						
C1.2	20	Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process						
C1.3	20	Describes how and to whom assessment information should be reported						
C1.4	20	Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented						
C2.	21	**Reports to Management**						
C2.1	21	Identifies what project QA status reports are needed and how frequently						
C2.2	21	Identifies who should write these reports and who should receive this information						
D	22	**DATA VALIDATION AND USABILITY**						
D1.	22	**Data Review, Verification, and Validation**						
D1.1	22	Describes SWAMP criteria that should be used for accepting, rejecting, or qualifying project data; re-iterates or refers to element 7						
D2	23	**Verification and Validation Methods**						
D2.1	23	Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any						

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D2.2	23	Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.						
D2.3	23	Identifies issue resolution process, and method and individual responsible for conveying these results to data users						
D2.4	23	Attaches checklists, forms, and calculations including electronic formulae if using spreadsheets						
D3.	24	**Reconciliation with User Requirements**						
D3.1	24	Describes procedures to evaluate the uncertainty of the validated data [or refer them to previous elements]						
D3.2	24	Describes how limitations on data use should be reported to the data users						
D3.3	24	Identifies how the data will be used in the context of the SWAMP umbrella and the SWAMP database						