

Delta RMP QAPP v2.1:

List of changes that have been made since the final approval of QAPP v1.2 on May 17, 2016.

No.	Section/Element	Change
1	Approval Signatures	Added MLML personnel
2	Table of Contents	Updated tables of content, figures, and tables
3	Table 0-1. Distribution List.	Added MLML personnel
	Table 3-2. RMP Target Parameters and Reporting Units.	
1	IMPORTANT: The project’s Action Limits or Water Quality goals related to the identified beneficial uses must be included somewhere. They can be included here or within the table with MDL/RLs. I suggest both.	The Delta RMP provides data to decision-makers; however, decisions based on the data generated by the Program are made <i>outside</i> of the program. The QAPP now includes tables that list the Beneficial Uses to which initial prioritized assessment questions apply as well as existing water quality objectives and benchmarks for target analytes.
	4. Quality Objectives and Criteria for Measurement Data	
2	<p>IMPORTANT:</p> <p>DQO and DQI are confused here. The section included in your QAPP is a great narrative of the data quality indicators. So, above this section, you should describe how the data will be used and the level of QC needed to support that use (the DQOs).</p> <p>A DQO process describes:</p> <p>the decisions to be made by the data the study boundaries, when/where data should be collected. the criteria on which the decisions will be made (e.g., regulatory standards, action levels, beneficial uses evaluated, etc.) If a contaminant does not have an action level, or will not be used in decision making, the text should discuss how the data for that contaminant will be used. If the action level is below the reporting limit, discuss how this will be handled.</p> <p>It was stated above that this data is being collected to answer the management questions in Appendix A. So what level of QC is needed to do that? Start with what are the projects water</p>	The language in the QAPP has been edited to distinguish DQIs from DQOs. Section 3.2 (Evaluation of Data) was added to provide context that explains that the program generates data for informational purposes, and that decisions based on the data will be made outside the program. Therefore, the program does not have a detailed assessment framework that would describe, e.g, how action levels below RLs are to be handled. The described level of QC is gleaned from existing programs and projects with similarly broad objectives and aims to support defensible conclusions about the data. The program is expected to produce high-quality data. Legal defensibility presents an ideal case, however, the data are not collected for the purpose of legal action. The program could be characterized as a “research only” program.

	quality goals/action limits for the Beneficial uses of interest. Then discuss the level of QC needed to support use of the data collected (303d use?). High/medium/low? Legally defensible? Research only?	
Table 4-1. Purposes of field and laboratory QC sample types applicable to the Delta RMP.		
3	<p>IMPORTANT: The definition in this QAPP is inconsistent with EPA Region 9, Water Boards, and SWAMP.</p> <p>In summary, the definition utilized is that RL is reported with 99% confidence and represents lowest spike value. The MDL is then method based calculation of lowest possible detection that is not 0. Then, values detected between RL and MDL are then qualified as detected, but not quantifiable values (DNQ).</p> <p>RLs should then be a few magnitudes lower than the water quality goal/action limits. If any detect of an analyte is a violation of the anti-degradation policy, ensure RL is lowest possibly achieved by the currently available methodology.</p>	The issue is that in USGS studies the MDL is the RL. USGS is not a commercial or regulatory lab and does not use the same MDL derivation methods that many commercial or regulatory labs use.
4	Equipment blanks - Ensure field crews use decontamination procedures, if applicable. This blank is only required if such procedures are used.	Removed from table. We will not require equipment blanks regularly and will employ them only to diagnose serious field blank issues found.
<i>4.3.1 Laboratory QC Measurements</i>		
<i>Precision</i>		
5	IMPORTANT: Calculations for RPD and RSD missing.	Added calculation for RPD. RSD is not used and discussed here.
6	This is the first reference to "P-score". Suggest including definition or use similar language as the MQOs.	Comment has been addressed.
Table 4-4. Summary of Reporting Limits (RL) and Method Detection Limits (MDL) of Delta RMP constituents.		
7	<p>IMPORTANT:</p> <p>See above comment regarding definition of MDL and RL. This would eliminate RL=MDL in most instances</p>	See responses to Comments 1 and 3.

