

Analytical Services

GENERAL GUIDELINES
FOR
DATA VERIFICATION AND VALIDATION

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1. INTRODUCTION

This document provides an overview of the methodology used to perform the Sample Data Package review required by the Analytical Services Performance Assurance data assessment program. This General Verification and Validation Guideline (DA-GR01) contains data examination, verification, and validation instructions that are common to all Sample Data Packages generated under Parameter Specific Analytical Modules (PSA Modules) of the RFETS Analytical Services Statement of Work (SOW). This document is to be used in conjunction with PSA Module Verification and Validation Guidelines including but not limited to the following:

- DA-SS01 Verification and Validation Guidelines for Volatile Organics Analyses (PSA Module SS01)
- DA-SS02 Verification and Validation Guidelines for Semivolatile Organics Analyses (PSA Module SS02)
- DA-SS03 Verification and Validation Guidelines for PCB/Pesticides Analyses (PSA Module SS03)
- DA-SS04 Verification and Validation Guidelines for Dioxins/Furans Analyses (PSA Module SS04)
- DA-SS05 Verification and Validation Guidelines for Inorganics Analysis (PSA Module SS05)
- DA-SS06 Verification and Validation Guidelines for Water Quality Parameters Analyses (PSA Module SS06)
- DA-SS07 Verification and Validation Guidelines for Biological and Taxonomic Analyses (PSA Module SS07)
- DA-SS08 Verification and Validation Guidelines for Waste Characteristics Analyses (PSA Module SS08)
- DA-SS09 Verification and Validation Guidelines for Herbicides Analysis (PSA Module SS09)
- DA-SS10 Verification and Validation Guidelines for EPA Method TO-14 Analysis (PSA Module SS10)
- DA-RC01 Verification and Validation Guidelines for Isotopic Determinations by Alpha Spectrometry (PSA Module RC01)
- DA-RC02 Verification and Validation Guidelines for Tritium Analysis by Liquid Scintillation Counting (PSA Module RC02)
- DA-RC04 Verification and Validation Guidelines for Gross Alpha and Gross Beta by Gas Flow Proportional Counting (PSA Module RC04)
- DA-RC05 Verification and Validation Guidelines for Radiometric Strontium by Gas Proportional Counting (PSA Module RC05)
- DA-RC06 Verification and Validation Guidelines for Total Uranium by Laser Induced Phosphorescence (PSA Module RC06)
- DA-BA01 Verification and Validation Guidelines for General Bioassay Services (PSA Module BA01)
- DA-IH01 Verification and Validation Guidelines for Industrial Hygiene - General Chemistry (PSA Module IH01)
- DA-IH02 Verification and Validation Guidelines for Industrial Hygiene - Asbestos (PSA Module IH02)
- DA-IH03 Verification and Validation Guidelines for Industrial Hygiene - Breathing Air (PSA Module IH03)
- DA-DW01 Verification and Validation Guidelines for Safe Drinking Water - General Chemistry (PSA Module DW01)
- DA-DW02 Verification and Validation Guidelines for Safe Drinking Water - Radiochemistry (PSA Module DW02)
- DA-DW03 Verification and Validation Guidelines for Safe Drinking Water /Surface Water - Microbiology (PSA Module DW03)

Instructions contained in PSA Module Verification and Validation Guidelines shall supersede the General Guidelines For Data Verification And Validation.

The data verification and validation program outlined in this procedure has been developed to provide measures for lab performance as well as apply usability qualifiers to analytical data generated in conjunction with Environmental Monitoring and Restoration activities, Bioassay, Safe Drinking Water Act, Waste Characterization, and Industrial Hygiene activities. The data verification and validation program completes the quality assurance and quality improvement process initiated through issue of the PSA Modules. The PSA Modules foster continuous self evaluation by the subcontract laboratories and allow for objective monitoring and evaluation of laboratories through a numerical rating system. Through these ratings, Analytical Services communicates expectations for data quality and subcontract compliance to each lab. The verification and validation process serves to assess data quality as well as to improve future data through feedback with laboratory personnel and by guiding analytical work to labs with superior performance measures. Feedback in subcontract compliance is designed to reduce data costs by producing a consistent product from the subcontract laboratories, thereby reducing costs for data filing, package checks, verification, and validation.

The data verification and validation procedures identified in this guideline are performed in conjunction with the Rocky Flats Environmental Technology Site (RFETS) Analytical Services Division (ASD) Data Assessment Program. The Data Assessment Program is described in Kaiser-Hill Analytical Services Division procedure ASD-001, Performance Assurance Data Assessment Program.

This guideline addresses the procedures and terminology used to assess data verification and validation of analytical data through evaluation of laboratory quality control data. This guideline does not address the use of field duplicates, field blanks, trip blanks, and equipment blanks in evaluating the overall quality of sample results. The frequency of field quality control samples and the procedures used to evaluate the impact of field quality control results on overall assessment of the data are determined according to individual sample program requirements. The specification and assessment of field QC samples are performed by the client and not by Analytical Services.

The remainder of this guideline includes the following sections:

- Determination of Data Verification and Validation Review Levels, Data Qualifiers, and Reason Codes
- Overview of Review Levels
- Data Review Checklist Examination Instructions
- General Verification and Validation Instructions
- References
- Revision History
- Attachments

2. DETERMINATION OF DATA VERIFICATION AND VALIDATION REVIEW LEVELS, DATA QUALIFIERS, AND REASON CODES

All analytical data generated in conjunction with the PSA Modules Statement of Work are subject to data assessment through data verification or validation. The results of the data assessment process as well as the level of the assessment are documented using the following designations:

- Review Levels
- Data Qualifiers
- Reason Codes

The review level, data qualifiers, and reason codes are all incorporated to assign a complete data qualifier to each data point.

2.1. Review Levels

The levels of data assessment review that can be performed are provided in Table 2-1 below. The data review level is indicated by a 1, 2, or no number directly following the data qualifier (e.g. V1). The data assessment review levels are described in Section 3 of this procedure.

TABLE 2-1 DATA QUALITY ASSESSMENT REVIEW LEVELS

Review Level Designation	Example Review Level Depiction	Review Level Description
2	V2	Data Review Checklist (DRC) Examination
1	J1	Package Verification (partial or complete)
none	V	Data Validation

2.2. Data Qualifiers

Data qualifiers are assigned to individual data points to provide an indication of the level of data quality associated with the specific data points. The common data qualifiers in use for this program are UJ, V, J, NJ and R. Table 2-2 provides a brief description of these general data qualifiers which are assigned to results in the data review process. Additional data qualifiers may be defined in PSA Module Verification and Validation Guidelines.

Table 2-2 Common Data Qualifiers

Qualifier	Description
V	No problems with the data were observed at the indicated review level.
J	The associated value is an estimated quantity.
NJ	The associated value is presumptively estimated
UJ	The associated value is considered estimated at an elevated level of detection
R	The data are unusable. (Note: Analyte may or may not be present.)

2.2.1. **Application:** All data is considered valid, "V", unless through the data assessment process, other qualifiers are assigned to individual data points.

2.2.1.1. Multiple data qualifiers may be identified for an individual data point. When this occurs, one data qualifier flag will be assigned according to the following hierarchy:

- R
- NJ
- UJ
- J
- V

2.3. Reason Codes

Reason codes are three-digit designators which accompany all J, UJ, NJ and R qualified data. In addition, some V-qualified data may also include reason codes that indicate problems or discrepancies that did not result in qualification. These reason codes reference statements which further describe data problems. The reason code system description and the current version of the reason code table itself, is maintained on the Analytical Services Data Server.

2.3.1. Reason codes are used to describe validation codes, but they are also used to describe and quantify subcontract noncompliance which does not affect data. It is because of this dual function, that reason codes may be applied to V-qualified data.

2.3.2. Reason codes may also be applied at the RIN level to indicate specific non-compliance, or performance issues.

2.4. Data Qualifier Format

A complete data qualification includes the qualifier letter(s), the review level (2, 1, or blank) followed by one or more three-digit reason code(s) if applicable. For example, the rating R1 101, indicates that verification was performed on the data, the data were rejected, and the reason code for the rejection is 101.

