Attachment B

"Region I Tiered Organic and Inorganic Data Validation Guidelines",
July 1, 1993, DRAFT

REGION I

TIERED ORGANIC AND INORGANIC DATA VALIDATION GUIDELINES

JULY 1, 1993

INTRODUCTION

Historically, Region I has required that analytical data for Superfund sites undergo full validation according to the Region I Laboratory Data Validation Functional Guidelines documents.

Full validation, however, does not always meet the Data Quality Objectives (DQOs) for each site activity, and it can contribute to high costs and missed deadlines. To address this problem, Region I's Environmental Services Division (ESD) has created a tiered approach to data validation which accomplishes the following:

- enables data users to select the level of validation necessary to meet their DQOs
- saves time and money
- promotes consistent evaluation of data quality between Superfund sites

Three tiers have been established and are described in the next section. Tier III is equivalent to the full validation currently performed in Region I, and includes the procedures performed under Tiers I and II.

TIERED APPROACH TO DATA VALIDATION

The inorganic and organic data validation process can be broken down into three distinct levels: Tier I, Tier II, and Tier III.

Tier I: A completeness evidence audit is performed to ensure that all laboratory data and documentation are present. Completeness evidence audits are performed in accordance with procedures contained in the Region I CSF Completeness Evidence

Audit Program, dated 7/3/91. (This document is the currently used procedure as referenced in the memorandum titled "Region I CSF Completeness Evidence Audit Program" from the Region I CLP-TPOs to Region I Contractors, dated 7/7/91.)

Tier II: A Tier I completeness evidence audit is performed, and, in addition, the results of all Quality Control (QC) checks and procedures are evaluated and used to assess and qualify sample results. Tier II data validation is performed primarily from information contained on the tabulated data reporting forms. It has been estimated by ESD that Tier II validation takes 50% of the time required to perform a Tier III validation.

Tier III: A full data validation is performed. Tier III includes Tier I and Tier II procedures plus an in-depth examination of all raw data to check for technical, calculation, analyte identification/analyte quantitation, and transcription errors. Tier III data validation is performed in accordance with the Region I CSF Completeness Evidence Audit Program and the Region I Laboratory Data Validation Functional Guidelines.

At a minimum, all data should be carried through Tiers I or II. Tier I is mandatory, regardless of the immediate intended use of the data, to ensure that all laboratory documents have been obtained for future data validation, potential litigation, and/or to defend site decisions. Validation requirements must always be documented in an approved QAPP prior to sampling. Several examples of when a Tier I or Tier II validation may suffice to meet DQOs are as follows:

- Design run data which are collected during a treatability study. Data used to support the final design parameters, however, should undergo Tier III validation.

- Long-term monitoring data which have only "minimal changes" in constituent concentrations from the previous round. The magnitude of these allowable changes, as well as the procedures to be followed if QAPP requirements are not met, must be documented in an approved QAPP prior to sampling. (If QAPP requirements are not met, a Tier II or Tier III validation should be performed.)

- EPA oversight split data which "compare well" with PRP data. The comparison criteria, as well as procedures to be followed if QAPP requirements are not met, must be documented in an approved QAPP prior to sampling. (If QAPP requirements are not met, a Tier II or Tier III validation should be performed.)

Full validation (Tier III) can always be performed at a later date as long as Tiers I or II have been initially completed. The entire data package (Tier III) or just individual parameters, matrices, sample locations, and/or risk compounds (partial Tier III) could then be specified for full validation. If a subset of the entire data package was targeted for full validation, then a Tier II validation would be performed on the entire data package (if it hadn't already) and a partial Tier III validation would be performed for individual parameters, etc. (whatever was to comprise the subset validation). The first paragraph of the data validation memorandum must explicitly document the level of validation performed, i.e. Tier II plus partial Tier III validation for benzene, Tier II plus partial Tier III validation for sample location MW-100, Tier II plus partial Tier III validation for volatile organics, etc.

In certain circumstances, full validation (Tier III) may be deemed necessary from the start of a project. Several examples of when full validation is needed are as follows:

- Only one set of data for a particular sample location, type and/or parameter is available and a decision of whether to remediate will be based on this sample. An example of this is background data.

- The data will be used to define a critical site boundary.

- The data will be used to determine compliance with clean-up goals.

TIER II DATA VALIDATION PROCEDURE

To perform a Tier II data validation, a Tier I review is completed and the results of all QC checks and procedures are evaluated and used to assess and qualify sample results. During a Tier II review,

the raw data for field samples and QC checks are not evaluated (with a few exceptions, i.e. pH check for volatile organics, metals, and cyanide to verify proper sample preservation). The goal is to validate data using information contained mainly on the tabulated data reporting forms and chain-of-custody (COC) forms. Tier II assumes that all results are reported by the laboratory and that all reported results are correct.

