

REGION 1 - EPA NEW ENGLAND
ENVIRONMENTAL DATA REVIEW PROGRAM
GUIDANCE



REGION 1 - EPA NEW ENGLAND
EPA Quality Assurance Unit & TechLaw Environmental
Services Assistance Team (ESAT) Contract Support
Office of Environmental Measurement and Evaluation (OEME)

June 2018

Preface

This Region 1 EPA document supports the implementation of an Environmental Data Review Program in accordance with the most current Agency quality requirements and with the *EPA New England Quality Management Plan*, May 2016, available at: <https://www.epa.gov/sites/production/files/2017-11/documents/qaqmp-2016qmp0.pdf>.

The EPA Order CIO 2105.0 requires that environmental data used to support Agency decisions are of adequate quality and usability for their intended purpose. The term “environmental data” refers to measurements or information that describe environmental processes, conditions, or location; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature. Specific data review procedures, roles and responsibilities are described in applicable planning documents including quality assurance project plans (QAPPs) or other equivalent documents.

As a regional implementation document, this *Region 1 - EPA New England Environmental Data Review Program Guidance* (<https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-1>):

- outlines regional processes to ensure measurement data are adequately reviewed prior to use;
- incorporates program-specific and general data review guidance;
- ensures that “existing” data collected for purposes other than that of the current project (e.g., modeling applications, total maximum daily load (TMDL) determinations, survey reports) will also be technically reviewed prior to use;
- describes the roles and responsibilities of project management and personnel; and,
- is intended to be used in conjunction with the *Region 1 - EPA New England Environmental Data Review Supplement* to ensure region-specific technical criteria are applied to sample results based on blank contamination, field duplicates, etc.

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Region 1 - EPA New England Environmental Data Review Program Guidance

1.0 Introduction

All environmental data collected, produced, and used by or for the Agency must undergo adequate technical review to ensure that only data of known and documented quality are used to support Agency actions and decisions. Verification and validation are the first steps in the data review process followed by usability assessment. EPA recognizes that verification, validation and usability assessment form a continuum and that the distinction between the steps is somewhat artificial.¹ Therefore, this Region defines “data review” as a process by which:

- a specific data set, including field information, is evaluated for completeness, correctness, and conformance/compliance against method, procedural or contractual requirements;
- a specific data set, including field information, is evaluated against measurement and data quality objectives developed for the project or against established validation criteria;
- all project data (based on results of previous technical reviews) are evaluated to determine whether they meet defined project quality objectives; and,
- limitations or restrictions on the use of the data are documented and reported.

2.0 Scope

Based on Agency requirements, the *Region 1 - EPA New England Environmental Data Review Program Guidance* (hereafter referred to as the *Data Review Program*) provides the framework for reviewing environmental data collected by and for the Region. Along with other regional quality programs including quality planning and assessment, this program guidance forms the basis of the EPA New England (NE) quality system, as documented in the *EPA New England Quality Management Plan*, May 2016 <https://www.epa.gov/sites/production/files/2017-11/documents/gaqmp-2016qmp0.pdf>, that supports the generation, collection and use of scientifically and legally defensible data. Program-specific data verification, validation and usability assessment guidance documents should be used when so directed by the EPA National Program Office (NPO).

R1 EPA adopts a “graded approach” when planning, implementing, assessing and documenting projects. The level of detail and stringency of data review procedures will depend on the project objectives. For example, data review procedures for projects determining human health and ecological risk assessment are typically more extensive than those used for screening purposes.

¹ USEPA *Guidance on Environmental Data Verification and Data Validation* (EPA QA/G-8), November 2002, EPA/240/R-02/004, <https://www.epa.gov/quality/guidance-environmental-data-verification-and-data-validation>

Some data review procedures include the application of data “flags” or “qualifiers” to qualify sample results; other data review procedures do not. Also, while some projects only require that laboratory deliverables are checked for completeness, other project objectives require the verification of raw data and calculations for accuracy.

The scope of the regional data review program includes the use of automated data review whenever applicable. However, electronic data review evaluation, criteria and actions must be documented to ensure appropriate data review for the project is performed. Program-specific data review procedures are discussed below.

