

**EPA NEW ENGLAND**

**ENVIRONMENTAL DATA REVIEW PROGRAM  
GUIDANCE**



**U.S. EPA NEW ENGLAND**

**Quality Assurance Unit**  
**Office of Environmental Measurement and Evaluation**

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## Preface

This EPA New England 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* available at: <http://www.epa.gov/region1/lab/qa/qmp/index.html>.

On (projected timeframe-August 2013), the Agency issued updated requirements pertaining to environmental data quality (html). Similar to previous versions, the new standard EPA Chief Information Officer (CIO) 2106-S-01 *Quality Standard for Environmental Data Collection, Production, and Use by EPA Organizations* (hereafter the *Data Quality Standard*) conforms to the American National Standards Institute (ANSI)/American Society for Quality (ASQ) E4, *Quality Systems for Environmental Data and Technology Programs – Requirements with Guidance for Use*. In response to increasing use of existing (secondary) data and the application of environmental models in conducting environmental operations, the *Data Quality Standard* also includes additional pertinent quality requirements.

Among other requirements, the *Data Quality Standard* requires that results obtained from products or services involving environmental data shall be reviewed, verified, validated and qualified according, and prior, to their intended use. 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 *EPA New England Environmental Data Review Program Guidance* (<http://www.epa.gov/region1/oeme/index.html>):

- 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 *EPA New England Environmental Data Review Supplement* to ensure region-specific technical criteria are applied to sample results based on field duplicates, performance evaluation samples, etc.

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## **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.<sup>1</sup> 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
- any limitations or restrictions on the use of the data are documented and reported.

### **2.0 Scope**

Based on Agency requirements, the *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* (<http://www.epa.gov/region1/lab/qa/qmp/index.html>), 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).

EPA NE 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. Some data review procedures include the application of data “flags” to qualify sample results; other data review procedures do not. Also, while some projects only require that the laboratory

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<sup>1</sup> USEPA *Guidance on Data Verification and Data Validation* (EPA QA/G-8), December 2002, EPA/240/R-02/004, <http://www.epa.gov/quality/qs-docs/g8-final.pdf>

deliverables be checked for completeness, other projects require raw data and calculations to be verified 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:

- EPA New England personnel involved in collection, production or use of environmental data;
- other EPA Organizations including, HQ program offices and other Regions who review environmental data for use by EPA NE;
- other federal agencies under interagency agreements, federal facility agreements, and memoranda of understanding (MOUs) with EPA NE;
- 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 EPA NE, including institutions of higher education, hospitals, volunteer organizations, and interstate associations; and
- regulated parties under binding agreements with EPA NE (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 Data Verification and Data Validation* (EPA QA/G-8) <http://epa.gov/quality/qs-docs/g8-final.pdf> and the *Data Quality Assessment: A Reviewer's Guide* (EPA QA/G-9R) <http://epa.gov/quality/qs-docs/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 *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., *Model Quality Assurance Project Plan for the PM Ambient Air 2.5 Monitoring Program at State and Local Air Monitoring Stations*, EPA-454/R-98-005) and under current and approved QAPPs or equivalent planning documentation, as applicable. 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 Data Verification and Data Validation* (EPA QA/G-8) <http://epa.gov/quality/qs-docs/g8-final.pdf> and the *Data Quality Assessment: A Reviewer's Guide* (EPA QA/G-9R) <http://epa.gov/quality/qs-docs/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 *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 EPA NE implements through this document.

The ***Region I, EPA New England Data Validation Functional Guidelines 1996*** have expired and should no longer be used. Henceforth, national guidelines (as described below) should be used when applicable. In addition, EPA NE 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) and Non-Routine Analytical Services (Non-RAS)

Regional Superfund samples analyzed through national contracts (Contract Laboratory Program (CLP) Routine Analytical Services RAS & CLP Modified Analytical Services, and Dioxin and PCB Congener National Non-Routine 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.