Prior to performing a Tier II validation, conduct the Tier I completeness evidence audit according to the requirements contained in the Region I CSF Completeness Evidence Audit Program, dated 7/3/91, and request the missing deliverables from the laboratory. Begin the Tier II validation while waiting for any missing deliverables.

To perform a Tier II inorganic validation, the reviewer must have all data reporting forms for field sample and QC sample results (Forms I through XIV), as well as the COC forms in the data package. Validation is performed according to requirements contained in the attached table (Attachment I) and in conjunction with the Region I Laboratory Data Validation Functional Guidelines for Evaluating Inorganics Analyses, dated 6/13/88 (modified 2/89). This guidance is also applicable to inorganic analyses performed in accordance with the ILM01.0, ILM02.0, and ILM03.0 versions of the U.S. EPA CLP Statement of Work (SOW). Tier II reporting and deliverable requirements are the same as those for full validation (Tier III); only the actual validation procedures contained in Section 3 of the Region I Functional Guidelines have been modified to minimize examination of the raw data and to eliminate the recalculation of results.

To perform a Tier II organic validation, the reviewer must have all data reporting forms for field sample and QC sample results (Forms I through X), as well as the COC forms in the data package. Validation is performed according to guidance contained in the attached table (Attachment II) and in conjunction with the Region I Laboratory Data Validation Functional Guidelines for Evaluating Organics Analyses, dated 2/1/88 (modified 11/1/88). This guidance is also applicable to organics analyses performed in accordance with the OLM01.0 SOW, even though the 11/1/88 Region I Functional Guidelines document has not yet been modified to accomodate pesticide/PCB method changes contained in the OLM01.0 SOW. Tier II reporting and deliverable

requirements for data validation are the same as for full validation (Tier III); only the actual validation procedures contained in Sections 3 and 4 of the Region I Functional Guidelines have been modified to minimize examination of the raw data and to eliminate the recalculation of results.

The results for each QC parameter, specified in Attachments I and II, must be evaluated using the data reporting forms provided by the laboratory. The data provided on the forms are not verified with the raw data. Information contained on the forms should be used to verify that QC samples were analyzed with the correct analytes at the proper frequency and concentration, that the QC limits were met, and required corrective actions were taken. The QC parameters of System Performance and Compound Identification for the volatile and semivolatile fractions are not evaluated during the Tier II review as it would require that a substantial review of the raw data be performed.

As a result of the Tier II evaluation, the field sample results may be accepted, qualified as estimated, or rejected. In circumstances where the entire data package or data for multiple samples must be rejected or will be significantly qualified based upon the Tier II results, the reviewer must first consider the impact of rejected results and/or discrepant information on the data needs of the specific project. If the data are critical to the project needs, then examination of the raw data is strongly recommended to prevent faulty site decisions based on technical, transcription, and/or calculation errors. The EPA Remedial Project Manager (RPM) or Site Assessment Manager (SAM) must be contacted to approve a partial or complete Tier III validation prior to its initiation. If the RPM or SAM decides that no further validation is warranted based on the objectives of the sampling event and the nature of the data qualification, then the reviewer should document this decision in the first paragraph of the data validation (DV) memorandum. The nature of the data problem, the extent of data qualification, and the level of validation performed must also be documented in the DV memorandum. It is expected that raw data review might be required more frequently for pesticide/PCB data, since identification and quantitation of pesticides and PCBs is based solely on gas chromatography data with no mass spectral confirmation/quantitation.

The attached tables, Attachment I (Tier II Inorganic Data Validation)

and Attachment II (Tier II Organic Data Validation), consist of four columns which identify the specific QC criteria to be checked, the laboratory reporting form(s) to review, the specific sections of the Region I Functional Guidelines to follow, and the adjustments needed for the specific sections of the Region I Functional Guidelines to perform a Tier II validation.

