

Environmental Compliance Assurance Program

Summary

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QA Project Plan) as a tool for project managers and planners to document the type and quality of data needed for environmental decisions and to describe the methods for collecting and assessing those data. The development, review, approval, and implementation of the QA Project Plan is part of EPA's mandatory Quality System. The EPA Quality System requires all organizations to develop and operate management structures and processes to ensure that data used in Agency decisions are of the type and quality needed for their intended use. The QA Project Plan is an integral part of the fundamental principles and practices that form the foundation of the EPA Quality System.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA also requires that all environmental data used in decision making be supported by an approved Quality Assurance Project Plan (QA Project Plan). This requirement is defined in EPA Order 5360.1 A2 (EPA 2000), Policy and Program Requirements for the Mandatory Agency-wide Quality System, for EPA organizations. Non-EPA organizations funded by EPA are required to develop a QA Project Plan through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

Policy

All work funded by EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QA Project Plan. The QA Project Plan will be developed using a systematic planning process based on the graded approach. No work covered by this requirement shall be implemented without an approved QA Project Plan available prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

General Content

The QA Project Plan must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. In some cases, it may be necessary to add special requirements to the QA Project Plan. The EPA organization sponsoring the work has the authority to define any special requirements beyond those listed in this document. If no additional requirements are specified, the QA Project Plan shall address all required elements. Each EPA organization defines their organizational-specific requirements for QA Project Plan documentation in their Quality Management Plan. All applicable elements defined by the EPA organization sponsoring the work must be addressed.

The level of detail of the QA Project Plan should be based on a graded approach so that the level of detail in each QA Project Plan will vary according to the nature of the work being performed and the intended use of the data. As a result, an acceptable QA Project Plan for some environmental data operations may require a qualitative discussion of the experimental process and its objectives while others may require extensive documentation to adequately describe a complex environmental program.

Plan Preparation and Approval

The QA Project Plan may be prepared by an EPA organization, a contractor, an assistance agreement holder, or another Federal agency under an interagency agreement. Except where specifically delegated in the Quality Management Plan of the EPA organization sponsoring the work, all QA Project Plans prepared by non-EPA organizations must be approved by EPA before implementation.

Project Plan Implementation

None of the environmental work addressed by the QA Project Plan shall be started until the QA Project Plan has been approved and distributed to project personnel except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Subject to these exceptions, it is the responsibility of the organization performing the work to assure that no environmental data are generated or acquired before the QA Project Plan is approved and received by the appropriate project personnel. However, EPA may grant conditional approval to a QA Project Plan to permit some work to begin while non-critical deficiencies in the QA Project Plan are being resolved.

The organization performing the work shall ensure that the QA Project Plan is implemented as approved and that all personnel involved in the work have direct access to a current version of the QA Project Plan and all other necessary planning, implementation, and assessment documents. These personnel should understand the requirements prior to the start of data generation activities.

Project Plan Revision

Although the approved QA Project Plan must be implemented as prescribed; it is not inflexible. Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the approving official shall determine if the change significantly impacts the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QA Project Plan shall modify the QA Project Plan to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been received and approved (at least verbally with written follow-up) by project personnel, shall the change be implemented.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QA Project Plan, the QA Project Plans shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QA Project Plan must be revised and resubmitted for review and approval.

Project Plan Elements

The QA Project Plan is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QA Project Plan must provide sufficient detail to demonstrate that:

- the project technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, or data acquisition methods are appropriate for achieving project objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data operations require the coordinated efforts of many individuals, including managers, engineers, scientists, statisticians, and others. The QA Project Plan must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the QA Project Plan, such as the field sampling team, the analytical laboratory, modelers, and the data reviewers. In all aspects of the QA Project Plan, the use of national consensus standards and practices are encouraged.