3. OVERVIEW OF REVIEW LEVELS

The data assessment program includes the following levels of data review:

- Package Receipt Check
- Data Review Checklist (DRC) Examination
- Package Verification (partial or complete)
- Data Validation

A flowchart demonstrating the mechanisms used to determine the appropriate level of data assessment for a project is presented as Attachment 1 of this guideline.

A description of these levels of review included in the data assessment program follows:

The Package Receipt Check is performed on 100% of all Sample Data Packages and must be completed within 1 working day from the date of receipt by ASD.

3.1. Package Receipt Check

The Package Receipt Check consists of the following activities:

- 3.1.1.1. Verification of the RIN number for each Sample Data Package.
- 3.1.1.2. Verification that each Deliverable Section Number listed in Exhibit B of the PSA Module is included in the Sample Data Package.
- 3.1.1.3. Updating Sample Data Package (SDP) receipt status.

NOTE: The Package Receipt Check is performed by ASD when package receipt is logged. Detailed instructions are included in the ASD data receipt and log-in procedure L-5037, Analytical Projects Office Sample Management Procedure.

3.2. Data Review Checklist (DRC) Examination

The DRC Examination is performed on 100% of all Sample Data Packages upon receipt from the subcontract laboratories. The DRC forms are unique for each PSA Module and must be completed by the subcontract laboratory with each Sample Data Package. The laboratory self assesses the compliance of the Sample Data Package to GR01, "General Laboratory Requirements", and to PSA Module requirements. The DRC Examination process is the minimum verification level described in ASD-001 and must be performed for each data package. The DRC Examination must be completed by the ASD or their subcontractor within 3 working days from the date of completion of the Package Receipt Check.

3.2.1. Each DRC contains the following columns that are of interest during the DRC Examination and subsequent partial verification process:

3.2.1.1. **Reply Column:** The Reply column is completed by the subcontract laboratory and documents a checklist item is:

- In compliance, by placing a Y in the column,
- Not Applicable, by placing an NA in the column,
- Not in compliance, by placing an N in the column.

3.2.1.2. **√ Column:** The √ column is used to indicate each Reply item is examined during the DRC evaluation process. The specific codes that will be used in the √ column are described in further detail later in this procedure.

3.2.1.3. **C# Column:** The C# column is used to document specific verification results. The specific codes that will be used in the C# column are described in further detail later in this procedure.

3.2.2. The primary objectives of the DRC Examination are as follows:

- Verify that all items of the DRC were completed
- Evaluate and document the applicability of all NA entries on the checklist
- Evaluate and document the impact of all N entries on the checklist
- Determine of additional assessment activities

- 3.2.3. Review Level 2 data qualifiers will be assigned to all data points subject to the DRC examination checklist (pending any subsequent data verification or validation action).
- 3.2.4. Specific procedures for completing the DRC Examination process are provided in Section 4 of this guideline.

3.3. **Partial Package Verification**

Partial Package Verification is a quality control review designed to assess the impact of non-conformances or deficiencies identified on the DRC by the subcontract laboratory and to assess the impact of DRC sections that are not completed correctly by the subcontract laboratory.

- 3.3.1. Partial Package Verification is performed on a data package by ASD or their subcontractor under the following circumstances:
 - 3.3.1.1. The DRC Examination results indicate further review is necessary as indicated by 'X' codes in the $\sqrt{\quad}$ column of the checklist.
 - 3.3.1.2. When scheduled as part of the ASD Laboratory Evaluation Program
- 3.3.2. The partial verification will be completed in accordance with all of the verification instructions specified in Section 5 of this guideline as well as the applicable items of the PSA Module Verification and Validation Guidelines as indicated by the DRC items identified with an X. All verification results will be documented in:
 - 3.3.2.1. The C# column of the DRC
 - 3.3.2.2. In the Validation Qualifier and Reason Code fields of the Electronic Deliverable
 - 3.3.2.3. In the Data Quality Assessment Report
- 3.3.3. Appropriate Review Level 1 data qualifiers and reason codes will be applied to all data points subject to partial verification activities; Review Level 2 data qualifiers will be retained for all data points that were not examined under a partial verification action.
- 3.3.4. Partial verification must be completed within 3 working days from the completion of the DRC examination.

3.4. **Complete Package Verification**

Complete Package Verification consists of a review of sample data package summary information to evaluate the extent to which the subcontract laboratory met method and subcontract specific quality control and reporting criteria. Complete Package Verification is performed on a data package by ASD or their subcontractor under the following circumstances:

- 3.4.1. DRC results indicate that an extensive review is necessary due to excessive 'X' codes in the $\sqrt{\quad}$ column of the DRC checklist. (More than 5 "X" responses on the DRC will trigger a complete verification)

- 3.4.2. Partial Package Verification results indicate that an extensive review is necessary (ASD will determine on a case by case basis if complete verification is required)
- 3.4.3. Complete verification is scheduled (by ASD) as part of the ASD Laboratory Evaluation Program. A certain percentage of Sample Data Packages will be subject to complete verification. The percentage is based upon the level of demonstrated quality of the laboratory in submitting acceptable data packages and will therefore be determined by subcontractor performance.
- 3.4.4. Complete verification may also be scheduled (by ASD) according to program requirements of a specific project.
- 3.4.5. Complete verification will be completed in accordance with all of the verification steps identified in Section 5 of this procedure as well as all of the verification activities identified in the applicable PSA Module Verification and Validation Guidelines. Complete verification for a data package must be completed within 7 calendar days from the date of request. The Review Level 1 data qualifiers and reason codes will be applied as a result of the complete verification process. All Review Level 2 data qualifiers and reason codes are upgraded to Review Level 1 when a complete verification is performed.

3.5. Data Validation

The data validation process is designed to determine the extent to which the subcontract laboratory, accurately and completely, reported all sample and quality control results, and their adherence to PSA Module contractual requirements.

- 3.5.1. Data validation will be performed on packages when:
 - *Validation Required* has been indicated in the ASD database for the package. (ASD selects packages for validation and documents this selection in the ASD database.)
 - ASD selected additional packages for validation based upon poor verification results for a laboratory or other data assessment requirements.
 - Analytical Services minimum requirements, client program requirements, and other sources are used to determine validation frequency. Generally at least 25% of packages will be validated.
- 3.5.2. Data validation will be performed by ASD or by an independent validation subcontractor.
- 3.5.3. Some packages may be subject to both complete verification and validation. Those packages that receive both Validation and Verification are used to evaluate the performance of the verification staff, the validation staff, and the data assessment system.
- 3.5.4. Data validation activities will be completed in accordance with all of the verification and validation steps identified in Section 5 of this procedure as well as all of the verification and validation activities identified in the applicable PSA Module Verification and Validation Guidelines.
- 3.5.5. Routine validation reports must be completed within 30 calendar days from the date of request. Expedited validation will be handled on a case by case basis.

3.5.6. Review Level (null) data qualifiers will be used to document the validation results.

3.5.6.1. All Review Level 2 and Review Level 1 data qualifiers that were previously used will be replaced with the appropriate Review Level (null) data qualifiers.

4. DATA REVIEW CHECKLIST (DRC) EXAMINATION INSTRUCTIONS

The instructions presented below are for the completion of the DRC examination process.

4.1. DRC Examination Process Summary

4.1.1. The DRC Examination process is performed on all DRCs received by ASD.

4.1.2. Lines or response boxes on the DRC are referenced as Item numbers in Verification and Validation Guidelines. For example, item 5-c-5 on the SS05 DRC is the *discussion of all analyses performed by Method of Additions*.

4.1.3. Each DRC is examined for overall completeness and to determine the appropriateness of all replies. Results of the reply box examinations are recorded in the \checkmark column of the DRC. "Y" responses are accepted as accurate, "N" responses are marked for verification, "NA" responses are evaluated and marked as accurate or are marked for verification. All other responses and missing response items are marked for verification.

4.2. Footers and Signature Check

4.2.1. Check the footer for each page (including the *Data Assessment Use Only* page) for completion of the RIN number, Lab Name, Initials, and Analytical Batch Identification No.(s). If the footer is not complete on all pages enter an "X" in the appropriate box of the \checkmark column in Section 3 of the DRC.

