

**START**

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**RELEASE INSTRUCTIONS (RI)**

DOCUMENT NO.:

WHC-CM-5-4

PAGE 1 OF 1

TO:

D. A. Isom  
Copy #072

H6-08

TITLE: Laboratories Administration

RELEASE NO.: 056

DATE PREPARED: March 31, 1997

I have entered this release into the document per instructions.

Debbi Isom  
Signature

4/28/97  
Date

If you have any questions about this release contact:

Jean Feaster  
Phone: 373-4426

**INSTRUCTIONS**

1. REMOVE AND/OR INSERT INDICATED SECTIONS INTO DOCUMENT AS SHOWN BELOW.
2. UPDATE THE RELEASE RECORD AT THE FRONT OF THE DOCUMENT.
3. SIGN THIS FORM AND RETURN IT TO DOCUMENTATION ADMINISTRATION WITHIN 5 WORKING DAYS.

SECTION NO. AND TITLE(S)	REMOVE			INSERT		
	PAGES	REV	DATE	PAGES	REV	DATE
Table of Contents	1-6	55	03/12/97	1-6	56	03/31/97
Section 3.1, "Manual Administration"	1-6	5	03/29/95	1-8	6	03/31/97
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Section 3.15, "Data Package Administrative Verification"	--	--	--	1-4	1	03/31/97
Section 3.16, "Data Package Control Requirements and Procedure"	1-12	2	05/01/96	1-10	3	03/31/97
Section 3.19, "Sample Authorization Form (SAF) Issuance and Procedure"	1-2	0	03/30/95	1-2	0, Ch 1	03/31/97

**IMPLEMENTATION NOTICE**

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All procedures updated to current practices.

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**Jean Feaster T6-03**

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2.0	<b>ORGANIZATION</b>		
NOTE:	The charter for Analytical Services may be found in WHC-CM-1, <i>Company Policies and Charters</i> .		
2.1	Charters — Section Title (no text)		
2.1.1	222-S Analytical Operations Charter	3	04/13/95
2.1.2	222-S Facility Operations Charter (incorporated into 2.1.1)	<i>Canceled</i>	10/22/93
2.1.3	Program Management and Integration Charter	2	04/05/95
2.1.4	Work Control and Data Management Charter	<i>Canceled</i>	04/26/95
2.1.5	Office of Sample Management	<i>Canceled</i>	04/26/95
2.1.6	Plutonium Finishing Plant Engineering Laboratory	<i>Canceled</i>	07/06/95
2.1.7	Process Laboratories and Technology Charter	<i>Canceled</i>	07/11/95
2.1.8	PUREX Analytical Laboratories Charter	<i>Canceled</i>	07/20/95
2.1.9	Engineering and Technology Services Charter	1	03/31/95
2.2	Committees, Boards, and Task Teams	<i>Canceled</i>	08/17/95
2.2.1	Laboratory Instrument Control Board Charter	<i>Canceled</i>	09/18/96
2.2.2	Chemical Hygiene Committee Charter	1	05/31/95
2.2.5	Laboratories ALARA Committee Charter	<i>Canceled</i>	09/14/95
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2.2.8	Laboratory Facility Plant Review Committee Charter	<i>Canceled</i>	06/12/96
2.3.1	Waste Sampling and Characterization Facility — Startup Charter	<i>Canceled</i>	04/12/95
2.3.2	Waste Sampling and Characterization Facility — Analytical Operations Charter	2	02/26/96
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3.1-A	Manual Administration — Procedure (incorporated into Section 3.1, Rev. 5)	<i>Canceled</i>	04/05/95
3.2	Out-of-Tolerance Report System	<i>Canceled</i>	01/15/93
3.3	Corrective Action Requirements, Occurrence Categorization, Notification, and Reporting (moved to 6.7)	<i>Canceled</i>	09/13/93
3.4	Data Package Preparation	<i>Canceled</i>	03/03/97
3.5	Administration for Nuclear Materials	4	09/09/96
3.6	Laboratories Entry Requirements	0	03/07/95
3.7	222-S Complex Radiological Postings	<i>Canceled</i>	07/25/95
3.8	Shift Turnover at 222-S Laboratories Complex	<i>Canceled</i>	07/06/95
3.9	Laboratory Procedures Change 1 (3, 21-22)	5	01/15/96 02/20/97
3.10	Procedure Changes and Procedure Change Authorizations (incorporated into 3.9, Rev. 3)	<i>Canceled</i>	03/23/95
3.11	Format and Content Guide for Analytical Services Technical Procedures	0	11/03/95
3.12	Internal Audit Program (moved to 8.5)	<i>Canceled</i>	08/15/94
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March 31, 1997

Manual Administration

Approved by

 3/27/97

A. G. King, Manager  
Hanford Analytical Services

Author:  
Organization:

P. J. Noakes  
HAS Records

**1.0 PURPOSE**

This section establishes the administration of Hanford Analytical Services (HAS) controlled manual sections. The manual incorporates information such as administrative requirements, conduct of operations principles, training requirements, HAS job control system administration, control systems for safe lab operations, and radiological control information. It is used by all HAS personnel during normal work assignments unless specifically excluded.

