Region 9 Superfund Data Evaluation/Validation Guidance

R9QA/006.1

U.S. Environmental Protection Agency
Region 9
Quality Assurance Office
75 Hawthorne Street
San Francisco, CA 94105

DRAFT

December 2001

Region 9 Superfund Data Evaluation/Validation Guidance

Version 1

R9QA/006.1
December, 2001

This guidance document is designed by the U.S. Environmental Protection Agency (EPA) Region 9 Quality Assurance Office to provide assistance to project officers, Superfund contractors, and Superfund grantees in performing timely data evaluation and/or validation of laboratory data. Data review is considered a necessary step to ensuring that data are of sufficient quality to support decisions based on data quality objectives (DQOs) as defined in the appropriate project or site specific Quality Assurance Project Plan (QAPjP) or Sampling and Analysis Plan (SAP). The evaluation process which is described allows several tiers that require an increasingly more stringent review of the data. The appropriate tier can be chosen based on the data's intended use. The guidance defines Region 9 policy and provides examples of the various evaluation tiers as they might be applied to different types of Superfund projects.

Region 9 requires that the level of data quality review (i.e., the tier chosen) must be defined during the planning stage of the project and be documented in the QAPjP (or equivalent). It is expected that QAPjPs will be prepared in accordance with the QA R-5 (EPA Requirements for Quality Assurance Project Plan) guidance, and that SAPs will be prepared using one of Region 9's two SAP guidances (Sampling and Analysis Guidance and Template, Version 1, EPA Analytical Services Used, or Sampling and Analysis Guidance and Template, Version 2, Private Analytical Services Used), or if the SAP is prepared using another guidance or format, it will be consistent with these guidances.

This guidance is based on the assumption that full data packages are prepared in accordance with the Contract Laboratory Program (CLP) Organic or Inorganic Statements of Work (SOWs), or the Region 9 guidance, "Laboratory Documentation Required For Data Evaluation," R9QA/004.2 (August 2001). It is assumed that each data package should include twenty or less samples of the same matrix analyzed by a single analytical method. Each group of twenty samples is commonly called a "Sample Delivery Group (SDG)," if it is provided by the CLP or Region 9 Laboratory. This nomenclature may not be used for data generated by a private laboratory not under contract with EPA, but the assumption is that samples will be grouped together in lots of 20 or fewer samples, and that laboratory quality control samples will also track these groups of 20.

The data evaluation process should be tailored to meet the project's or site's specific data quality requirements. The U.S. EPA Region 9 Quality Assurance Office is available to assist in determining the appropriate evaluation tier(s) for each project. Please contact the Regional Quality Assurance Manager at 415-972-3798.

i

TABLE OF CONTENTS

ii

1.0   Introduction

The U.S. EPA Region 9 Quality Assurance Office data evaluation approach includes evaluation tiers that build on each other to become increasingly more inclusive and thorough. A combination of tiers may be appropriate for most projects. This approach may mean that one or more data packages produced using a particular analytical method is evaluated with a different degree of thoroughness than other data packages produced using the same or methods. For the purposes of this guidance, each tier will have the scope defined and then be followed by example of when and how data evaluated using this tier might be used for a project. Appendix ? (Region 9 QA Office's General Guidelines For Superfund Data Validation/Review) is ____ provide additional examples of the minimum expected data evaluation quirem____ should be considered during the data quality objectives (DQOs) as d____ned in the ____ project or sit specific Quality Assurance Project Plan (QAPjP) or Sam____ng and Ar____ysis P____.

Each project has specific data quality needs; therefore, th____ed examples shou____y be used as suggestions or starting points. The project's specific d____tion requirements should be included in the Quality Assurance Project Plan and/or the ____ Analysis Plan.

2.0   Evaluation Tier 1A

2.1   Scope

The goal of Evaluation Tier 1A is to quickly provide a brief summary of key analytical issues/deficiencies which might affect data quality, and, hence, user decisions based on the data.

Evaluation Tier 1A is employed when in-depth data review is not required as indicated in the QAPjP. Possible applications include recurrent monitoring activities, emergency or time-critical situations, data generated by field-based monitoring techniques, and priority environmental management activities. Please refer to Section 2.2 and Appendix B for more information.