4.2.2. If the Name, Title, Signature, and Date following the checklist accuracy paragraph is not complete or accurate on all pages enter an "X" in the appropriate box of the \checkmark column in Section 3 of the DRC.

4.3. Incorrect Replies

For all items in the *Reply* column which have no response entered or which have entries other than Y, N, or NA, enter "X" in the \checkmark column to indicate that verification is required for this item. In addition, enter an "X" in the appropriate box of the \checkmark column in Section 3 of the DRC.

4.4. Y Replies

Enter \checkmark in the \checkmark column beside each Y response in the *Reply* column. This \checkmark indicates that the Y response is accepted but not verified.

4.5. N Replies

For all items marked N in the *Reply* column, enter an "X" in the adjacent \checkmark column to indicate that the verification is required for this item.

4.6. Examination of NA Replies

The DRC Examination section of each PSA Module Verification and Validation Guidelines includes detailed instructions for evaluating *NA* replies. PSA Module Verification and Validation Guidelines will list specific items for which *NA* responses will be accepted (though not verified as appropriate).

4.6.1. Enter an “X” or √ in the √ column based upon the appropriateness of the *NA* response as detailed in the appropriate PSA Module Verification and Validation Guidelines. If an “X” is entered because of the inappropriate use of a *NA* response then enter an ‘X’ in the appropriate box of the √ column in Section 3 of the DRC.

4.7. Examination of the Sample Narrative

Read the sample narrative for information which indicates additional items to be verified. Items to check include statements about data qualifiers, blank or reagent contamination, and sample handling problems.

4.7.1. Enter an “X” in the √ column of the appropriate DRC item to indicate that the verification is required. In many cases, the PSA Module-Verification and Validation Guidelines will include additional instructions for narrative review.

4.8. PSA Module Verification and Validation Guideline Instructions

See the PSA Module Verification and Validation Guidelines for additional instructions for completing the DRC review.

4.9. Final Checks and Result Entry

4.9.1. Enter the version identifiers for DA-GR01 and the PSA Module Verification and Validation Guidelines used to perform the DRC check in the Assessment portion of the DRC.

4.9.2. Ensure each box in the √ column of the DRC has been entered as a “√” or “X”.

4.9.3. Mark the appropriate box in the Examination Section of the DRC to indicate the next Review Level of assessment required.

4.9.3.1. Certain items on the DRC are not assessed at the verification level. These items are indicated by a “φ” in the C# column of the DRC. If an “X” was marked in the √ column for an item that is not checked at the verification level (indicated by a “φ” in the C# column of the DRC), validation is required.

4.9.4. Mark the appropriate box in the Examination Section of the DRC to indicate the basis for the next Review Level of assessment.

4.9.5. Provide information in the Examination Notes Section of the DRC as necessary.

4.9.6. Complete Examiner signature block.

5. VERIFICATION AND VALIDATION STEPS

5.1. Overview of Verification and Validation Process

The general instructions for verification and validation activities provide an overview of the assessment process as well as a general discussion of the assessment activities that are applicable to all PSA modules and analytical methods. The verification and validation criteria contained within this section are to be used in conjunction with the appropriate PSA Module Verification and Validation Guidelines.

5.1.1. Instructions for assessing each DRC section will include the following:

- Review Items:** Lists the deliverable sections of the Sample Data Package which will be needed for the review step.
- Objective:** Includes a brief description of the goals for this check section.
- Requirement Source:** Lists reference locations for requirements which have been incorporated into the following evaluation section.
- Evaluation:** Identifies the verification and validation activities to be performed for each data review item. In most cases data validation includes review steps that exceed those required for verification.

5.1.2. Data evaluation results may include:

- 5.1.2.1. Assessments which result in assignment of data qualifiers which may or may not affect the lab performance score.
- 5.1.2.2. Errors or omissions for which corrections or additional information will be requested.
- 5.1.2.3. Errors or omissions for which corrections and additional information will not be requested but will be recorded as part of the lab evaluation/continuous improvement program.

5.1.3. All verification and validation results will be documented on a Data Quality Assessment Report. Verification results will also be documented on the DRC by reference to the comments contained on the Data Quality Assessment Report. An example Data Quality Assessment Report is presented as Attachment 3 of this Guideline.

5.1.4. Item 4-a of the DRC is completed for all packages that are subject to verification or validation .

5.1.5. PSA Module Verification and Validation Guidelines may include some or all verification or validation steps by reference to other documents. For example, all items in the QA Summary section may refer to published EPA data assessment guidelines.

5.1.6. Characters enclosed by square brackets, [] , indicate data qualifiers and reason codes to be assigned if evaluation indicates non-compliance to the evaluation item.

If the non-compliance causes a change in the validation qualifier, this code will include two parts: the data qualifier letter and the 3-digit reason code (e.g. **[J 545]**). If non-compliance does not involve a change in the data qualification status then the data qualifier will include only the reason code portion (e.g. **[545]**).

Note: Verification and Validation Instructions contained in DA-GR01 and PSA Module Verification and Validation Guidelines provide data qualifiers without Review Level Designation. The appropriate Review Level Designator is to be added to the qualifier at the time of assessment.

- 5.1.7. Non-compliant items may require corrective actions by the subcontracted laboratory to rectify problems with a specific sample data package or to prevent the problem from occurring in subsequent sample data packages. When these situations occur, ASD or their subcontractor shall issue a Non-Compliance Notification. An example Non-Conformance Notification is provided as Attachment 4 of this guideline.

5.2. General Instructions For Package Verification

- 5.2.1. **Partial Verification:** Partial verification will include Item (4-a) plus all items marked with an “X” in the \checkmark column during the DRC Examination.
- 5.2.1.1. Additional DRC items may be subject to verification when scheduled as part of the ASD Laboratory Evaluation Program
- 5.2.2. **Complete Verification:** Complete verification will include a review of all applicable verification items as specified in this Guideline and the PSA Module guidelines.
- 5.2.2.1. Complete verification may be scheduled as part of the ASD Laboratory Evaluation Program or based on demonstrated poor laboratory performance from previous data assessment activities.
- 5.2.3. **Verification Process:** To verify an item, follow the steps indicated for verification in this section and the appropriate sections of the PSA Module Verification and Validation Guidelines.
- 5.2.3.1. Verification is always preceded by or performed in conjunction with the DRC examination.
- 5.2.3.2. Numerals in the **C#** column preceded by the letter “A” for Action Item or “C” for Comment reference actions or comments contained in the Data Quality Assessment Report. These numbered actions/comments will contain all data qualifiers and reason codes assigned.
- 5.2.3.3. Numerals without letters in the **C#** column are used to reference information contained in the *Notes* Section of the DRC.
- 5.2.3.4. The codes, “ \checkmark ” and “ \emptyset ”, will be used to document verification results in **C#** column of the DRC as follows:

The **C#** column may be left blank if the \checkmark column contains a \checkmark .

- √ Y or N/A response was verified and is accepted. If the verifier wishes to elaborate, a comment numeral will be added to the letter code.
- √ N response is appropriate, no further verification is needed, no qualification of the data is needed, no subcontract non-compliance is indicated
- √ Verification of this N or N/A response revealed that the response should have been YES. This means that the data package appears to be correct, however, an N or N/A was incorrectly entered on the checklist.
- ∅ Indicates that this item is not checked at the verification level

5.2.3.5. A Data Quality Assessment Report is completed for each Sample Data Package verified (Partial or Complete).

- **Partial:** The verifier documents all errors, omissions, reason codes, and data qualifiers for all items marked with a "X" in the √ column of the DRC in the Data Quality Assessment Report.
- **Complete:** The verifier documents all errors, omissions, reason codes, and data qualifiers for all verification steps identified in the General Guidelines for Data Verification and Validation (DA-GR01) and in appropriate PSA Module Verification and Validation Guidelines.

5.2.3.6. Determine if further assessment is needed and mark the appropriate box(s) in either the Complete Verification or Validation sections of the DRC.

5.2.3.7. Provide additional information in the Verification Notes Section of the DRC that will not appear as a comment in the Data Assessment Report.

