[*QA Project Plan Coversheet w/ Signature Page*]



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**Acronyms/Abbreviations**

# SECTION A – PROJECT MANAGEMENT

**(A.1 and A.2 are previously provided as Approvals page and Table of Contents)**

**A.3 Distribution List**

*Recommended text for this subsection is provided below.*

Quality Assurance (QA) Project Plans and Standard Operating Procedures (SOPs) shall be controlled (through documented approvals) as required by Section 5.3 of the Office of Research and Development (ORD) Quality Management Plan. The project lead will be responsible for distribution of the current signed approved version of the QA Project Plan to project participants shown in Section A.4. Signed approved versions of SOPs will be available to project staff through the [ORD@Work SOP intranet site](https://webx.ord.epa.gov/quality-assurance/standard-operating-procedures-sops?combine=&field_sop_previous_number_value=&title=&field_lab_value=ceser&field_sop_contact_value=&field_discipline_value=&items_per_page=10). Signature approved electronic copies of this QA Project Plan, SOPs, and any associated QA assessment reports, will also be maintained in ORD QA Track.

The project lead will also be responsible for timely communications with all involved participants and will retain copies of all management reports, memoranda, and correspondence between research task personnel.

**A.4 Project/Task Organization**

*Identify the individuals and organizations participating in the research and discuss their specific roles and responsibilities. Include and all persons responsible for implementation. QA manager position must indicate independence from unit collecting/using data. A table summarizing this information is recommended.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Organization** | **Role** | **Responsibility** | **Distribution List** |
|  | EPA ORD | Project Lead | Scientific leadership for the research effort | Yes |
|  | EPA ORD | QA Manager | Oversight of QA program implementation | Yes |
|  |  |  |  |  |
|  |  |  |  |  |

*Provide a concise organization chart showing the relationships and the lines of communication among all project participants. Clearly identify the lead organization for the research effort and relationships to other organizations. The organization chart must also identify any subcontractor relationships relevant to environmental data operations, including laboratories providing analytical services.*

**A.5 Problem Definition/Background**

*State the specific problem to be solved, decision to be made, or outcome to be achieved.*

*Include sufficient background information to provide a historical, scientific, and regulatory perspective for this particular project.*

**A.6 Project Description**

*Provide a high-level discussion of how, when, and where the research effort will be conducted over the duration of the study. Include any research questions or hypotheses, purpose/ objectives, any dependencies (e.g., on other projects, certain funding levels, a certain measure of success at early stages of the project, etc.), and any critical issues. This could optionally include information on potential impact or customer/partner concerns. or equipment requirements.*

*Provide an estimated timeline for completion of key tasks (e.g., QA Project Plan and Health and Safety Plan development, data collect, etc.) with respect to the target dates for the research project deliverable(s).*

**A.7 Quality Objectives & Criteria**

*Discuss the quality objectives for the project and the performance criteria to achieve those objectives. EPA requires the use of a systematic planning process to define these quality objectives and performance criteria.*

* *State project objectives and limits, both qualitatively & quantitatively*
* *State & characterize measurement quality objectives as to applicable action levels or criteria*

**A.8 Special Training/Certification**

*Identify and describe any specialized training or certifications needed by personnel in order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.*

**A.9 Documents and Records**

*Recommended text for this subsection is provided below.*

Research activities must be documented according to the requirements of ORD QA Policies titled *Scientific Recordkeeping: Paper*, *Scientific Recordkeeping: Electronic*, and *Quality Assurance/ Quality Control Practices for ORD Laboratory and Field-Based Research*, as well as requirements defined in this QA Project Plan. The ORD QA Policies require the use of research notebooks and the management of research records, both paper and electronic, such that project research data generation may continue even if a researcher or an analyst participating in the project leaves the project staff.

Electronic project records will be maintained by the project lead on the ORD network drive:

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Electronic Records shall be maintained in a manner that maximizes the confidentiality, accessibility, and integrity of the data. ORD PPM Section 13.6 provides guidance on the maintenance of electronic records for ORD.

Records retention:

Records that are generated under this research effort will be retained in accordance with EPA Records Schedule 1035, and as required by Section 5.1 of the ORD Quality Management Plan for QA Category A Projects.

# SECTION B – DATA GENERATION & AQCUISITION

***Refer to subsection content specified in the applicable*** [***QA Project Plan Checklist (by Research Type)***](https://intranet.ord.epa.gov/ceser/quality-assurance-qa-project-plan-development)***.***

# SECTION C – ASSESSMENT AND OVERSIGHT

**C.1 Assessments and Response Actions**

*Recommended text for this subsection is provided below. If proficiency/performance evaluation (PE) samples will be needed to demonstrate analyst proficiency with a given method prior to analyzing research samples, include PE audit below.*

For QA Category A projects, at least one QA audit is required per ORD QA Policy titled *Use of the Graded Approach for Quality Assurance of Research*.

A technical systems audit (TSA) will be completed within one year of the initial QA Project Plan approval date for this research effort. The TSA will be conducted in accordance with ORD QA Policy titled *Audits of Technical and Quality Systems*.

Draft publications resulting from this project will undergo ORD clearance in STICS prior to dissemination as required by ORD Policy titled *ORD Clearance Policy and Procedures* and CESER SOP titled *Standard Operating Procedure for Product Clearance*.

**C.2 Reports to Management**

*Recommended text for this subsection is provided below.*

Results of QA audits will be reported in accordance with ORD QA Policy titled *Audits of Technical and Quality Systems*. Implementation of corrective actions for audit findings will be verified by the QA Manager, and status of implementation tracked through closure.

Required approvals for draft publications undergoing ORD clearance is documented in STICS.

# SECTION D – DATA VALIDATION AND USABILITY

**D.1 Data Review, Verification, and Validation**

*Itemize the information and records which must be included in the data report package and specify the reporting format for hard copy and any electronic forms. Records can include raw data, data from other sources such as databases or literature, field logs, sample preparation and analysis logs, instrument printouts, model input and output files, and results of calibration and QC checks.*

*Discuss responsibilities for conducting data review (data generator), verification (second reviewer), and validation (independent reviewer).*

*State criteria for accepting, rejecting, or qualifying data; include project-specific calculations or algorithms.*

*See also Agency guidance document titled Guidance on Environmental Data Verification and Data Validation.*

**D.2 Verification and Validation Methods**

*Describe the process for conducting data verification and validation reviews. Identify issue resolution procedure and responsible individuals. Identify the method for conveying results to data users. Provide examples of any forms or checklists to be used.*

**D.3 Reconciliation with User Requirements**

*Describe how the data will be summarized or analyzed (e.g., qualitative analysis, descriptive or inferential statistics) to meet the project objective(s).*

*If descriptive statistics are proposed, state what tables, plots, and/or statistics (e.g., mean, median, standard error, minimum and maximum values) will be used to summarize the data.*

*If an inferential method is proposed, indicate whether the method will be a hypothesis test, confidence interval, or confidence limit and describe how the method will be performed.*

# REFERENCES

REVISION HISTORY

|  |  |  |
| --- | --- | --- |
| Revision # | Description | Effective Date |
| 0 | Initial Version |  |
|  |  |  |