Such a review may include, but is not limited to: review of the data package for completeness; review of chain of custody forms (against laboratory reported information), for signatures, sample condition upon receipt by the laboratory, and sample preservation; review of holding times; review of Quality Control (QC) summaries; review of blank results for possible field or laboratory contamination; random checks of reported results against raw data, and random checks of raw data for interference problems or system control problems (e.g., baseline anomalies, baseline drifts, etc.).

The review deliverable from the QA Office for a 1A level review might include: a verbal discussion of the sample results with the data user, a memo summarizing the evaluated results, and/or a table of data showing data points (with associated qualifiers) that were considered to be biased or outside acceptance criteria for various data quality indicators by a large enough factor that use of the data might affect environmental decisions.

2.2   Example of Use

As noted above, an example of the appropriate use of Evaluation Tier 1A would be during a recurrent monitoring project. These projects usually have several years of data from the same sampling locations, and are often sampled multiple times each year. The Quality Assurance Project Plan and/or the Sampling and Analysis Plan should describe a combination of data assessment tools (e.g., performance evaluation samples, split samples, field QC samples, data validation, etc.) so that project decisions do not rely on validation results alone. Once the initial sampling and analysis protocols have been established, verified as appropriate and expected concentration levels of analytes determined for each location, then Evaluation Tier 1A can be used for a large percentage of the data packages. The remainder of the data packages should still undergo a higher evaluation tier. Additionally, if any major data quality deficiencies are noted during the Evaluation Tier 1A review, then the data package should undergo a more inclusive review. The percentage of data which is evaluated at a higher evaluation tier many also need to be increased.

3.0   Evaluation Tier 1B

3.1   Scope

The goal of Evaluation Tier 1B is to produce an automated summary which reflects whether contract required QC criteria and/or generic measurement quality objectives have been met. The summary can be quickly generated for the user. The summary can also be used to facilitate a full data quality review as discussed below in Evaluation Tier 3 if such a review is necessary.

Evaluation Tier 1B approach is employed alone when an in-depth data review is not required as indicated in the Quality Assurance Project Plan. Possible applications include recurrent monitoring activities, prioritization of site work, environmental management activities, and projects in which EPA is not the implementing agency as in EPA financial assistance agreements including Brownfields and Tribal projects. Grantees may be required to perform a more stringent data review tier depending on project requirements. Please refer to Section 3.2 and Appendix B for more information.

Such a review may include, but is not limited to: review of laboratory electronic data deliverables for completeness, review of holding times, review of QC summaries, review of blanks for contamination, checks of reported results against raw data, and performance checks of a majority of calculations used in the data set.

The QA Office could provide a review deliverable consisting of: a computer generated table of results and qualifiers (e.g., Computer-Aided Data Review and Evaluation (CADRE) or E-DATA report), a memo that discusses the evaluated results, and/or a table of data that has some qualifiers associated with the data points identified as having a larger error than permitted in the data review software system. Usually the data review software is based on criteria defined in the organic or inorganic CLP SOWs.

3.2   Example of Use

As noted above, an example of EPA use of Evaluation Tier 1B would be for a project in which EPA is not the lead agency as in EPA financial assistance agreements. These projects usually are being further evaluated for project specific use by another party. The grantees may be required to perform more stringent data review in addition to what EPA's analytical services offer. For example, if a site were to be a candidate for listing on the National Priorities List. The Quality Assurance Project Plan and/or the Sampling and Analysis Plan should include a combination of data assessment tools (e.g., performance evaluation samples, split samples, field QC samples, data validation, etc.) so that project decisions do not rely on validation results alone. The Quality Assurance Office can provide Evaluation Tier 1B results to grantees or other project requester upon request. This tier is only viable if data are available in the appropriate electronic format.

4.0   Evaluation Tier 2

4.1   Scope

The goal of Evaluation Tier 2 is to produce a Data Review report based on clearly defined and documented project-specific data quality criteria. The report identifies significant and noticeable data quality issues/deficiencies and indicates whether data quality is consistent with the intended use.