5.2.3.8. Complete the appropriate Verification signature block.

5.3. General Instructions For Package Validation

5.3.1. Validation is always preceded by DRC examination.

5.3.2. A Data Quality Assessment Report is completed for each Sample Data Package validated.

5.3.3. The validator documents all errors, omissions, reason codes, and data qualifiers by item in the Data Quality Assessment Report.

6. VERIFICATION AND VALIDATION INSTRUCTIONS

The sample data package assessment activities in the following subsections are applicable to all sample data packages. The instructions included in this section are to be used in conjunction with the PSA Module Verification and Validation Guidelines applicable to the Sample Data Package.

6.1. Sample Data Package (SDP) Cover Page

DRC Items 1-a through 1-d

Review Items: Deliverable Section Number 1, the SDP Cover Page.

Objective: Verify the SDP Cover Page information is complete and correct.

Requirement Source: GR01 Exhibit B § 4.5.

Evaluation: *The following steps apply to both verification and validation.*

Item 1-a Verify that the laboratory name, code, subcontract number, RIN, Site sample numbers, analyses, and report dates are accurately recorded.

- If this information is not complete, include a comment in the Data Quality Assessment Report and assign the reason code **[804]** for all data.

Item 1-b Verify that all Site sample identifications are cross-referenced with all lab identifications. (If the laboratory uses Site Ids only throughout the analysis process, the cross-reference table is not needed or required.).

- If a cross reference list is required to continue assessment and not provided, initiate a Non-Conformance Notification for missing documentation and assign the reason code **[801]** to all results. If possible, verification or validation may continue without this documentation.

Item 1-c Verify that the verbatim compliance and authorization statement is present with the dated signature of the Laboratory Manager or designee.

- If the Cover Page is not signed and dated, issue a Non-Compliance Notification for non-conformance to the SOW and assign the reason code **[802]**. Verification or validation may continue without this documentation

Item 1-d Verify that any problems with the receipt are explained.

- If this information is not complete, include a comment in the Data Quality Assessment Report and assign reason code **[804]** for all data.

6.2. Table of Contents Requirements

DRC Item 2-a

Review Items: Deliverable Section Number 2, the Table of Contents.

Objective: To verify a Sample Data Package Table of Contents which meets requirements and is consistent with the SDP received.

Requirement Source: GR01 Exhibit B§4.6 and PSA Modules Exhibit B

Evaluation: *The following step apply to both verification and validation.*

Item 2-a. Verify that the Table of Contents contains all Sample Data Package deliverable section headings applicable to the PSA Module and that each section heading includes the first page number of the section.

- If the Table of Contents is not provided or not completed, comment in the Data Quality Assessment Report and assign the reason code [802].

Note: Check the PSA Module Data Verification and Validation Guidelines for additional instructions.

6.3. Data Review Checklist (DRC) and Sample Data Package (SDP)

DRC Items 3-a through 3-k

Review Items: All Deliverable Sections.

Objective: To check overall composition and conformance of the deliverable to requirements.

Requirement Source: Content and format requirements are listed primarily in GR01 Exhibit B Sections 4 and 5, Exhibit F Section 4.

Evaluation: *The following steps apply to both verification and validation.*

Item 3-a Determine if the DRC is present.

- If the DRC is missing, issue a Non-Compliance Notification for non-conformance to the SOW and assign the reason code [802]. A Complete Validation of the sample data package is required if validation was not already requested.

Item 3-b Determine if *Reply* blocks contain an appropriate response.

- If all *Reply* blocks of the DRC are not completed with a “Y”, “N” or “NA” include a comment in the Data Quality Assessment Report and assign reason code [808].

Item 3-c Determine if the case narrative includes an explanation for all “N” replies.

- If any of the *Reply* blocks of the DRC marked with a “N” are not explained in the case narrative include a comment in the Data Quality Assessment Report and assign the reason code [808].

Item 3-d Determine if footers are complete and certification statement is signed.

- If any page footer of the DRC is incomplete or if the laboratory manager or designee did not sign and date the DRC following the certification statement, include a comment in the Data Quality Assessment Report and assign the reason code [808].

Item 3-e Determine if all SDP deliverable sections are present.

- If a SDP deliverable section is missing issue a Non Compliance Notification for the missing documents and assign the reason code [801]. Do not continue verification or validation when deliverable section(s) are missing. Return the SDP to ASD

Item 3-f This item cannot be assessed through the verification/validation process.

Item 3-k Check that the complete sample data package is consecutively paginated by examining at least ten sheets for increasing page numbers and that all pages are single sided.

- If double sided pages or problems with pagination are found, comment and assign the reason code [804].

Evaluation: *The following steps apply to validation only.*

- Item 3-g** Check that all components of the SDP are original documents except where data included are photocopies of original data bound in a logbook maintained by the Laboratory. (Photocopies of original documents are allowed if the original data were previously submitted under another RIN (see GR01A, Exhibit B, Section 4.2).
- If an original data package component is missing, comment and assign the reason code **[802]**.
- Item 3-h** Determine if SDP required items are referenced in other SDPs.
- If required items, not critical to verification or validation, are referenced in another SDP, comment and assign the reason code **[802]**.
 - If required items that are critical to verification or validation are referenced in another SDP, issue a Non-Compliance Notification for missing documentation and assign the reason code **[801]**.
- Item 3-i** Determine if other than Site samples are used for Sample Matrix QC.
- If other than Site samples are used for Sample Matrix QC, issue a Non-Compliance Notification for non-conformance to the SOW and assign the reason code **[806]**.
 - Qualify all sample results associated with Sample Matrix QC from Non-Site samples that do not match the matrix of the Site samples as rejected **[R 233]**.
- Item 3-j** Determine if Non-Site samples are reported with Site Samples.
- If Non Site samples are reported with Site samples, comment in the Data Quality Assessment Report and assign the reason code **[809]**.

6.4. Chain of Custody, Holding Times, and Sample Preservation

DRC Item 4-a through 4-g

Review Items: Deliverable Section Numbers 2, 4, 7, 9, and raw data and other sources.

Objective: The objective is to ascertain the validity of results based on the holding time and preservation of the sample and to check that Sample COC documentation is included in the SDP.

Requirement Source: GR01 Exhibit B § 4.8 and GR01 Exhibit F § 3 (GR01 Exhibit B §§ 3 and 4, GR01 Exhibit F §§ 2 and 3)

Evaluation: *The following steps apply to both verification and validation.*

- Item 4-a** Verify that COCs are included for all samples listed on the Cover Page of the SDP.
- If COCs are not included for all samples, initiate a Non-Conformance Notification for the missing documentation and assign the reason code **[801]**
 - If COC records were not generated for a sample, qualify the sample as rejected and assign the reason code **[R 218]**.

Verify that originals of COCs are included if only one PSA-Module is specified on the COC. A photocopy of the COC may be included if the

original COC was submitted to the CTR with a Sample Data Package from another PSA Module.

- If original COC is expected and not included, comment and assign reason code **[807]**.

Verify that the continuity of each sample's custody is evidenced on the chain of custody with the dates, times, and signatures of each transaction from sampling to final disposition. This continuity is verified through the following specific items:

- ◇ All documents accompanying the samples were signed and dated (including time) by the sample custodian at the time of sample shipment and by the lab sample custodian or alternate at time of sample receipt.
- ◇ Verification that the following were recorded by the sample custodian (or alternate) on COC forms, in the sample log, or on preprinted sample log-in sheets.
 - * Condition of the shipping container
 - * Presence or absence and condition of custody seals on shipping and/or sample containers
 - * Custody seal numbers, when present
 - * Presence or absence of airbills or airbill stickers
 - * Airbill or airbill sticker numbers
 - * Presence or absence of Site custody records
 - * Presence or absence of Site packing lists
 - * Verification of agreement or non-agreement of information recorded on shipping documents and sample containers
 - * Temperature of shipping container, if appropriate
 - * pH of the samples, when appropriate
 - * Problems or discrepancies.
- If a non-conformance exists and does not impact the ability of the reviewer to evaluate the sample COC, comment and assign the reason code **[804]**.
- If a non-conformance exists and impacts the ability of the reviewer to evaluate the sample COC, issue a Non Compliance Notification for the missing documentation and assign the reason code **[803]**.

