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**Quality Assurance Project Plan (QAPP) Template:
Initiatives Exploring the Use of
Environmental Management Systems (EMSs) in a Regulatory Context
Funded by EPA State Innovation Grants (SIGs)**

[REMOVE THESE TWO PAGES BEFORE SUBMITTING.]

PURPOSE: This template is intended to help improve the quality assurance (QA) capabilities and understanding of State Innovation Grant (SIG) recipients that are undertaking what can be termed "EMS-regulatory" initiatives—projects that attempt to integrate the use of environmental management systems (EMSs) into regulatory approaches such as permitting. This template is expected to improve the rigor and consistency of Quality Assurance Project Plans (QAPPs) submitted to EPA and thereby improve both SIG project design and the quality and usability of the data and analysis resulting from SIG projects. The design of this template is also expected to streamline the QAPP submission and review process, potentially leading to earlier project implementation.

BACKGROUND: This QAPP template was prepared based upon review of EPA guidance on QAPPs, sample SIG proposals and QAPPs for initiatives exploring the use of EMSs in a regulatory context, and an existing template for Environmental Results Programs. In its structure, this template adheres closely to the recommended QAPP review sheet. This structure will help ensure broad applicability and a streamlined review process for EPA Regions and Headquarters. In content, the template provides "boilerplate" language that is likely to be useful for many SIG recipients. However, every project is unique, and you should tailor the text to suit your needs.

Please note that this template is not an official EPA document, has not undergone review by all relevant EPA QA specialists, and may be modified in the future based upon such review.

ASSUMPTIONS: This template was prepared to meet the needs of a "typical" state EMS-regulatory program. It assumes that participating facilities and the state Agency will reach facility-specific agreements about incentives (like reduced oversight) tied to the implementation of an EMS and satisfactory improvements in environmental performance. It assumes that the project will not involve statistical sampling. If your initiative differs in any of these respects, you may need additional guidance beyond that which is provided in the template.

USAGE: Text that is enclosed in square brackets and highlighted in yellow is meant to be changed by the user. (You might want to change other text as well, depending on the nature of your initiative.) Guidance/advice for particular sections is enclosed in Microsoft Word comments. If you are using a version of Microsoft Word from 2003 or later, set View to "Print Layout" and comments will appear in the right-hand margin. If you are using an earlier version of Word, you will see the comments when the mouse passes over particular flagged passages or in a window at the bottom of the screen. With these earlier versions of Word (or with other word processors), you might find it easier to view a hardcopy or electronic copy of the Adobe PDF version of the template, also available from EPA's National Center for Environmental Innovation. You may find it helpful to view the hardcopy while editing the electronic text in your word processor.

Hyperlink usage. Depending on your version of Microsoft Word and your user settings, you might be able to access hyperlinked documents and web pages by simultaneously pressing "Ctrl" and right-clicking with your mouse, or you might need to copy and paste the URL directly into your browser.

PRE-SUBMISSION CLEANUP: Before submitting your customized QAPP to EPA, it is recommended that you remove yellow highlighting, make sure all bracketed text has been replaced with your own text,

and update the table of contents and lists of tables and/or figures. You may also wish to remove Microsoft Word comments that you and other readers are not likely to need in the future. Instructions on how to carry out these tasks are included below. Note that the instructions were developed based on commands and functions available in Microsoft Word 2003. If you are using a different version of Microsoft Word, you may find that the commands in your version are slightly different than the commands described here.

Removing highlighting. To remove all highlighting, first select all text in the document by choosing "Edit/Select All" from the menu. Click on the arrow next to  (the highlighting icon) on the toolbar and then select "None" from the color options available in the pop-up window. (If you do not see  on the toolbar, make sure that the formatting toolbar is visible by right-clicking anywhere in the toolbar area. If "Formatting" is not selected, click on it.) Highlighting in the header must be taken out separately. Double-click on the header, select the highlighted text, and proceed as above.

Removing bracketed text. To make sure that all bracketed text has been replaced, use the search function in Microsoft Word, found under "Edit/Find" on the menu. Type "[" or "]" in the box next to "Find What" and then click "Find Next." Replace any brackets you find and repeat the process until a pop-up window appears, indicating that no occurrences of the search term were found. Be sure to check the header for bracketed text as well.

