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Development of a Quality Assurance Program for the State of California Surface Waters Ambient Monitoring Program

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Abstract

The State of California's Surface Water Ambient Monitoring Program (SWAMP) used a progressive approach to develop its quality assurance (QA) program. California's size and varied water bodies presented SWAMP special considerations and obstacles to the traditional method of QA. SWAMP is administered by the California State Water Resources Control Board with implementation of monitoring activities carried out by the state's nine Regional Water Quality Control Boards. Other organizations involved include the California Department of Fish and Game, the US Geological Survey, and the Moss Landing Marine Laboratory's Data Management Team. In development and design of a QA program all organizations need to be satisfied even if goals and means differ. With the added burden of today's budgeting constraints, development of a standout QA program was challenging.

The SWAMP QA program utilizes many of the traditional QA elements, but it is how they are implemented and the level of documentation that is interesting and unique. The QA Team and SWAMP management created a flexible program allowing for varied method detection and reporting limits. They also implemented a website QA toolbox for participants to quickly access items such as boiler-plate contract language, standard operating procedures for data verification/validation, and a QA calendar of events. The QA Officer's role evolved into that of a consultant to the state's Regions and contract laboratories. For example, the QA Team brings together expert focus groups to evaluate new ideas for sample collection, analysis, and reporting. The QA Team also works one-on-one with contract laboratories to help write and refine standard operating procedures and create QA systems and documentation.

It was essential to develop a QA program that is adaptable to changing scientific needs and budgeting constraints. "Flexibility," "science-based decisions" and "application-appropriate data" entered SWAMP's daily vocabulary. A progressive QA program crossed the borders of programmatic compliance to a philosophy embraced by all

stakeholders. The SWAMP QA program was designed to satisfy a wide variety of stakeholders and produce excellent data.

Introduction

The goal was to provide SWAMP with a world-class QA program. The SWAMP QA Officer began by developing a management tool that makes it possible to design a QA program that is financially viable while ensuring rigorous QA. This tool allows programs to adjust to changes in scope or funding. The QA Officer also worked closely with program management and the QA Team to create QA Team goals and values, in addition to a vision for the future. To accomplish this approach we designed systems for each QA program component. These systems facilitate efficiency by enabling each program to easily modify itself and enhance long-term success by outlasting any current staff.

Funding and Design of a QA Program (Flexibility)

A step-by-step method generated the QA program outline and management tool. Quality assurance components were presented to program management as a QA Menu with each component fleshed out in vast detail, step-by-step processes, approximate time commitments over 18 months, and projected budgetary requirements. The program must set up a series of systems for each QA component; therefore, program costs vary as systems are set in place and maintained. The menu presented was a design for a stand-out QA program that would encompass all the QA components needed to place SWAMP in world-class standing.

The QA Menu provides focus for discussions between QA professionals and program management on funding possibilities and constraints, combinations of QA components suited to the program, long-term planning, and vision. The menu provides the means by which program management is well educated on the possibilities. Using the menu with the guidance of QA professionals, the program management may be walked through different scenarios and what those scenarios might achieve. This is vitally necessary given contemporary funding constraints and the sheer size of SWAMP.

In order to describe this process in an example, assume a program's total annual funding budget is $1,000,000. The program looks at tissue, sediment, and water samples for conventional, inorganic, and organic analytes. It also takes field measurements, examines toxicity-testing in waters, and conducts bioassesment studies. The program's data is uploaded to a master database and could be utilized by any end-user group for the purposes of state listings, academic research, health advisories, remediation plans, environmental decision making, and many other areas. A fully funded QA program would be 25% of total program costs, or $250,000 (Table 1).

Table 1. Example Exercise: Funding allocations for QA components in fully-funded program

Component	*Percentage of Funding*	*Funding Allocation*
Communication/Daily Management	4.8%	$12,000
Organizational Chart and Calendar	2.4%	$6,000

QA Reports to Management and Management Assessment	6%	$15,000
Quality Management Plan (and Regional QAPPs)	8%	$20,000
Data Review (verification and validation)	16%	$40,000
Intercomparison Studies/PE Studies/Inter-laboratory Precision	14%	$35,000
QA audits of research plans and sampling plans	8%	$20,000
On-site audits for analytical laboratories	7.2%	$18,000
Corrective Action File	2.4%	$6,000
MDL Studies	2%	$5,000
QC Sample Control Charts	4%	$10,000
SOP review and approval	4%	$10,000
On-site audits of field sampling	5.2%	$13,000
Expert Panel	8%	$20,000
QA Training and QA "toolbox" for SWAMPers	8%	$20,000
Total for Example Exercise	100%	$250,000

This breakdown allows program management to play with different ideas and combinations of components guided by QA professionals who explain implications of various combinations. The percentage projections for QA components are estimates for the first 18-24 months of large-scale programs.