Item 4-b Determine if the COC continuity was corrupted.

- If the COC continuity was corrupted, verify for documentation of correspondence with the CTR. Any non-conformances are documented for inclusion into a non-compliance report. If appropriate documentation indicates the laboratory was not responsible for the corruption of the COC continuity, and the custody of the samples cannot be verified, qualify all affected results as rejected and assign the reason code **[R 704]**.
- If appropriate documentation is not available and the custody of the samples cannot be verified, qualify all affected results as rejected and assign the reason code **[R 218]**.

Item 4-c Verify that Line Item Codes are listed on the COC for each sample analysis requested.

- If sample analyses were not requested according to Line Item Codes specified under GR01, check for written data assessment instructions from the ASD which specify Line Item Codes for performing the data assessment .
 - If no reference to Line Item Codes is found, then the package cannot be assessed to this procedure and must be returned to the ASD with reason code [206].
- Item 4-d** Determine that required preservation was verified upon receipt of the sample by checking verification recorded on the COC or applicable documentation.
- If checks are not documented, comment and assign the reason code [804].
- Verify that the COC documented preservation is consistent with preservation requirements of the applicable PSA Modules.
- If preservation is non-compliant, comment and assign the reason code [703].
- Item 4-e** Verify that any conflicting, incorrect, or missing information related to all Item 4 requirements above are identified and documented, and documentation of the resolution is included. Also, verify a summary of this documentation is on the SDP Cover Page.
- If documentation is not included, issue a Non-Compliance Notification and assign the reason code [804].
- Item 4-f** Calculate actual holding times by comparing the sampling date on the Site COC with dates of analysis found in the laboratory raw data and data summary forms. PSA Module Verification and Validation Guidelines include holding time requirements for date of sample collection to date of preparation or extraction and for date of preparation or extraction to date of analysis.
- Apply the appropriate holding time criteria and actions given in the PSA Module.
- Item 4-g** Determine if samples were properly preserved prior to analysis.
- If documentation indicates samples were not properly preserved prior to analysis, apply the appropriate actions from the PSA Module.

6.5. Electronic Data Deliverable (EDD)

Last DRC Section, Item a through Item c (Electronic Data Deliverable)

Review Items: Deliverable Section Number *.

Objective: To ensure that electronically-reported data are accurate.

Requirement Sources: GR01 Exhibit B, and GR02

Evaluation: *The following step applies to verification only.*

- Item *-a** Successfully complete Item *-b and then verify 5 random analyte results from the EDD hard copy against those on the SDP sample results summary (Form 1 or equivalent).
- If discrepancies are found, initiate a Non-Compliance to obtain correct problems associated with the EDD and/or Sample Data Package.. Assign the reason code [803]. Do not complete other verification until a corrected EDD is provided. Return the SDP to ASD.

- Item *-b** Verify that a EDD hard copy is included in the SDP and the hardcopy includes the data filename and specific means of file transmittal and destination.
- If a hard copy of the EDD is not present and a copy cannot be obtained from the ASD computer data base, issue a Non-Compliance Notification for missing documentation, and assign reason code **[802]**.
 - If the hard copy of the EDD does not include the data filename and specific means of file transmittal and destination, assign reason code **[804]**.

- Item *-c** No action is required. A successful automated EDD verification must be completed prior to verification and validation.

Evaluation: *The following step applies to validation only.*

- Item *-a** Compare uploaded EDD data with data reported on the hardcopy sample data package. Results reported on electronically data deliverables (EDD) must agree with data reported on result summary forms.
- If there are any discrepancies found, initiate a Non-Compliance Notification to obtain correct problems associated with the EDD and/or Sample Data Package. Assign the reason code **[803]**. Do not complete the verification or validation until corrected electronic deliverables are provided. Return the SDP to ASD.

*Note: * refers to the appropriate DRC section in each PSA Module.*

6.6. **SDP Narrative Requirements**

Follow the requirements of the PSA Module Verification and Validation Guidelines to verify compliance of PSA Module Narrative requirements.

6.7. **Review of Remaining Deliverable Sections**

Follow the PSA Module Verification and Validation Guidelines to verify SDP compliance to PSA Module deliverable requirements.

7. **COMPLETION OF THE DATA ASSESSMENT RECORD**

7.1. **Verification Documentation**

When performing verifications, complete the applicable *Data Assessment Use* portions of the DRC and the PSA Module *Data Quality Assessment Report*.

7.2. **Validation Documentation**

When validating, complete all portions of the PSA Module *Data Quality Assessment Report*.

7.3. **Data Quality Assessment Report**

All partial verification, complete verification, and validation activities must include a completed Data Quality Assessment Report. An example Data Quality Assessment Report template completed for PSA Module SS05 is included as Attachment 3 of this guideline.

7.3.1. At a minimum each report will contain the following information:

- RIN Number

- Site Sample Numbers
- Analytical Method(s) and PSA Module Line Item Code(s)
- Review Level of Data Quality Assessment (Partial Verification, Complete Verification, Validation)
- Scope of Verification Activities (“*Reviewed*” column of Data Quality Assessment Report. All items under this column should be “Y” when validation is performed)
- Identification of Non-Conforming Criteria
- Data Assessor Signature and Date
- Data Assessment Reviewer Signature and Date (*Validation Only*)
- Entity performing Data Assessment
- Specific Action Items identifying level of qualification, reason code, samples affected, and applicable elements or compounds
- Comments with reason codes describing non-compliances that did not result in the qualification of data.

7.3.2. All Data Quality Assessment Reports must also contain the following items as attachments to the report:

- Completed DRC
- Data Validation Worksheets (if applicable)
- A copy of all Non-Compliance Notifications
- Data Summary forms with data qualifiers and reason codes. (When EDD is not available)

7.3.3. Upon completion of the Data Quality Assessment Report, the report will be submitted for entry of data qualifiers and reason codes into the Analytical Services database by ASD or Subcontracted personnel.

8. REFERENCES

- Guidance for Radiochemical Data Validation, Draft RD4, October 4, 1995, prepared by Office of Transportation, Emergency Management & Analytical Services (EM 26), Office of Compliance and Program Coordination, Environmental Management, U.S. Department of Energy.
- Reason Codes for Data Assessment, Analytical Services Document
- Performance Assurance Data Assessment Program.
- Analytical Projects Office Sample Management Procedure.

9. REVISION HISTORY

- DA-GR01v1, prepared by Carol Gies of Kaiser-Hill Analytical Services, is the first issue of this procedure.
- Final drafting of DA-GR01-v1 was completed by Ed Brovsky of Kaiser-Hill Analytical Services on November 19, 1997. This is draft revision included: formatting for consistency with DA-GR01-v1, formatting to separate evaluation and action criteria, inclusion of new and revised reason codes, corrections and additions of evaluation and action criteria, and general editing.