**2.0 SCOPE**

This section applies to the HAS controlled manual, WHC-CM-5-4, *Laboratories Administration*.

**3.0 DEFINITIONS**

**Annual Review**

The process of ensuring that a section meets and reflects all applicable changes that have been made since the last revision.

**Approval Authority**

The Manager, Hanford Analytical Services, is the approval authority for the WHC-CM-5-4 manual. The manager may delegate approval authority to other staff members as needed.

**Laboratory Technical Information Center (LTIC)**

Information center in which copies of HAS records and historical information reside.

**Manual Administrator**

HAS Records staff member who processes sections and maintains controlled copies of this manual.

**Section Champion**

Section Champions are facility-designated personnel with the necessary knowledge and experience to fulfill the applicable responsibilities. Section champions are assigned responsibility for section content and annual review.

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\*This revision is a total rewrite; therefore, no redlines are used to indicate changes.

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**Manual Administration**

**WHC-CM-5-4 Section Review and Approval Form (RAF)**

The form used to document changes, annual reviews, and approvals of WHC-CM-5-4 sections.

**4.0 REQUIREMENTS**

Each manual section is required to have an annual review. This review is documented on a WHC-CM-5-4 Section RAF and maintained in the history files.

The manual administrator is required to promptly notify manual users of all updates and to ensure that updates are distributed, both electronically and in hard copy form, in a timely manner to manual holders. A number of controlled copies are maintained by the manual administrator. A listing of controlled copy holders is located on the Laboratory Procedures network drive, along with the current electronic copy of the manual.

Manual holders external to Hanford Analytical Services are required to update their hard copy manual and return signed Release Instruction forms to HAS Records.

**5.0 RESPONSIBILITIES**

**5.1 Manual Administrator**

The manual administrator is responsible for processing and distributing manual sections, and maintaining controlled copies both electronically and in hard copy form, in a timely manner.

**5.2 Section Champion**

Section champions are responsible for reviewing assigned manual sections for compliance and applicability on an annual basis. In addition, they determine designated reviewers and disposition comments resulting from section reviews.

**5.3 Designated Reviewers**

Designated reviewers are appointed by the section champion and are responsible for reviewing manual sections in their field of expertise.

**5.4 Approval Authority**

The approval authority is responsible for final approval of each manual section.

**5.5 Manual Custodians**

Manual custodians are responsible for maintaining and updating assigned reference copies of the WHC-CM-5-4 manual.

**Manual Administration****6.0 RECORDS**

In addition to the requirements listed below, any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

**6.1 History Files**

History files are maintained by the manual administrator and the LTIC. They contain background information regarding manual revisions, signed master copies of each revision, and lists of individuals assigned copies of the manual.

**6.2 Working (In Process) Files**

Working or in process files are maintained by the manual administrator. These files contain information regarding the change currently in process, such as designated reviewers and comments submitted during the review process.

**7.0 PROCEDURE**

HAS employee submits addition, deletion, change, or new section information to Manual Administrator.

If section already exists, skip to Step 7.2. If a section is new, the following steps are performed.

**7.1 New Section**

- 7.1.1 Manual Administrator assigns and issues number for section.
- 7.1.2 Manual Administrator enters information regarding section into database for tracking purposes.
- 7.1.3 Manual Administrator performs preliminary section formatting and submits for editing.
- 7.1.4 When editing is complete, Manual Administrator submits section to Section Champion for review and approval.
- 7.1.5 Section Champion determines designated reviewers, such as the following:
  - Section Champion
  - Peer review
  - Environmental compliance
  - Industrial Safety, Industrial Hygiene, or Radiological Control
  - Quality Systems
  - Outside independent review

**Manual Administration**

- Manager/approval authority.

7.1.6 Section Champion resolves and dispositions comments, and submits to Manual Administrator.

7.1.7 Manual Administrator incorporates comments.

7.1.8 Manual Administrator prepares document for approval authority signature.

7.1.9 Manual Administrator submits document to approval authority for final signature.

7.1.10 Approval authority returns document to Manual Administrator for issuance.

7.1.11 Manual Administrator assists in resolving and dispositioning any comments from the approval authority with Section Champion.

7.1.12 Manual Administrator incorporates any remaining comments and prepares document for issuance.

7.1.13 Manual Administrator electronically distributes section to reference manual custodians.

7.1.14 Manual Administrator distributes hard copies of sections to controlled copy locations.

7.1.15 Manual Administrator notifies management by sending notification via cc:Mail that changes have been made.

7.1.16 Manual Administrator files working package in history files.

7.1.17 Manual Administrator ensures current version of section is transferred to network drive, previous versions are removed from active directory, and electronic manual users are notified that a new section is available for use.

**7.2 Revision**

If section already exists and the change is determined to be a revision, the following steps are performed. If the change is determined to be editorial or minor in nature, a page change may be instituted. Refer to Section 7.3 for information regarding page changes.

