Fall 11-23-2021

EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK

Nikia Greene

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QAPP/FSP/SAP for: *(check appropriate box)* **GRANTEE** **CONTRACTOR** **EPA** **Other**	**Entity** *(grantee, contract, EPA AO, EPA Program, Other)* Atlantic Richfield (PRP)	**Regulatory Authority** **and/or** **Funding Mechanism**	**___ 2 CFR 1500 for Grantee/Cooperative Agreements** **___ 48 CFR 46 for Contracts** **___ Interagency Agreement (FFA, USGS)** **___ EPA/Court Order** **___ EPA Program Funding** **___ EPA Program Regulation** **___ EPA CIO 2105**
Document Title ***[Note: Title will be repeated in Header]***	Final Butte Reduction Works (BRW) QAPP for Microbial Analysis and Biotreatability Study		
QAPP/FSP/**SAP Preparer**	Pioneer Technical Services, Inc. for Atlantic Richfield Company (AR)		
Period of Performance *(of QAPP/FSP/SAP)*	**2021**	**Date Submitted for Review**	11/23/2021
EPA Project Officer **EPA Project Manager**	Nikia Greene	PO Phone # **PM Phone #**	(406) 457-5019
QA Program Reviewer or **Approving Official**	Nikia Greene	**Date of Review**	1/19/2021

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 / NA
SOW/TO for contracts? Yes / No / NA

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 the Project 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.

Element	Acceptable *Yes/No/NA*	Page/ Section	Comments
A. Project Management			
A1. Title and Approval Sheet			
a. Contains project title		Title Page	
b. Date and revision number line (for when needed)		Approval Page	
c. Indicates organization's name		Title Page	
d. Date and signature line for organization's project manager		Approval Page	
e. Date and signature line for organization's QA manager		Approval Page	
f. Other date and signatures lines, as needed		Approval Page	
A2. Table of Contents			
a. Lists QA Project Plan information sections		Pages i to iii	
b. Document control information indicated		Footer	
A3. Distribution List			
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization		Distribution List	
A4. Project/Task Organization			
a. Identifies key individuals involved in all major aspects of the project, including contractors		Section 8.0	
b. Discusses their responsibilities		Section 8.0	
c. Project QA Manager position indicates independence from unit generating data		Section 8.0, Figure 6	
d. Identifies individual responsible for maintaining the official, approved QA Project Plan		Section 8.0	
e. Organizational chart shows lines of authority and reporting responsibilities		Figure 6	
A5. Problem Definition/Background			
a. States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained		Section 1.1	
b. Clearly explains the reason (site background or historical context) for initiating this project		Section 1.0, Section 2.0	

c. Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project		Section 1.0/ Section 2.4	
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		Section 1.1	
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		Table 1	
c. Details geographical locations to be studied, including maps where possible		Figure 3	
d. Discusses resource and time constraints, if applicable		Section 3.0	
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		Section 3.0	
b. Discusses precision		Section 3.1, Table 6	
c. Addresses bias		Section 3.1, Table 6	
d. Discusses representativeness		Section 3.1	
e. Identifies the need for completeness		Section 3.1, Table 6	
f. Describes the need for comparability		Section 3.1	
g. Discusses desired method sensitivity		Section 3.1	
A8. Special Training/Certifications			
a. Identifies any project personnel specialized training or certifications		Section 4.1.1	
b. Discusses how this training will be provided		Section 4.1.1	

c. Indicates personnel responsible for assuring training/certifications are satisfied		Section 4.1.1	
d. identifies where this information is documented		Section 4.1.1	
A9. Documentation and Records			
a. Identifies report format and summarizes all data report package information		Section 5.4, Section 6.4, Section 9.1.2	
b. Lists all other project documents, records, and electronic files that will be produced		Section 5.4	
c. Identifies where project information should be kept and for how long		Section 5.4	
d. Discusses back up plans for records stored electronically		Section 5.4	
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		Section 4.1.1, Section 8.0	
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		Section 4.0	
b. Details the type and total number of sample types/matrix or test runs/trials expected and needed		Section 4.4, Table 3	
c. Indicates where samples should be taken, how sites will be identified/located		Section 4.2, Table 2	
d. Discusses what to do if sampling sites become inaccessible		Section 4.2	
e. Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.		Section 4.2	
f. Specifies what information is critical and what is for informational purposes only		Section 4.2	
g. Identifies sources of variability and how this variability should be reconciled with project information		Section 4.2	
B2. Sampling Methods			

a. Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken		Table 2, Table 3, Appendix A	
b. Indicates how each sample/matrix type should be collected		Table 2, Table 3, Appendix A	
c. If in situ monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data		Section 4.4	
d. If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages		NA	
e. Indicates how samples are to be homogenized, composited, split, or filtered, if needed		Section 4.4	
f. Indicates what sample containers and sample volumes should be used		Table 3	
g. Identifies whether samples should be preserved and indicates methods that should be followed		Table 3	
h. Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of		Appendix A	
i. Identifies any equipment and support facilities needed		Section 4.0	
j. Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented		Section 6.0	
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		Table 3	
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)		Section 4.3, Section 4.4.4, Section 4.5	
c. Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible		Section 4.3, Section 4.4.4, Section 4.5	

d. Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan		Section 4.3	
e. Identifies chain-of-custody procedures and includes form to track custody		Section 4.5.2	
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		Table 3, Table 5, Appendix A	
b. Identifies equipment or instrumentation needed		Section 4.4	
c. Specifies any specific method performance criteria		Section 3.1, Table 3	
d. Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation		Section 5.0	
e. Identifies sample disposal procedures		Appendix A, Lab SOPs	
f. Specifies laboratory turnaround times needed		Section 4.5.3	
g. Provides method validation information and SOPs for nonstandard methods		Section 9.0, Appendix A, Appendix C	
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		Section 5.0	
b. Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented		Section 5.0	
c. Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data		Section 3.1, Table 6	
B6. Instrument/Equipment Testing, Inspection, and Maintenance			
a. Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this		Section 5.2	

b. Identifies testing criteria		Section 5.2	
c. Notes availability and location of spare parts		Section 5.2	
d. Indicates procedures in place for inspecting equipment before usage		Section 5.2, Appendix A	
e. Identifies individual(s) responsible for testing, inspection and maintenance		Section 8.0	
f. Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented		Section 5.2, Section 6.0	
B7. Instrument/Equipment Calibration and Frequency			
a. Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration		Section 5.0, Section 6.0, Appendix A	
b. Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment		Section 5.0, Section 6.0, Appendix A	
c. Identifies how deficiencies should be resolved and documented		Section 5.0, Section 6.0, Appendix A	
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		Section 5.3	
b. Identifies the individual(s) responsible for this		Section 5.3	
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		Section 2.3	
b. Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project		Section 2.3	
c. Indicates the acceptance criteria for these data sources and/or models		Section 2.3, Section 3.1	
d. Identifies key resources/support facilities needed		Section 2.3	
e. Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing		Section 2.3	
B10. Data Management			

a. Describes data management scheme from field to final use and storage		Section 4.5, Section 5.4	
b. Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs		Section 5.4	
c. Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately		Section 5.4	
d. Identifies individual(s) responsible for this		Section 5.4	
e. Describes the process for data archival and retrieval		Section 5.4	
f. Describes procedures to demonstrate acceptability of hardware and software configurations		Section 5.4	
g. Attaches checklists and forms that should be used		Section 5.4, Appendix D	
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		Section 6.0	
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		Section 6.0	
c. Describes how and to whom assessment information should be reported		Section 6.0	
d. Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented		Section 6.2, Section 6.3	
C2. Reports to Management			
a. Identifies what project QA status reports are needed and how frequently		Section 6.4	
b. Identifies who should write these reports and who should receive this information		Section 6.4	
D. Data Validation and Usability			
D1. Data Review, Verification, and Validation			

Describes criteria that should be used for accepting, rejecting, or qualifying project data		Section 9.0	
a. Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any		Section 9.0	
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.		Section 9.0	
c. Identifies issue resolution process, and method and individual responsible for conveying these results to data users		Section 9.0	
d. Attaches checklists, forms, and calculations		Section 9.0; Appendix D	
D3. Reconciliation with User Requirements			
a. Describes procedures to evaluate the uncertainty of the validated data		Section 9.0	
b. Describes how limitations on data use should be reported to the data users		Section 9.0	