Effective Date:
December 3, 1997

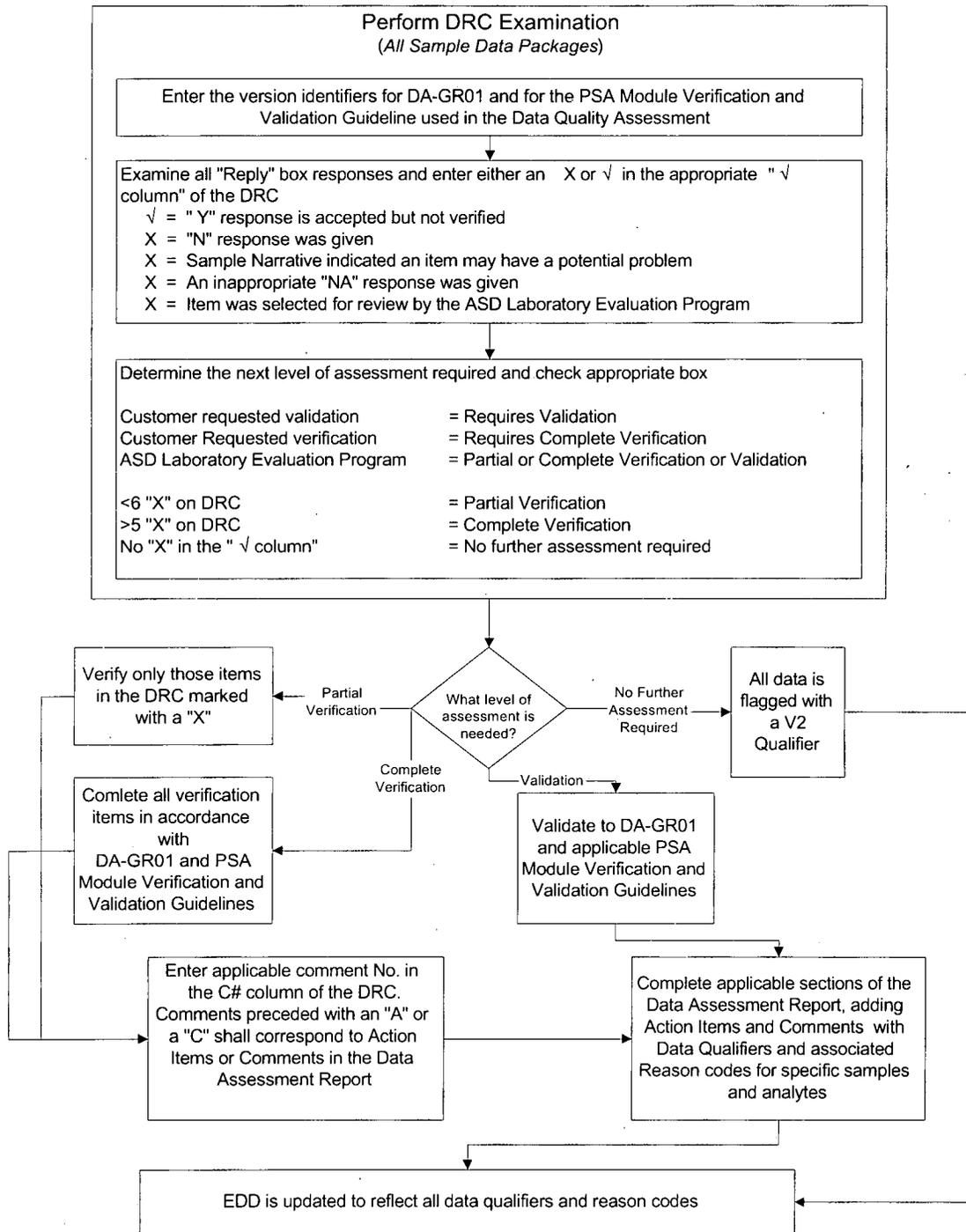
Analytical Services General Guidelines for
Data Verification and Validation

Page No.
DA-GR01-v1-20

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Attachment 1: Data Quality Assessment Flow Diagram

Data Quality Assessment Flow Diagram



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Attachment 2: Example Data Review Checklist

Data Review Checklist SS05 Sample Data Package

1. SAMPLE DATA PACKAGE COVER PAGE	Reply	√	C#
a) The laboratory name, code, subcontract number, RIN, Site sample numbers, Line Item codes (LIC-analyses), sample matrix, and report dates are accurately recorded.	Y	√	C2
b) All Site sample identifications are cross-referenced with all lab identifications.	Y	√	
c) The verbatim compliance and authorization statement is present with the dated signature of the Laboratory Manager or designee.	Y	√	
d) Any problems with the receipt are explained (e.g., broken containers, incorrect COC documentation, etc.)	Y	√	
2. TABLE OF CONTENTS	Reply	√	C#
a) The Table of Contents is included and contains all Sample Data Package Deliverable Section Titles with their beginning page numbers.	Y	√	C1
3. DATA REVIEW CHECKLIST (DRC) and SS05 SAMPLE DATA PACKAGE (SDP)	Reply	√	C#
a) The SS05 DRC is present and in strict conformance with the formatting and content of the form contained in the current version of the SS05, Appendix A. All discrepancies were identified and documented, accordingly.	Y	√	
b) All DRC <i>Reply</i> blocks are completed with either a "Y", "N" or "N/A".	Y	√	
c) All DRC <i>Reply</i> blocks completed with an "N" are explained in the Narrative.	Y	√	
d) The DRC footer is completed for each page; the laboratory manager or designee signed and dated the DRC.	Y	√	
e) All SDP deliverable sections appear in the SDP in order by deliverable section number	Y	√	
f) Only one SDP is submitted for each SS05 and RIN request.	Y	√	N/A
g) All components of the SDP deliverables contain original documents where possible.	Y	√	φ
h) There is no inclusion of required items in the SDP by reference to another SDP.	Y	√	φ
i) Site samples are exclusively used for sample matrix QC	Y	√	φ
j) Site and non Site samples are not reported together in any way	Y	√	φ
k) The complete sample data package is single sided and consecutively paginated.	Y	√	
4. CHAIN-OF-CUSTODY, HOLDING TIMES, AND SAMPLE PRESERVATION	Reply	√	C#
a) The continuity of each sample's custody is evidenced by the chain of the date, time and signatures of each transaction from sample collection to receipt by the laboratory.	Y	√	
b) If the continuity was corrupted, documentation of correspondence with the CTR is included.	Y	√	
c) All samples are identified on the COC with the corresponding Line Item Codes (analyses).	Y	√	
d) The pH of each sample and the shipping container temperature are recorded, where applicable; preservation was consistent with PSA Module.	Y	√	
e) Any conflicting, incorrect, or missing information are identified and documented; and there is documentation of the resolution.	Y	√	
f) Analytical and preparation holding times were met for all sample analyses.	Y	√	
g) Following sample receipt by the lab, samples were properly adjusted to the correct pH and were stored at the appropriate temperature, if required.	Y	√	

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Data Review Checklist
SS05 Sample Data Package

5. NARRATIVE	Reply	√	C#
a) Contains a synopsis of the analytical and preparation methods; and identifies base methods and any deviations of the base methods.	Y	√	
b) Contains a description of the samples; describes samples which are of a similar matrix..	Y	√	
c) Contains synopsis of Analytical Batch QC assessment. All anomalies, deficiencies, interferences, reanalyses, and deviations from approved SOPs related to the analysis are explained. Contains a QC assessment for the RIN which includes a discussion of all items with an "N" reply on the SSO5 DRC.	Y	√	
1) statement about N, *, and E flags	Y	√	
2) statement if dilutions were required, and all dilutions explained	Y	√	
3) statement that RDLs were or were not met for all analytes	Y	√	
4) discussion of any RDLs which were not met	Y	√	
5) discussion of all analyses performed by Method of Additions	Y	√	
d) Samples requiring reanalysis are identified with the reason for reanalysis, the original and reanalysis Analytical Batch Identification Numbers, and a synopsis of the reanalysis Analytical Batch QC assessment is included.	Y	√	
e) For any deviations that required CTR approval, the correspondence and approval are documented.	Y	√	
f) Any holding-time compliances and violations are described in Narrative.	Y	√	

6. SAMPLE AND QC RESULTS SUMMARY	Reply	√	C#
The Sample and QC Sample Results Summary Package is present and all pages are labeled with the Lab Code and the RIN. The Sample and QC Sample Results Summary Package includes:	Y	√	
a) Form 1s (Sample Results) are present for each sample in the RIN for this PSA Module and each includes:	Y	√	
1) one and only one result for each requested analyte.	Y	√	
2) correct results reported in the correct units for each requested analyte.	Y	√	
3) results for detected analytes factored by all dilutions.	Y	√	
4) results for non-detected analytes reported as IDLs factored by all dilutions.	Y	√	
5) results reported to the correct number of significant figures.	Y	√	
6) C, and M qualifiers entered correctly for each analyte.	Y	√	
7) Q qualifiers entered for all samples associated with QC samples receiving qualifiers.	Y	√	
8) the (IDL * dilution factor) for non-detected analyte is ≤ the specified RDLs.	Y	√	
b) Form 2As (Calibration Verification) are present and each includes:	Y	√	
1) all ICV and CCV results for all requested analytes	Y	√	
2) results for an ICV from the beginning of the run, and a CCV at the end of the run.	Y	√	φ
3) CCV results reported such that no more than 10 solutions (except CCB or ICB) were analyzed between analysis of ICVs or CCVs.	Y	√	φ
4) all ICV and CCV results within limits.	Y	√	
5) if the preceding item was marked "N", no sample data were reported when results were not within limits.	Y	√	
6) at least the minimum number of standards prescribed for each method were used to establish the initial calibration	Y	√	φ
7) The correlation coefficients of the calibration curves were > 0.995 for all GFAA and CVAA analyses.	Y	√	φ

