CORRESPONDENCE DISTRIBUTION COVERSHEET

Author	Addressee	Correspondence No.
C. T. Narquis, 373-5992	T. K. Teynor, RL	9554116

Subject: THE 222-S LABORATORY QUALITY ASSURANCE PLAN, REVISION 1

INTERNAL DISTRIBUTION

Approval	Date	Name	Location	w/att
		Correspondence Control	A3-01	X
		R. Akita	T6-20	
		W. W. Baird	T6-51	
		T. H. Bushaw	T6-30	
		T. F. Dale	T6-20	
		J. L. Deichman	T6-03	
		L. F. Ermold	S7-84	
		D. G. Farwick	T6-03	
		G. B. Griffin	T6-16	
		T. G. Ibsen	S3-30	
		J. R. Jewett	T6-09	
		S. M. Joyce	H4-21	
		A. G. King	T6-03	
		J. G. Kristofszki	T6-06	
		K. K. Lachut	T6-03	
		L. P. Markel	T6-16	
		R. P. Marshall	T6-14	
X	7/31/95	H. K. Meznarich	T6-16	
		P. M. Morant	H4-25	
		S. R. Moreno	B3-06	
X	7/31/95	C. T. Narquis	T6-16	
		J. R. Prilucik	T6-24	
		A. D. Rice	T6-06	
		G. L. Troyer	T6-50	
		K. B. Wehner	S3-28	
		W. I. Winters	T6-50	
		O.S.T.I. (2)	L8-07	X
		Central Files (2)	L8-04 A3-36	X

DISCLAIMER

DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.

Westinghouse
Hanford Company

P.O. Box 1970 Richland, WA 99352

July 31, 1995 9554116

Mr. T. K. Teynor, Director
Waste Programs Division
U.S. Department of Energy
Richland Operations Office
Richland, Washington 99352

Dear Mr. Teynor:

THE 222-S LABORATORY QUALITY ASSURANCE PLAN, REVISION 1

References: (1) Letter, T. K. Teynor, RL, to Distribution, "Issuance of Hanford Analytical Services Quality Assurance Plan (HASQAP)," WPD:KKK, dated July 25, 1995.

(2) DOE/RL-94-55-02, Hanford Analytical Services Quality Assurance Plan, Revision 2, dated June 30, 1995.

(3) Letter, M. L. Bell, WHC, to J. M. Hennig, RL, "Hanford Analytical Services Quality Assurance Implementation Plan for the Westinghouse Hanford Company 222-S and Waste Sampling and Characterization Facility Laboratories," 9550126, dated January 12, 1995.

Attachment 1 is the Westinghouse Hanford Company 222-S Laboratory Quality Assurance Plan (LABQAP), Revision 1. The LABQAP is the vehicle through which 222-S Laboratory implements the Hanford Analytical Services Quality Assurance Plan (HASQAP). The HASQAP was recently revised (Reference 2) and LABQAP was modified to accommodate the revision. Attachment 2 is a draft form letter for further transmittal of LABQAP to the U.S. Environmental Protection Agency and the State of Washington Department of Ecology.

This letter and its attachments partially satisfy the U.S. Department of Energy, Richland Operations Office (RL) Milestone AS-95-027, "Submit 222-S and Waste Sampling and Characterization Facility Laboratories Quality Assurance Plans to Richland Operations Office." Although HASQAP, Revision 2, is dated June 30, 1995, it was not formally distributed by RL until July 25, 1995 (Reference 1). The 222-S Laboratory worked with draft language and thoroughly reviewed the HASQAP revision in order to complete our LABQAP revision in a timely and comprehensive manner. Achievement of this milestone reflects both good faith and strong commitment to the establishment of improved Quality Assurance (QA) and Quality Control (QC) at 222-S Laboratory.