#### **6.1.1 CLP Routine Analytical Services & CLP Modified Analytical Services: Data Review for Organic and Inorganic Data**

- 1) Based on the project DQOs, select the data review “Tier Level” in accordance with the Chapter 3 of the *EPA NE Environmental Data Review Supplement* and the electronic “Validation Stage” in accordance with *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*;
- 2) Document the project-specific data review procedures 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 *CLP National Functional Guidelines for Superfund Organic Methods Data Review and CLP National Functional Guidelines for Inorganic Superfund Data Review*; and,
- 4) Apply the *EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

#### **6.1.2 Dioxin and PCB Congener National Non-Routine Analytical Services Data: Data Review**

- 1) Based on the project DQOs, determine the “Validation Stage” in accordance with *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use* and using the project-specific DQOs (**Note: Dioxin and PCB Congener analyses must undergo a Tier 2 data review**);
- 2) Document the project-specific data review procedures per project-specific DQOs in a QAPP, SAP, or equivalent planning document;
- 3) Apply the Superfund Electronic Data Exchange & Evaluation System (EXES) review of staged Electronic Data Deliverable (SEDD) formatted deliverables. Electronic data review qualifiers and actions are based on the *National Functional Guidelines for Chlorinated Dioxin/Furan Data Review*; and,
- 4) Apply the *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.

### **6.2.1 Organic and Inorganic Analytes – Data Review Process**

- 1) Based on the project DQOs, select the data review Tier Level in accordance with the Chapter 3 of the *EPA NE Environmental Data Review Supplement* and the electronic “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: <http://www.epa.gov/superfund/programs/clp/guidance.htm>; and,
- 3) Apply the *EPA NE Environmental Data Review Supplement* which describes additional region-specific procedures for data review and usability reporting.

### **6.2.2 Non-traditional Matrices and Analytes – Data Review Process**

- 1) Based on the project DQOs, select the data review Tier Level in accordance with the Chapter 3 of the *EPA NE Environmental Data Review Supplement* and the electronic “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: <http://www.epa.gov/superfund/programs/clp/guidance.htm>. In addition, the *Guidance on Data Verification and Data Validation* (EPA QA/G-8), December 2002, EPA/240/R-02/004, may be useful in evaluating non-traditional matrix or analytes; and,
- 3) Apply the *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 EPA NE 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, Waste Management, Underground Storage Tank, Federal Facilities, RCRA PCB Clean-up and Toxics and Pesticides 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 the EPA NE specific guidance:  
<http://www.epa.gov/region1/lab/qa/pdfs/PlanDocBrownfieldsappendAB.pdf>
  - For Federal Facilities, apply program-specific guidance:  
<http://www.epa.gov/fedfac/documents/qualityassurance.htm>
  - For Underground Storage Tanks, apply program-specific guidance:  
<http://www.epa.gov/oust/cat/MONITOR.HTM>

If none are available, refer to the *Guidance on Data Verification and Data Validation* (EPA QA/G-8) <http://epa.gov/quality/qs-docs/g8-final.pdf> and the *Data Quality Assessment: A Reviewer's Guide* (EPA QA/G-9R) <http://epa.gov/quality/qs-docs/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 *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 provides *Guidance on the Development, Evaluation, and Application of Environmental Models* available at: [http://www.epa.gov/crem/library/crem\\_guidance\\_0309.pdf](http://www.epa.gov/crem/library/crem_guidance_0309.pdf). In addition, regional guidance is provided at: <http://www.epa.gov/region1/lab/qa/qamodeling.html>

## 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 Data Verification and Data Validation* (EPA QA/G-8), December 2002, EPA/240/R-02/004, regional guidance is provided at: <http://www.epa.gov/region1/lab/qa/pdfs/EPANESecondaryDataGuidance.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 Policy Council Peer Review Handbook*, available at <http://www.epa.gov/peerreview/pdfs/prhandbk.pdf>. Peer Review is performed on completed technical reports when deemed necessary by the program.

## 11.0 Regional Pre-Dissemination Review of Information Products

In accordance with the *Agency Information Quality Guidelines* [http://www.epa.gov/quality/informationguidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf), regional review procedures <http://r1-gis-web.r1.epa.gov:9876/oeme/IQGPDR.htm> ) 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 Data Usability Report may be required.