Updating table of contents, etc. To update a table of contents or other reference table (e.g., list of figures), first select the reference table by clicking anywhere on the table. With the table selected, press the F9 key. Note that when you update a reference table, any text or formatting that you have added to the table is lost. Note also that the table of contents and other reference tables are generated based upon the formatting styles used for the headings for different sections and subsections of this template.

Removing comments. To delete all comments from the document, click on the arrow next to  ("Reject Change/Delete Comment") and then click "Delete All Comments in Document." (If you do not see  on the toolbar, make sure that the reviewing toolbar is visible by right-clicking anywhere in the toolbar area. If "Reviewing" is not selected, click on it.) To delete an individual comment, right-click on the comment and click "Delete Comment."

AMENDING THE QAPP: This template assumes that the QAPP submitted with your proposal/workplan will not have all of the details you will need before you begin data collection. It assumes that you will amend your QAPP in the future after completion of key planning steps, but before data collection begins.

[Insert State Agency name here]

[Insert project title here]

Quality Assurance Project Plan

[Insert Agency name and address here]

[Insert full contact information for project manager]

PLEASE DO NOT PHOTOCOPY THIS DOCUMENT

Distribution of this document is controlled in order to avoid having multiple versions of the document in circulation. Please see [QA Officer] to obtain additional copies or add individuals to the distribution list.

Abstract: This document details a quality assurance plan to guide the successful implementation of [name of project]. [Provide a very brief summary of the project, to orient the reader. Two to three sentences should be sufficient. A more detailed description of the project will be given in A6.]

A PROJECT MANAGEMENT

A1. Approval Sheet

[Insert name of project manager] [Insert Agency name] [Insert title]	Date
--	------

[Insert QA Officer name] [Insert Agency name] Quality Assurance Officer	Date
---	------

[Insert name of partner] [Insert organization name] [Insert title]	Date
--	------

[Insert name of partner] [Insert organization name] [Insert title]	Date
--	------

A2. Table of Contents

[Be sure to update table of contents & header.]

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A3. Distribution List

The following individuals will receive a copy of this Quality Assurance Project Plan (QAPP) and any subsequent revisions:

Table 1: Distribution List

Copy #	Name	Project Title or Position	Organizational Affiliation	PT/O	Contact Information
C1		Project Manager		PT	
C2		QA Officer		PT	
C3		EPA Liaison		PT	
C4		Contractor		PT	
C5		Partner		PT	
C6		NGO Observer		O	

PT = Project team member, O = Observer

Additional copies of the QAPP may be requested from the QA Officer.

A4. Project/Task Organization

Personnel involved in project implementation are listed in Table 2. Following the table, the responsibilities of key personnel are enumerated. Lines of authority and communication are shown in the organization chart in Figure 1.

Table 2: Project Implementation Personnel

Name	Role in Project, Title, Organizational Affiliation	Contact Information

The Project Manager will be responsible for the following activities:

- Conduct outreach with potential participants and stakeholders
- Oversee participant enrollment, data collection, and data analysis tasks
- Issue quarterly and annual reports to EPA
- [Insert other tasks here]

The QA Officer will be responsible for the following activities:

- Maintain QAPP and amend as needed
- Distribute QAPP and maintain distribution list
- Conduct readiness reviews
- [Insert other tasks here]

[Contractor, if applicable; if a contractor has yet to be selected, say “Contractor to be determined”] will be responsible for the following activities:

- [Insert contractor tasks here, including tasks specifically related to QA/QC]

[Partner, if applicable; if partner has yet to be identified, say “Partner to be determined”] will be responsible for the following activities:

- [Insert partner tasks here, including tasks specifically related to QA/QC; e.g., a community group assisting in the identification of the facility universe]

Figure 1: Project Organizational Chart

[Insert chart. Chart should demonstrate that the QA Officer is independent of the units generating the data.]

A5. Problem Definition/Background

Rationale for initiating the project

[Insert text describing the problem this project is trying to solve]

Objectives of the project

The project is designed to deliver the following short-term, intermediate, and long-term outcomes, and enable the Agency to make the following decisions.