For the SWAMP QA program, management allocated a 12% (of total program funding) budget. The QA professionals and program management worked through different scenarios and discussions about dropping whole QA components, or streamlining specific QA components. While it is the program's long-term goal to encompass all the QA components, funding and efficiency demanded that components be addressed in phases rather than collectively. Keeping with the above example program funded at $1,000,000, $120,000 would be allocated to QA.

After considering a variety of combinations, program management arrived at the list shown below (Table 2). Keep in mind that QA program funding may go up or down as a percentage but total program funding stays the same.

Table 2. Example Exercise: Funding allocations exceeding 100% of available budget.

Component	*Percentage of Funding*	*Funding Allocation*
Communication/Daily Management	10%	$12,000
QA Reports to Management and Management Assessment	12.5%	$15,000
Quality Management Plan (and Regional QAPPs)	16.7%	$20,000
Data Review (verification and validation)	33.3%	$40,000
On-site audits of field sampling	10.8%	$13,000
QA Training and QA "toolbox" for SWAMPers	16.7%	$20,000
Organizational Chart and Calendar	5%	$6,000
Intercomparison Studies/PE Studies/Inter-laboratory Precision	29.2%	$35,000
On-site audits for analytical laboratories	15%	$18,000
Total for Example Exercise	149.2%	$179,000

This list was still too costly, almost 50% higher than funding allowed. The "QA Menu" was again very helpful in deciding on further cuts. We removed more components, revised some components' details and phased in some details over a longer term. The final list (Table 3 and Figure 1) covered the first 12 months. Our plan was to have all components on board within 24 months.

Table 3. Example Exercise: Appropriate funding allocations for a customized program.

Component	*Funding Allocation*
Communication/Daily Management	$6,000
Organizational Chart and Calendar	$6,000
Quality Management Plan (and Regional QAPPs)	$20,000
Data Review (verification and validation)	$35,000
Intercomparison Studies/PE Studies/Inter-laboratory Precision	$10,000
On-site audits for analytical laboratories	$18,000
On-site audits of field sampling	$13,000
QA Training and QA "toolbox" for SWAMPers	$12,000
Total for Example Exercise	$120,000

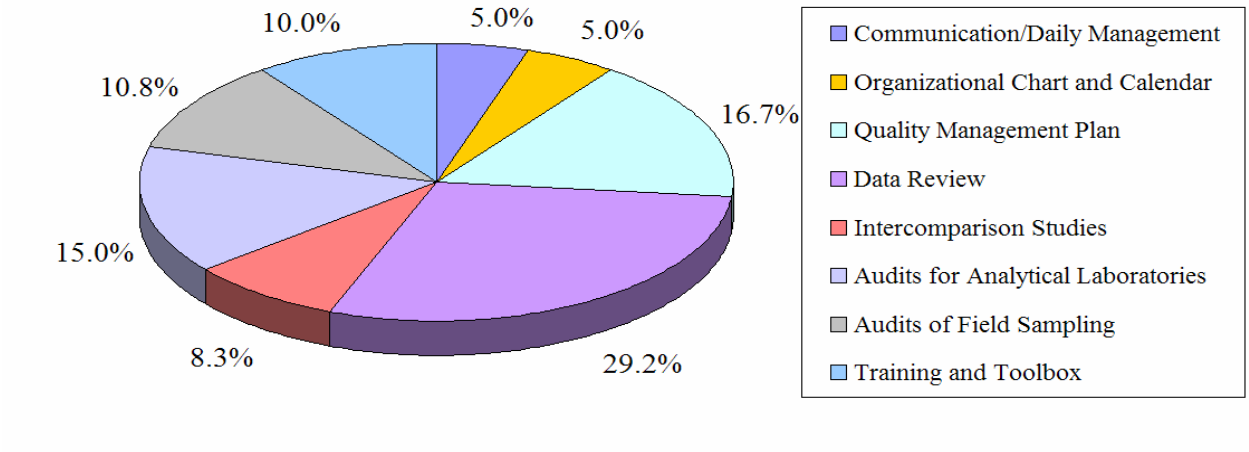

Figure 1. Appropriate funding allocations for a customized program.