ATTACHMENT I

TIER II INORGANIC DATA VALIDATION

TIER II INORGANIC DATA VALIDATION

QC CRITERIA	DATA REPORTING FORMS TO REVIEW	APPLICABLE SECTIONS IN FUNCTIONAL GUIDELINES[3]	COMMENTS
Data Completeness	! Complete SDG File (CSF) 1. Original Sample Data Package including Cover Page, Forms I through XIV, DC-1, DC-2, raw data 2. Original shipping and receiving documents 3. All original lab records of sample transfer, preparation and analysis, as well as telephone contact logs.	! I., p. 21	! Perform a Tier I completeness evidence audit according to procedures in the Region I CSF Completeness Evidence Audit Program, dated July 3, 1991, to ensure that all laboratory data and documentation are present. Request missing deliverables from the laboratory following appropriate procedures.
Holding Times	! Forms I, XIII, XIV ! Chain-of-Custody/Traffic Report ! Sample Digestion/Distillation Logs	! II. A through D, pp. 21-22	! Examine Chain-of-Custody/Traffic Report Forms to determine if samples were properly preserved in the field. ! To verify sample pH upon laboratory receipt, review sample digestion logs as this information is not included on the forms.
Calibration	! Forms IIA, IIB, XIV	! III. A through B, pp. 22-23 C.1-3, pp. 23-24 C.5 and 6, p. 24 C.8 and 9, p. 24 D.1-3, pp. 24-25 D.5-8, pp. 25-26	! Calibration correlation coefficients for AA, Hg, and CN are not reviewed since this information is not included on the forms.
Blanks	! Forms I, III, X, XIII, XIV ! Chain-of-Custody/Traffic Report	! IV. A through D, pp. 26-28	! Review data reporting forms only. Do not verify with raw data.
ICP Interference Check Sample	! Forms I, IV, X, XI, XIV	! V. A through B, p. 28 C.1 and 2, p. 28 C.4, p. 29 D, pp. 29-31	! Review data reporting forms only. Do not verify with raw data. ! Paragraph C.4: For evidence of results with an absolute value >2xIDL for those analytes which are not present in the ICS A solution, evaluate Form IV. Do not check the raw data.

SEE NOTE ON PAGE 3 OF 3.

[3]REGION I LABORATORY DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING INORGANICS ANALYSES, 6/13/88, MODIFIED 2/89

TIER II INORGANIC DATA VALIDATION

QC CRITERIA	DATA REPORTING FORMS TO REVIEW	APPLICABLE SECTIONS IN FUNCTIONAL GUIDELINES[3]	COMMENTS
Matrix Spike Sample Analysis	! Forms VA, VB, XIII ! Chain-of-Custody/Traffic Report	! VI. A through B, pp. 31-32 C.1, p. 32 C.3-5, p. 32 D, pp. 32-33	! Review data reporting forms only. Do not verify with raw data. ! Review Chain-of-Custody/Traffic Report Forms to verify that samples identified as field blanks are not used for spiked sample analysis.
Laboratory Duplicate Sample Analysis	! Forms VI, XIII ! Chain-of-Custody/Traffic Report	! VII. A through B, p. 33 C.1, p. 33 C.3 and 4, p. 34 D, p. 34	! Review data reporting forms only. Do not verify with raw data. ! Review Chain-of-Custody/Traffic Report Forms to verify that samples identified as field blanks are not used for duplicate sample analysis.
Field Duplicates	! Form Is ! Chain-of-Custody/Traffic Report	! VIII. A through D, pp. 34-35	! No change from current procedures.
Laboratory Control Sample Analysis (LCS)	! Forms VII, XIII	! IX. A through B, p. 35 C.1, p. 35 C.3, p. 36 D, p. 36	! Review data reporting forms only. Do not verify with raw data.
Furnace Atomic Absorption Analysis	! Forms I, VIII, XIII, XIV	! X. A through B, p. 37 C.1 and 2, p. 37 C.4, p. 37 D, pp. 37-38	! Review data reporting forms only. Do not verify with raw data. ! Review Form Is for the presence/absence of "M" flags indicating the failing/passing of the duplicate injection precision criteria for field samples. ! Do not verify post-digestion spike recoveries reported on Form XIV with the raw data. ! To verify that the Furnace Atomic Absorption Analysis Scheme was followed, evaluate Form XIV for spike recoveries not within 85-115%, initial and reanalyses, and dilution factors. In addition to Form XIV, evaluate Form I for sample concentrations to verify that an MSA analysis was not required for any result quantitated directly from the calibration curve and for which spike recoveries were not within 85-115%.
ICP Serial Dilution Analysis	! Forms IX, X, XIV	! XI. A through B, pp. 38-39 C.1, p. 39 C.3, p. 39 D, p. 39	! Review data reporting forms only. Do not verify with raw data. ! Paragraph C.3: For evidence of negative interference, evaluate Form IX. Do not check the raw data.

SEE NOTE ON PAGE 3 OF 3.