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D a t a R e v i e w C h e c k l i s t
SS05 Sample Data Package

(continued)	Reply	√	C#
8) The calibration and ICV standards were from independent sources..	Y	√	φ
c) Form 2Bs (CRDL Standard) are present and each includes:	Y	√	
1) RDL standard results at specified concentrations for every requested analyte.	Y	√	φ
2) RDL standard results for the beginning, end, and each 8 hours within each ICPES run and at the beginning of each GFAAS and CVAA run.	Y	√	φ
3) RDL standard results were within 80-120% limits for ICP analyses.	Y	√	
d) Form 3s (Verification and Preparation Blanks) are present and each includes:	Y	√	
1) all ICB and CCB results for all requested analytes; results reported to IDLs.	Y	√	
2) results for an ICB from the beginning of the run, and a CCB at the end of the run.	Y	√	φ
3) CCB results reported such that no more than 10 solutions (except CCV) were analyzed between analysis of ICBs or CCBs.	Y	√	φ
4) the absolute values of all ICB and CCB results are less than specified IDLs.	Y	√	A1/C2
5) if the preceding item was marked "N" and the blank results are > RDL, then only results >10* the blank concentration are reported from the non-conforming analytical batch	Y	√	
6) PB results for all analytes for each analytical batch in the RIN.	Y	N	
7) the absolute values of analyte concentrations in all PBs are less than specified IDLs.	Y	√	
8) if the preceding item was marked "N" and the PB results are > RDL, then the samples containing >10* the PB concentration only are reported for that analyte from the non-conforming analytical batch.	Y	√	
e) Form 4s (Interference Check Sample) are present and each includes:	N/A	√	
1) ICSA & ICSAB results as specified for every requested analyte determined by ICPES.	N/A	√	
2) ICSA & ICSAB results for the beginning, end, and each 8 hours within each ICPES run	N/A	√	
3) all ICSA, ICSAB, and other interference check sample results within limits	N/A	√	φ
f) Form 5As (Matrix Spike) are present and each includes:	Y	√	
1) one Form 5A for each matrix, waste type, and analytical batch (max. of 20 samples).	Y	√	
2) control limits for %R assigned according to CLP-SOW	Y	√	
3) Spikes reported and completed for all applicable elements according to CLP-SOW and SS05.	Y	√	
4) "N" flags present in the Q column if %R is outside limits according to CLP-SOW	Y	√	A2
g) Form 5Bs (Post Digestion Spike) are present for each matrix and for analytes receiving N flag for ICPES or FLAAS analyses.	Y	√	
h) Form 6s (Duplicate) are present and each includes:	Y	√	
1) one Form 6 for each matrix, waste type, and analytical batch.	N	X	√
2) control limits for RPD assigned according to CLP-SOW	Y	√	
3) RPDs reported and calculated according to CLP-SOW	Y	√	φ
4) "*" flags present in the Q column if RPD is outside limits according to CLP-SOW.	Y	√	
i) Form 7s (Laboratory Control Sample) are present and each includes:	Y	√	
1) A Form 7 or LCS result for each analytical batch is present; results for all requested elements.	Y	√	
2) LCS results for all requested analytes and percent recoveries within the control limits.	Y	√	
j) Form 8s (Standard Additions) are present for each sample and analyte with Form 1 results indicating analysis by MSA.	Y	√	
k) Form 9s (Serial Dilution) are present and each includes:	N/A	√	
1) one Form 9 serial dilution for at least one sample from each matrix type and for each analytical batch analyzed by ICPES or ICP/MS.	N/A	√	

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Data Review Checklist
SS05 Sample Data Package

(continued)	Reply	√	C#
2) control limits for %D assigned according to CLP-SOW	N/A	√	
3) %D calculated according to CLP-SOW	N/A	√	φ
4) 'E' flags present in the Q column if RPD is outside limits according to CLP-SOW.	N/A	√	
l) Forms 10 (Instrument Detection Limits) are present and include IDL values for each method reported; for all reported analytes, that are less than or equal to the required RDLs.	Y	√	
1) A valid IDL study was prepared within 3 months of date of analysis for all methods	Y	√	
m) Form 11s (Interelement Correction Factors) are present for each ICPES instrument used to report data	N/A	√	
n) Form 12 (Linear Range Studies) is present for each ICPES instrument used to report data	N/A	√	
1) All reported results are from analyses within the linear range of each instrument.	N/A	√	φ
o) Form 13 (Preparation Logs) is present for each analytical batch reported and includes:	Y	√	
1) preparation data for all reported samples.	Y	√	φ
2) properly identified samples, duplicates, spikes, PBs, and LCSs.	Y	√	φ
3) QC Sample Identifiers clearly link each preparation batch QC sample (duplicate, spike, LCS, and preparation blank) with associated Site samples.	Y	√	φ
4) at least one set of duplicates, spikes, PBs, LCSs samples for each analytical batch.	Y	√	φ
5) at least one sample from each matrix type in the batch run in duplicate and spiked.	Y	√	φ
6) batch sizes of < 20 analytical samples.	Y	√	φ
p) Form 14s (Instrument Run Log) are present for each run performed and include:	Y	√	
1) all information (e.g., instrument Ids, analysis run dates, DF) are correctly entered.	Y	√	φ
2) analytical spike recoveries correctly entered for each GFAAS run.	Y	√	φ
3) reported data indicated as specified in CLP-SOW.	Y	√	φ

7. PREPARATION RAW DATA	Reply	√	C#
a) The preparation raw data (benschets and/or preparation logs) are included and document the required items as specified in the Preparation Summary Section of SS05, Exhibit B.	Y	√	φ
b) Sufficient raw data are included to allow manual calculation of the final sample results and QC sample recoveries.	Y	√	φ
c) Samples were prepared using an approved procedure in SS05 Exhibit C.			

8. STANDARDS SUMMARY	Reply	√	C#
a) For primary standards that were diluted and used for LCS and any in-house prepared instrument calibration sources, the required items as specified in the Standards Summary Section of SS05, Exhibit B are included.	Y	√	φ
b) All standard identifiers are traceable to primary certificates, which are traceable to NIST.	Y	√	φ
c) All standards and sources traceable to NIST were valid (not expired) at the time of use.	Y	√	φ

9. INSTRUMENT RAW DATA	Reply	√	C#
a) The instrument raw data for the RIN are included and document the required items as specified in SS05 Exhibit B Section 2. All data entries were verified as accurate by the reviewer.	Y	√	φ
b) The data were reviewed, signed, and dated by the area spectroscopist as acceptable.	Y	√	φ

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Data Review Checklist
SS05 Sample Data Package

c) Sufficient raw data are included to allow manual calculation of the final sample results and QC sample chemical recoveries.	Y	√	φ
d) All batch QC samples were prepared and analyzed in the same manner as the samples in the Analytical Batch, in the same time frame, and using the same instrument parameters, etc.	Y	√	φ
10. ELECTRONIC DATA DELIVERABLE (EDD)	Reply	√	C#
a) The EDD accurately reflects the data contained in the Sample Data Package	Y	√	
b) The hard copy of the EDD as specified in Exhibit B Section 4 is included with the Sample Data Package. The hard copy includes data file name and means of transmittal.	Y	√	
c) An automated EDD verification check has been performed.	Y	√	φ

Shaded areas are for Site use only.

*Respond to each checklist item in the "Reply" column with a Y (yes), N (no), or NA (not applicable).
Complete footer information, including the initials of the laboratory manager or designee on each page.
Refer to Module GR01, Exhibit B, Section 4 for instructions to complete this form.*

I certify that all responses to this checklist accurately reflect the completeness and quality aspects of this sample data package as outlined in GR01 and SS05. Furthermore, I understand that inaccuracies in the completion of this checklist will be considered a nonconformance to Subcontract Requirements as evidenced by the following signature of the laboratory manager or designee.