	Action limit/Water quality goal (+ reference) should also be listed to demonstrate RLs are appropriate for the use of the data	
	<i>4.4 Data Quality Objectives and Test Acceptability Criteria for Toxicity Testing and Associated Water Quality Measurements</i>	
	Table 4-7. Data quality objectives for toxicity testing and associated water quality measurements.	
	Clarified the use of sample duplicates for RPD calculations for toxicity tests.	
	<i>4.4.1 Quality Assurance Activities</i>	
8	No discussion of bias	We have included the discussion of bias and variability in this section.
9	“Deviations from protocols must be reported to the QAO, the project manager, and in interim and final reports.” This should be better defined. If “deviations” include alternate test procedures or surrogate species, this info should be discussed prior to test initiation.	We have clarified this statement under this section.
	<i>Test sensitivity</i>	
10	Positive control tests. “ The LC ₅₀ for survival or EC ₂₅ sublethal endpoints....” Describe these point estimate endpoints?	These have been further clarified.
	<i>Precision</i>	
11	Field duplicates will be conducted at a rate of 5% - Of total project sample count?	Yes, of total project sample count. This has been clarified within the text and in Table 4.9.
	<i>Data Analysis</i>	
12	“....and shows the results of the tests according to the standardized statistical method used in aquatic toxicology monitoring and regulation throughout the United States.”- Not sure what this means.	Deleted, as suggested.
13	CETIS software - Describe?	We have included additional information about this software.
	Table 4-8. Quality control measures and acceptable limits for toxicity testing.	
14	Table 4.8 claims that the promulgated methods will be followed, and some of these SOPs differ from the EPA methodology/SWAMP MQOs.	Edits should have addressed this comment.
	Table 4-9. Quality control measures and acceptable limits for toxicity testing.	

15	This table doesn't include required holding times or recommended preservation	We have clarified this table by the inclusion of holding times and preservations. MQOs have been addressed in an additional table, Table 4.10
16	The SWAMP QAPrP lists the reporting limit for ammonia as 0.1 mg/L	The acceptability limit here refers to the NH3 concentration threshold and not to the RL.
17	Conductivity < 1500 mS/cm for <i>S. capricornutum</i> , <1900 for <i>C. dubia</i> and <1900 for <i>P. promelas</i> ; >100 mS/cm for <i>C. dubia</i> , <i>P. promelas</i> and <i>H. azteca</i> . 1) Unless a conductivity control is used? 2) Appropriate salinity controls must be included when the MQO is exceeded to be SWAMP comparable. Dilution is not recommended (dilution is noted in the SOPs)	<ul style="list-style-type: none"> The lower conductivity MQOs for <i>C. dubia</i> and <i>P. promelas</i> were added, along with the upper and lower conductivity MQOs for <i>H. azteca</i>. It should be noted that the conductivity limits in the QAPrP's SOPs differ from SWAMP's MQOs for <i>S. capricornutum</i> (no limits), <i>P. promelas</i> (< 3,000 µmhos), and <i>H. azteca</i> (salinity < 15 ppt). A uniform frequency, based upon SWAMP's MQOs, was added for each of the analytes listed.
18	DO < 8.6 mg/L (<i>H. azteca</i> < 8.9 mg/L)" Mention that this is the saturation point?	We have mentioned that this is the saturation point in this table.
<i>4.4.3 Quality Assurance Activities</i>		
19	I believe there may be confusion over the use of the term "corrective actions" here. The term within a QAPP refers to the actions a laboratory must take should the QC fall outside of the acceptable limits within the MQOs. Corrective actions are then fundamental to ensure the data is of the best quality for use by the project. I suggest including the recommended corrective actions from SWAMP or including the laboratory specific SOPs that should include corrective actions.	We have included the recommended corrective actions from SWAMP in this section.
6. Documents and Records		
20	Laboratory QA Plan: - Suggest including as appendix	Will request from labs, add to Google Drive repository, and include a list of available Laboratory QA Plan documents as an Appendix that will include links to these documents.
<i>Electronic Data Deliverable (EDD) Template</i>		
21	Suggest including narrative detailing the level of review and qualification a laboratory is required to perform prior to submission to SFEI.	Comment has been addressed by adding text.