[3] **REGION I LABORATORY DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING INORGANICS ANALYSES, 6/13/88, MODIFIED 2/89**

TIER II INORGANIC DATA VALIDATION

QC CRITERIA	DATA REPORTING FORMS TO REVIEW	APPLICABLE SECTIONS IN FUNCTIONAL GUIDELINES[3]	COMMENTS
Detection Limits	! Forms I, X, XIII, XIV	! XII. A through D, pp. 39-40	! Paragraph C.3: To verify that sample weights, volumes, and dilutions are taken into account when reporting sample quantitation limits, evaluate Forms I, X, XIII, and XIV.
Sample Result Verification	! Forms I, XII, XIII, XIV	! XIII. A through B, pp. 40-41 C.3, p. 41 D, p. 41	! Review data reporting forms only. Do not verify with raw data. ! For any result reported on Form I for which the sample result is greater than the linear range for ICP (Form XII) and greater than the calibrated range for non-ICP parameters (Form XIV), verify that the result was reported from a diluted sample analysis (Form XIV) and that the diluted sample result falls within the respective ranges. Dilution and preparation factors are found on Forms XIII and XIV. Do not check the raw data.
Overall Assessment of Data for a Case		! XIV., p. 42	! Limit to the sections evaluated during Tier II review.

NOTE: IN CIRCUMSTANCES WHERE THE ENTIRE DATA PACKAGE OR DATA FOR MULTIPLE SAMPLES MUST BE REJECTED OR WILL BE SIGNIFICANTLY QUALIFIED BASED UPON THE TIER II RESULTS, THE REVIEWER MUST FIRST CONSIDER THE IMPACT OF REJECTED RESULTS AND/OR DISCREPANT INFORMATION ON THE DATA NEEDS OF THE SPECIFIC PROJECT. IF THE DATA ARE CRITICAL TO THE PROJECT NEEDS, THEN EXAMINATION OF THE RAW DATA IS STRONGLY RECOMMENDED TO PREVENT FAULTY SITE DECISIONS BASED ON TECHNICAL, TRANSCRIPTION, AND/OR CALCULATION ERRORS. THE EPA REMEDIAL PROJECT MANAGER (RPM) OR SITE ASSESSMENT MANAGER (SAM) MUST BE CONTACTED TO APPROVE A PARTIAL OR COMPLETE TIER III VALIDATION PRIOR TO ITS INITIATION.

[3] **REGION I LABORATORY DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING INORGANICS ANALYSES, 6/13/88, MODIFIED 2/89**

ATTACHMENT II

TIER II ORGANIC DATA VALIDATION

TIER II ORGANIC DATA VALIDATION

QC CRITERIA	DATA REPORTING FORMS TO REVIEW	APPLICABLE SECTIONS IN FUNCTIONAL GUIDELINES[3]	COMMENTS
Data Completeness	! Complete SDG File (CSF) 1. Original Sample Data Package including Cover Page, Forms I through X, DC-1, DC-2, raw data 2. Original shipping and receiving documents 3. All original lab records of sample transfer, preparation and analysis, as well as telephone contact logs.		! Perform a Tier I completeness evidence audit according to procedures in the Region I CSF Completeness Evidence Audit Program, dated July 3, 1991, to ensure that all laboratory data and documentation are present. Request missing deliverables from the laboratory following appropriate procedures.
Holding Times VOA & SVOA	! Form Is ! Chain of Custody / Traffic Report ! SDG Narrative	! I. A through D, pp. 21-22	! Examine Chain-of-Custody/Traffic Report Forms to determine if samples were properly preserved in the field. ! To verify sample pH upon laboratory receipt, review the SDG Narrative as this information is not included on the forms.
Pest/PCB		! I. A through D, p. 48	
GC/MS Tuning VOA & SVOA	! Form Vs	! II. A through B, pp. 22-23 C.3.a and c, p. 23 D, pp. 24-26	! Review data reporting forms only. Do not verify with raw data and do not recalculate reported values.
Calibration VOA & SVOA	! Forms IV, VI, VII	! III. A through B, pp. 26-27 C.1.a.2, p. 27 C.1.b.2, p. 28 C.2.a.1, p. 28 C.2.b.2, p. 29 D, pp. 29-30	! Review data reporting forms only. Do not verify with raw data. Do not recalculate %RSD, RRF or %D values. ! Review Form IV to determine the samples associated with each calibration.
Instrument Performance/Calibration Pest/PCB	! Forms VI, VII, VIII, IX	! II. A, p. 49 B.1-4, pp. 49-51 C through D, pp. 51-54 ! III. A through B, pp. 54-55 C.1.c and e, pp. 55-56 C.2, p. 56 D, p. 56	! Review data reporting forms only. Do not verify with raw data and do not recalculate reported values.