Anticipated outcomes

[Examples of anticipated short-term outcomes (changes in awareness and attitudes) might include:

- Increased awareness of impacts on the environment
- Improved understanding of opportunities to reduce environmental impacts

- Increased commitment to improve environmental performance
- Increased awareness of the value of EMSs

Examples of anticipated intermediate outcomes (changes in behavior) might include:

- More widespread adoption of EMSs
- Continuing environmental performance improvement among program participants (including environmental aspects that are currently regulated, as well as those such as energy and water use that are not traditionally regulated)

Examples of anticipated long-term outcomes (changes in conditions) might include:

- Improvement of environmental quality (environmental conditions may be expected to improve overall, in a target region or watershed, or in a target community with environmental justice concerns).
- Increased recognition of environmental leaders among key stakeholders (e.g., the public, local community members, employees, or investors)
- Greater efficiency and cost savings for participating facilities
- More efficient allocation of state Agency resources
- Cost savings for the state Agency
- Development of a policy approaches that could be used in other contexts, such as different sectors, environmental media and/or states
- Improved communication and understanding between regulators and the regulated community
- Greater collaboration among state agencies
- Enhanced networking and peer mentoring within the regulated community]

Anticipated decisions

[Examples of decisions to be taken based upon data collected might include:]

- Will program incentives be implemented and/or expanded?
- Should [Agency] continue/discontinue/expand its EMS-regulatory initiative?
- Based on the experience of this project, how should [Agency] modify the EMS-regulatory program? (e.g., what incentives are most effective? Should [Agency] further modify its traditional regulatory approach? How far should [Agency] relax regulatory oversight of facilities that achieve similar benchmarks?)]

The following logic model shows the relationships among project activities and major outcomes and decisions.

Figure 2: Logic Model

[Insert logic model.]

Regulatory information, applicable criteria and action limits

Only facilities with a satisfactory history of regulatory compliance will be allowed to participate in the program. "Satisfactory regulatory compliance" will be defined as [insert compliance definition here].

A6. Project/Task Description

Project overview

[Insert a short description of the project and how it will meet the objectives described above. This template was developed under the assumption that the project will involve an exploration of the use of EMSs in a regulatory context. Most likely you can use language from your State Innovation Grant proposal/workplan here. You may want to amend this section later as you refine the goals and measures.]

Project summary and work schedule

This project's major tasks and timetable are outlined in the table below.

Table 3: Schedule of Major Project Tasks

Task Name	Task Description	Start Date	End Date
Outreach to candidate facilities	Preliminary outreach to candidate facilities to generate interest in project participation.		
Outreach to stakeholders	Preliminary outreach to stakeholders to generate interest in observing and/or participating in the project.		
Goals identification	Finalization of project goals, upon which metrics will be based		
Determination of criteria for participation	Finalization of criteria used to evaluate whether candidate facilities are eligible to join the EMS-regulatory program.		
Recruitment and enrollment	Recruitment and enrollment of candidate facilities and other stakeholders.		

Table 3: Schedule of Major Project Tasks

Task Name	Task Description	Start Date	End Date
Definition of specific conditions for participation	In the case of each facility, preparation of a “contract” (e.g., a permit or other legally binding document) agreed upon by the facility, stakeholders, the state Agency, and EPA, laying out the roles and responsibilities of each party. The crucial component is reaching agreement on what goals the facility undertakes to accomplish and what incentives the facility receives in return.		
Measures identification	Finalization of performance metrics to be tracked by this the project. This will include identification of metrics/data to be provided by participating facilities.		
Analytical methodology	Development of a methodology to drive performance measurement and analytical tasks.		
Data input & management strategy	Development of an approach for collecting and managing project data.		
QAPP finalization & approval	Finalization of the QAPP based upon results of the measures identification, analytical methodology, and data management tasks. Includes process of review and approval by EPA.		
Internal training	Training of Agency staff responsible for program implementation. The training of staff responsible for data collection and analysis will include a review of the relevant parts of the QAPP.		
Baseline characterization	Collection of current/historical data from each facility to establish a baseline for performance measures and normalization factors. If applicable, aggregation of baseline data from facilities to establish project-wide or other baselines.		
[Additional program activities, one per row]	Describe additional program activities, such as EMS implementation and related training, mentoring, reporting, provision of incentives, technical assistance, etc.		