The QA Project Plan shall be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. These elements are presented in that order and have been arranged for convenience into four general groups. The four groups of elements and their intent are summarized as follows:

- **Project Management** - The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.
- **Data Generation and Acquisition** - The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.
- **Assessment and Oversight** - The elements in this group address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.
- **Data Validation and Usability** - The elements in this group address the QA activities that occur after the data collection or generation phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

Post-COVID-19 Environmental Compliance Checklist

This checklist is intended to assist EHS assessing its environmental compliance status after COVID-19 federal and state limitations are lifted or reduced. It is not meant to be exhaustive, but to provide guidelines to minimize the risk of future enforcement actions based on the state and federal guidance issued by environmental agencies to date. As with everything related to the COVID-19 pandemic, the situation is constantly changing, and this checklist may need to be modified as agencies further clarify expectations and requirements.

Employees undertaking this assessment should also consider reviewing recent guidance provided by OSHA to help identify risk levels in workplace settings and determine any appropriate control measures to implement as well as state-specific mandates that are likely to address overall COVID-19 best practices to keep employees, consultants and contractors safe and healthy.

Start-up of a closed facility or resuming normal production

Prior to initiating start-up (if facility was closed)

- ☐ If the facility provided notice of shut-down to a local or state agency or U.S. EPA voluntarily or based on a state requirement (e.g., cessation of regulated operations), provide notice of start-up in accordance with applicable requirements.
- ☐ Review the facility's environmental permits for any required start-up procedures.
- ☐ Verify that available staff can meet applicable compliance requirements (e.g., has required hazardous waste training, etc.).

Upon start-up or resumption of normal production, conduct a compliance assessment (ideally at the direction of the legal department)

This assessment is intended to determine the facility's compliance with all permits, orders and regulatory requirements during shut-down or ramp-down. The list below contains examples of typical requirements but is not meant to be exhaustive.

Air and water

- ☐ Was all required sampling, testing or monitoring performed?
- ☐ Has necessary equipment (e.g., pollution control devices, oil water separators) been inspected and confirmed to be operational?
- ☐ Did the facility comply with necessary record-keeping requirements (in addition to U.S. EPA's COVID19-specific recordkeeping requirements – see below)?

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- ☐ Were all required reports submitted (in addition to U.S. EPA's COVID-19-specific reporting requirements – see below)?
- ☐ If the facility's air emission source typically exceeds permit limits during start-up, assess the state's "start-up, shutdown, and malfunction" regulations, which may provide relief in certain circumstances.
- ☐ Did the facility take any action (e.g., drain tanks, etc.) that would increase the volume or change the type of wastewater generated, which may require additional notifications or approvals?

Hazardous waste

- ☐ Is there any hazardous waste accumulated beyond permissible time limits?
- ☐ Were hazardous waste storage areas inspected?
- ☐ Were all necessary reports submitted and documentation maintained?
- ☐ Does the facility anticipate initial increases in hazardous waste generation requiring notice of an episodic generation event?
- ☐ Were process units containing hazardous substances out of operation for greater than 90 days?

Spill prevention and control

- ☐ Were required inspections conducted and documented?
- ☐ Do any new conditions warrant action?

Resumption Continued

- ☐ Was EPCRA reporting completed?
- ☐ Were all periodic reports required under administrative or judicial orders and agreements submitted?
- ☐ Were permit renewal applications for expired or expiring permits submitted or extensions confirmed?
- ☐ Was any required employee training/certification missed?

If noncompliance items are known or identified

Prepare detailed documentation of any noncompliance item in accordance with U.S. EPA and state agency guidance. Ideally, the facility should have prepared documentation at the time of noncompliance, but review documentation for completeness and create or supplement as necessary. Factors to document include:

- ☐ Dates of noncompliance.
- ☐ Reason for noncompliance (e.g., stay-at-home order, staff reduction to comply with CDC guidelines, sickness (i.e., COVID-19 diagnosis), inability to access data or conduct inspection remotely, disruption Post-COVID-19 Environmental Compliance Checklist 3 in waste disposal service, disruption in laboratory services, disruption in contractor performance, lack of necessary supplies).
- ☐ Process to return to compliance. Note: U.S. EPA's March 26, 2020 memorandum, "COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program," states that it will not require "catch-up" compliance for missed monitoring or reporting if the interval is less than three months or if late bi-annual or annual monitoring and/or submission should occur. Each state may have its own parameters to consider.
- ☐ Lack of impact on human health or the environment (if possible).
- ☐ How to prevent noncompliance in a similar situation in the future (if possible).
- ☐ Cite applicable portions of U.S. EPA COVID-19 guidance or state COVID-19 guidance.
- ☐ Consider voluntary disclosure of noncompliance to U.S. EPA and/or the appropriate state agency (where applicable state policies exist).
- ☐ Prepare documentation of return to compliance.
- ☐ Consider retraining on area of noncompliance.