7.2.1 With concurrence of Section Champion, Manual Administrator incorporates changes.

7.2.2 Manual Administrator reformats section (if necessary) and submits for editing.

7.2.3 When editing is complete, Manual Administrator submits section to Section Champion for review and approval.

7.2.4 Section Champion determines designated reviewers, such as:

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- Section Champion
- Peer review
- Environmental compliance
- Industrial Safety, Industrial Hygiene, or Radiological Control
- Quality Systems
- Outside independent review
- Manager/approval authority.

7.2.5 Section Champion resolves and dispositions comments, and submits to Manual Administrator.

7.2.6 Manual Administrator incorporates comments.

7.2.7 Manual Administrator prepares document for approval authority signature.

7.2.8 Manual Administrator submits document to approval authority for final signature.

7.2.9 Approval authority returns document to Manual Administrator for issuance.

7.2.10 Manual Administrator assists in resolving and dispositioning any comments from the approval authority with Section Champion.

7.2.11 Manual Administrator incorporates any remaining comments and prepares document for issuance.

7.2.12 Manual Administrator electronically distributes section to reference manual custodians.

7.2.13 Manual Administrator distributes hard copies of sections to controlled copy locations.

7.2.14 Manual Administrator notifies management by sending notification via cc:Mail that changes have been made.

7.2.15 Manual Administrator files working package in history files.

7.2.16 Manual Administrator ensures current version of section is transferred to network drive, previous versions are removed from active directory, and electronic manual users are notified that a new section is available for use.

7.2.17 If a waiver to a previously published section is required, the Manual Administrator processes the waiver in accordance with WHC-CM-1-3, *Management Requirements and Procedures*, MRP 2.21, "Controlled Manual Waiver Process."

**7.3 Page Changes**

7.3.1 With concurrence of Section Champion, Manual Administrator incorporates changes.

**Manual Administration**

7.3.2 Section Champion obtains required signatures. Minimum signatures for a page change include:

- Section Champion
- Manual Administrator
- Approval Authority

Other signatures may be obtained at the request of the Section Champion.

7.3.3 Manual Administrator identifies page change in the header of the affected page(s). A page change is documented in the Table of Contents of the manual.

7.3.4 Manual Administrator distributes page change in accordance with Section 7.4 below.

**7.4 Distribution of Changes**

WHC-CM-5-4 manual sections are available electronically immediately after section approval. Designated controlled copy custodians will receive hard copies, which are maintained by HAS Records, to ensure immediate availability to users.

After each section has been reviewed and approved, the following steps are performed.

7.4.1 Manual Administrator prepares a Release Instruction to accompany the manual section. Each issuance of a section may be considered a "release" or several sections may be combined. An updated Table of Contents containing the revision information and new release number is distributed with each release.

7.4.2 Manual Administrator distributes the section to designated custodians.

7.4.3 Manual Administrator distributes the section (via plant mail) to designated reference copy custodians.

**7.5 Section Cancellation**

7.5.1 Section Champion submits RAF to Manual Administrator.

7.5.2 Manual Administrator obtains any additional signatures needed on the RAF.

7.5.3 Manual Administrator notifies manual users via cc:Mail that section has been canceled.

7.5.4 Manual Administrator removes section from the Lab Procedures Drive.

7.5.5 Manual Administrator ensures that section cancellation is incorporated into upcoming release of manual so that all copies are removed in a timely manner.

7.5.6 If a canceled section needs to be reactivated, the procedure for a new or revised section is followed to ensure all necessary reviews and concurrences are obtained.

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Manual Administration

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**8.0 DESIGNATED REVIEWERS**

<u>Designated Reviewing Organizations</u>	<u>MSIN</u>
HAS Records (Champion)	T6-03

**9.0 FORMS**

WHC-CM-5-4 Section Review and Approval Form (RAF)

**10.0 REFERENCE**

WHC-CM-1-3, *Management Requirements and Procedures*.  
MRP 2.21, "Controlled Manual Waiver Process"

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March 31, 1997

Laboratory Sample Tracking	Approved by  3/27/97 A. G. King, Manager Hanford Analytical Services
	Author: B. M. Colley Organization: Sample Management

### 1.0 PURPOSE

This section establishes the requirements for tracking samples and documenting nonconformance. Sample data packages will be tracked from the time of collection through final transmittal to the Records Holding Area (RHA) or until inserted into the Supporting Document (SD) publishing system. Sample tracking activities are to be performed in accordance with Quality Assurance requirements set forth in WHC-CM-4-2, *Quality Assurance Manual*, QR 8.0, and QR 15.0.

### 2.0 SCOPE

This procedure establishes the method used by Sample Management (SM) to track samples and document nonconformance of samples. Samples are tracked from the time they are collected to transmittal of the analytical laboratory data package to the Records Holding Area (RHA).

### 3.0 DEFINITIONS

#### Analytical Laboratory Data Package

Consists of documentation (hard copy) generated during transport and receipt of field samples, sample movement in the laboratory, preparation for analysis, laboratory analyses output, raw and processed data, analytical results, reanalysis, quality control sample results, and instrument calibration data, plus a summary of final results for each batch or delivery group.

#### Laboratory Specific Notebook

Consists of "information only" copies of the Chain of Custody, Sample Analysis Request, and shipping documentation received from laboratories for all Project Hanford Management Contract (PHMC) samples received by that specific laboratory.