Table 3: Schedule of Major Project Tasks

Task Name	Task Description	Start Date	End Date
Follow-up or scheduled data collection	Facility reports, site visits, surveys, etc.		
Data analysis	Analysis of baseline, operational, follow-up, and normalization data to understand change in facility performance and overall outcomes of interest. Assessment of project efficiency.		
QA Review	Validation and verification of results.		
Reporting of results	Reporting to EPA, participating facilities, other stakeholders, and the general public.		

Geographic focus

Facilities from every part of the state are expected to participate. The actual distribution of facilities will be described in reports that [Agency] prepares on program results.

Resource and time constraints

[Insert], to best of your knowledge]

A7. Quality Objectives and Criteria

[Agency] recognizes the importance of ensuring that data are of sufficient quality to meet the needs of the project. [Agency] is committed to collecting primary data and obtaining secondary data of the highest quality possible within the constraints of project resources. Data quality can be characterized in terms of precision, bias, representativeness, completeness, comparability, and sensitivity. These characteristics are termed data quality indicators (DQIs).

Precision

For environmental measurements, the Agency will [encourage/require] facilities to meet the precision standards achievable by the use of EPA-approved analytical methods with proper sample collection and handling protocol.

[Also identify other measures you will take to ensure the precision of various data sets. For example:

- Will facilities be required to document their anticipated, and actual, data collection methods? If so, you will have opportunities to intervene to ensure high-quality data, and to judge the quality of data already collected.

- Will the wording of data collection instruments like surveys and reporting forms be reviewed to remove ambiguity? The more precise the wording of the data collection instruments, the more confidence one can have in the precision of the responses.
- Will facilities receive guidance in the form of voluntary or mandatory training sessions?
- Will facilities be required to certify reports that they submit and face penalties for submission of false data? Arguably, a requirement to formally certify could encourage facilities to QA their data more thoroughly.]

Bias

[Agency] anticipates the following kinds of bias may impact the ability to draw conclusions from the data: [Insert recognized biases here]

To reduce concerns about facility self-reporting bias, the Agency will require facility-specific environmental performance goals, data collection procedures, and the choice of normalization factors to be agreed upon before the facility begins to collect data. In its initial review of the facility's performance goals, the Agency will check for signs of potential cross-media transfers or double-counting of environmental improvements. Although facility results will be self-reported, . . . [describe your approach to minimizing the impact of potential self-reporting bias. Will data be maintained in auditable form? Will the Agency or a contractor audit data or inspect data collection instruments? Will there be random or scheduled site visits? Will the achievement of performance goals be incorporated into EMS reporting? Will non-audited results be differentiated from audited results in public reports?]

To reduce concerns about bias in the Agency's own reporting of project results, progress reports and the final project report will report potential biases in the data and justify all conclusions reached on the basis of project data, and project data will be open to EPA inspection for [x] years.

Representativeness

[Describe how the project will optimize the representativeness of samples taken, and minimize the impact of any unrepresentative data on the analysis.]

To ensure representativeness of physical samples, the Agency will review each facility's sampling plan to ensure that environmental sampling from every medium will be collected in accordance with guidelines and "best practices" established by the state or EPA.

To ensure that facility data are representative of overall facility performance, facilities will be required to commit to and measure against facility-wide goals, rather than process-specific goals.

Completeness

[Describe goals for completeness in each important data set. If you wish, specify a minimum reporting rate: E.g., what percentage of data do you expect to collect?]

When data used for analysis are incomplete, the potential impact of their incompleteness on the analysis will be described in all relevant reports.

Comparability

The most important comparisons to be made in this project are between baseline data and follow-up data from individual facilities. For the sake of comparability, in all cases such comparisons will be normalized. The Agency will work with facilities to ensure that appropriate normalization factors are chosen.

In general, all quantitative comparisons (e.g., among facilities, among industries, across programs) will be normalized whenever appropriate normalization data can be obtained. If normalization is not possible, the Agency will make note of any considerations that would affect confidence in the comparison. Data from different sources will never be combined unless they were collected in a comparable manner.