Table 6.2 CEDEN QA Codes	
22	<p>Batch Verification Codes? Compliance Codes?</p> <p>Comment has been addressed by adding a Batch Verification Code table and Compliance Code tables to Section 17, Verification and Validation Methods, since these codes are added by the QAO.</p>
<i>6.1.1. Analytical and QA data results</i>	
Additional clarification and relevant links were added to the portion of the “Analytical and QA data results” subsection that addresses data submittal to SWAMP/OIMA.	
<i>6.2 Data Reporting Requirements</i>	
23	<p>“Only data that have met MQOs or that have deviations explained appropriately will be accepted from the laboratory. When QA requirements have not been met, the samples will be reanalyzed when possible. Only the results of the reanalysis should be submitted, provided they are acceptable.” - Suggest more detail. IE required columns must be filled out with true values (not nulls) where applicable. Dates/times/preparations/extractions should be filled out to the furthest extent possible. Qualification must occur at the results and batch level. Batches must reviewed for QC completeness and any deviation in QC results. Detailed batch comments must be provided (<255 char) with appropriate batch verification codes, for any deviation noted. Incomplete batches shall be.....? Suggest including list of required fields. Those fields must be throughout enough for data verification and validation procedures to occur successfully.</p> <p>Comment has been addressed.</p>
<i>6.3 Data Storage/Database</i>	
24	<p>IMPORTANT: Please note that data funded by SWAMP, must be submitted to SWAMP. SWAMP templates and SWAMP Online Data Checker must be used for those data.</p> <p>We added this paragraph to section 6.1.1 Analytical and QA data Results and paragraph 2 in Ch. 13 Data Management:</p> <p>“Toxicity data that is funded by SWAMP should be submitted to SWAMP by the data provider using SWAMP templates and the SWAMP data checker. Once these data have been approved by SWAMP, the SWAMP Data Manager should</p>

		provide the data in CEDEN EDD templates to SFEI/ASC for further processing.”
25	QA/QC review and data validation => Provide SOPs on how this will be performed.	We do have a detailed SOP for QA/QC, but it is internal and describes the queries that we run for evaluating QA/QC. QA/QC requirements are discussed in detail in Section 4 and those requirements are what are followed when evaluating data for QA/QC compliance.
7. Sampling Process Design		
<i>7.3 Study area and period</i>		
26	The program will be continually adjusted to optimize data collection. – A section discussing sources of natural variability and delta complexity should be included.	Discussed in Monitoring Design Summary document.
8. Sampling Methods		
<i>8.3 Corrective Action</i>		
<i>Laboratory Chemical Analyses</i>		
27	If it is determined that laboratory procedures are the likely cause, then the PI (if applicable) and Laboratory Manager will ensure that proper procedures as outlined in the QAPP are being implemented and to develop any additional procedures to bring QA sample results in line with data quality objectives. In each case, any changes to field or laboratory procedures will be fully documented. Important: Not enough information. Suggest referencing SWAMP or attaching laboratory corrective actions. Table 10.2 has some, but is an incomplete list.	Comment addressed. Referencing SWAMP.
<i>Toxicity Testing</i>		
28	OK. SWAMP MQOs do not address these, but I can see the project following a research based adaptation. For all of these conditions, where the sample matrix is adjusted, will the data be uniquely identified to explain that fact to the user?	We have added guidance from the SWAMP MQO and Quality Control Tables here for reference.
9. Sample Handling and Custody		
<i>9.1 Field Sample Handling and Shipping Procedures</i>		

	<i>Current Use Pesticides</i>	
29	Filter Blank recommended per lot of filters.	Added filter blanks (Table 4-3).
30	Samples for dissolved copper, DOC, and POC will be placed in a cooler on wet ice and shipped overnight to the USGS NWQL in Lakewood CO. - - Holding time post filtration?	Hold time for POC after filtration is 100 days. Holding time for DOC is 28 days. Holding time for Cu is 180 days. See edits to Table 9.1.
	<i>Toxicity Testing</i>	
31	this holding time may be extended to 120 hours for precipitation-based events, when courier delivery schedules on weekends and holidays limit the availability of test organisms. - Will the affected samples be flagged accordingly?	Yes, the samples will be flagged. We have clarified this in the text.
32	DOC/POC- Same comment	Hold time extension not necessary for DOC/POC as they are processed at OCRL within 24 hrs of collection.
	10. Analytical Methods	
33	IMPORTANT: The section on sample archive and disposal is missing.	I added a disposal section. We are not archiving samples
	<i>10.2 Laboratory Methods</i>	
	Table 10-2. Corrective actions procedures for analytical laboratories.	
34	Applies to matrix and field QC only. Incomplete.	Brief summaries of lab corrective actions are added to table and for details readers are referred to section 4.3
	11. Instrument/Equipment/Supplies	
35	If the instrument response is demonstrated to be linear over the entire concentration range to be measured in the samples, the use of a calibration blank and one single standard that is higher in concentration than the samples may be appropriate. - ? replacing the curve or extending the curve?	Not all methods require a multi-point calibration, so wording in section changed to be more specific about using multi- or single point calibration as described in the method.
	13. Data Management	
36	The Lab should apply the QA codes and batch verification codes. The project QA officer should then review their codes applied by the lab for completeness, accuracy, validation (if needed) and compliance with the QAPP. I suggest providing the lab with required columns,	Comment has been addressed by referencing Section 6.2.

