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ENGINEERING CHANGE NOTICE

Page 1 of 2

1. ECN 191327

Proj. ECN

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Station # 21

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18. Change Impact Review: Indicate the related documents (other than the engineering documents identified on Side 1) that will be affected by the change described in Block 12. Enter the affected document number in Block 19.

SDD/DD	[]	Seismic/Stress Analysis	[]	Tank Calibration Manual	[]
Functional Design Criteria	[]	Stress/Design Report	[]	Health Physics Procedure	[]
Operating Specification	[]	Interface Control Drawing	[]	Spares Multiple Unit Listing	[]
Criticality Specification	[]	Calibration Procedure	[]	Test Procedures/Specification	[]
Conceptual Design Report	[]	Installation Procedure	[]	Component Index	[]
Equipment Spec.	[]	Maintenance Procedure	[]	ASME Coded Item	[]
Const. Spec.	[]	Engineering Procedure	[]	Human Factor Consideration	[]
Procurement Spec.	[]	Operating Instruction	[]	Computer Software	[]
Vendor Information	[]	Operating Procedure	[]	Electric Circuit Schedule	[]
OM Manual	[]	Operational Safety Requirement	[]	ICRS Procedure	[]
FSAR/SAR	[]	IEFD Drawing	[]	Process Control Manual/Plan	[]
Safety Equipment List	[]	Cell Arrangement Drawing	[]	Process Flow Chart	[]
Radiation Work Permit	[]	Essential Material Specification	[]	Purchase Requisition	[]
Environmental Impact Statement	[]	Fac. Proc. Samp. Schedule	[]		[]
Environmental Report	[]	Inspection Plan	[]		[]
Environmental Permit	[]	Inventory Adjustment Request	[]		[]

19. Other Affected Documents: (NOTE: Documents listed below will not be revised by this ECN.) Signatures below indicate that the signing organization has been notified of other affected documents listed below.

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Chem. Proc. Div.				
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7. Abstract

This document outlines a strategy for Environmental Characterization, Remediation and Verification Sample Analysis and Data Validation.

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1.0 INTRODUCTION

In order to complete the Hanford Site environmental restoration process in a cost-effective and timely manner, a sample analysis and data verification and validation strategy is needed that balances site data needs and data quality necessary to achieve work plan data quality objectives (DQOs) against cost and schedule considerations. The traditional approach of analyzing large numbers of samples at a fixed laboratory (using prescriptive methodologies and the most stringent reporting requirements) leads to high cost and probable schedule delays. Alternative strategies are therefore required. These alternative strategies must continue to ensure that specified work plan DQOs can be met, and must demonstrate a reduction in the cost and turnaround time necessary to produce defensible analytical results.

The purpose of the strategy presented below is to provide guidance for implementing site-specific work plans at the Hanford Site as related to analytical and data validation resources. The strategy ensures that the data collected will meet requirements for data defensibility as well as operational needs for the availability of reliable and timely analytical results while minimizing costs. This is accomplished by providing mechanisms for the selection of appropriate, reliable analytical methods, analyte lists and appropriate validation effort levels through the proper application of the data quality objective process.

This strategy focuses resources on critical samples (those samples that are crucial to the decision-making process), provides options for the utilization of field or fixed base laboratory resources and allows for the tailoring of the data verification and validation process as appropriate for determining data quality and the attainment of work plan objectives. The implementation of this strategy is consistent with applicable and relevant guidance as will be further detailed in Section 3.0, is consistent with the development of remedial response activity DQOs and will enable EPA and other regulatory agencies to stand behind records of decision (RODs) that are based on defensible analytical data.

While this paper discusses the strategy in terms of the remedial action process under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), it is also applicable to environmental investigations conducted under the Resource Conservation and Recovery Act (RCRA) corrective action program. It can therefore be applied to RCRA facility investigations/corrective measures studies (RFI/CMSs) as well as CERCLA remedial investigations/feasibility studies (RI/FSs).

Finally this strategy discusses the use of CLP and SW-846 analytical methods in general terms only and is not intended to compare the advantages or disadvantages of CLP versus SW-846. CLP methods are discussed as examples of highly structured methods with limited applicability; on the other hand, SW-846 methods are presented as examples of broadly applicable, flexible protocols that will provide the environmental restoration personnel with options for selecting appropriate methods for analyses.

2.0 BACKGROUND

Terms specific to this paper will be defined in Section 2.1 after which a discussion of concerns regarding the use of alternate methods and data reporting requirements will be presented.