#### Nonconformance

A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

#### Sample Disposition Report (SDR)

A document used to identify, record, and direct laboratory disposition of sample anomalies.

**Laboratory Sample Tracking****4.0 REQUIREMENTS**

- | 4.1 Sample documentation may be tracked through Hanford Analytical Services (HAS).
- | 4.1.1 If HAS is used, the HAS project coordinator will be responsible for initiation and distribution of documentation on sample anomalies and/or nonconformance, including:
- | 1. Generation of sample disposition report (SDR) forms for recording sample anomalies and directing the laboratory's disposition of the sample.
  - | 2. Transmittal of SDR forms to the Customer Technical Representative for approval.
  - | 3. Distribution of the approved SDR to the laboratory.
- | Projects electing not to utilize HAS for sample tracking will provide an alternative method providing equal accountability/traceability.
- | 4.2 Receiving laboratories will be notified of sample shipments.
- | 4.2.1 The field sampler will provide documentation to Sample Management within 24 hours of sample shipment. The HAS Project Coordinator will provide advance notice to the receiving laboratory if sample shipments will be made on holidays or weekends.
- | 4.3 Sample Management will provide administration of:
- | • Sample tracking activities.
  - | • Closure activities associated with SDRs.
  - | • SDR tracking activities.
  - | • Verifying completeness of Chain-of-Custody (COC) information copies and associated documentation.
  - | • Identification and submission of documentation deficiencies to the Project Coordinator.
  - | • Database entry.
- | 4.4 Customer/Technical Representatives will interface with Sample Management.
- | 4.4.1 The customer/technical representative will notify Sample Management of sample shipments and participate in SDR reviews, including:
- | a. Ensuring that Chain-Of-Custody (COC) and shipping documentation is transmitted to Sample Management via facsimile or plant mail within 24 hours of sample shipment.

## Laboratory Sample Tracking

- b. Reviewing, approving, and transmitting SDRs to the HAS Project Coordinator.

## 5.0 PROCEDURE

**NOTE:** If sample is shipped to arrive at off-site laboratory during normal work week, Step 1 is performed. If sample is shipped to arrive at off-site laboratory on weekend or holiday, Steps 3 and 4 shall be performed.

- |                     |  |
|---------------------|--|
| Field Sampler       | <ol style="list-style-type: none"> <li>1. Send via facsimile "information only" copies of Chain-of Custody (COC), Sample Analysis Request (SAR), and shipping documentation to Sample Management within 24 hours of sample shipment.</li> <li>2. Determine when sample will arrive at laboratory.</li> </ol> <p><u>If sample will arrive on weekend or holiday:</u></p> <ol style="list-style-type: none"> <li>3. Provide the following information to the project coordinator within 24 hours of sample shipment:           <ol style="list-style-type: none"> <li>a. Airbill number</li> <li>b. Sample number(s)</li> <li>c. Type of sample(s)</li> <li>d. Sample priority</li> <li>e. Number of coolers shipped.</li> </ol> </li> </ol> |
| Project Coordinator | <ol style="list-style-type: none"> <li>4. Receive notice from field sampler. Telephone the off-site laboratory and provide the information received in Step 3 to the laboratory.</li> </ol>  |
| Data Entry          | <ol style="list-style-type: none"> <li>5. Enter the following information into the sample tracking database from the field copies of the COC, SAR, and shipping documentation:           <ol style="list-style-type: none"> <li>a. Client sample number/Hanford Environmental Information System number</li> <li>b. Laboratory</li> <li>c. Date sample collected</li> </ol> </li> </ol>  |

Laboratory Sample Tracking

- d. Sampling site
- e. Matrix
- f. Program
- g. Priority of analysis
- h. Remarks
- i. Analyses requested.

6. Stamp copies of COC, SAR, and shipping documentation with "FIELD COPY" stamp and place in the laboratory specific notebook.

**NOTE:** The laboratory specific notebook shall be stored in a 1-hour fire rated cabinet until COC is received in an analytical laboratory data package.

- 7. Receive facsimile copy of COC, SAR and shipping documentation from the laboratory.
- 8. Stamp copies "LABORATORY COPY."
- 9. Ensure that COC was maintained by verifying field sampler and receiving laboratory signatures are present on COC form. Also ensure that date and time of receipt are noted on COC form.

**NOTE:** Sample anomalies shall be resolved by the project coordinator and Sample Management.

**Project Coordinator**

If Deficiencies or irregularities are discovered during laboratory COC documentation verification and sample tracking:

10. Initiate a Sample Disposition Report. If no deficiencies or irregularities are discovered go to Step 18.

If Deficiencies or irregularities are discovered:

11. Generate an SDR in the sample tracking system.

12. Enter the following information on the SDR:

- a. SDR number
- b. Date initiated

Laboratory Sample Tracking

- | c. SDR status
- | d. SDR class
- | e. Issue type
- | f. Sample Identification Number(s)
- | g. Disposition type
- | h. Issue description
- | i. Disposition description

13. Request Customer/Technical Representative to review and approved completed SDR.

| Data Entry Clerk | 14. Place copy of completed SDR in Sample Management technical file.