With this established, the QA program developed goals, values and a vision for the future. Such aspects are usually absent, outside of data quality objectives (DQOs), but are necessary for program success and QA Team morale. Developing systems and implementing them effectively with a varied participant body can lead to burnout for QA professionals. Goals, values and a vision for the future can help the QA Team get through the first 18 months of implementing a large-scale program.

The SWAMP QA Team set three goals: to develop a progressive, innovatively cost-effective and well-defined program, coherent and attractive to all stakeholders; to retain a key focus on how to best serve dischargers and Regional Boards; and to provide new techniques for the QA profession and regulatory communities.

The Team adopted four values: to develop comparability between programs/projects in order to answer big-picture (state-wide) questions; to help the program produce defensible data, valid for future interpretation; to create tools and systems for improving efficiency, usable by other programs/projects; and to remain sensitive to budget challenges with a creative approach to program requirements.

The Team's vision for the future is: to develop and implement a large-scale QA approach that ensures data is suitable for intended use, to show that quality assurance and its quality control requirements reduces costs while producing data valid for future use and interpretation, and to provide a model for other programs and projects.

Varied Method Detection and Reporting Limits (Application-Appropriate Data)

SWAMP incorporation of multiple Regions in one program presented a challenge during the DQO planning phase. There were questions about how to best mandate method detection limits (MDLs) and reporting limits (RLs). What would yield the most usable results? What were the questions we wanted to answer with this data? The data would need to answer questions at the local (Regional) and state level.

A knee-jerk reaction might have been to mandate MDLs and RLs and demand uniform compliance. Tight budgets and differences in Regions and contracting laboratories required that we find a way to incorporate, accept and document variances to target MDLs and RLs so that data and decisions are later defensible.

The QA Team developed a system for assessing higher MDLs and RLs on a case-by-case basis. If participants or projects within the program chose to meet the SWAMP QAMP target MDLs and RLs, then the SWAMP QAMP and DQOs only need to be referenced in the project-specific QA Project Plan. If the project desires to raise MDLs or RLs, then a system had to be created. The QA Team answered this need and developed a standard operating procedure that details the how, why and what objective information must be presented for a variance to be granted. Some of the evidence given should address historical data, regulatory concerns, listing purposes, local or federal standards, and recent publications or academic research.

In order to illustrate this process, one may look at a recent example. The SWAMP target RL for nitrate (as N) in waters is 0.01 mg/L. One of the Regions requested raising the RL to 0.1 mg/L for an agricultural waiver program. The Regional representative wrote a memorandum to the SWAMP QA Officer detailing points such as:

- A review of the historical data on nitrate from the initial working site list for the project showed that a RL of 0.1 mg/L would result in a total non-detected (below the MDL) or non-quantified (above the MDL but below the RL) rate of 3.6%. In addition, a review of the entire Regional database showed that a RL of 0.1 mg/L would results in a 14.7% non-quantified rate.

- For listing purposes, all of the sampling sites are located in water bodies that are currently listed on the 303(d) list for agricultural pollutants, are proposed for listing, or have groundwater basins that are impacted by nitrate, some of the water bodies routinely exceed the drinking water standard.

- In comparison, the municipal drinking water standard (10 mg/L as N) is 100-fold greater than the requested RL of 0.1 mg/L and EPA Region 9 has recommended that 1.0 mg/L be the level for water body listing of aquatic life impairment (10x higher than the requested RL).

- Finally, based on the supporting evidence, sites with concentrations at or below the requested RL would be considered in very good condition from the standpoint of nitrate.

In a memorandum to the Regional board and the SWAMP Coordinator at the State Board, the SWAMP QA Officer recommended permission to raise the RL in this situation. The memorandums and supporting documents were public for two weeks to allow time for comment from SWAMP stakeholders. In this case no comments came in and the variance was officially granted.

QA Officer as Consultant (Science-based Decisions)

The QA Officer's position has evolved into a consultancy for the Regions and contract laboratories. The QA Officer and QA Team work directly with labs before, during and after laboratory audits to develop more rigorous and efficient quality systems. This process has the incidental benefit of ensuring that contract laboratories comply with all relevant SWAMP requirements.