The 222-S Laboratory is committed through Milestone AS-95-002 to demonstrate final compliance with HASQAP, Revision 2, by August 31, 1995. We are currently working to that schedule (Reference 3); however, several detail issues within LABQAP may be interpreted as being noncompliant with HASQAP. The attached table (Attachment 3) lists these detail issues. The 222-S Laboratory will continue to work with RL and the HASQAP team to determine final resolution.

A major change in HASQAP, Revision 2, is the change in scope to include certain research and development activities. Our position is that the process development work carried out predominantly by J. R. Jewett's group is exploratory development and, therefore, is still not covered by HASQAP. An audit currently in progress is expected to confirm the validity of this position.

The 222-S Laboratory will come into full compliance with Revision 1 of LABQAP via the implementation schedule in Chapter 19. When all compliance issues have been resolved, we will revise the LABQAP Chapter 19 to indicate the actual implementation dates rather than the target dates. This will remain as documentation of the transition from the previous QA/QC program to LABQAP.

Please direct questions and/or comments to Dr. H. K. Meznarich at 373-1672, of my staff.

Very truly yours,

A. Gaylord King, Manager
Analytical Services
TWRS Characterization Project

llu

Attachments 3

RL - C. A. Babel
R. P. Carter
P. K. Clark
K. K. Kawabata
S. J. Veitenheimer
A. H. Wirkkala (w/o attachment)

9554116

ATTACHMENT 1

222-S Laboratory Quality Assurance Plan, Revision 1

Consisting of 74 pages

ENGINEERING CHANGE NOTICE

Page 1 of 2

-1. ECN 701701

Proj. ECN

2. ECN Category (mark one)	3. Originator's Name, Organization, MSIN, and Telephone No.	4. Date
Supplemental ☐ Direct Revision ☒ Change ECN ☐ Temporary ☐ Standby ☐ Supersedure ☐ Cancel/Void ☐	H. K. Meznarich, 222-S Analytical Operations, T6-16, 373-1672	7/28/95

5. Project Title/No./Work Order No.	6. Bldg./Sys./Fac. No.	7. Impact Level
NA	222-S Lab Complex	~~3~~ 0 HKM 7/31/95

8. Document Numbers Changed by this ECN (includes sheet no. and rev.)	9. Related ECN No(s).	10. Related PO No.
WHC-SD-CP-QAPP-016, Rev. 0	None	None

11a. Modification Work	11b. Work Package No.	11c. Modification Work Completed	11d. Restored to Original Condition (Temp. or Standby ECNs only)
☐ Yes (fill out Blk. 11b) ☒ No (NA Blks. 11b, 11c, 11d)	NA	NA Cog. Engineer Signature & Date	NA Cog. Engineer Signature & Date

12. Description of Change

Revision of WHC-SD-CP-QAPP-016, Rev. 0, is made for clarification of text, for information on implementation completion date, and on page number changes.

13a. Justification (mark one)	13b. Justification Details
Criteria Change ☐ Design Improvement ☐ Environmental ☐ As-Found ☒ Facilitate Const. ☐ Const. Error/Omission ☐ Design Error/Omission ☐	Clarification for auditors and affected lab personnel.

14. Distribution (include name, MSIN, and no. of copies)

See attachment.

RELEASE STAMP

OFFICIAL RELEASE BY WHC

DATE JUL 31 1995

Stale

A-7900-013 (06/92)

ENGINEERING CHANGE NOTICE

1. ECN (use no. from pg. 1): 701701

15. Design Verification Required	16. Cost Impact		17. Schedule Impact (days)
	ENGINEERING	CONSTRUCTION	
☐ Yes	Additional ☐ $ NA	Additional ☐ $ NA	Improvement ☐ NA
☒ No	Savings ☐ $ NA	Savings ☐ $ NA	Delay ☐ NA

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

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.

