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EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK

QAPP/FSP/SAP for: <i>(check appropriate box)</i>	Entity (<i>grantee, contract, EPA AO, EPA Program, Other</i>)	Regulatory Authority	___ 2 CFR 1500 for Grantee/Cooperative Agreements
<input type="checkbox"/> GRANTEE	Click here and type Entity	and/or	___ 48 CFR 46 for Contracts
<input type="checkbox"/> CONTRACTOR			___ Interagency Agreement
<input type="checkbox"/> EPA			___ EPA/Court Order
<input type="checkbox"/> Other			___ EPA Program Funding
Document Title <i>[Note: Title will be repeated in Header]</i>	Click here and type Title	Funding Mechanism	___ EPA Program Regulation
QAPP/FSP/SAP Preparer			___ EPA CIO 2105
Period of Performance <i>(of QAPP/FSP/SAP)</i>		Date Submitted for Review	
EPA Project Officer EPA Project Manager		PO Phone # PM Phone #	
QA Program Reviewer or Approving Official		Date of Review	

Documents to Submit for Review:

- A QAPP written by a Grantee or EPA must include for review:
Work Plan(WP) / Statement of Work (SOW) / Program Plan (PP) / Research Proposal (RP) and funding mechanism
- A QAPP written by Contractor must include for review:
 - Copy of signed QARF for Task Order/Work Assignment
 - Copy of Task Order/Work Assignment SOW
 - Provide reference to a hard or electronic copy of approved QMP
 - If QMP not approved, provide Contract SOW
 - Copy of EPA/Court Order if applicable
- Field Sampling Plan (FSP) and/or Sampling & Analyses Plan (SAP) must include the Project QAPP or
 - FSP or SAP submitted as a stand-alone QA document must contain all QAPP required elements (Project Management, Data Generation/Acquisition, Assessment and Oversight, and Data Validation and Usability).
 - SOPs can only be reviewed with a QA document that contains all QAPP elements.

Documents Submitted for QAPP Review:

- QA Document(s) submitted for review:**

QA Document	Document Date	Document Stand-alone	Document with QAPP
QAPP		Yes / No	
FSP		Yes / No	Yes / No
SAP		Yes / No	Yes / No
SOP(s)			Yes / No
- WP/SOW/TO/PP/RP Date** _____
WP/SOW/TO/RP Performance Period _____
- QA document consistent with the:**
WP/SOW/PP for grants? Yes / No
SOW/TO for contracts? Yes / No
- QARF signed by R8 QAM** Yes / No / NA
Funding Mechanism IA / contract / grant / NA
Amount _____

Summary of Comments (*highlight significant concerns/issues*):

- Comment #1
- Comment #2
- Comment #3

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4. The Click here and type Entity must address the comments in the Summary of Comments, as well as those identified in the Comment section(s) that includes a “Response (date)” and Resolved (date)”.			
Element	Acceptable <i>Yes/No/NA</i>	Page/ Section	Comments
A. Project Management			
A1. Title and Approval Sheet			
a. Contains project title			
b. Date and revision number line (for when needed)			
c. Indicates organization’s name			
d. Date and signature line for organization’s project manager			
e. Date and signature line for organization’s QA manager			
f. Other date and signatures lines, as needed			
A2. Table of Contents			
a. Lists QA Project Plan information sections			
b. Document control information indicated			
A3. Distribution List			
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization			
A4. Project/Task Organization			
a. Identifies key individuals involved in all major aspects of the project, including contractors			
b. Discusses their responsibilities			
c. Project QA Manager position indicates independence from unit generating data			
d. Identifies individual responsible for maintaining the official, approved QA Project Plan			
e. Organizational chart shows lines of authority and reporting responsibilities			
A5. Problem Definition/Background			
a. States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained			