Continuing close interaction between the QA Officer and contract laboratories after the auditing process leads to instances where guidelines specified in the SWAMP QAMP can be amended or altered to more closely suit contract laboratories, either individually or collectively. The goal is to modify the QAMP to reflect cutting-edge science rather than to use it to mandate protocols just for consistency. Too often, QA programs do not remain flexible to scientific discoveries as they become available. The SWAMP QA program and its QAMP are designed to allow rapid adjustments while retaining comparability of data over time. In such instances, this deviation must be documented and scientifically justified using a carefully-defined study.

For example, the SWAMP QA Team has worked with contract laboratories to examine QAMP guidelines pertaining to sample containers and sample extract holding times. An environmental-consulting firm suggested that one of the Regions change the type of its toxicity sample containers. The container type differed from QAMP specifications. The consulting firm presented a study design to test the proposed container's suitability for toxicity testing. The Region did not have the expertise, or the tools to assess the study properly.

In response, the QA Team called upon world-known experts in various fields to assess the container study design. The QA Officer reviewed the study from a statistical and quality standpoint. An organics expert, an expert in container types for sampling toxicity, and a toxicity testing expert then contributed their technical assessment of the study. The QA Officer asked

these experts to approach the study as if it were for peer-review in a journal. After each expert responded with questions and comments, the QA Officer combined them into a memorandum issued to the Region. The memorandum spelled out the necessary steps to create a study that would meet publication requirements. The QA Team offered to work with the Region and the consulting firm in order to make the amended study a reality.

Another example of how this approach works is its flexibility regarding sample holding times. The QA Team learned that many contract laboratories specializing in organics analysis have a difficult time meeting holding times between sample extraction and analysis. Consequently, the QA Team is currently working with a contract laboratory to study limits of this crucial time period. The study is designed for publication in a journal such as *The Analyst* or *Analytical Chemistr*y so that SWAMP hold-time protocols, as well as the industry standards on which they are based, have valid scientific and statistical bases.

In the examples provided above the QA program directed the changes to sampling, analysis, and reporting protocols, thus enabling SWAMP to quickly make technically-defensible adaptations.

Data Verification and Validation (Creating a System)

After four years of collecting data, SWAMP needed a system for data verification and validation that was centralized and streamlined. While most programs do not require contract labs to follow a program-written and standardized operating procedure (SOP) for data handling, the sheer number of SWAMP contract laboratories and analytes required consistency.

The QA Team developed a rigorous SOP for contract labs to use and apply to data verification and validation prior to submittal to the SWAMP data management team (DMT). Data verification ensures that reported results accurately depict work performed by the contract laboratory. Data validation confirms that the verified data batch meets the overall quality requirements of the SWAMP project. Presenting these processes separately ensures that a data batch's usability is not considered prior to a standardized peer review. With this SOP, the DMT receives fewer unusable data batches.

The data handling SOP was designed to be easily adopted so that it would be used. It is general in its scope and tone. This allows its guidelines to be applied to, and incorporated with, each contract laboratory's existing data-handling protocols. Nonetheless, the SOP mandates strict adherence to QAMP. Flexibility does not come at the expense of overall program goals.

The ability to quickly review quality control parameters at a data batch level is helpful throughout the reporting process such as data verification, QA review, and transfer of information to a database. Method-specific quality control (QC) check sheets were designed to facilitate comparisons of data batch QC results to program requirements and to provide a snapshot assessment of precision, accuracy, and contamination on a batch level.

The process begins with laboratories completing the tables on the QC check sheet prior to submitting electronic data deliverables (EDDs) to the DMT for uploading to the database.

Information captured on the check sheets includes sampling date, preparation/analysis method and date, matrix spike and certified reference material recoveries, replicate relative percent differences, and blank results. The tables also include method-specific DQOs and QC frequencies required by SWAMP, providing an efficient method to check the data batch for comparability with those parameters without having to refer to other documents.

The completed QC check sheet provides a tool for the laboratory to quickly review the data and ensure that the program's data quality indicators (DQIs) have been met. If they have not been met, the form provides a straightforward manner to distinguish which results require qualifier flags or re-analysis before submittal to the database. The QC check sheets can also be used by a project manager to document QC results from blind replicates or field blanks.