Project Coordinator | 15. Transmit facsimile copy of SDR to laboratory and mail original (to laboratory).

NOTE: Ensure that all sample anomalies have been identified and sample disposition instructions are included on SDR before it is filed/mailed.

Data Entry Clerk | 16. Enter the following information into the sample tracking database when the laboratory copy of the COC is received from the laboratory.

a. Date/time sample received by laboratory

| b. Sample delivery group (SDG) number

| c. SDG closure date

d. Remarks.

| 17. Remove "FIELD COPY" from laboratory specific notebook and place "LABORATORY COPY" in notebook.

| 18. Destroy "FIELD COPY."

NOTE: The laboratory specific notebook shall be stored in a 1-hour fire rated cabinet until the analytical laboratory data package with the COC documentation is received.

**Laboratory Sample Tracking**

- | 19. Enter the following information into the sample tracking database upon receipt of the analytical laboratory data package:
  - | a. Data package status
  - | b. Sample status information
- | 20. Complete verification and validation process of analytical laboratory data package.
- | 21. Send data package to permanent storage.
- | 22. Enter the following information into the sample tracking database:
  - a. Date record copy transmitted
  - b. Record copy transmitted number.
- | 23. Receive signed copy of the transmittal form from the permanent storage transmittal.
- | 24. Enter the date received at the permanent storage destination into the sample tracking database.

**6.0 RECORDS**

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

**7.0 DESIGNATED REVIEWERS**

<u>Designated Reviewing Organizations</u>	<u>MSIN</u>
Sample Management	E6-06
Quality Systems	T6-04

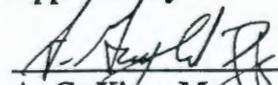
**8.0 REFERENCES**

WHC-CM-4-2, *Quality Assurance Manual*,  
 QR 8.0, "Identification and Control of Items."  
 QR 15.0, "Control of Nonconforming Items."

March 31, 1997

Data Package Administrative  
Verification

Approved by

  
A. G. King, Manager  
Hanford Analytical Services

Author:  
Organization:

B. M. Colley  
Sample Management

**1.0 PURPOSE**

This procedure identifies the administrative verification method used by Sample Management to ensure data package quality and completeness prior to transmittal of the record copy to the Records Holding Area (RHA). The data verification process is performed in accordance with Information Resource Management requirements set forth in WHC-CM-3-5, *Document Control and Records Management Manual*, Section 9, "Quality Assurance Records," and WHC-CM-4-2, *Quality Assurance Manual*, Section QR 7.0, "Control of Purchased Items and Services."

**2.0 SCOPE**

This procedure applies to all data packages that are received by the Sample Management organization of Hanford Analytical Services.

**3.0 DEFINITIONS**

**Analytical Laboratory Data Packages**

Documentation (hard copy) generated during transport and receipt of field samples, sample movement in the laboratory, preparation for analysis, laboratory analyses output, raw and processed data, analytical results, reanalysis, quality control sample results, and instrument calibration data, plus a summary of final results for each batch or delivery group.

**Verification**

The act of reviewing, inspecting, checking, auditing, or otherwise determining and documenting whether analytical laboratory data packages conform to specified requirements.

**4.0 RESPONSIBILITIES**

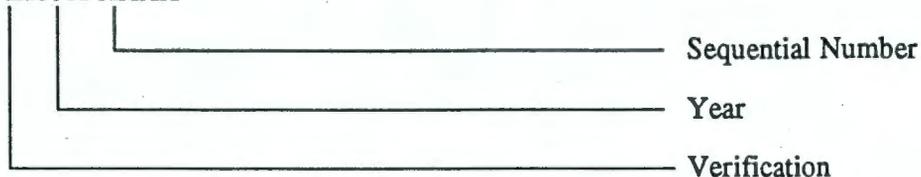
The Sample Management (SM) organization is responsible for the performance of all steps in this section.

**Data Package Administrative Verification****5.0 PROCEDURE**

**NOTE:** All steps are performed by the SM data management clerk, unless otherwise noted.

**5.1** Assign identification number as follows upon completion of receipt/control activities.

VER-9X-XXXX



**NOTE:** An analytical laboratory data package verification log is maintained to track sequential numbers.

**5.2** Enter the following information on the Administrative Verification Form:

- a. Verification Start Date/Verifier
- b. Sample Delivery Group
- c. Laboratory
- d. Sample Number(s)
- e. Sample Authorization Form (SAF) number
- f. Project

**NOTE:** Analytical laboratory data package will not be written on during the verification process.

**5.3** Perform a page by page review of the analytical laboratory data package to verify that it is paginated, of good copy quality, and complete.

**5.4** Document each deficiency noted in Step 5.3 on the Administrative Verification Form.

**5.5** Sign the Administrative Verification Form.

**5.6** Perform data entry into sample tracking databases to track verification form numbers and process dates.

**5.7** Submit all deficiencies to the laboratory for correction.

**5.8** File a copy of the Administrative Verification Form in the analytical laboratory data package and in the Sample Management technical files until closure occurs.

Data Package Administrative Verification

- 5.9 Close the Administrative Verification Form upon return of corrected items from the laboratory.
- 5.10 Replace previous copies in the analytical laboratory data package and technical files with closed Administrative Verification Form(s).
- 5.11 Update Sample Management databases to reflect closure of verification documentation dates.

