**EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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**  **\_\_\_ 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).  **c**. 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)”.** | | | | | | | | |
| **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 | | |  | |  |  | | |