2.1 DEFINITIONS

Critical samples: Samples defined as being too costly to reacquire; samples that may define areas of potential risk; samples from an area that can not be easily and economically re-sampled due to the nature of the sampling and health and safety concerns; samples which potentially define the extent of site contamination; samples from areas which do not have analogous facilities within the operable units being sampled for comparison purposes.

Data of insufficient quality: Sample data that has been rejected due to quality deficiencies identified during data verification and validation such that it is deemed unusable for decision making. Data loss due to sample container breakage or loss in the field, during sample transport, within the laboratory, or from unforeseen circumstances will not be considered a critical data loss since these actions are inevitable and not entirely preventable.

Data of sufficient quality: Sample data that has been verified, validated, qualified to address any minor deficiencies and usable for decision making.

Non-critical samples: Samples not defined as "critical", usually those that may be easily and economically re-acquired; ground water samples are an example of non-critical samples since they can be re-sampled easily.

Environmental medium: Refers to air, biota, ground water, soil (i.e., unsaturated and saturated soils), surface water, or surface water sediments.

EPA Contract Laboratory Program- (CLP-) equivalent: A level of known and defensible data quality, suitable for use in supporting remediation decisions, obtained through the application of standard laboratory analytical procedures, rigorous quality assurance/quality control (QA/QC), and data verification and validation processes.

Screening: An analytical process whereby results are obtained more rapidly (on the order of minutes, hours, or days, as opposed to weeks or months) and inexpensively than through the use of standardized laboratory analytical procedures; screening results may be obtained either in the field or the laboratory using hand-held or bench-top instruments; screening results may be directly representative of either a single target parameter or a group of such parameters.

Source: An area of environmental medium of concern (or stratum within such medium) that, based on initial scoping efforts, is anticipated to contain maximum contaminant concentrations and diversities. Source areas would generally be found near the original point of disposal or release; there may be more than one such source area per medium for each site; initial samples of the source areas are regarded as critical.

Standard laboratory methods: Analytical methods used in the laboratory (mobile or fixed) which are based on published methods (e.g., DOE, EPA, American Society for Testing of Materials (ASTM), or American Public Health Association (APHA), U.S. Geological Survey (USGS), ...) with tailored QA/QC as sufficient for the attainment of work plan DQOs.

Target parameter list: A minimal list of analytes and compounds needed to characterize the extent of site contamination for each environmental medium of concern; the list is developed during the work plan development process in consideration of DQOs.

Validation: A systematic review process conducted to confirm the degree of accuracy and precision in an analytical measurement; the process includes the review of all pertinent sample analysis, QA, and QC data in comparison to recognized standard procedures or criteria; the review is conducted to ensure that data are acceptable for their intended use(s).

Verification: A systematic review process conducted to confirm that contractual obligations were met for a group of analytical measurements; the process includes review of data packages for completeness, checks for transcription errors and unit conversion errors and to determine if the data are sufficiently complete for validation.

2.2 DATA QUALITY CONCERNS

There has been concern expressed from the local regulatory community that data of sufficient quality will not be available for site decisions if critical, and to some extent non-critical samples are not analyzed using vigorous methods, reported with stand-alone data deliverables and verified and validated at the highest level possible. However, there is currently a consensus between EPA Region 10, EPA Headquarters and DOE Headquarters which considers CLP and other EPA methodologies (SW-846) to be equivalent therefore this concern may no longer applicable.

2.3 ANALYTICAL QA/QC CONCERNS

Concern has also been expressed that analytical methods other than CLP are inadequate to address the necessary QA/QC to support data quality objectives. The CLP statements of work (SOWs) detail specific QA/QC, contractual and reporting requirements that are not specifically outlined in other methods such as SW-846; however, CLP was designed to satisfy the data needs for enforcement actions in support of EPA-funded response actions on National Priorities List (NPL) sites. SW-846 provides a compendium of analytical methods for analytes not covered by the CLP/SOWs that may be tailored to site-specific data quality objectives. SW-846 methods, by definition, can provide comparable quantitative data and data quality by tailoring the QA/QC requirements contained therein. Finally, DOE-HQ is in the process of adapting SW-846 and other methodology for the analysis of mixed waste for chemical and radiochemical constituents. The result of this process will be the publishing of a compendium of analytical procedures that can be used for mixed waste site investigations.

3.0 APPLICABLE AND RELEVANT GUIDANCE

This section presents applicable and relevant guidance which supports the use of alternative analytical and data validation approaches to Hanford Site characterization.