3.0 Applicability

This guidance applies to:

- R1 EPA personnel involved in the collection, production or use of environmental data;
- other EPA Organizations including, HQ program offices and other Regions who review environmental data for use by R1 EPA;
- other federal agencies under interagency agreements, federal facility agreements, and memoranda of understanding (MOUs) with R1 EPA;
- contractors;
- states, tribes and local governments under financial assistance agreements with EPA, including grants and cooperative agreements;
- non-profit organizations under financial assistance agreements with R1 EPA, including institutions of higher education, hospitals, volunteer organizations, and interstate associations; and,
- regulated parties under binding agreements with R1 EPA (e.g., permits, unilateral or consent enforcement agreements).

4.0 Water Programs

All environmental data collection activities conducted by or for the various Agency Water programs must be conducted in accordance with program-specific project planning guidance and under current and approved QAPPs or equivalent planning documentation. The following steps should be taken, as applicable, to determine the data review procedures for an environmental data operation.

- 1) Use the national program office (NPO) data review procedures as available. If none are available, refer to the *Guidance on Environmental Data Verification and Data Validation* (EPA QA/G-8), November 2002, <https://www.epa.gov/quality/guidance-environmental-data-verification-and-data-validation> and the *Data Quality Assessment: A Reviewer’s Guide* (EPA QA/G-9R), February 2006, <https://www.epa.gov/sites/production/files/2015-08/documents/g9r-final.pdf> for guidance in developing data review procedures;

- 2) Based on the data quality objectives (DQOs), select and document the project-specific data review procedures in a QAPP or other planning document; and,
- 3) Apply the *R1 - EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

5.0 Air Programs

All environmental data collection activities conducted by or for the various Agency Air programs must be conducted in accordance with program-specific project planning guidance (e.g., *Quality Assurance Handbook for Air Pollution Measurement Systems: "Volume II: Ambient Air Quality Monitoring Program"*, EPA-454/B-17-001, January 2017, https://www3.epa.gov/ttn/amtic/files/ambient/pm25/qa/Final%20Handbook%20Document%201_17.pdf) and under current and approved QAPPs or equivalent planning documentation, as applicable. Quality assurance guidance documents are available at <https://www3.epa.gov/ttn/amtic/qalist.html>.

The following steps should be taken, as applicable, to determine the data review procedures for an environmental data operation.

- 1) Use NPO data review procedures as available. If none are available, refer to the *Guidance on Environmental Data Verification and Data Validation* (EPA QA/G-8), November 2002, <https://www.epa.gov/quality/guidance-environmental-data-verification-and-data-validation> and the *Data Quality Assessment: A Reviewer's Guide* (EPA QA/G-9R), February 2006, <https://www.epa.gov/sites/production/files/2015-08/documents/g9r-final.pdf> for guidance in developing data review procedures;
- 2) Based on the data quality objectives (DQOs), select and then document the project-specific data review procedures in a QAPP or other planning document; and,
- 3) Apply the *R1 - EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

6.0 Superfund Program

All environmental data collection activities conducted by or for the Superfund program must be performed under current and approved QAPPs or equivalent planning documentation, as applicable. The Superfund NPO provides program-specific data review guidance which R1 EPA implements through this document.

National guidelines (as described below) should be used for data review when applicable. In addition, R1 EPA implements the *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use* per OSWER Directive 9200.1-85.

6.1 Data Generated Through National Analytical Services - Contract Laboratory Program (CLP) Routine Analytical Services (RAS), CLP Non-Routine Analytical Services (Non-RAS), and CLP Modified Analytical Services

Regional Superfund samples analyzed through national contracts (CLP RAS, CLP Non-RAS, and CLP Modified Analytical Services) undergo the national data review process described below. Samples analyzed through the national analytical services mechanisms produce staged electronic data deliverable (SEDD) formatted data reports which allow for electronic data review.