[If financial and/or personnel resource data are being collected, provide a description of how you will ensure comparability for these data.]

[If your project involves a control group that does not participate in program activities, discuss the criteria you will use to select control facilities (e.g., sector, size, ownership characteristics, location, etc.) to make them as comparable as possible to participating facilities. Since the two groups can not be perfectly comparable, also explain how you expect that the differences may limit the conclusions that can be drawn from comparison of the control group and the "treatment" group (i.e., the group of participants).]

Sensitivity

For environmental measurements, the Agency will [encourage/require] facilities to meet the sensitivity standards achievable by the use of EPA-approved analytical methods with proper sample collection and handling protocol.

A8. Special Training/Certification

To the extent practicable, [Agency--and, applicable, insert contractor/partner name] will develop and deliver [mandatory/voluntary] training sessions to key parties to ensure quality data.

Training will be provided by [Agency/contractor/mentor facilities/non-profit partners] to the following individuals to ensure quality primary data collection:

- Facility personnel who will be collecting baseline and follow-up data
- Data-entry personnel who will be processing data from inspections and self-certification responses
- QA/QC personnel (if any additional training is needed to familiarize them with the project)

Each session will cover proper data collection/handling and QA procedures. Training will be augmented by debriefing personnel shortly after their tasks have begun, to correct and clarify appropriate practices. Technical assistance will also be provided to facilities by [Agency/contractor/mentor facilities/non-profit partners].

The Project Manager is responsible for ensuring that all personnel involved with data generation (including state personnel, contractors, and partners) have the necessary QA training to successfully complete their tasks and functions. The Project Manager will document attendance at all training sessions. Attendance records for voluntary trainings may not include names, given privacy/confidentiality concerns.

A9. Documents and Records

Project data reporting--format and content

[Identify all standardized reports, data collection forms, etc., to be used during the project. For each one, specify the format and content.]

Reports and forms include:

[modify the list below to suit your project]

- Application form for facilities
- Facility performance report
- Audit checklist for [Agency] or third-party auditors
- Reports analyzing member characteristics, performance commitments, and results

Other documents/records

Other documents and records to be produced by the project include:

[modify the list below to suit your project]

- EMS documentation
- Independent EMS assessments
- Facility reports to stakeholders
- Facility permit
- Enforcement documentation
- Facility outreach materials
- Program web site
- Amended QAPP
- Readiness reviews
- Data handling reports
- Quarterly and annual progress reports to EPA
- Project final report

Storage of project information

While the project is underway, project information will be stored [in a central filing cabinet at Agency headquarters, and on the Agency's secure computer network, according to the Agency's data management plan/standard policy]. Upon completion of the project, paper records, photographs, and audio-visual material will be retained for [x] years [at Agency headquarters]. Electronic records will be stored for [x] years [on the Agency's main computer network and at a secure off-site location].

[If the project will rely on the presence of auditable records or other information that facilities will maintain at their own sites, specify what requirements for record maintenance facilities will have to meet.]

Backup of electronic files

[Specify electronic back-up policies. Is there an Agency-wide policy about back-up and storage of email and files on the main network? Will staff be encouraged to regularly back up electronic data and documents on CD or other media while in the field?]

QAPP preparation and distribution

This QAPP conforms to the format described in the United States Environmental Protection Agency publication *EPA Requirements for Quality Assurance Project Plans* dated March 2001 (QA/R-5). The QAPP shall govern the operation of the project at all times. Each responsible party listed in Section A4 shall adhere to the procedural requirements of the QAPP and ensure that subordinate personnel do likewise.

This QAPP shall be reviewed at least annually to ensure that the project will achieve all intended purposes. All the responsible persons listed in Section A4 shall participate in the review of the QAPP. In addition, it is expected that from time to time ongoing and perhaps unexpected changes will need to be made to the project. The Project Manager shall authorize all changes or deviations in the operation of the project. Any significant changes will be noted in the next progress report to EPA (see Element C2), and shall be incorporated into an amended QAPP.

