**EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK**

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| --- | --- | --- | --- |
| **QAPP/FSP/SAP for:***(check appropriate box)* | **Entity** *(grantee, contract, EPA AO, EPA Program, Other)*Click here and type Entity | **Regulatory Authority**  **and/or****Funding Mechanism** | **\_\_\_ 2 CFR 1500 for** G**rantee/Cooperative Agreements** **\_\_\_ 48 CFR 46 for Contracts****\_\_\_ Interagency Agreement (FFA, USGS, )****\_\_\_ EPA/Court Order****\_\_\_ EPA Program Funding** **\_\_\_ EPA Program Regulation****\_\_\_ EPA CIO 2105**  |
|  | **GRANTEE** |
|  | **CONTRACTOR** |
|  | **EPA**  |
|  | **Other** |
| **Document Title** ***[Note: Title will be repeated in Header]***  | Click here and type Title |  |  |
| **QAPP/FSP/SAP Preparer** |  |  |  |
| **Period of Performance** *(of QAPP/FSP/SAP)* |  | **Date Submitted for Review** |  |
| **EPA Project Officer****EPA Project Manager** |  | **PO Phone #****PM Phone #** |  |
| **QA Program Reviewer or****Approving Official** |  | **Date of Review** |  |
| ***Documents Submitted for QAPP Review* (QA Reviewer must complete)*:*****1. 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 |

**2. WP/SOW/TO/PP/RP Date \_\_\_\_\_\_\_\_\_\_\_** **WP/SOW/TO/RP Performance Period \_\_\_\_\_\_\_\_\_\_\_\_\_****3. QA document consistent with the:**  WP/SOW/PP for grants? Yes / No  SOW/TO for contracts? Yes / No**4. QARF signed by R8 QAM** Yes / No / NA**Funding Mechanism**  IA / contract / grant / NA  **Amount \_\_\_\_\_\_\_\_\_\_\_\_\_**  | **Notes for Document Submittals:** **1.** A QAPP written by a Grantee, EPA, or Federal Partner must include for review: Work Plan(WP) / Statement of Work (SOW) / Program Plan (PP) / Research Proposal (RP) and funding mechanism **2.** A QAPP written by Contractor must include for review:**a)** Copy of Task Order Work Assignment/SOW**b)** Reference to a hard or electronic copy of the contractor’s approved QMP**c)**Copy of Contract SOW if no QMP has been approved **d)** Copy of EPA/Court Order, if applicable **e)** The QA Review must determine (with the EPA CO or PO) if a QARF was completed for the environmental data activity described in the QAPP.**3.** **a**. Field Sampling Plan (FSP) and/or Sampling & Analyses Plan (SAP) must include theProject QAPP ***or*** must be a stand-alone QA document that contain all QAPP required elements (Project Management, Data Generation/Acquisition, Assessment and Oversight, and Data Validation and Usability).   **b**. SOPs must be submitted with a QA document that contains all QAPP required elements. |
| **Summary of Comments** *(highlight significant concerns/issues)***:** 1. Comment #1
2. Comment #2
3. Comment #3
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)”.**
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| **Element** |  **Acceptable** *Yes/No/NA* | **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 organizations name |  |  |  |
| d. Date and signature line for organizations project manager |  |  |  |
| e. Date and signature line for organizations 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 |  |  |  |
| 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 projects 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 |  |  |  |
| 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 |  |  |  |
| 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** |
| 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 |  |  |  |
| **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 |  |  |  |
| 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 |  |  |  |
| 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 |  |  |  |