6.0 RECORDS

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

7.0 DESIGNATED REVIEWING ORGANIZATIONS

<u>Designated Reviewing Organizations</u>	<u>MSIN</u>
Sample Management (Champion)	E6-06
Quality Systems	T6-04

8.0 REFERENCES

WHC-CM-3-5, *Document Control and Records Management Manual*

WHC-CM-4-2, *Quality Assurance Manual*

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WHC-CM-5-4, *Laboratories Administration*

3.15

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Data Package Administrative Verification

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March 31, 1997

Data Package Control Requirements and Procedure	Approved by  A. G. King, Manager Hanford Analytical Services
Author: Organization:	B. M. Colley Sample Management

1.0 PURPOSE

This section applies to analytical data packages and related quality affecting data. The Hanford Analytical Services (HAS) Sample Management group involved in data package activities has the requirement to provide security and positive control of analytical data packages and associated documentation.

NOTE: For the purpose of this section, data packages, analytical cards, raw data, and other associated items will be referred to as "documents."

2.0 REQUIREMENTS

2.1 Receipt Control

2.1.1 Sample Management (SM) file custodian(s) will process received documents.

- This will include completion of receipt activities, document identification and marking, and data entry into SM databases.

2.1.2 SM will log documents into the sample tracking system.

- Procedural steps for the receipt of documents can be found in section 3.0 of this manual section.

2.2 Access Control

2.2.1 Documents will be access controlled until final disposition.

- Access will be controlled through the use of limited access areas, custodian logbooks and/or in/out cards as applicable. All documents will be controlled until their final disposition, be it issuance as a Supporting Document or archival in accordance with WHC-CM-3-5, *Document Control and Records Management Manual*.

\*This is a total revision; therefore, no redlines have been used to indicate changes.

Data Package Control Requirements and Procedure

2.2.2 Limited access areas will be designated by management.

- Areas for the storage and preparation of data packages will be assigned by the responsible managers. Egress will be limited by lockable doors. Compliance with requirements for protection and control will be maintained (see WHC-CM-3-5).

2.2.3 Personnel allowed access will be approved by the responsible manager.

- The responsible manager or their designee has the authority to approve access. Personnel not on the access list but performing work or having reason to be in the access controlled area will be escorted by a member of the responsible organization.

2.2.4 Approved personnel may take temporary custody of documents.

- Personnel authorized access may remove documents from the controlled area with proper documentation. The documents will be signed-out by the file custodian, maintaining chain-of-custody.

2.2.5 Documentation will be kept to track records outside of limited access areas.

1. Documentation used will be as follows:

- |                                  |   |
|----------------------------------|---|
| a. 200 West Area, MO-028         | A logbook will be used for tracking possession. All documents will be logged in and out until issuance.     |
| b. Hanford Training Center (HTC) | In/Out Cards will be used to track possession. The cards will be used to replace a file when it is removed. |

2.2.6 Signature and date are required to release documents.

- A signature and date are required on either an In/Out Card or in the appropriate logbook before documents may be released from the limited access area.

2.2.7 The limited access area will be locked when unattended.

2.2.8 Level of protection will be maintained outside of limited access areas.

- Personnel receiving a document as the temporary custodian are required to provide equivalent access control and security until the document is returned. Documents removed from the HTC access control area will be returned the same working day.

Data Package Control Requirements and Procedure

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**2.3 Validation Control**

- 2.3.1 The project coordinator will notify data administrator when a project group is to be validated.
- 2.3.2 Data validation activities shall be performed using current revisions of the following documents:
- WHC-SD-EN-SP-001, *Data Validation Procedures for Radiochemical Analyses.*
  - WHC-SD-EN-SP-002, *Data Validation Procedures for Chemical Analyses.*

**2.4 Transmittal Control**

- 2.4.1 SM is responsible for the transmittal of documents to the appropriate destination.
- This includes the control over documents to be transmitted to validation contractors or to the Records Holding Area (RHA).
- 2.4.2 The SM Data Management Administrator will review and approve transmittal and authorization forms.
- Further information on forms and approval requirements can be found in section 3.0 of this manual section.
- 2.4.3 The Data Management Administrator will authorize the transmittal of documents to the RHA.
- The project coordinator will coordinate with the technical representative to determine if it is necessary to maintain the documents in the limited access area past specified holding times.
- 2.4.4 Documents will be transmitted to RHA as defined in requirements.
- Document transmission will be in accordance with requirements set forth in WHC-CM-3-5, Section 9.
- 2.4.5 Transmittal letters will be used for all shipments.
- Incoming shipment transmittal records will be filed in the appropriate deliverable.

**Data Package Control Requirements and Procedure****3.0 PROCEDURE**

**NOTE:** "Not applicable" is entered in those boxes on forms that are not applicable to the documentation being submitted.