	qualifiers and review level (and comments required) prior to submission.	
16. Data Review, Verification, and Validation		
37	More information needed. Is there an SOP for these steps? Highly recommended for inclusion	It would be possible to write an SOP for each specific step, but unclear what benefit that would provide, and to what level of detail the procedures need to be documented. The MQOs are already specified in section 4, but the causes and varieties of deviations are numerous and would take a pretty extensive list of branching if/then statements as well as some decision making trees as to whether particular prescribed response actions are appropriate to specific scenarios. If there is an SOP that would be considered as a sufficient level of detail, we can reference and adopt those procedures wholesale, with modification as needed for this project.
17. Verification and Validation Methods		
38	“Analyses sometimes produce results that fail MQOs and may not be possible to overcome for a small number of analytes within a large group of related compounds. For example, there may be contamination that is impossible to eliminate for all analytes, when analyses are conducted at ultra-trace levels. With agreement of the SFEI-ASC Project Manager and QAO in consultation with the Laboratory, results for sample groups with data outside of MQOs may be flagged, to indicate the greater uncertainty in the quantitation of those data. Results on individual analytes that are greatly outside the target MQO range (e.g. z-scores >2) will be censored as needed rather than subjected to repeated analysis. Reports, graphs, tables, or summary statistics generated from datasets with censored data should note their exclusion or other handling”- Detailed SOPs recommended. This language is very non-specific and does not address which codes will be applied and what column/s they will be recorded (or other documentation practices...corrective actions reports. Etc.).	<p>This would take some time to write out. It is certainly possible to write simple rule sets but those can result in erroneous impressions and are also easier to “game” by choosing to run more of the passing/easier QC sample types, choosing reference materials with higher concentrations or simpler matrices, etc.</p> <p>We have a very long SOP for the Bay RMP with long lists of qualifier codes we primarily use but these evolve over time as labs encounter new situations or we use different labs with different methods and potential issues and as CEDEN changes or adds more qualifiers. The Bay RMP rules also describe these general principles and preferences rather than laying out a fully branched and rigidly delineated decision tree for the possible combinations and degrees of failures and passes for the different types of QC.</p> <p>If one could write out such a decision tree, it could provide the basis for an artificial intelligence QC checking expert system, which could implement a series of checks without human judgment or intervention.</p>
39	“As a good practice, sample results in batches	