- 1) Based on the project DQOs, select the data review “Tier Level” in accordance with Chapter 3 of the *R1 - EPA NE Environmental Data Review Supplement* and the “Validation Stage” in accordance with *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*. **Note: Dioxin and PCB Congener High Resolution analyses must undergo a Tier 2 data review;**
- 2) Document the project-specific data review procedures per project-specific DQOs including data review procedures for non-routine analytes, matrices, reporting limits, etc., in a QAPP, Sampling and Analysis Plan (SAP), or equivalent planning document;
- 3) Apply the Superfund Electronic Data Exchange & Evaluation System (EXES) for electronic review and reporting of CLP Staged Electronic Data Deliverable (SEDD) formatted deliverables. Electronic data review qualifiers and actions are based on the *National Functional Guidelines for Organic Superfund Methods Data Review; National Functional Guidelines for Inorganic Superfund Methods Data Review; and National Functional Guidelines for High Resolution Superfund Methods Data Review;* and,
- 4) Apply the *R1 - EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

6.2 Data Generated Through Alternate (Regional) Analytical Services – Data other than CLP and Non-RAS

Apply the following steps to determine data review procedures for Superfund samples analyzed through the non-national services, including the OEME laboratory, EPA Field Sampling Contractors’ laboratories and regionally contracted laboratories. Organic and Inorganic analytes, as well as non-traditional matrices and analytes undergo the data review process described below.

- 1) Based on the project DQOs, select the data review Tier Level in accordance with Chapter 3 of the *R1 - EPA NE Environmental Data Review Supplement* and the “Validation Stage” in accordance with *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*;

- 2) Document project-specific data review procedures in a QAPP, SAP, or equivalent planning document. Agency Superfund data review guidance should be referenced and applied when applicable and is available at:
<https://www.epa.gov/clp/superfund-clp-national-functional-guidelines-data-review>.
In addition, the *Guidance on Data Verification and Data Validation* (EPA QA/G-8), November 2002, EPA/240/R-02/004, may be useful in evaluating non-traditional matrix or analytes; and,
- 3) Apply the *R1 - EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

6.3 Data Generated by Potentially Responsible Parties

All Superfund data collection activities performed for EPA under enforcement consent decrees, agreements, and orders with R1 EPA must be conducted under current and approved QAPPs. Where EPA concurrence is required in lieu of approval, QAPPs must also be kept current. Data review procedures outlined in Section 6.2 should be described, as applicable, in project QAPPs.

State and/or organization-specific data review procedures may be used when documented in the QAPP and approved by EPA.

7.0 Other Environmental Programs (Brownfields, RCRA Corrective Action, Underground Storage Tanks, Federal Facilities, Toxics and Pesticides Programs, Technical Enforcement Office, and DEP Media Programs)

All environmental data collection activities conducted by or for other environmental programs must also be conducted under current and approved QAPPs or an equivalent planning document. The following steps should be taken, as applicable, to determine the data review procedures for an environmental data operation.

- 1) Use program-specific data review procedures as available, such as;
 - For Brownfields, apply Federal and R1 EPA specific guidance: *2017 Brownfields Federal Programs Guide*, May 2017, available at:
https://www.epa.gov/sites/production/files/2017-06/documents/final_2017_bf_fed_guide_5-8-17.pdf; and
Planning and Documenting Brownfields Projects Generic Quality Assurance Project Plans, and Site-specific QAPP Addenda, March 2009, available at:
<https://www.epa.gov/sites/production/files/2017-07/documents/plandocbrownfields.pdf>
 - For Federal Facilities, apply program-specific guidance:
<https://www.epa.gov/fedfac/assuring-quality-federal-cleanups>

- For Underground Storage Tanks, apply program-specific guidance:
<https://www.epa.gov/ust>

If none are available, refer to the *Guidance on Environmental Data Verification and Data Validation* (EPA QA/G-8), November 2002 <https://www.epa.gov/quality/guidance-environmental-data-verification-and-data-validation>, and the *Data Quality Assessment: A Reviewer's Guide* (EPA QA/G-9R), February 2006 <https://www.epa.gov/sites/production/files/2015-08/documents/g9r-final.pdf> for guidance on developing data review procedures.