Document Number/Revision	Document Number/Revision	Document Number/Revision
NA	NA	NA

20. Approvals

Signature	Date	Signature	Date
OPERATIONS AND ENGINEERING		ARCHITECT-ENGINEER	
Cog. Engineer H. K. Meznarich H Meznarich	7/28/95	PE NA	
Cog. Mgr. G. B. Griffin	7/31/95	QA NA	
QA D. G. Farwick M J White for D.G. Farwick	7/31/95	Safety NA	
Safety NA		Design NA	
Security NA		Environ. NA	
Environ. NA		Other NA	
Projects/Programs NA			
Tank Waste Remediation System NA			
Facilities Operations NA		DEPARTMENT OF ENERGY	
Restoration & Remediation NA		Signature or Letter Number	
Operations & Support Services NA		NA	
IRM NA		ADDITIONAL	
Other NA		NA	

RELEASE AUTHORIZATION

Document Number:	WHC-SD-CP-QAPP-016, REV 1
Document Title:	222-S Laboratory Quality Assurance Plan
Release Date:	7/31/95

This document was reviewed following the procedures described in WHC-CM-3-4 and is:

APPROVED FOR PUBLIC RELEASE

WHC Information Release Administration Specialist:

Kara M. Broz 7/31/95

Kara M. Broz

SUPPORTING DOCUMENT

1. Total Pages 131 HK 730

2. Title	3. Number	4. Rev No.
222-S Laboratory Quality Assurance Plan	WHC-SD-CP-QAPP-016	1

5. Key Words

Quality Assurance Plan, 222-S Laboratory, Standards Laboratory, quality assurance, and quality control.

6. Author

Name: H.K. Meznarich

Signature: H.K. Meznarich 7/28/95

Organization/Charge Code 75900/J8E04

7. Abstract

This document provides quality assurance guidelines and quality control requirements for analytical services. This document is designed on the basis of Hanford Analytical Services Quality Assurance Plan (HASQAP) technical guidelines and is used for governing 222-S analytical and quality control activities.

8. RELEASE STAMP

OFFICIAL RELEASE BY WHC (12)

DATE JUL 31 1995

Sta 6

RECORD OF REVISION	(1) Document Number WHC-SD-CP-QAPP-016	Page 1

(2) Title
222-S Laboratory Quality Assurance Plan

CHANGE CONTROL RECORD

(3) Revision	(4) Description of Change - Replace, Add, and Delete Pages	Authorized for Release	
		(5) Cog. Engr.	(6) Cog. Mgr. Date
0	(7) Date of release - April 5, 1995 EDT-600[illegible]	H Heimarck	7/31/95
1 RS	Changes are marked in red-lines for clarification, information on implementation completion date, and page numbering changes. Incorp. ECN-701701	H Heimarck	7/31/95

222-S LABORATORY QUALITY ASSURANCE PLAN

Prepared by

222-S Analytical Operations

Issued by

Analytical Services

For Public Release

222-S LABORATORY QUALITY ASSURANCE PLAN

Approvals:

G. B. Griffin	Manager, 222-S Analytical Operations	7/31/95 Date
L. P. Markel	Quality Assurance Officer	July 28, 1995 Date

Table of Contents

TABLES

FIGURE

Acronym List

%D	percent difference
%R	percent recovery
AA	atomic absorption
ACE	Analytical Card Enhancement
AEQA	Analytical Environmental Quality Assurance
AO	222-S Analytical Operations
AS	Analytical Services
ASTM	American Society for Testing Materials
CBRS	Component Based Recall System
CCV	continuing calibration verification
CERCLA	*Comprehensive Environmental Response, Compensation, and Liability Act*
CFR	U.S. Code of Federal Regulations
CLP	Contract Laboratory Program
CM	control manual
DLR	decision level count rate
DOE	U.S. Department of Energy
DQO	data quality objective
ECN	Engineering Change Notice
EDT	engineering data transmittal
EPA	U.S. Environmental Protection Agency
EQL	estimated quantitation limit
ETS	Engineering & Technology Services
GC	gas chromatograph
GC/MS	gas chromatograph/mass spectrometer
GEA	gamma energy analysis
HASQAP	*Hanford Analytical Services Quality Assurance Plan*
HATS	Hanford Action Tracking System
HIP	Hanford Inventory Program
HLAN	Hanford Local Area Network
IC	ion chromatography
ICP	inductively coupled plasma (spectrometer)
ICP/MS	inductively coupled plasma (spectrometer)/mass spectrometer
ICV	initial calibration verification
IDL	instrument detection limit
IPM	instrument preventive maintenance
IRM	Information Resource Management
LCCS	Laboratory Customer Communication System
LIMS	Laboratory Information Management System
LMCS	Laboratory Measurement Control System
LMS	Laboratory Measurement System
LQAO	Laboratory Quality Assurance Officer
MDA	minimum detectable activity
MDC	minimum detectable concentration
MDL	method detection limit
NESHAP	*National Emission Standards for Hazardous Air Pollutants*
NIST	National Institute of Standards and Technology
OJT	on-the-job training
OQA	Office of Quality Assessment