The Quality Assurance Officer is responsible for updating the QAPP, documenting the effective data of all changes made in the QAPP, and distributing new revisions to all individuals listed in A3 whenever a substantial change is made. The Quality Assurance Officer will distribute the QAPP by hand if possible, or by post, and attempt to retrieve outdated versions while distributing revised versions. Copies of each revision will be numbered, to make retrieval of outdated versions easier. The Quality Assurance Officer and the Project Manager will approve all updates.

B DATA GENERATION AND ACQUISITION

B1. Experimental Design

Detailed performance measures

[For each of the project objectives listed in A5, explain what measures you will use to determine whether anticipated outcomes have been achieved and what criteria you will use to make determinations. For each objective, specify what quantities you will be measuring, what data sources you will rely on, and what operations will be performed on the data.

For example:

Increased commitment to improve environmental performance.

Agency will track the number of participating facilities from year to year, and also the number of facilities that express interest in participating.

Continuing environmental performance improvement among program participants.

Normalized baseline and follow-up results will be compared to determine performance improvements at each participating facility. In each medium, results from multiple facilities will be combined to provide annual program-wide results.]

Implementation

[In narrative form, describe the scope of the project in quantitative and qualitative terms: for example, how many facilities do you anticipate will participate? What are the criteria for recruitment and enrollment (e.g., will they be from a single industry, will they already have EMSs in place, will EMSs be independently verified)? Will the number of participants be capped? How representative do you expect them to be of the larger community of facilities you are seeking to influence (e.g., are they already high environmental achievers)? What provisions are in place for facilities withdrawing or being dismissed from the program?

Explain in a similar level of detail: how stakeholders will be recruited; what principles will guide the demands made of and the incentives offered to facilities; and what project data will be collected, how, and by whom. There is no need to reiterate in detail information you have already provided in other sections, such as Section A7.]

This section of the QAPP will be amended as the project progresses, more specific information becomes available, and objectives and methods are refined.

B2. Sampling/Experimental Methods

[Explain how primary data will be collected. For example, you could state that environmental samples will be collected by facilities (and/or the Agency) in accordance with EPA and state protocols. You could also state that other types of data will be collected by asking participants to

fill out standardized forms (described in Element A9) or by inspection by trained staff (training described in Element A8), if applicable.]

B3. Sample Handling and Custody

[Will there be a protocol for handling and custody of data and/or physical samples? You can state that facilities will be encouraged or required to follow state and EPA protocols when handling physical samples. For other types of data, you might state that:

- Data will be mailed, emailed, or delivered by hand to the Agency or a contractor
- Electronic data will be backed up according to the protocol described in Element A9
- Procedures for entering hand-written data into the database will follow standard quality assurance procedures (e.g., 100% verification using independent double key entry), consistent with your Agency's Quality Management Plan.

[If quality assurance procedures for data entry and acceptance will be prepared during the development and implementation of a data management strategy, state that the final QAPP will reflect the strategy.]

B4. Analytical Methods

[Will there be a requirement that physical samples, if any, be analyzed at state-certified laboratories using standard EPA methods?]

B5. Quality Control (QC)

[Describe quality control standards. Will EPA and state QC protocols be followed in analysis of physical samples? What QC steps, such as cross-checking and identifying data anomalies, will the Agency take in regard to data and sampling plans submitted by facilities? (See the subsections immediate below for more information on crosschecking data and data anomalies.) Refer to your Agency's Quality Management Plan (QMP), if one is available.]

Crosschecking data

Application forms will be scrutinized by trained Agency staff to identify potential problems or inadequacies in the facility's commitments or its monitoring strategies, such as potential cross-media transfers, intra-facility transfers (if a performance commitment is for a subset of operations, not the entire facility), and double-counting of environmental improvements. To the extent possible, primary data collection forms (see Element A9) will be designed in such a way as to allow internal crosschecking of data by comparing answers of different questions to each other, and such crosschecking will be automated during electronic entry of data, to the extent possible. Errors caught during cross-checking will be flagged and corrected, to the extent possible, in consultation with data collection staff and facility managers.