EPA NE applies assessment factors and considerations described in the *Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (2003) <http://www.epa.gov/osa/stpc/pdfs/assess3.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., *Data Usability in Risk Assessment* Publication 9285.7-09A PB92-963356 April 1992).

## 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.

The project team defines the quality of the data by setting acceptability limits for the project, otherwise 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 undergo an independent review prior to use. In general, data review should be performed by independent reviewers that were not involved in sample collection or analysis. The project team will determine if external data (third party) review is warranted for the project. For small projects with limited resources, the project manager or QA manager may serve as data reviewer.

An organizational chart, or detailed discussion, should clearly indicate the reporting relationships between EPA NE 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 EPA NE QA Unit is responsible for reviewing and approving data review procedures described in project QAPPs and equivalent planning documents. The Unit is 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 legally defensible data and data quality objectives have been met. When QAPP review and approval has been delegated by the EPA NE 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 peer 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**

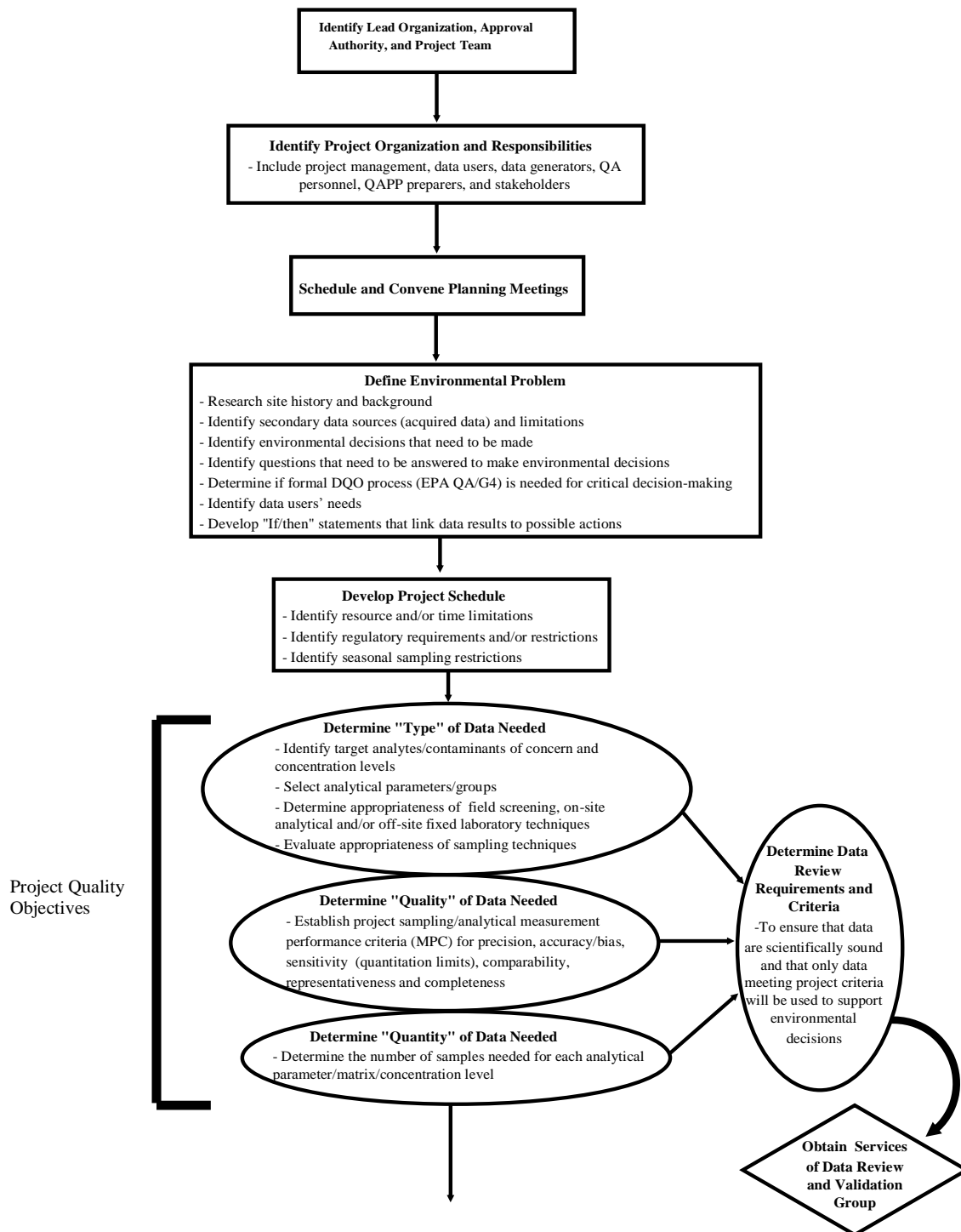
Document control procedures should be applied to data review and usability reports to ensure that reports are traceable to the original project data. Project files, including data review records, memos and reports, must be retained in accordance with Agency Records Schedules <http://www.epa.gov/records/policy/schedule/schedules.htm>.