**3.1 Receipt Control**

**NOTE:** Onsite documents are delivered by courier or hand delivered by laboratory personnel.

**3.1.1** The File Custodian will perform the following actions.

1. Stamp documents with date received and record copy signifier upon receipt.
2. Verify and/or enter the following information in the SM tracking system:
  - a. Hanford Environmental Information System (HEIS) sample number or client sample number
  - b. Analysis received
  - c. Project
  - d. Analytical laboratory data package status
  - e. Comments.

**NOTE:** If the laboratory that performed the analysis does not assign a delivery group number to the documents, SM will assign a delivery group number.

**3.1.2** The File Custodian will perform the following actions.

1. Place analytical laboratory document into a file folder for identification and handling protection.
2. Place original transmittal letter in appropriate analytical data package.
3. Assign a form number to a Data Folder Traveler Sheet (DFTS) and fill in the log-in and receipt information.
4. Place DFTS in the front of the document in file.

Data Package Control Requirements and Procedure

**3.2 Document Identification and Storage**

**3.2.1** Affix the following labels to the file folder:

- a. Analytical laboratory sample delivery group number
- b. Project

**3.2.2** Create a data package file index to include the following:

- a. File location
- b. Data package identification number
- c. Delivery group
- d. Project
- e. Sample numbers.

**3.2.3** File the original copy of the data package file inventory in the front of the file drawer that contains the document.

**3.2.4** Place a copy of the data package file inventory in the SM Data Package File Inventory notebook.

**NOTE:** Documents are temporarily stored by SM until verification and validation activities have been completed before transmittal to permanent storage.

**3.3 Document Transmittal To Validation Contractors**

**NOTE:** Record copy analytical laboratory data packages that require validation services are transmitted to validation contractors off-site.

**3.3.1** The Data Management Administrator will perform the following action.

- 1. Generate a Validation Services Request to notify the validation coordinator of services required.

**3.3.2** The Project Coordinator will perform the following action.

- 1. Notify Data Management when validation will occur on a project group.

**3.3.3** The File Custodian will perform the following actions.

- 1. Pull all applicable analytical laboratory documents to be validated.

**Data Package Control Requirements and Procedure**

2. Send documents to duplicating services upon completion of all verification activities to generate a dual storage copy.

**NOTE:** Data entry will be performed in SM databases to track document movement in each step in the procedure. Data entry is performed from the DFTS.

3. Perform a page-by-page review to assure the dual storage copy and the record copy are complete upon return from duplicating. If there are missing pages, contact the appropriate laboratory for replacement pages.
4. File the dual storage copy in a folder with the data package identification number of the record copy on the label.
5. Place the copy in the SM files.
6. Check the record copy for any outstanding Sample Disposition Reports (SDRs).

**NOTE:** If an SDR is open, the document will be placed in a holding drawer and the project coordinator notified for closure action.

7. Notify the validator by facsimile and follow-up phone call that the analytical laboratory data is ready for transmittal.
8. File the DFTS until the document and/or validation report is received.

**3.3.4** The Validation Clerk will perform the following actions.

1. Receive and date stamp the validation report and associated analytical laboratory data package from the validation contractor upon completion of validation.
2. Perform data entry into sample tracking database to record delivery date and documentation identification number.
3. Deliver validation report and analytical laboratory data to SM file custodian for check-in activities.
4. Perform a page-by-page review to verify completeness of the analytical laboratory data package upon receipt of record copy from validation.

**NOTE:** If the record copy is complete, the dual storage copy will be disposed.

5. Place the record copy of the document in the SM files.
6. Check-out the validation report to the validation coordinator for review.

**Data Package Control Requirements and Procedure**

3.3.5 The Validation Coordinator will perform the following actions.

1. Coordinate submittal of validation reports through the following technical reviews:
  - Project Coordination
  - QA Organization
  - DOE Contractor (if required).

**NOTE:** All comments from reviews will be reported on a Review Comment Record (RCR).

3.3.6 The Validation Clerk will perform the following actions.

1. Perform data entry to track all RCRs generated.
2. Compile RCRs and forward to validator for disposition.
3. Coordinate responses, corrections, and disposition closure, with validation contractor.
4. Receive validation report and perform data entry to record review process.
5. Provide Technical Representative with a cc:Mail copy of the validation report.
6. Return the validation documentation to SM.

3.3.7 The File Custodian will perform the following action.

1. File validation documentation in the appropriate analytical laboratory data package.

### 3.4 Document Transmittal to the Records Holding Area (RHA)

**NOTE:** Completed analytical laboratory data packages that are Tri-Party Agreement affected will have sample summary information duplicated for inclusion in the Administration Record (AR) file prior to transmittal to the RHA for permanent storage.

3.4.1 The Data Management Administrator will request a block of transmittal number labels from the records management specialist.

Data Package Control Requirements and Procedure

3.4.2 The Data Management Clerk will perform the following actions.

1. Compile projects data for transmittal.
2. Place appropriate documents in approved record storage boxes.

**NOTE:** Case file documentation will be transmitted separately on a Records Transfer/Data Input form.

3. Fill out a Quality Assurance Transmittal form including the following information:

- Retiring Department
- Data Management Administrator
- Area/Building/Room/Mail Stop/Identification Number
- Phone Number
- Organization Code
- Box Number
- Delivery Group Number
- Classification
- Inclusive Sampling Dates
- Disposal Authority
- QA Classification
- Signature of Data Management Administrator
- Index of delivery group numbers to sample numbers.