3.1 TRI-PARTY AGREEMENT GUIDANCE

Section 6.5 and 7.8 of the Tri-Party Agreement (Ecology, EPA and DOE-RL 1990) state: "The QA/QC requirements shall range from those necessary for non-laboratory field screening activities to those necessary to support a comprehensive laboratory analysis that will be used in final decision-making."; further, "Based upon the data quality objectives, the DOE shall comply with EPA guidance documents for QA/QC and sampling and analysis activities which are taken to implement the Agreement. Such guidance includes:

- "Guidelines and Specifications for Preparing Quality Assurance Program Plans" (QAMS-004/80);
- "Interim Guidance and Specifications for Preparing Quality Assurance Project Plans" (QAMS-005/80);
- "Data Quality Objectives for Remedial Response Activities" (EPA/540/G-87/003 and 004)"; and
- "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA/SW-846)," (in Section 6.5 only).

The implementation of an approach that includes a range of analytical and data validation activities is in compliance with the aforementioned guidance and will meet the data quality objectives (DQO's) for current Hanford Site RI/FS (and FI/CMS) activities. Finally, the use of a combination of differing analytical techniques or levels based on DQO's is the overall theme of the DQO guidance document (CDM Federal Programs Corporation 1987).

3.2 EPA GUIDANCE

EPA's RI/FS guidance (EPA, 1988) recommends: "To facilitate the most efficient completion of the RI, mobile or non-CLP laboratories can be used to initially document the nature and extent of contamination. Selected duplicate samples can be sent to CLP laboratories to confirm and validate the analytical results from the mobile or non-CLP laboratories."

The approach presented in Section 4.0 will allow for the majority of analyses to be completed by field and laboratory methods with accompanying data verification and validation; however, samples deemed critical to the project will be sent for CLP-equivalent analyses and validated in compliance with CLP requirements to ensure that data quality objectives are met.

4.0 APPROACH

This section presents an approach to using standard methods in addition to CLP methods for Hanford Site characterization. Section 4.1 presents an analytical and data validation approach for source and near surface investigations, Section 4.2 presents the same for vadose zone investigations and Section 4.3 presents an approach for groundwater investigations. Finally, Sections 4.4 and 4.5 present an approach to analytical data reporting and data validation that is common to all three types of investigative activities.

4.1 SOURCE INVESTIGATIONS

Source investigations that require sampling and analysis activities will generally consist of sampling liquids, sludges, surface soils, and ecological materials for hazardous/radioactive substances. The target parameters analyzed will be consistent with DQOs defined in specific sampling and analysis plans. All critical samples will be analyzed using CLP-equivalent methods for the target parameter list so defined and reported with complete stand-alone data packages. Stand-alone data reports shall comply with the CLP data package format to the extent possible.

Non-critical samples will be analyzed for the parameters so designated using field screening, mobile laboratory and standard laboratory methods with data summary reports (Section 4.4.2). For samples analyzed by field screening and mobile laboratory methods a minimum number of samples will be split and analyzed as described for critical samples. The percentage of samples selected will be based on project-specific data quality objectives.

Laboratory analytical QA/QC, data reporting and data validation requirements will be as described in Sections 4.4 and 4.5.

4.2 VADOSE ZONE INVESTIGATIONS

Vadose zone investigations will generally consist of borehole sampling and analysis in and around specific locations known or suspected as representing "worst case" contamination. Sampling will generally be conducted at 5-ft depth intervals to 5-ft below the depth of detectable contamination (using field screening) or to 5-ft below the water table. Critical and non-critical sample analysis will be conducted as described in Section 4.1. Laboratory analytical QA/QC, data reporting and data validation requirements will be as described in Sections 4.4 and 4.5.

4.3 GROUNDWATER INVESTIGATIONS

Samples from groundwater wells will be considered non-critical since they can be easily re-acquired and analysis will be conducted as described in section 4.1 for non-critical samples. Laboratory analytical QA/QC, data reporting and data validation requirements will be as described in Sections 4.4 and 4.5.

4.4 LABORATORY QA/QC AND DATA REPORTING REQUIREMENTS

4.4.1 Laboratory QA/QC

Critical samples will be analyzed and reported as described in Section 4.1. Recommended laboratory QA/QC requirements for all non-critical samples are provided in Table 4-1. For the purposes of this paper, SW-846 QA/QC requirements are specified for organic and inorganic analyses, and the EG&G Rocky Flats (EG&G 1991) QA/QC protocols are specified for radiochemistry analyses. These requirements are included as examples only and are meant to facilitate further discussion of analytical, QA/QC and data reporting requirements.