OSCR	off standard condition report
OSHA	*Occupational Safety and Health Act*
PC	project coordinator
PCA	Procedure Change Authorization
PCB	polychlorinated biphenyl
PM&I	Program Management & Integration
PNL	Pacific Northwest Laboratories
PRAF	procedure review and approval form
PS	project support
QA	quality assurance
QAPP	Quality Assurance Program Plan
QAP_jP	Quality Assurance Project Plan
QC	quality control
RCRA	*Resource Conservation and Recovery Act*
RF	response factor
RHA-MIS	Records Holding Area - Management Information System
RIDS	Records Inventory Disposition Schedule
RL	U.S. Department of Energy, Richland Operations Office
RO	reverse osmosis
RPD	relative percent difference
RSA	request for special analysis
RSD	relative standard deviation
SD	supporting document
SV	semivolatile (organics)
TCLP	toxicity characteristics leaching procedure
TOC	total organic carbon
Tri-Party	*Hanford Federal Facility Agreement and Consent Order* Agreement
TSD	treatment, storage, and disposal
TWRS	Tank Waste Remediation Systems
VOA	volatile organic analyte (analysis)
WHC	Westinghouse Hanford Company

1.0 INTRODUCTION

This Quality Assurance Plan provides quality assurance (QA) guidance, regulatory QA requirements (e.g., 10 CFR 830.120), and quality control (QC) specifications for analytical service. This document follows the U.S Department of Energy (DOE) issued Hanford Analytical Services Quality Assurance Plan (HASQAP). In addition, this document meets the objectives of the Quality Assurance Program provided in the WHC-CM-4-2, Section 2.1. Quality assurance elements required in the *Guidelines and Specifications for Preparing Quality Assurance Program Plans* (QAMS-004) and *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (QAMS-005) from the U.S. Environmental Protection Agency (EPA) are covered throughout this document. A quality assurance index is provided in the Appendix A.

This document also provides and/or identifies the procedural information that governs laboratory operations. The personnel of the 222-S Laboratory and the Standards Laboratory including managers, analysts, QA/QC staff, auditors, and support staff shall use this document as guidance and instructions for their operational and quality assurance activities. Other organizations that conduct activities described in this document for the 222-S Laboratory shall follow this QA/QC document.

Sample analysis in support of the following activities shall be in compliance with this document: (1) hazardous waste treatment, storage, and disposal units; (2) hazardous waste facility permitting, closure, and post-closure; and (3) remedial and corrective action

Sample analysis under regulatory requirements not specified in the Tri-Party Agreement (TPA) including the *Clean Air Act*, *Clean Water Act*, *National Emission Standards for Hazardous Air Pollutants* (NESHAP), *National Pollution Discharge Elimination System*, and *Occupational Safety and Health Act* (OSHA) shall meet or exceed the QA protocols described in this document.

The 222-S Laboratory provides analytical services to various clients including, but not limited to, waste characterization for the Tank Waste Remediation Systems (TWRS), waste characterization for regulatory waste treatment, storage, and disposal (TSD), regulatory compliance samples, radiation screening, process samples (e.g., evaporator samples, effluent samples), and TPA samples. A graded approach is applied on the level of sample custody, QC, data verification, and data reporting to meet the specific needs of the client. Unique QA/QC requirements that differ from this document shall be described in the work statement, analysis plan, or Quality Assurance Project Plan (QAP_jP).