- 2) Based on the data quality objectives (DQOs), select and then document the project-specific data review procedures in a planning document.
- 3) Apply the *R1- EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

8.0 Projects Involving Environmental Models (e.g., TMDLs)

Projects that involve the development, evaluation and/or application of mathematical or computerized models require QAPPs in accordance with program requirements. The Office of the Science Advisor, Council for Regulatory Environmental Modeling produced the *Guidance on the Development, Evaluation, and Application of Environmental Models*, March 2009, available at: https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf.

The *Guidance for Quality Assurance Project Plans for Modeling* (EPA QA/G-5M) December 2002 is available at: <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf>.

Additional Modeling QAPP document links are available on the web page “Design and Implementation of New Tools for Quality Assurance in Modeling” available at: <https://www.epa.gov/quality/design-and-implementation-new-tools-quality-assurance-modeling>

In addition, a regional modeling checklist is provided at: <https://www.epa.gov/sites/production/files/2015-07/modelingjournal.doc>

9.0 Projects Involving Existing (Secondary) Data

Data collected for purposes other than that of the current project must also be reviewed for their suitability for use in the current work. In addition to the Agency *Guidance on Environmental Data Verification and Data Validation* (EPA QA/G-8), November 2002, EPA/240/R-02/004, for regional guidance refer to *EPA New England Quality Assurance Project Plan Guidance For Environmental Projects Using Only Existing (Secondary) Data* <https://www.epa.gov/sites/production/files/2015-06/documents/EPANESSecondaryDataGuidance.pdf> .

10.0 Agency Peer Review

Agency Peer Review is a documented critical review of a specific scientific or technical work product conducted in accordance with Agency policies described in the *Science and Technology Policy Council Peer Review Handbook*, 4th Edition, October 2015 available at: https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf. Peer Review is performed on completed technical reports according to program requirements.

11.0 Regional Pre-Dissemination Review of Information Products

In accordance with the Agency *Information Quality Guidelines*, October 2002 <https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf>, regional review procedures <http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.htm> (EPA only intranet link) are implemented to ensure adequate review of information products prior to dissemination.

12.0 Data Usability Reporting

Project reports should have readily identifiable sections that describe the applied QA and QC; explain the limitations of the data; and, discuss general usability of the data based on project data quality objectives. Based on the complexity and/or critical nature of the study, a separate Data Usability Report may be required.

R1 EPA applies assessment factors and considerations described in the *Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (2003) <https://www.epa.gov/sites/production/files/2015-01/documents/assess2.pdf> when evaluating the quality and relevance of scientific and technical information. These general assessment factors are based on Agency guidelines, practices, and procedures that constitute EPA's information and quality systems, including existing program-specific quality assurance policies. Program-specific usability guidance should also be followed when available (e.g., *Guidance for Data Usability in Risk Assessment (Part A)* Publication 9285.7-09A, PB92-963356, April 1992; https://www.lm.doe.gov/cercla/documents/rockyflats_docs/SW/SW-A-005912.pdf).

13.0 Roles and Responsibilities

The Lead Organization is responsible and accountable for all phases of the environmental project, including data review and usability reporting. The Lead Organization may perform the project work directly or contract for field sampling, analytical, data review, data usability reporting, and/or oversight assessment services. Planning (scoping) meetings are convened to identify the project objectives; environmental decisions that will be made with the collected data; project action limits; type and quantity of data; and, how "good" the data must be (the data quality) to support the decisions that will be made. These are some of the many aspects determined through project scoping.

The project team defines the quality of the data by setting acceptability limits for the project, also known as measurement performance (or acceptance) criteria. Once the measurement performance criteria have been determined, the project team can select sampling and analytical methods that have appropriate quantitation limits and quality control limits to achieve project objectives. Similarly, data review criteria and procedures are selected based on project objectives during the planning phase and are documented in the QAPP. (See Figure 1)

The Lead Organization's project team is responsible for ensuring that data are reviewed prior to using the data for decisions. The amount and scope of data review should be discussed by the project team to ensure that project objectives are achieved. In general, data review should be performed by reviewers that were not involved in sample collection or analysis. However it is understood that data review must support a range of project objectives, from a small project with limited resources, where the project manager, QA manager, or project personnel may serve as data reviewers, to a highly litigious project, where external data review may be necessary to support the project objectives.