EPA NE 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. Quality Standard for Environmental Data Collection, Production, and Use by EPA Organizations, CIO Standard 2106-S-01, ([website to be added](#))
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 Data Verification and Data Validation* (EPA QA/G-8), December 2002, EPA/240/R-02/004, <http://www.epa.gov/quality/qs-docs/g8-final.pdf>
4. *EPA NE England Quality Management Plan*, July 28, 2011  
<http://www.epa.gov/region1/lab/qa/qmp/index.html>
5. *EPA NE Quality Assurance Project Plan Program Guidance*, 2010  
<http://www.epa.gov/region1/lab/qa/pdfs/QAPPProgram.pdf>
6. *EPA NE Assessment Program*, 2002
7. *USEPA Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*, OSWER Directive 9200.1-85,  
<http://www.epa.gov/superfund/policy/pdfs/EPA-540-R-08-005.pdf>
8. *USEPA Science Policy Council Peer Review Handbook* -  
<http://www.epa.gov/peerreview/pdfs/prhandbk.pdf>
9. *USEPA Science Policy Council Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, 2003  
<http://www.epa.gov/osa/stpc/pdfs/assess3.pdf>
10. *USEPA Guidance on the Development, Evaluation, and Application of Environmental Models* [http://www.epa.gov/crem/library/cred\\_guidance\\_0309.pdf](http://www.epa.gov/crem/library/cred_guidance_0309.pdf)
11. *EPA New England Data Review Supplement*, 2012,  
<http://www.epa.gov/region1/oeme/index.html>
12. *USEPA CLP National Functional Guidelines for Superfund Organic Methods Data Review*  
<http://www.epa.gov/superfund/programs/clp/download/somnfg.pdf>
13. *USEPA CLP National Functional Guidelines for Inorganic Superfund Data Review*  
<http://www.epa.gov/superfund/programs/clp/download/ism1nfg.pdf>
14. *USEPA Analytical Services Branch (ASB) National Functional Guidelines for Chlorinated Dibenzo-p-Dioxins (CDDs) and Chlorinated Dibenzofurans (CDFs) Data Review*  
<http://www.epa.gov/superfund/programs/clp/download/dlm/dlm2nfg.pdf>
15. *Quality Assurance Handbook for Air Pollution Measurement Systems*, EPA-454/R-98-004  
[http://itep68.itep.nau.edu/itep\\_downloads/DAI%20resources/EPA%20QA%20Guidance%20Docs/QA\\_Handbook\\_Redbook.pdf](http://itep68.itep.nau.edu/itep_downloads/DAI%20resources/EPA%20QA%20Guidance%20Docs/QA_Handbook_Redbook.pdf)
16. EPA Records Management Schedules  
<http://www.epa.gov/records/policy/schedule/schedules.htm>
17. *Data Usability in Risk Assessment* Publication 9285.7-09A PB92-963356 April 1992

**Figure 1. EPA NE Systematic Planning Process**



**Figure 1. EPA NE Systematic Planning Process cont.**