SEE NOTE ON PAGE 3 OF 3.

[3] **REGION I LABORATORY DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING ORGANICS ANALYSES, 2/1/88, MODIFIED 11/1/88**

TIER II ORGANIC DATA VALIDATION

QC CRITERIA	DATA REPORTING FORMS TO REVIEW	APPLICABLE SECTIONS IN FUNCTIONAL GUIDELINES[3]	COMMENTS
Blanks VOA & SVOA	! Forms I, IV ! Chain of Custody / Traffic Report	! IV. A through B, p. 30 C.2, pp. 30-31 D, pp. 31-33	! Review data reporting forms only. Do not verify with raw data.
Pest/PCB		! IV. A through B, p. 57 C.2 and 3, p. 57 D, pp. 57-59	
Surrogate Recovery VOA & SVOA	! Form IIs	! V. A through B, pp. 33-34 C.2.a-c, p. 34 C.3.a-c, p. 34 D, pp. 34-35	! Review data reporting forms only. Do not verify with raw data.
Pest/PCB		! V. A through B, p. 59 D, pp. 59-60	
Matrix Spike & Matrix Spike Duplicate VOA & SVOA	! Forms I, III	! VI. A through B, pp. 35-36 C.1 and 3, p. 36 D, pp. 36-37	! Review data reporting forms only. Do not verify with raw data.
Pest/PCB		! VI. A through B, p. 60 C.1 and 3, pp. 60-61 D, p. 61	
Field Duplicates VOA & SVOA	! Form Is ! Chain of Custody / Traffic Report	! VII. A through D, pp. 37-38	! No change from current procedures.
Pest/PCB		! VII. A through D, pp. 61-62	
Internal Standards Performance VOA & SVOA	! Form VIIIs	! VIII. A through B, p. 38 C.2 and 3, p. 38 D, pp. 38-39	! Review data reporting forms only. Do not verify with raw data.
Compound Identification VOA & SVOA	---	---	! Not evaluated during Tier II review.
Pest/PCB	! Forms I, X	! VIII. A, B, pp. 62, 63 C, D, pp. 63, 64	! Review data reporting forms only. Do not verify with raw data.

SEE NOTE ON PAGE 3 OF 3.

[3] **REGION I LABORATORY DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING ORGANICS ANALYSES, 2/1/88, MODIFIED 11/1/88**

TIER II ORGANIC DATA VALIDATION

QC CRITERIA	DATA REPORTING FORMS TO REVIEW	APPLICABLE SECTIONS IN FUNCTIONAL GUIDELINES[3]	COMMENTS
Compound Quantitation & Reported Detection Limits VOA & SVOA	! Form Is ! SDG Narrative	! X. C.4, p. 41 D, p. 41	! Only reported quantitation limits can be evaluated during a Tier II review. ! Review the SDG Narrative to identify and explain any anomalies on the Form Is. Qualify data accordingly. ! Review data reporting forms only. Do not verify with raw data.
Pest/PCB		! IX. C.2, p. 64 D, pp. 64-65	
Tentatively Identified Compounds VOA & SVOA	! Form Is	---	! Verify that target compounds are not reported as TICs in another fraction.
System Performance VOA & SVOA	---	---	! Not evaluated during Tier II review.
Overall Assessment of Data for a Case			! Limit to the sections evaluated during Tier II review.

NOTE: IN CIRCUMSTANCES WHERE THE ENTIRE DATA PACKAGE OR DATA FOR MULTIPLE SAMPLES MUST BE REJECTED OR WILL BE SIGNIFICANTLY QUALIFIED BASED UPON THE TIER II RESULTS, THE REVIEWER MUST FIRST CONSIDER THE IMPACT OF REJECTED RESULTS AND/OR DISCREPANT INFORMATION ON THE DATA NEEDS OF THE SPECIFIC PROJECT. IF THE DATA ARE CRITICAL TO THE PROJECT NEEDS, THEN EXAMINATION OF THE RAW DATA IS STRONGLY RECOMMENDED TO PREVENT FAULTY SITE DECISIONS BASED ON TECHNICAL, TRANSCRIPTION, AND/OR CALCULATION ERRORS. THE EPA REMEDIAL PROJECT MANAGER (RPM) OR SITE ASSESSMENT MANAGER (SAM) MUST BE CONTACTED TO APPROVE A PARTIAL OR COMPLETE TIER III VALIDATION PRIOR TO ITS INITIATION.

[3] **REGION I LABORATORY DATA VALIDATION FUNCTIONAL GUIDELINES FOR EVALUATING ORGANICS ANALYSES, 2/1/88, MODIFIED 11/1/88**