CERCLA, RCRA, TSCA or UST sites where work was stopped or postponed

If a notice was provided to U.S. EPA or any state agency about delay or nonperformance, provide a follow-up notice, and if no notice was provided, notify as soon as possible:

- ☐ If a force majeure clause was triggered, identify the end of force majeure event or need for an extension.
- ☐ Dates of delay or noncompliance.

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- ☐ Reason for delay or noncompliance (stay-at-home order, safety and availability of work crews, not possible to conduct work when following CDC guidelines, sickness (i.e., COVID-19 diagnosis), close interaction with high-risk groups (i.e., residents), logistical challenges (e.g., transportation, lodging, meals), disruption in waste disposal service, disruption in laboratory services, lack of necessary supplies).
- ☐ Describe any missed sampling, reporting, investigation or remediation activities.
- ☐ If U.S. EPA or a state agency approved the deferral or postponement, reference agency response.
- ☐ Cite U.S. EPA's "Interim Guidance on Site Field Work Decisions Due to Impacts of COVID-19" (if applicable) and any applicable state guidance.
- ☐ Plan to return to compliance; consider conducting missed work versus skipping event.
- ☐ Lack of "critical" nature of work, i.e., not "mission critical" (if possible).
- ☐ Lack of impact on human health and the environment (if possible).
- ☐ Consult all applicable orders and decrees for relevant provisions or requirements.
- ☐ If noncompliance included work that was not on-site, such as failure to prepare or submit investigation reports, modeling, cleanup documentation, work plans or financial assurance, consider additional reasons for noncompliance as set forth in the "Start-up of a closed facility or resuming normal production" section above.
- ☐ As work resumes, confirm that health and safety plans have been modified to address COVID-19 prevention.

If the company is paying a penalty to the Department of Justice (DOJ) under a consent Decree

- ☐ Were necessary payments made?
- ☐ If payments were missed, see the April 14, 2020 memorandum "Debt Collection Activities During the COVID19 Pandemic" issued by the Environment and Natural Resources Division of the DOJ Environmental Enforcement Section, which confirms that DOJ suspended debt collection through May 31, 2020.
- ☐ Determine the ability and time frame to make payments and provide the required notifications to DOJ.

Create a task force to prepare a contingency plan for a future return to stay-at-home or similar circumstances

This type of proactive action can serve to further mitigate any identified noncompliance.

- ☐ Are additional remote compliance options available to maintain compliance during a closure?
- ☐ Can back-up contractors be identified?
- ☐ Is there an appropriate signature process in place for remote submission of environmental reports and documents?
- ☐ Are compliance obligations tracked in a portable and easy to follow format?
- ☐ Are remediation obligations tracked in a portable and easy to follow format?

Be prepared for agency actions and alternative enforcement

It is likely that federal and state agencies will return to work in waves and that there may be reduced staff, reduced funding and continued reliance on a work from home format. These circumstances still require companies' continued vigilance for risk mitigation. Short-term agency enforcement may be supported by:

- Written agency information requests.
- Informal letters seeking information or support related to potential noncompliance.
- Phone calls from regulators seeking information related to employee complaints or potential noncompliance.

E&B initial response to any of these inquiries sets the foundation for potential mitigation and/or penalties, so information must be provided in a strategic, thoughtful manner in accordance with applicable COVID-19 policies (if COVID-related).

A reduced agency response can also lead to increased risk and liability through citizen suits or litigation by residents in the area of a facility. Assess the value of proactive notifications / communications to all stakeholders for any COVID19-related noncompliance.

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