Print/Typed Name: _____ Title: _____

Signature _____ Date _____

For Data Assessment Use Only

DATA REVIEW CHECKLIST EXAMINATION		
Assessment of this Sample Data Package is based on the following documents: DA-GR01 Version <u>1</u> DA-SS05 Version <u>1</u>		
This Sample Data Package requires the following assessment level: <input type="checkbox"/> No Further Assessment <input type="checkbox"/> Partial Verification <input checked="" type="checkbox"/> Complete Verification <input type="checkbox"/> Validation Assessment Level is based on: <input type="checkbox"/> Examination <input checked="" type="checkbox"/> Customer <input type="checkbox"/> Laboratory Assessment Program		
Notes:		
_____	_____	_____
Examiner	Signature	Date

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Analytical Batch Identification No.(s): BL0123

PARTIAL VERIFICATION

- This Sample Data Package requires no further assessment (See attached Data Quality Assessment Report)
- This Sample Data Package requires further assessment at the following level:
 - Complete Verification
 - Validation

Notes:

Data Verifier

Signature

Date

COMPLETE VERIFICATION

- This Sample Data Package requires no further assessment (See attached Data Quality Assessment Report)
- This Sample Data Package requires validation

Notes:

Data Verifier

Signature

Date

RIN: 97L1234 Lab Name: Best Lab Initials: _____

Analytical Batch Identification No.(s): BL0123

Attachment 3: Data Quality Assessment Report Example

SS05

**Data Quality Assessment Report
Rocky Flats Environmental Technology Site**

RIN Number	Analytical Method/PSA Line Item	Review Level
97A1234.	Mercury SS05B025	Complete Verification

Analytical Laboratory	Assessment Performed by	Number of Samples/ Matrix
Best Lab	ASD	3/Soil, 1/Water

Sample Numbers: ABC-1, ABC-2, ABC-3, FB-1

Quality Control Item	Reviewed	Non-Compliance Identified
General (Cover Page, Table of Contents, DRC Checklist, General SDP Requirements Narrative)	Y	Comments 1 & 2
Chain of Custody, Preservation, and Holdings	Y	N
Sample Results	Y	N
Calibration Verification, CRDL Standard	N/A	N
Verification and Preparation Blanks	Y	Action Item 1
Interference Check Sample	N/A	N
Matrix Spike	Y	Action Item 2
Duplicates	Y	N
Laboratory Control Sample	Y	N
Standard Additions	N/A	N
ICP Serial Dilution	N/A	N
Instrument Detection Limits	N	N
Other: Interelement Correction Factors, Linear Range Studies, Preparation Logs, Instrument Run Log	Y	N
Preparation and Instrument RAW Data	Y	N
Standards	N	N
EDD	Y	N

Y Item was reviewed or non-compliance was identified

N Item was not reviewed or non-compliance was not identified

N/A Item is not applicable to the Line Item

Action Items:

A Non-Compliance Notification was issued for the following comment:

1. *(Item 6-d-4)* The following sample results were qualified as estimated and undetected (J 107) due to negative ICB and CCB results (Reference May 1,1997 Non-Compliance Notification for Problem #1):
 - Mercury in samples ABC-1, ABC 2, and FB-1

2. *(Item 6-f-4)* The following sample results were qualified as estimated [J 112] due to the matrix spike recovery was less than 75%:
 - Mercury in samples ABC-1, ABC 2, ABC-3, and FB-1

Comments:

1. *(DRC Item 2-a)* The Table of Contents page was not numbered. Reason code [804] was assigned to all data points in the Sample Data Package.

A Non-Compliance Notification was issued for the following comment:

2. *(DRC Item 1-a)* The cover page for this RIN is missing. Reason Code [802] was assigned to all data points in the Sample Data Package. Reference May 1,1997 Non-Compliance Notification for Problem #2.

Verification/Validation Signature _____

Date: _____

Reviewer Signature _____
(Validation Only)

Date: _____

GENERAL GUIDELINES

Author	Reference	ID Number	Version	Issue	Status
Kaiser-Hill	General Guidelines for Data Verification and Validation	DA-GR01	v1	3-Dec-97	Superceded
			v2	1-Oct-02	Active

RADIOCHEMISTRY GUIDELINES

Author	Reference	ID Number	Version	Issue	Status
Kaiser-Hill	V&V Guidelines for Isotopic Determinations by Alpha Spectrometry	DA-RC01	v1	13-Feb-98	Superceded
			v2	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for Tritium Analysis by Liquid Scintillation Counting	DA-RC02	v1	16-Feb-98	Superceded
			v2	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for the Determination of Radionuclides by Gamma Spectrometry	DA-RC03	v1	14-May-98	Inactive
			v2	Not Issued	N/A
Kaiser-Hill	V&V Guidelines for Gross Alpha and Gross Beta by GPC	DA-RC04	v1	13-Feb-98	Superceded
			v2	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for Radiometric Strontium by GPC	DA-RC05	v1	13-Feb-98	Superceded
			v2	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for Total Uranium by Laser Induced Phosphorescence	DA-RC06	v1	16-Feb-98	Active
Kaiser-Hill	V&V Guidelines for Radionuclides by Gamma Spectrometry	DA-GAM	v1	1-Oct-02	Active

STANDARD SERVICES GUIDELINES

Author	Reference	ID Number	Version	Issue	Status
Kaiser-Hill	V&V Guidelines for Volatile Organics	DA-SS01	v1	3-Dec-97	Superceded
			v2	Not Issued	N/A
			v3	1-Oct-02	Superceded
			v4	15-Nov-02	Active
Kaiser-Hill	V&V Guidelines for Semivolatile Organics	DA-SS02	v1	3-Dec-97	Superceded
			v2	Not Issued	N/A
			v3	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for PCB/Pesticides Analyses	DA-SS03	v1	14-Jan-98	Superceded
			v2	Not Issued	N/A
			v3	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for Metals	DA-SS05	v1	18-Dec-97	Superceded
			v2	Not Issued	N/A
			v3	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for Water Quality Parameters Analyses	DA-SS06	v1	19-Dec-97	Superceded
			v2	Not Issued	N/A
			v3	1-Oct-02	Active
Kaiser-Hill	V&V Guidelines for Waste Characteristics Analyses	DA-SS08	v1	12-Feb-98	Inactive
			v2	Not Issued	N/A
Kaiser-Hill	V&V Metals Determinations by XRF	DA-XRF	v1	15-Nov-02	Superceded
			v2	17-Apr-03	Active

OTHER GUIDELINES

Author	Reference	ID Number	Version	Issue	Status
Lockheed-Martin	Evaluation of Radiochemical Data Usability, ES/ER/MS-5				
US EPA	USEPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review	540/R-94/013			
US EPA	USEPA Contract Laboratory Program National Functional Guidelines for Organic Data Review	540/R-94/012			

Attachment 4: Non-Compliance Notification Example

Date: May 1, 1997

To: Best Lab

From: Jane Doe, CTR, Kaiser-Hill Performance Assurance

Affected RIN: 97A1234

Parameter Specific Analytical Module: SS05B.1

Problem #1 Explanation:

Negative CCB and ICB results with absolute values greater than the IDL are not properly recorded on Form 3. All ICB and CCB results which are below the negative value of the IDL must be reported as the actual measured concentration. CCBs analyzed by Instrument ID *TJA61E* at 10:23, 11:06, and 12:49 contained analyte values which were less than the negative IDL but were reported as IDL U.

Problem #1 Source Requirements:

- SS05 Exhibit D, Section SS05-A Exhibit D Sections 4.9 and 4.10
- ILM4.0 Exhibit B Section III, Blanks, (bottom of page B-25)

Problem #1 Required Actions:

Please provide a corrective action plan and implementation date to prevent further occurrences of this non-compliance within two weeks of the date listed above.

Problem #2 Explanation:

The Cover Page for this RIN is missing.

Problem #2 Source Requirements:

- GR01 Exhibit B § 4.5.

Problem #2 Required Actions:

Please provide the Cover Page within one week of the date listed above.

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