Evaluation Tier 2 is based on a more focused evaluation of selected analytes, a limited number of locations, or it may also focus on a selected aspect of a particular analysis (such as only on tentatively identified coumpounds). It is confined to data within a single data package and is used in conjunction with a 1A/1B review of the remainder of the data. It is employed when Evaluation Tier 3 is not required as indicated in the QAPjP. Logic on why this Evaluation Tier is appropriate should be included in the QAPjP or SAP. This evaluation tier does not involve an in-depth review of all raw data. Possible applications include monitoring activities; delineation of environmental impacts caused by pollutants, contaminants, or toxic constituents; data used in support of EPA or other regulatory agency enforcement; possible litigation; public health and ecological assessments; commitment of substantial EPA funds, etc. Please refer to Section 4.2 and Appendix B for more information.

Such a review may include, but is not limited to use of Evaluation Tier 1A/1B for some of the data plus a more detailed evaluation of other data in the context of project DQOs defined in the QAPjP or SAP. This evaluation may focus on specific target compounds or classes of compounds, or, alternatively, data from areas identified as being of particular concerns that show potential high/low bias or false positive/false negative potential where results are close to action or regulatory levels may be the focus.

The QA Office could provide two types of review deliverables. For data not undergoing extensive review, deliverables would be as described above for Tiers 1A or 1B. For the data that underwent the more comprehensive review, a memorandum would be provided that discusses the evaluated results along with an attached table of data that has qualifiers

associated with those data points identified as having a bias due to larger than expected errors as established in the project's or method's QC criteria. These QC criteria should have been defined in the QA Plan as data quality indicators.

4.2   Examples of Use

As noted above, Evaluation Tier 2 is more of an exception, than a rule. It is only used when Evaluation Tier 1A/1B is not inclusive or thorough enough for the project objectives, but Evaluation Tier 3 is not warranted. It should focus on specific items that are detailed in the data evaluation section of the Quality Assurance Project Plan and/or the Field Sampling and Analysis Plan. These plans should also include a combination of data assessment tools (e.g., performance evaluation samples, split samples, field QC samples, data validation, etc.) so that project decisions do not rely on validation results alone. If any major data quality deficiencies are noted in Evaluation Tier 2 review, then the data should undergo a more inclusive review.

An example of the appropriate use of Evaluation Tier 2 would be a site assessment investigation. If the site is deemed to not need further EPA involvement based on preliminary data, then a focussed review may be sufficient. The focus of this review could be an Evaluation Tier 1A/1B review plus an evaluation for the potential of false negatives and/or significant low bias for those chemicals or areas that would be most likely to impact the scoring of the site. These would be the factors that would most significantly impact the decision that no further EPA involvement is necessary.

Similarly, a Brownfields site investigation may be deemed to require no further action based on the preliminary data. A focussed approach including an Evaluation Tier 1A/1B plus an evaluation for false negatives and/or significant low bias may be sufficient to support that decision.

Other decisions at Brownfields sites may require different focuses for data evaluation. For example, if decisions will be based on specific compounds of concern and their acceptable bias around a specific action level, than the focus of the data evaluation should reflect those concerns. This scenario might be that only a few compounds were historically used at the site. These compounds were included as part of a larger list of compounds that are analyzed by a particular laboratory method. Therefore, only a few compounds may need to be evaluated more stringently for the decision at hand. Evaluation Tier 3 (full validation) could be applied on the few compounds of concern, while data for the other compounds reported from that method for the same sample(s) are handled using Evaluation Tier 1A/1B. Since this combination of two levels of review is for the same method for the same sample(s) (i.e., within the same data package), it is considered to be an application of Evaluation Tier 2.

5.0   Evaluation Tier 3

5.1 Scope

The goal of Evaluation Tier 3 is to produce a detailed Data Validation report based on clearly defined and documented project-specific data quality control criteria and/or measurement quality objectives. Such a report identifies significant and noticeable data quality issues/deficiencies and indicates whether the quality of the data is sufficient for the intended use. Note that this process only evaluates the data based on method defined or QA Plan defined QC criteria. Whether the data meet the uncertainty criteria or confidence criteria which may have been defined by the DQO process, whether there are sufficient data points for decision making, or whether the samples collected accurately represent the target area, must be determined through the data quality assessment step, which is outside the scope of this guidance.

Evaluation Tier 3 involves an in-depth review of the data. Possible applications include monitoring activities; delineation of environmental areas caused by pollutants, contaminants, or toxic constituents; data used in support of EPA enforcement or litigation; data supporting a record of decision; data supporting ecological assessments; data related to commitment of substantial EPA funds; data supporting inclusion of a site on the National Priority List, etc. Please refer to section 2 and Appendix B for more information.