This document supersedes WHC-SD-CP-QAPP-001, WHC-SD-CP-QAPP-002, and WHC-SD-CP-QAPP-003 and shall be reviewed annually and revised as appropriate.

This page intentionally left blank.

2.0 ORGANIZATION AND RESPONSIBILITY

The charters and responsibilities for each organizations are published in Section 2 of WHC-CM-5-4.

2.1 Management Policy

The policy of the TWRS Characterization Project and Analytical Services (AS) management is to direct activities in a manner that ensures the results meet or exceed the customer's requirements and provides supporting documentation. This policy shall be implemented through the following.

- Personnel are responsible for the quality of their own work. Personnel shall check their supplies to ascertain that the items are correct and suitable for use.
- All levels of management accept responsibility for their organization's activities and are held accountable for achieving quality.
- Management provides adequate resources and budget to support effective quality assurance practices that fulfill the customer's program goals and performance objectives.
- Management provides facilities, instruments, support equipment, and materials required to meet the customer's current and projected requirements.
- Laboratory personnel shall have acceptable qualifications and training for their specific job assignments.
- Documentation is controlled and maintained in a manner that ensures that the laboratories can demonstrate compliance to customers' requirements.
- Quality is achieved and improved by planned, systematic and self-assessments, and measured actions.
- Quality control data document the accuracy and precision performance of instruments and methods.

2.2 Organization And Responsibility

The 222-S Analytical Operations currently reports to the TWRS Characterization Project to support TWRS characterization activities. The 222-S Analytical Operations is also closely associated with AS as shown in the Appendix B. Other organizations in the AS that provide services to the 222-S Laboratory include Program Management & Integration, Office of Quality Assessment (OQA), and Engineering and Technology Services.

If changes in organizational structure occur, which do not reflect a change in the overall laboratory functions, this QA plan shall remain valid. Information corresponding to such organizational changes shall be incorporated in the next revision of this QA plan.

Overall organizational functions and responsibilities that manage, perform, or assess activities affecting quality are described in the following sections.

2.2.1 222-S Analytical Operations

The Analytical Operations (AO) organization is responsible for providing analytical services in support of TWRS characterization activities, Westinghouse Hanford Company (WHC) environmental and waste management activities, and for routine identification.

The Hot Cell and Sample Preparation group is responsible for sample receiving and handling, chain-of-custody, preparing applicable procedures, sample preparation, and disposal of sample.

The Organic Chemistry, Inorganic Chemistry, and Radioanalytical Chemistry groups are responsible for preparing applicable procedures, calibrating analytical measurements systems, performing analyses, generating, calculating, and reviewing data, evaluating data and preparing the case narrative, developing new or modifying existing methods, and supporting the establishment of data quality objectives.

Program Support is responsible for coordinating sample scheduling and data quality objective(s) between the laboratory and the client. Program Support is also closely associated with the Characterization Technical Basis organization from the TWRS Characterization Project for defining analysis requirements, scheduling, and data reporting. They are also responsible for laboratory quality control and preparing data packages.

Shift Operations is responsible for calibrating the analytical measurements systems (when applicable), performing analyses, and generating, calculating, and reviewing data.

Laboratory Quality Assurance staffs are responsible for laboratory data quality control and quality assurance (see 2.3.4 for details).

Hazardous Material and Control is responsible for controlling and disposing of the hazardous waste generated in the laboratory.

Building Operations is responsible for maintaining and operating the laboratory facilities.

2.2.2 Other Organizations Supporting The Analytical Operations

The following services are provided by organizations either within or outside Analytical Services in order to achieve a quality assurance program for the 222-S Laboratory Operations.