4.4.2 Data Reporting

Stand-alone report deliverables for organic and inorganic analyses will comply with the CLP protocols to the extent possible. Stand-alone deliverables for radiochemistry will comply with the deliverable schedule detailed in Table 4-2 which is presented as an example only. In addition, all data will be reported electronically according to the requirements specified in the appropriate protocols. Actual deliverable requirements may change slightly when the Hanford Analytical Services Management (HASM) group implements a new statement of work during the next contract extensions scheduled for completion in Spring 1993.

Data summary reports on non-critical sample analyses shall at a minimum contain the following:

- Summary of sample results
- Chain of custody, sample analysis request and shipping paper work
- Case narrative
- Matrix spike/matrix spike duplicate results
- Surrogates
- Duplicates
- Blanks

4.5 DATA VERIFICATION AND VALIDATION

Data verification and validation will be conducted by comparing data against the criteria contained in the Westinghouse Hanford procedures (WHC 1990, WHC 1992a and WHC 1992b), which include checking for calculation and transcription errors and comparing data against the work plan data quality objectives for precision, accuracy, and completeness. Representativeness and comparability of data will be assessed on a periodic basis or at the completion of a project as specified in the governing work plan.

4.5.1 Data Verification

All sample data will be verified in accordance with the applicable procedures referenced above in order that data validation may be conducted as described in Section

4.5.2. The verification process will consist of checking data completeness to ensure all analyses requested are reported properly and in the correct units and that all required deliverables are included. Once verification is complete data validation may be conducted to evaluate data quality.

4.5.2 Data Validation

The frequency and level of data validation will depend on the category of site data and whether the sample is a critical or non-critical sample. Sample selection for data validation will be dependant upon the intent of the data usage. It is recommended that key samples or sampling sites (examples are basins, cribs, structures, trenches or discrete sites within and operable unit) be identified and validated at the frequency below:

- In all cases, critical and non-critical reported sample results in each sample delivery group (SDG) shall be verified at a frequency of 100% against raw data (if reported) to insure proper transcription onto the laboratory report forms, to insure reporting of results in the correct units and insure reported sample and QA/QC results meet contractual requirements and work plan DQOs.

- In addition to 100% results verification, sample results for critical samples shall be further validated and recalculated from the raw data at the following frequencies:

  Investigation data - or data used to determine the nature and extent of contamination shall be validated at a frequency of 20%.

  Remediation data - or data used to monitor remedial cleanup or verify cleanup levels have been achieved shall be validated at a frequency of 10%.

  Verification data - or data used to verify contaminant levels following remedial cleanup activities shall be validated at a frequency of 100%.

- In all cases, QC sample results (blanks, duplicates, matrix spike/matrix spike duplicates, spike samples, field blanks, split samples and performance audit samples) shall be validated and recalculated at a frequency of 100% for the first five (5) data packages and 5 percent of the remaining data packages produced for the particular operable unit investigation. These remaining data packages shall be selected at specified intervals to encompass the entire investigation. In addition, the frequency of validation and recalculation of QC samples shall be increased to 100% to encompass five additional data packages when a new laboratory is used during the course of the investigation, a new analytical method is used or when specified by the WHC project coordinator.

A narrative summary report will be prepared after validation of all samples collected for a particular investigation are completed. The checklists and summary forms specified in the WHC procedures (WHC 1990, WHC 1992a and WHC 1992b) will be completed along with the qualified sample results on a sample data package basis and submitted with the reviewed data packages to the project QA record.

Table 4-1. Recommended Laboratory QA/QC Requirements.
(Page 1 of 2)

ORGANICS (TCL volatiles, semivolatiles, chlorinated pesticides/PCBs)	
Quality Control Required	Frequency/Acceptance Criteria
Tuning and Mass Calibration	Daily/as per 8240/8270
Initial Calibration	As needed, based on calibration check performance/RRF ≥0.05, %RSD ≤ 20
Calibration Check	Daily/RRF >0.05, %D ±25%, if exceeded, re-calibrate
Matrix Spike/Matrix Spike Duplicate	One per 20 samples/as per 8240, 8270, 8080
Surrogates	All samples, blanks, standards/as per 8240, 8270, 8080
Internal Standards	All samples, blanks, standards/as per 8240, 8270, 8080
Method Blanks	One per 20 samples/no constituent >5X CRQL
INORGANICS (TAL metals and cyanide, selected anions)	
Initial Calibration	Daily/linear correlation ≥0.995
Calibration Check	Immediately following initial calib. and every 10 analyses thereafter/%R within ±20% of true value
Spike Sample (pre-digestion)	One per 20 samples/%R within ±25% of true value unless sample concentration >4X spike concentration
Duplicate Sample	One per 20 samples/RPD ≤20% for waters, ≤35% for soils
ICP Interference Check	Daily/%R within ±20% of true value
ICP Serial Dilution Check	Daily/%D <10%
Analytical Spikes/Duplicate Injections for graphite furnace AA analyses	All samples/%R ±15% of true, RSD ≤20%, MSA required if %R exceeded and sample absorbance >50% of spike absorbance.