4. Fill out a Records Transfer/Data Input form to transfer corresponding case file documentation. Include the following information:

- |              |                           |
|--------------|---------------------------|
| • Company    | • MSIN                    |
| • Department | • Concurrence on disposal |
| • Custodian  | • Box number              |

**Data Package Control Requirements and Procedure**

- Location of records
- Date
- Retiring unit
- Manager
- Organization Code
- Retention Period
- Description of record
- Classification
- Inclusive dates
- Cubic feet
- Disposal authority

5. Submit the completed QA transmittal and Records Transfer/Data Input forms to the appropriate records management specialist assigned to the analytical laboratory data for review and approval.
6. Place a copy of the QA transmittal and Records Transfer/Data Input forms in the "in-process" storage boxes in SM until the signed original of the forms are received from RHA.
7. Duplicate all "sample summary information" for inclusion into the AR file if applicable.

3.4.3 A Records Management Specialist will perform the following actions.

1. Receive record copy of document.
2. Contact transportation for pickup of submittal.
3. Return a copy of the signed form to SM.

3.4.4 The Data Management Clerk will perform the following actions.

1. Update SM sample tracking databases to reflect transmittal of the document record copy to the RHA.

**NOTE:** If the copy of the signed transmittal form is not returned within 5 working days after transmittal, the RHA should be contacted to verify data package receipt.

2. File the signed copy of the QA transmittal form in the SM technical files.
3. Destroy any "in-process" transmittal forms after the signed copy has been filed.

**Data Package Control Requirements and Procedure****4.0 RECORDS**

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

**5.0 DESIGNATED REVIEWERS**

<u>Designated Reviewing Organizations</u>	<u>MSIN</u>
Sample Management (Champion)	E6-06
Quality Systems	T6-04

**6.0 REFERENCES**

WHC-CM-3-5, *Document Control and Records Management Manual*.

WHC-CM-4-2, *Quality Assurance Manual*, QR 17.0, "Quality Assurance Records."

WHC-SD-EN-SP-001, *Data Validation Procedures for Radiochemical Analyses*.

WHC-SD-EN-SP-002, *Data Validation Procedures for Chemical Analyses*.

March 31, 1997

Approved by

Sample Authorization Form (SAF) Issuance  
and Procedure  
A. G. King, Manager  
Hanford Analytical Services

Author:

B. M. Colley

Organization:

Sample Management

## 1.0 PURPOSE

This section identifies the process used to issue Sample Authorization Forms (SAFs), which authorize programs to collect samples for laboratory analysis. This section does not apply to sampling activities being managed by other Project Hanford Management Contract organizations.

## 2.0 REQUIREMENTS

2.1 Sampling authorization is in accordance with Hanford Facility Agreement.

2.1.1 Sample authorization is performed as a requirement of the *Hanford Agreement and Consent Order*, Section 3.0 "Unit Identification, Classification, and Prioritization," and Section 11.0 "Work Schedule and Other Work Plans."

2.2 Samples tracked through Hanford Analytical Services (HAS) have a SAF.

2.2.1 Sample numbers issued by HAS are directly linked to a SAF.

2.3 SAFs are approved by the Technical Representative.

2.3.1 All drafts of SAFs are reviewed and authorized by the HAS Project Coordinator. The Technical Representative approves final issuance of the SAF.

## 3.0 PROCEDURE

The following steps are taken after Hanford Analytical Services has received notification of an upcoming sampling event. Notification is received by a Project Coordinator.

3.1 The Technical Representative will notify the HAS Project Coordinator of an upcoming sampling event.

3.2 The Project Coordinator will generate a draft SAF and Field Sample Requirement (FSR) per the Technical Representative specifications.

- NOTES:**
- All information fields on the SAF and FSR are completed prior to the Project Coordinator review. Verification of charge code validity is also performed.
  - Each applicable laboratory has a unique FSR under the SAF.

3.3 The Project Coordinator will review, initial and date draft SAFs and FSRs for approval.

3.4 The Project Coordinator will perform the following actions.

3.4.1 Fax the Technical Representative a draft copy of the Coordinator reviewed SAF and FSR for approval.

3.4.2 Incorporate final comments and issue a copy of the SAF and FSR to the Technical Representative, Sample Management Data Management Administrator, and the appropriate laboratories.

**NOTE:** The Technical Representative is responsible for contacting the appropriate sampling organization to schedule sampling.

3.4.3 File the original SAF and FSR documentation in the Sample Coordination technical files.

#### 4.0 RECORDS

Any records generated as a result of activities described in this section will be managed in accordance with applicable Records Inventory and Disposition Schedules.

#### 5.0 DESIGNATED REVIEWING ORGANIZATIONS

<u>Designated Reviewing Organization</u>	<u>MSIN</u>
Sample Management (Champion)	E6-06
Quality Systems	T6-04

#### 6.0 REFERENCES

Hanford Facility and Consent Order, 89-10;  
Section 3.0, "Unit Identification, Classification and Prioritization"  
Section 11.0, "Work Schedule and Other Work Plans."