An organizational chart, or detailed discussion, should clearly indicate the reporting relationships between R1 EPA and the Lead Organization's project personnel, including contractors and subcontractors. All data review personnel are responsible for reading, understanding, and applying project-specific review procedures as described in the QAPP.

The Lead Organization and the R1 EPA QA Unit are responsible for reviewing and approving data review procedures described in project QAPPs and equivalent planning documents. They are also responsible for reviewing QA/QC sections of final project reports or for approving an authorized person as designated in the QAPP to confirm that report conclusions are supported by defensible data and that data quality objectives have been met. When QAPP review and approval has been delegated by the R1 EPA QA Unit to another organization, that organization is responsible for ensuring adequate data review procedures are applied to environmental data. Upon completion of the review, all data quality issues are resolved prior to external review, release, publication, or dissemination. The QA Unit has the authority to conduct internal and external assessments to ensure data review procedures are properly implemented.

14.0 Records Management

Document control procedures should be applied to data review and usability reports to ensure that reports are traceable to the original project data. Project files, including data review records, memos and reports, must be retained in accordance with Agency Records Schedules <https://www.epa.gov/records>.

R1 EPA retains the authority to request project/program files for any extramural project/program during the period of performance of the extramural agreement.

15.0 References

1. EPA Order CIO 2105.0 Policy and Program Requirements for the Mandatory Agency-Wide Quality System, May 2000, https://www.epa.gov/sites/production/files/2015-09/documents/epa_order_cio_21050.pdf
2. *Quality Systems for Environmental Data and Technology Programs - Requirements with Guidance for Use*, American National Standard, (ANSI/ASQ E4 -2004), February 2004
3. *USEPA Guidance on Environmental Data Verification and Data Validation* (EPA QA/G-8), November 2002, EPA/240/R-02/004, <https://www.epa.gov/quality/guidance-environmental-data-verification-and-data-validation>
4. *EPA New England Quality Management Plan*, May 2016, <https://www.epa.gov/sites/production/files/2017-11/documents/qagmp-2016qmp0.pdf>
5. *EPA New England Quality Assurance Project Plan Program Guidance*, January 2010, <https://www.epa.gov/sites/production/files/2015-06/documents/QAPPPProgram.pdf>
6. *USEPA Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*, OSWER Directive 9200.1-85, EPA 540-R-08-005, January 2009, <https://www.epa.gov/clp/superfund-clp-analytical-services-guidance-documents>
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9. *USEPA Guidance on the Development, Evaluation, and Application of Environmental Models*, March 2009, EPA/100/K-09/003, https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf
10. *Region 1 - EPA New England Data Review Supplement for Region 1 Data Review Elements and Superfund Specific Guidance/Procedures*, 2018, <https://www.epa.gov/quality/managing-quality-environmental-data-epa-region-1>
11. *USEPA National Functional Guidelines for Organic Superfund Methods Data Review*, January 2017, https://www.epa.gov/sites/production/files/2017-01/documents/national_functional_guidelines_for_organic_superfund_methods_data_review_013072017.pdf
12. *USEPA National Functional Guidelines for Inorganic Superfund Methods Data Review*, January 2017, https://www.epa.gov/sites/production/files/2017-01/documents/national_functional_guidelines_for_inorganic_superfund_methods_data_review_01302017.pdf
13. *USEPA National Functional Guidelines for High Resolution Superfund Methods Data Review*, April 2016, https://www.epa.gov/sites/production/files/2016-05/documents/hrsm_nfg.pdf
14. *Quality Assurance Handbook for Air Pollution Measurement Systems*, Volume II, Ambient Air Monitoring Program, EPA-454/B-17-001, January 2017, <https://www3.epa.gov/ttnamti1/files/ambient/pm25/qa/Final%20Handbook%20Document%2017.pdf>

15. EPA National Records Management Program, <https://www.epa.gov/records>
16. *Guidance for Data Usability in Risk Assessment (Part A)*, Publication 9285.7-09A, PB92-963356, April 1992,
https://www.lm.doe.gov/cercla/documents/rockyflats_docs/SW/SW-A-005912.pdf