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b. Clearly explains the reason (site background or historical context) for initiating this project			
c. Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project			
A6. Project/Task Description			
a. Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project's goals			
b. 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			
c. Details geographical locations to be studied, including maps where possible			
d. Discusses resource and time constraints, if applicable			
A7. Quality Objectives and Criteria			
a. Identifies - performance/measurement criteria for all information to be collected and acceptance criteria for information obtained from previous studies, - including project action limits and laboratory detection limits and - range of anticipated concentrations of each parameter of interest			
b. Discusses precision			
c. Addresses bias			
d. Discusses representativeness			
e. Identifies the need for completeness			
f. Describes the need for comparability			
g. Discusses desired method sensitivity			
A8. Special Training/Certifications			
a. Identifies any project personnel specialized training or certifications			
b. Discusses how this training will be provided			
c. Indicates personnel responsible for assuring training/certifications are satisfied			

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d. identifies where this information is documented			
A9. Documentation and Records			
a. Identifies report format and summarizes all data report package information			
b. Lists all other project documents, records, and electronic files that will be produced			
c. Identifies where project information should be kept and for how long			
d. Discusses back up plans for records stored electronically			
e. States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individual responsible for this			
B. Data Generation/Acquisition			
B1. Sampling Process Design (Experimental Design)			
a. Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample			
b. Details the type and total number of sample types/matrix or test runs/trials expected and needed			
c. Indicates where samples should be taken, how sites will be identified/located			
d. Discusses what to do if sampling sites become inaccessible			
e. Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.			
f. Specifies what information is critical and what is for informational purposes only			
g. Identifies sources of variability and how this variability should be reconciled with project information			
B2. Sampling Methods			
a. Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken			
b. Indicates how each sample/matrix type should be collected			

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c. If in situ monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data			
d. If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages			
e. Indicates how samples are to be homogenized, composited, split, or filtered, if needed			
f. Indicates what sample containers and sample volumes should be used			
g. Identifies whether samples should be preserved and indicates methods that should be followed			
h. Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of			
i. Identifies any equipment and support facilities needed			
j. Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented			
B3. Sample Handling and Custody			
a. States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for in-situ or continuous monitoring, the maximum time before retrieval of information			
b. Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)			
c. Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible			
d. Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan			
e. Identifies chain-of-custody procedures and includes form to track custody			
B4. Analytical Methods			

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a. Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures			
b. Identifies equipment or instrumentation needed			
c. Specifies any specific method performance criteria			
d. Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation			
e. Identifies sample disposal procedures			
f. Specifies laboratory turnaround times needed			
g. Provides method validation information and SOPs for nonstandard methods			
B5. Quality Control			
a. For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency			
b. Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented			
c. Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data			
B6. Instrument/Equipment Testing, Inspection, and Maintenance			
a. Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this			
b. Identifies testing criteria			
c. Notes availability and location of spare parts			
d. Indicates procedures in place for inspecting equipment before usage			
e. Identifies individual(s) responsible for testing, inspection and maintenance			
f. Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented			

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B7. Instrument/Equipment Calibration and Frequency			
a. Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration			
b. Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment			
c. Identifies how deficiencies should be resolved and documented			
B8. Inspection/Acceptance for Supplies and Consumables			
a. Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials			
b. Identifies the individual(s) responsible for this			
B9. Use of Existing Data (Non-direct Measurements)			
a. Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used			
b. Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project			
c. Indicates the acceptance criteria for these data sources and/or models			
d. Identifies key resources/support facilities needed			
e. Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing			
B10. Data Management			
a. Describes data management scheme from field to final use and storage			
b. Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs			
c. Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately			
d. Identifies individual(s) responsible for this			
e. Describes the process for data archival and retrieval			

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f. Describes procedures to demonstrate acceptability of hardware and software configurations			
g. Attaches checklists and forms that should be used			
C. Assessment and Oversight			
C1. Assessments and Response Actions			
a. Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates			
b. Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process			
c. Describes how and to whom assessment information should be reported			
d. Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented			
C2. Reports to Management			
a. Identifies what project QA status reports are needed and how frequently			
b. Identifies who should write these reports and who should receive this information			
D. Data Validation and Usability			
D1. Data Review, Verification, and Validation			
Describes criteria that should be used for accepting, rejecting, or qualifying project data			
D2. Verification and Validation Methods			
a. Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any			
b. 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.			
c. Identifies issue resolution process, and method and individual responsible for conveying these results to data users			

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d. Attaches checklists, forms, and calculations			
D3. Reconciliation with User Requirements			
a. Describes procedures to evaluate the uncertainty of the validated data			
b. Describes how limitations on data use should be reported to the data users			