A. Program Management & Integration

Functions of Program Management & Integration (PM&I) include program management services, serving as a single-point-of-contact for laboratory customers, and maintaining a continuously updated laboratory master schedule. Services provided by Documentation Administration include records management, administration of laboratory procedures and the WHC-CM-5-4 manual, and maintenance of the Laboratory Technical Information Center.

B. Engineering & Technology Services

The Engineering & Technology Services (ETS) organization provides engineering services, operational ensurance and support, chemical standards services, information and automated data processing systems, AS maintenance, and work control.

Information Systems is responsible for developing and maintaining the automated data processing system (e.g., LABCORE). It is also responsible for managing the Laboratory Customer Communication System (LCCS) and Laboratory Measurements Control System (LMCS) and for phasing out both systems in the future. The Standards Laboratory is responsible for procuring and preparing chemicals, standards, and reagents. The Laboratory Engineering organization is responsible for calibrating balances and conducting instrument preventive maintenance when requested. Operations Assurance & Support is responsible for the mandatory training program and maintaining the Hanford Action Tracking System (HATS).

The AS Maintenance and Work Control is responsible for work control and material procurement and control.

C. Office of Quality Assessment

The Office of Quality Assessment (OQA) organization provides quality assurance oversight and performs annual audits of the 222-S Laboratory.

D. Other Supporting Organization Outside the Analytical Services

The Analytical and Environmental Quality Assurance organization provides QA support and services and has QA oversight responsibility for the 222-S Laboratory.

2.3 222-S Analytical Operation's Responsibility For The Quality Assurance Program

The manager of 222-S Analytical Operations is responsible for the overall quality of the laboratory analyses and services. Laboratory Quality Assurance (LQA) staffs are responsible for performing and overseeing quality assurance/quality control activities and reporting to the manager of the 222-S Analytical Operations.

Personnel at each level that are involved in generating data are responsible for knowing the content of the laboratory quality assurance plan and upholding the standards. Each

person shall carry out his/her daily tasks in a manner consistent with the policy expressed in this manual and in accordance with the laboratory procedures.

2.3.1 Managers Of The Analytical Operations

The manager and deputy manager of 222-S Analytical Operations are responsible for all laboratory activities, for supporting the Quality Assurance program, and shall encourage the cooperation of laboratory personnel in this program.

2.3.2 Line Managers In The 222-S Analytical Operations

Line managers and shift managers shall ensure that daily QC activities are carried out in compliance with the QA/QC requirements in this document and laboratory procedures and to ensure the quality standards for the operations and services are upheld. Line managers and shift managers are also responsible for the evaluation, maintenance, and growth of the technical and quality-related skills of the personnel.

2.3.3 Analyst/Technologist

The analyst and/or technologist and operational staff have the primary responsibility for carrying out the daily QC activities, maintaining the quality standards, and working with the operations team members to ensure a smooth flow of work.

2.3.4 Laboratory Quality Assurance Staff

Responsibilities of the 222-S Laboratory QA/QC staff and QA officer include the following:

- Ensure the QA program is implemented
- Oversee and/or identify project QA/QC requirements
- Prepare and maintain Laboratory QA Plan
- Oversee and/or coordinate the performance evaluation program
- Oversee, perform, and/or coordinate audits, assessment, and surveillances
- Oversee/initiate corrective action
- Generate and summarize quality control reports
- Ensure the status of the QA program is reported to management
- Evaluate and verify data quality.

2.4 Authority

Personnel involved in the generation of data are responsible for the QA/QC program. In addition, such personnel have the authority to initiate the following appropriate actions:

- Prevent reporting results from a measurement system that is out of control; prevent further sample analysis and reporting until corrective action has been completed

- Identify any laboratory method or procedure that poses quality problems
- Provide solutions through designated channels and monitor effectiveness
- Initiate a stop-work order where safety, serious quality or health conditions exist.

This page intentionally left blank.