	<p>with detected blank contamination will be flagged (for field samples with analyte concentration >3x those found in method blanks) or censored (for results <3x those in blanks) by SFEI-ASC, but data users should be aware of the possible influence of sporadic contamination in other batches analyzed around the same time, particularly for samples with low concentrations similar to those in blanks." - Confusing. Please provide more specific rules that will be followed, along with applicable codes that will be used.</p>	
40	<p>"Similar analogies can be made with failures of precision or accuracy QC measurements. Individual failures may fall within the range of the true variance in the measurement, e.g. NIST acceptance ranges are sometimes in excess of $\pm 50\%$ of the mean values, and while reporting only successful reanalysis batches may appear to produce more consistent and certain results, without fundamental changes to the analytical process, the underlying uncertainty may only have been masked/censored rather than truly reduced for the reported field samples. This is not to say that reanalyses are never warranted or desirable, but rather to underscore that improved results on QC measurements, which can sometimes be achieved simply by repeat analysis and discarding previous failed results, should not be confused with improved measurements, which are only achieved by making real substantive changes to the sampling and/or analytical methods. If reanalyses are to be attempted, it is therefore imperative that the Project Manager and QAO work in consultation with laboratory staff to identify and change the factors that may have led to MQO deviances, rather than simply repeat the analyses until the QC passes. For MQO deviations (z-score or p-score >1) for which causes are not identified and that are not fixed by corrective actions, field sample results may be qualified, or censored if grossly deviating (z-score or p-score >2). The QC data used for determination of flagging is subject to the availability of data on various QC sample types and the professional judgment of the QAO, but where possible, data for flagging recovery should</p>	<p>E.g., here are a couple of scenarios that illustrate limitations of simple rule sets. For example, one could make a rule that "if any two or more recovery QC samples fail MQOs, then results are flagged". However, such a rule could provide a disincentive for repeated measures beyond the minimum required since once there are 2 fails no number of additional passes helps reduce the probability of the data being flagged, and if there are already 3-4 passes, any additional analyses have some chance of failure and increase the probability of results being flagged. Choosing higher concentration or simpler matrix recovery sample types could also reduce the probability of results being flagged. The rule would lead to better predictability of what your flagging outcomes will be, but less information on what you care about, i.e. the "real world" uncertainty of these measurements.</p> <p>For a regulatory compliance program, predictability may be the most important consideration. Rules are to be written out and strictly followed in the regulatory context. A disadvantage might be that even as you find ways people game the rules, you are stuck until you get approval to change the rule.</p> <p>For more research oriented monitoring, you can develop things more fluidly but document where and why decisions were made a particular way for specific data sets, and that warns people if they would make different choices, and the data is available to evaluate alternative ways of flagging and censoring or not. Bay RMP is based more on this model, which is not to say Delta RMP can't be different if the objectives are deemed to be very different.</p>

	<p>be 1) in a similar matrix as samples, 2) with externally validated expected values, 3) in a quantitative range, and 4) in a similar concentration range as field samples. Thus for evaluating recovery, the order of preference is generally CRM>LRM>MS>LCS, with exceptions and changes in preference made for factors such as non-certified values, certified values with wide uncertainty bands, and concentrations greatly different from those in field samples. Similarly, for evaluation and flagging of lab precision, QC samples should be 1) in the same matrix as field samples, 2) isolate lab variation from other causes, 3) in a quantitative range, and 4) in a similar concentration range as field samples, where available. For evaluating precision then, the preferred sample types for replicates are: lab > field > MS ~ CRM > LCS, again with exceptions made depending on the available sample types, their inherent variability, concentration ranges, and other factors.” - This section is a nice discussion, but more explicit documentation is recommended for each scenario for this plan. Please include exact rules, codes applied, and level of comments needed and where applied (result, batch, etc.) for each scenario. This can be provided as an SOP if lengthy.</p>	
41	<p>" should not be confused with improved measurements, which are only achieved by making real substantive changes to the sampling and/or analytical methods." - Should this be documented somehow for the lab? How would a data user know that a single data point is usable in the meantime? Does this justify flagging data but not-reanalyzing when warranted/expected?</p>	<p>The usability (or conversely, the uncertainty) of the field data is reflected in the flagging applied to the field samples. The next few sentences after the cited excerpt describe the handling: "For MQO deviations (z-score or p-score >1) for which causes are not identified and that are not fixed by corrective actions, field sample results may be qualified, or censored if grossly deviating (z-score or p-score >2). The QC data used for determination of flagging is subject to the availability of data on various QC sample types and the professional judgment of the QAO," ... We also added "decisions will be documented in a narrative summary of the QA review." to make it clear where you would find what indicators were used to base the flagging.</p>
18. Reconciliation with User Requirements		
42	<p>"The QA Report describes non-conformances with</p>	<p>Comment has been addressed by adding text</p>

	QAPP specifications – “Suggest that these findings be recorded within the data as well through compliance codes and batch verification codes so that a data user (outside of the project) will have the most amount of information at their fingertips.	
43	“Delta RMP adaptations of CEDEN’s business rules.” - Are these documented? If not please document and include as an SOP.	There are no Delta RMP adaptations to CEDEN business rules. We modified the sentence to remove that text.
APPENDIX C. List of SOPs		
Toxicity Testing		
44	These SOPs should be cited in the toxicity section of the QAPP	Changed citations as appropriate.
45	Moreover, certain aspects of these documents do not lend themselves to SWAMP comparability.	We have amended sections of test protocols that seem to not align with SWAMP comparability