Such a review may include, but is not limited to, all portions of Evaluation Tier 1A/1B plus a random check (percentage determined by professional judgement of the data evaluator on a project specific basis) of the various calculations in the data set (e.g., verifying and recalculating concentration standards including checking of expiration dates of standards from standard preparation logs, confirming calibration criteria were met, verifying QC sample results were calculated, etc.), checking raw data for correct integration, confirming ion spectra matches (if applicable), and assessing interference problems or system contamination problems (e.g., baseline anomalies, baseline drifts, etc.). These checks should be conducted in the context of project data quality objectives. A more in-depth evaluation will be performed on target compounds or analytes identified in the Quality Assurance Project Plan and/or Sample and Analysis Plan. An evaluation of high/low bias or false positive/false negative results around project action levels will be the primary focus. The attached validation definition worksheet will detail other aspects of the evaluation.

For a data set that underwent the more comprehensive review, a memorandum or detailed report will be provided that discusses the evaluated results along with an attached table of the data that has qualifiers associated with those data points identified as having a bias due to larger than expected errors as established in the project's or method's QC criteria. This detailed report would discuss data point qualification, as well as any additional information that may affect the use of the data. Method or project QC criteria should have been defined in the QA Plan as data quality indicators either directly or by reference (such as to the CLP SOW).

5.2 Example of Use

As noted above, an example of the appropriate use of Evaluation Tier 3 would be data used in support of EPA enforcement projects. The Quality Assurance Project Plan and/or the Sampling and Analysis Plan should include a combination of data assessment tools (e.g., performance evaluation samples, split samples, field QC samples, data validation, etc.) so that project decisions do not rely on validation results alone. Evaluation Tier 3 is the most inclusive and thorough review of data and is used to document the quality of data to be directly used for decision making by the Agency, sepecially the Superfund Program.

APPENDIX A: Region 9 Data Validation Definition

Data Validation is a sample- and analyte-specific process that extends beyond method or contractual compliance. Data validation is based on regionally defined data quality criteria and limits, professional judgment of the data validator, and (if available) the project-specific Quality Assurance Project Plan (QAPjP), and/or Sampling and Analysis Plan (SAP). Its purpose is to assess the usability of specific sample and analyte results for use in decision making at the regional, site and/or project level.

Data validation may include the following items:

• Determination of data usability

• Qualification of data based on project-specific data quality criteria and/or professional judgment

• Interpretation and evaluation of raw data, e.g., chromatograms and mass spectra

• Assessment of data based on their intended use and compliance with the project or site QAPjP and SAP

• Verification of analyte identification and/or quantification

• Assessment and incorporation of site specific factors that may affect data usability

• Determination of how the nature of the sample inhibits attainment of analytical specifications

• Assessment and application of data from field duplicates, performance evaluation samples, blind spikes, and blind blanks

• Evaluation and assessment of analytical problems that may be documented in the SDG narrative

• Evaluation of the impact of multiple data issues on the final analytical result

• Preparation of final validation narratives, reports, comments, or findings

APPENDIX B

Region 9 QA OFFICE'S GENERAL GUIDELINES FOR SUPERFUND DATA VALIDATION/REVIEW

Intended Use/ Types of $F Decisions	Tier 1A	Tier 1B	Tier 2	Tier 3
Site Discovery; Hot Spot Id.; PA w/sampling	80 %		20%	
Time-Critical Removal/Risk Reduction	100 %			
Prioritization of Site Assessment	100 %			
Site Assessment/HRS			100%	*
Site Characterization/RI	80 %		10%	10%
Risk Assessment			100% **	
Treatability Studies	100 %			
Treatment Optimization	50 %		50%***	
On-Going-Monitoring	90 %		5%	5%
No Further Action (Brownfields)			100%	
Site Close-out			50%	50%
Investigation Derived Wastes	100 %			
Five Year Review/ Confirmation Studies			50%	50%

* = 100% Tier 3 if used for site listing.

** = Field data can only be reviewed using Tier 1A; use Tier 2 for target compound review.

*** = Investigation of bi-product may require Tier 3.

Note: Radiochemistry could only be reviewed using Tier 1A due to the lack of associated raw data in the package(s).

Assumptions/Basis: The percentage of data subject to validation/review in this table are based solely on scientific determination and are not qualified by resource constrains.