Figure 1. R1- EPA NE Systematic Planning Process

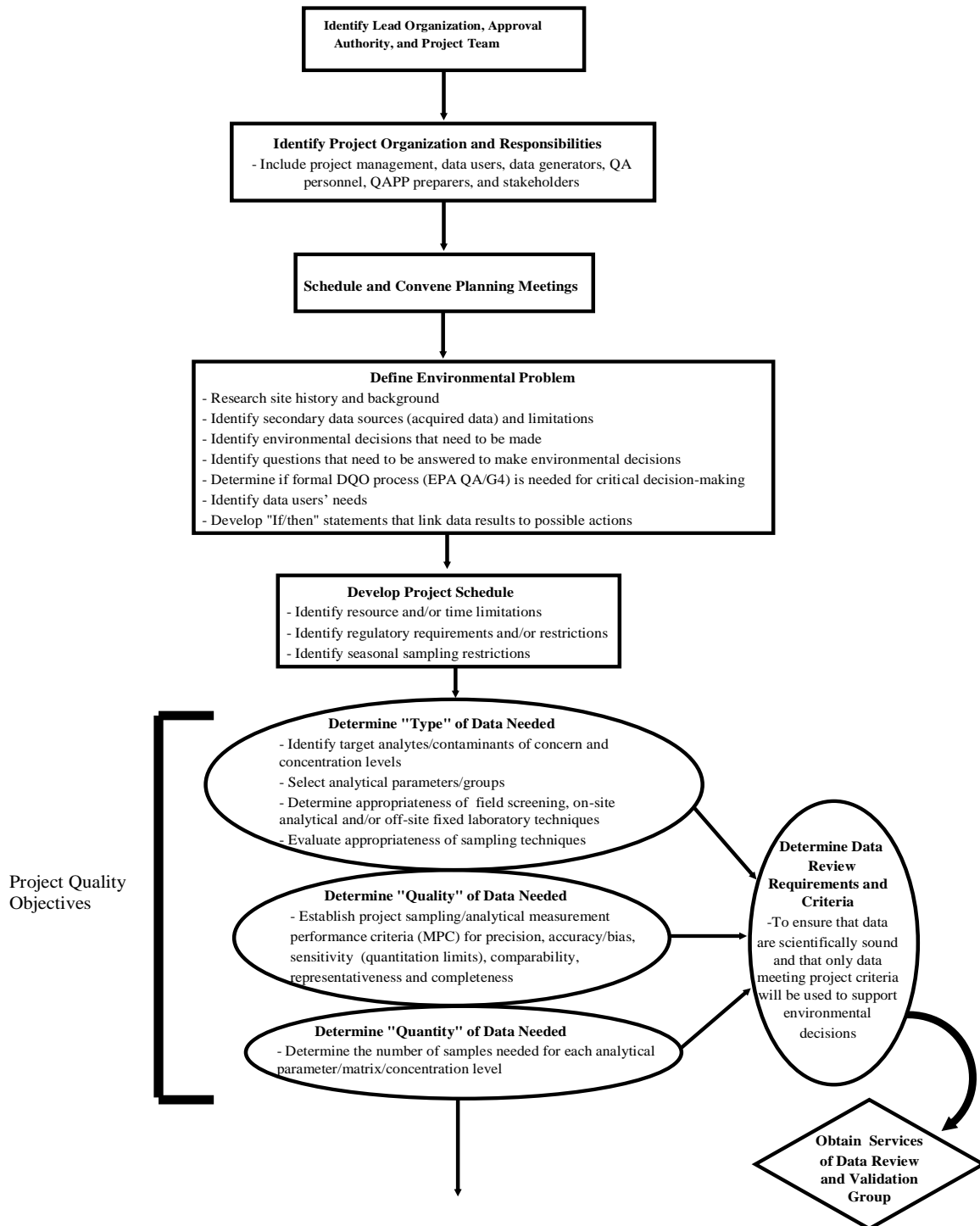


Figure 1. R1- EPA NE Systematic Planning Process cont.