3.0 PERSONNEL QUALIFICATION AND TRAINING

3.1 Qualification

The 222-S Laboratory considers education, experience, and training as components of personnel qualifications. All personnel must meet or exceed minimum qualification requirements for their functional positions. Minimum education and experience requirements are stated in WHC-CM-5-4, Section 4.3, Table 1. In addition, the laboratory maintains job-specific training requirements specified in WHC-CM-5-4, Section 4.4.

3.2 Personnel Selection

Employee selection and job assignment are based upon an evaluation of the requirements of the position and the candidates education, training, and previous experience. Only those candidates meeting minimum requirements are selected. Minimum education and experience requirements are stated in WHC-CM-5-4, Section 4.3, Table 1.

3.3 Training Plans

The 222-S Laboratory employees have an employee-specific training plan, determined by their immediate supervisor using the Training Matrix Program system (TMX). The training plan includes job-specific required training courses, required on-the-job training (OJT), and remedial training to correct performance deficiencies. The training plan also includes optional development including training from courses offered by AS, AO, WHC, off-site seminars, symposia and short courses, other work-related training, or professional development activities, as appropriate.

The 222-S internal training program is described in WHC-CM-5-4, Section 4.5, "Training Programs". Within this program are specific sets of required coursework designed to maintain familiarity with company, facility and specific technical aspects of each job within 222-S. The program specifies required coursework, applicability, and retraining requirements. Based on the training program information in Section 4.5, managers establish training plans for exempt employees in the TMX.

In addition to meet the formal training requirements in WHC-CM-5-4, Section 4, 222-S Laboratory provides continuing improvement in the awareness and proficiency of all employees. Where practical, access to other WHC, as well as off-site training and professional development opportunities is encouraged.

3.4 General Personnel Training

3.4.1 All Employees

222-S personnel are oriented to the mission and objectives of the laboratory, the general requirements of HASQAP, and the individual's responsibility within their organization to follow an established QA plan.

222-S personnel are trained in basic facility orientation, general safety training, building emergency procedures, and self-monitoring. All training requirements described in Section 3.4 are detailed in WHC-CM-5-4, Section 4.5, Appendixes A and B. In addition to these mandatory training requirements, specific training related to each job category is described in the following sections.

3.4.2 Chemical Technologists

Chemical technologist training includes initial laboratory familiarity progressing to more specific training with laboratory procedures and company-specific training for their work assignment.

3.4.3 Chemists/Scientists

Chemist/scientist training includes operational specific procedures for working in the laboratory and procedure author training.

3.4.4 Managers

The role and responsibilities as a laboratory manager to lead, direct and motivate people are emphasized. Manager training also includes familiarization with the various safety, engineering, and work control systems in use at the 222-S Laboratory.

3.4.5 Additional Job-Specific Training

Additional, job-specific coursework may be required to develop and/or maintain proficiency in areas of hot cell operation, sample preparation, maintenance, building operations, shift supervision, waste management, facility engineering, and OJT instruction.

3.5 Continuing Training Requirements

Control manual, WHC-CM-5-4, Section 4, contains retraining requirements for each course title referenced above. These retraining requirements are typically either annual or biennial. Retraining requirements are called out in the individual annual training plan, by routine requalification tickler from the training department, or by specific training identified through the continuous improvement program. Continuing training programs are structured around specific position needs and are designed to enhance personnel proficiency.

3.6 On The Job Training

The 222-S Laboratories use an OJT checklist to ensure the proficiency of the chemical technologist in the performance of laboratory procedures. The checklist covers training in laboratory procedures and is detailed in WHC-CM-5-4, Section 4.4 "On-the-Job Training."

In general, the training is designed to identify what a trainee should be thinking and what they should know when actually performing the procedure. In addition to safety

hazards and procedure limitations, reagents and supplies, and good procedural and housekeeping techniques, the following components need to be considered for all training:

Method

- Method chemistry
- QC built into the procedure
- Recordkeeping requirements
- Normal operation

Instrument

- Location and use of maintenance and performance logbooks
- Location of spare parts
- Mechanism for reporting/addressing physical or operational problems
- Facility utility tie-ins
- Waste management and safety/health hazards

Data

- Proper reporting of analytical results and data validation
- Proper shift transfer.