Data anomalies

Trained [Agency/contractor] staff will check for data anomalies (e.g., missing data, data that fall outside the range of the expected or plausible based on industry averages, non-standard environmental aspects/indicators, incorrect/non-standard units, incorrect reporting years, incorrect normalizing factors or bases of normalization, incorrect calculations or conversions, etc.). When possible, checking for data anomalies will be automated as part of the electronic data entry process. Data anomalies will be flagged and corrected, to the extent possible, in consultation with data collection staff and facility managers.

Quality control statistics

The Data Entry Manager will prepare summary statistics of data quality problems at the close of the project (i.e., unresolved data anomalies as a percentage of the number of data points) and a narrative description of problems encountered and any potential bias in the data caused by data anomalies. This documentation will be reviewed by the QA Officer, and the Project Manager will include this information in the data evaluation section of the final project report (see Element D3).

B6. Instrument/Equipment Testing, Inspection, and Maintenance

[If physical samples are to be taken, explain here how the instruments and equipment used for taking, handling, and analyzing those physical samples are to be tested, inspected, and/or maintained (e.g., according to EPA and/or state protocols). If participating facilities or other parties will be taking the physical samples, explain whether and how the Agency can or will assure quality relative to this issue.]

B7. Instrument/Equipment Calibration and Frequency

[If physical samples are to be taken, explain here how instruments to be used in the collection and analysis of such physical samples are to be calibrated (e.g., in accordance with EPA and/or state protocols). If participating facilities or other parties will be taking the physical samples, explain the extent to which the Agency can or will assure quality relative to this issue.]

B8. Inspection/Acceptance for Supplies and Consumables

[If physical samples are to be taken, explain here how supplies and consumables are to be inspected (e.g., in accordance with EPA and/or state protocols). If participating facilities or other parties will be taking the physical samples, explain the extent to which the Agency can or will assure quality relative to this issue.]

B9. Non-Direct Measurements (i.e., Secondary Data)

Secondary data to be collected for this project, their intended uses, and their limitations are described in the table below.

Table 4: Secondary Data

Data	Source	Intended Use	Limitations / Acceptance Criteria
List of candidate facilities	[Insert Agency name] database of facilities	Basis for identifying target facilities	Agency database is not complete--only facilities with certain types of permits are included.
State environmental compliance records from the past three years	[Insert Agency name] compliance database	Compliance records will be used to determine the eligibility of facilities to participate in the project. Also, information on the number and severity of compliance violations in [x] industry, and the amount of staff time spent on high environmental achievers and low environmental achievers (terms to be defined) will be used as a baseline to evaluate changes during the project period	None
Internal EMS documentation and third-party audits	Participating facilities, auditors	Verification that the facility has a properly functioning EMS	The reports will only be used to establish that the EMS is functioning as designed, not to make determinations about environmental compliance or performance

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Table 4: Secondary Data

Data	Source	Intended Use	Limitations / Acceptance Criteria
Results of EMS-regulatory initiatives in other states	EPA, Other States	A basis for evaluating the success of project components (e.g., how did the results of our initiative, in which facility assistance was provided by non-profit partners, compare--in terms of environmental improvement, cost-effectiveness, and participant retention--with the results of initiatives in which facility assistance was provided by Agency staff at seminars, or provided by "mentor" facilities from a higher tier?)	Only initiatives with similar approaches will be considered. The comparisons must be made with caution, since each initiative has its own idiosyncrasies and it is hard to isolate a single variable.
[insert other known data sources, with similar language for each column]			

Key resources/support facilities needed

[Insert Agency name] will require access to the data sources mentioned above. When appropriate, data will be uploaded or manually entered into the project database using the same QC protocols described above for primary data (Element B5). [Insert Agency name] does not anticipate any obstacles to this approach.

Determining limits to validity and operating conditions

Describe the steps you will take, if any, to establish the quality of acquired secondary data (e.g., independently verifying a representative sample of data points).