Table 4-1. Recommended Laboratory QA/QC Requirements.
(Page 2 of 2)

RADIONUCLIDES	
Quality Control Required	Frequency/Acceptance Criteria
Initial calibration	Annual detector calibration/efficiency ≥20% (as applicable)
Continuing calibration	Daily check within ±3σ of mean (as applicable)
Detector background	Daily check within ±3σ of mean (as applicable)
Laboratory Control Sample	One per 20 samples/matrix/batch, results within 80 - 120% of true values or ±3 σ of mean, whichever is smaller or greater
Laboratory Blanks	One per 20 samples/matrix/batch, results less than MDA.
Laboratory Duplicates	One per 20 samples/matrix/batch, results ≤20% RPD for waters, ≤35% RPD for soils, or within ±3σ of mean
Resolution (FWHM)	Shall be ≤2.0% for alpha spectroscopy systems and ≤8% for gamma spectroscopy systems.
Minimum Detectable Activities (MDA)	Reported for each sample/analyte/matrix, results must meet work plan detection limits
Chemical Yield	Reported for each sample/analyte/matrix as appropriate for the method. Recovery must be within 30% to 100% range.
Tracer Recoveries	Reported for each sample/analyte/matrix as appropriate for the method. Recovery must be within 30% to 115% range.
Quench Values	Reported for each sample batch (Tritium), quench results shall be within ±3σ of mean standard value.
Self absorption factors	Self absorption curves shall be prepared annually for each detector. Sample mounts shall be within the range of the self absorption curve.

Table 4-2. Recommended Report Deliverables, Radiochemistry (Page 1 of 2)

DATA PACKAGE ITEM	CONTENTS
Case Narrative	Narrative/Cover Page Chain of Custody Sample Analysis Request Shipping Documentation
Sample Results	Printed Results MDA for each nuclide Analysis Dates Detector Identification Detector background Raw Data Calculation Worksheets Sample Preparation Sheets
Calibration Data	Detector Identification Calibration Dates Detector Efficiencies Raw Data Calculation Worksheets Standards traceability Standards dilution log Control Charts
Blanks	Detector Identification Blank Identification Analysis Dates Blank Results Raw Data Preparation Data Control Charts
Duplicates	Detector Identification Duplicate Sample Identification Analysis Dates Primary and Duplicate Results/RPDs Raw Data Preparation Data Control Charts
Laboratory Control Samples	Detector Identification LCS Sample Identification Analysis Dates LCS Results/Limits/Ranges Raw Data Preparation Data Control Charts

Table 4-2. Recommended Report Deliverables, Radiochemistry (Page 2 of 2)

DATA PACKAGE ITEM	CONTENTS
Spikes/Tracers/Chemical Yields	Detector Identification (as applicable) Amounts of Chemical/Tracer Added Traceability Certificates Recovery Results/ Limits/Ranges Raw Data Preparation Data Control Charts
Other QC	Instrument performance data, spectra, system setup data, gain, FWHM, resolution

5.0 SUMMARY

Alternative methods of sample analysis, data reporting and data validation are needed to reduce the time involved to produce validated data for Hanford Site environmental investigations. This paper describes an approach which balances the use of expensive and time-intensive sample analyses with more economical and faster alternatives. This approach includes the following components:

- Source and vadose zone investigation samples determined to be critical for decision making processes will be analyzed by CLP-equivalent methods for target parameters and reported with stand-alone report deliverables. A percentage of these samples will be "fully validated" in accordance with WHC procedures; and

- All groundwater and remaining source and vadose zone samples will be analyzed by appropriate methods for target parameters and reported with data summary report deliverables and validated at a minimum level in accordance with WHC procedures.

The advantages of this approach are:

- A reduction in analytical costs since all samples will be analyzed for project-specific target parameters which are selected based on DQOs;

- Reductions in turn around times for validated results since only key samples will be "fully validated"; and

- Work plan data quality objectives will be met since key samples will always be analyzed, reported and validated at a level appropriate for the data quality needs of individual investigations.

Because the RI/FS is an iterative process refinements will be made in data collection requirements as laboratory data are evaluated. However, for this to occur data must be made available in a timely manner. The approach presented in this paper will provide both traditional, rigorously documented, analytical results with timely, appropriately documented analytical data, both of which will be continuously validated, and evaluated to ensure site data quality objectives are met.

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