Upon receiving the EDD, members of the DMT are able to quickly spot any QC concerns in the data batch by reviewing the completed QC check sheet. For example, if the time period between the sample collection date and the extraction date exceeds the holding time listed on the check sheet, the DMT member can call the lab and check if there was a documentation error or if the data must be flagged before being entered in the database.

In addition, the QC check sheets can streamline internal or external QA overview of the data batch. The reviewer can quickly observe any trends within a data batch such as a general high bias or contamination in the blanks before delving into the entire data set. The check sheets could also be used for insight into a problem. For instance, a review of multiple check sheets for the same method could show if a QC concern is a single occurrence or a recurring item. The check sheets could be used as part of an analyst's training record as documentation of ability to routinely perform a particular method, as well.

In addition to the systems developed for verification and validation by contract laboratories, the QA Team and the DMT developed SOPs for data verification (to SWAMP DQIs) by the DMT and data validation (to SWAMP DQOs) by the QA Team.

These various checks provide end users with only high-quality or properly-flagged data. Though the process (Figure 2) may appear to be labor-intensive, it has proven to save time and funding resources. The key to success with any data-gathering program is to find problems and initiate corrective action steps in "real time".

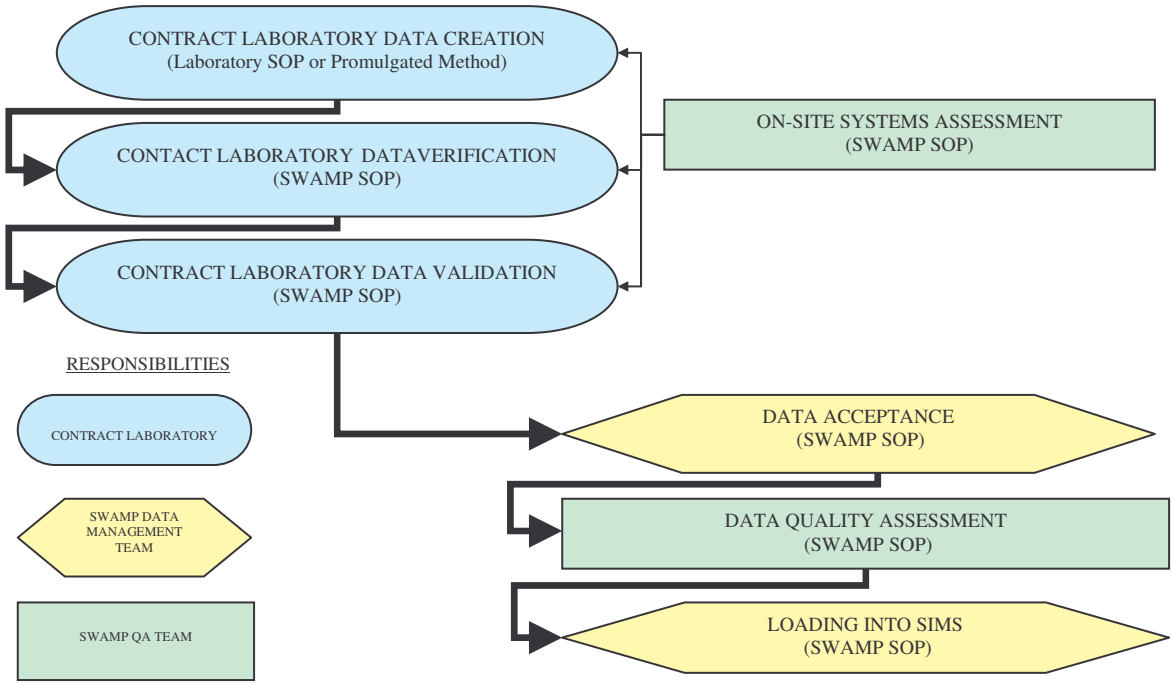

Figure 2. Flowchart of SWAMP Data Verification and Validation Systems.

Conclusion

California's size, the variety of its water bodies, and customary funding restraints presented many challenges in the QA program design stage. A program was developed to satisfy a wide variety of stakeholders, produce excellent data and maximize efficiency. Long-term visions for how each SWAMP QA component could be developed into an efficient and flexible working system allowed the program to implement QA components in steps and over time. The result is a QA program that can evolve from programmatic compliance into a philosophy embraced by all stakeholders.

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