B10. Data Management

As part of this project, [Insert Agency name] [if applicable, also mention contractor involvement] will develop a data management strategy, and amend the QAPP based upon the strategy. The Project Manager is responsible for ensuring that that strategy is developed and that

the QAPP is amended to reflect that strategy. The strategy will be consistent with the existing [Insert Agency name]'s Quality Management Plan. Once amended, this QAPP section on data management will provide information on the following:

- Data management scheme, from field to final use and storage (including flowcharts, if available)
- Standard recordkeeping and tracking practices, and document control system (e.g., “hand-recorded data records will be taken with indelible ink, and changes to such data records will be made by drawing a single line through the error with an initial by the responsible person. The Project Manager will have ultimate responsibility for any and all changes to records and documents. Similar controls will be put in place for electronic records.” If relevant Agency documentation of standard practices is available, you may cite that documentation instead of listing all practices here.)
- Data handling equipment/procedures that will be used to process, compile, analyze, and transmit data reliably and accurately
- Individuals responsible for elements of the data management scheme
- Process for data archival and retrieval
- Procedures to demonstrate acceptability of hardware and software configurations

Include examples of any checklists and forms.

C ASSESSMENT/OVERSIGHT

C1. Assessment and Response Actions

The Quality Assurance Officer will conduct a Readiness Review prior to each major primary data collection step [specify which steps]. The QA Officer will report findings to the Project Manager, who will take corrective action (if any is necessary). Corrective action will be reviewed by the QA Officer. Collection of primary data will not begin until the QA Officer certifies readiness. The Project Manager and QA Officer will meet regularly with project implementation staff to identify emerging/unanticipated problems and take corrective action, if necessary.

C2. Reports to Management

Three kinds of reports will be prepared: readiness reviews (described above), regular quarterly and annual progress reports, and project final report. Progress reports will note the status of project activities, identify any QA problems encountered, and explain how they were handled. Project final report will analyze and interpret data, present observations, draw conclusions, identify data gaps, and describe any limitations in the way the results should be interpreted.

Table 5: Project QA Status Reports

Type of Report	Frequency	Date(s)	Preparer	Recipients
Readiness Review	Before each major data collection task		[Insert Agency name] QA Officer	[Insert Agency name] Project Manager
Progress Report	Quarterly		[Insert Agency name] Project Manager	EPA Project Officer (Copying US EPA OPEI)
Progress Report	Annually		[Insert Agency name] Project Manager	EPA Project Officer (Copying US EPA OPEI), stakeholders
Final Project Report	Once		[Insert Agency name] Project Manager	EPA Project Officer (Copying US EPA OPEI), stakeholders

D DATA REVIEW AND EVALUATION

D1. Data Review, Verification and Validation Criteria

During data review, verification, and validation, staff will be guided by the data quality criteria listed in A7 (i.e., “collecting primary data and obtaining secondary data of the highest quality possible within the constraints of project resources,” bearing in mind the six data quality indicators discussed in that section), as well as any additional criteria discussed in B1, in B2-B8 for generation of primary data, and in B9 for acquisition of secondary data.

D2. Verification and Validation Methods

To confirm that QA/QC steps have been handled in accordance with the QAPP, the QA Officer will prepare a readiness review before key data collection steps (as described in Element C1). Also, the Data Processing Manager will prepare data handling reports, to be reviewed by the QA Officer, after each data collection step and each data analysis step. These reviews and reports will be guided by the quality criteria described in Element D1, above, and performed in accordance with [Insert Agency name]'s Quality Management Plan.

If at any point during verification and validation the QA Officer identifies a problem (e.g., the use of substandard data when higher-quality data are available, a faulty algorithm, a mismatch between a data set and the question it is meant to answer), the Project Manager, QA Officer, and any other relevant staff will discuss corrective action. If necessary, the Project Manager will issue a stop-work order until a solution is agreed upon. The Project Manager will implement corrective action. If the solution involves changes in project design, the QA Officer will amend the QAPP as necessary and distribute the new revision.

D3. Evaluating Data in Terms of User Needs

The final project report will contain an evaluation of the certainty of project results. The Project Manager will prepare this evaluation in consultation with the QA Officer. For each conclusion reached by the project (i.e., each determination that an anticipated outcome has or has not been achieved, and the basis for each decision made or recommended by project authorities), this evaluation will describe, in narrative form: the quality of data and the methodologies used to inform the conclusion, the subsequent confidence in the conclusion, and the validity of generalizing results beyond the project.