On-the-job training makes use of competent, trained OJT instructors. All OJT is evaluated by an OJT evaluator, who signifies a trainee's satisfactory completion of a performance or operational evaluation by signing the appropriate spaces on an OJT checklist. The OJT checklist is used to document the completion of training to laboratory procedures.

3.7 Training Records

The laboratory maintains a personnel file for all employees. These files document completed company training courses, performance issues, and other external training, symposia or conferences attended. Exempt employees have current resumes/competence records in these files. A "Training Completion Record Form C" (A-6000-821) must be submitted by the attendee on completion of external training outside the WHC Training Department. The attendee is responsible for forwarding the completed form to Training Records.

Bargaining unit employees also have procedure training binders or electronic files that document all laboratory procedure training.

Annual training plans are maintained in the individual's personnel file.

This page intentionally left blank.

4.0 QUALITY ASSURANCE OBJECTIVES

4.1 Data Quality Objectives

Quality assurance (QA) objectives provide a set of recognized parameters to monitor performance of an analytical measurement system and to qualify analytical data. Establishment of data quality objectives criteria can be achieved based on the following factors:

- Regulatory requirements, (e.g., *Resource Conservation and Recovery Act* [RCRA], *Comprehensive Environmental Response Compensation and Liability Act* [CERCLA], and *Clean Air Act*
- Hanford Analytical Services Quality Assurance Plan
- Data use (e.g., regulatory, process control, screening, planning, and development).

The laboratory policy is to have a written agreement on client project data quality objectives before analytical work is begun. The laboratory either participates in or provides recommendations for establishing data quality criteria.

The agreement between the laboratory and client is established by several mechanisms depending on the size and nature of the project (e.g. through Data Quality Objectives planning, test plan, quality assurance project plan, or using the Request for Special Analysis [RSA] form).

In the agreement, the following information shall be provided when appropriate:

- Applicable regulatory requirements
- Process knowledge, sample source, and sample conditions known to the client that could impact the laboratory worker's safety
- Handling of radioactive samples in the transport process and in the laboratory
- Estimated number and matrix of samples
- Sample handling relative to specific sample or matrix
- Analysis methods and analyte lists for sample analysis
- Quality control sample (frequency, type, and acceptance criteria)
- Expected date of sample receipt, sample preservation, delivery methods, storage and container types and volumes, and holding times by method
- Format and content of sample analysis reports

- Turnaround time (from date of sample receipt to date of data delivery) in the laboratory
- Name, address, telephone number of client, laboratory contacts responsible for the project, and information to establish electronic data transfer
- Return of samples and disposition of waste.

4.1.1 System For Notification Of Unique Data Quality Requirements

A communication system in the laboratory for notification of unique data quality requirements after the laboratory - client agreement has been finalized is set up in the following manner.

- Unique data quality requirements are communicated to the appropriate personnel using the sample status meeting held weekly by the Program Support Manager. Alternatively, a special meeting with appropriate laboratory supervisor or managers, QA representative(s), and project coordinator(s) can be used.
- Written instructions/minutes shall be prepared and distributed by the originator to appropriate persons with lead responsibility.

4.1.2 Client Complaints And Resolution

The laboratory notifies the client when situations such as anomalies and noncompliances occur. Resolution for minor or technical issues and complaints shall be coordinated at the chemist or line manager level. Corrective action shall be initiated in a reasonable time frame. Resolution for more significant issues that have a potential negative impact on data quality shall be coordinated by the project coordinator. For example, for nonconforming samples upon submission to the laboratory: either stop processing the samples until the concern is resolved or revise the original work requests.

Issues, complaints, and resolutions from the client shall be documented by the Program Support Organization.

4.2 Client Data Quality Requirements

Five parameters are often used by the client to define project data quality requirements. These include precision, accuracy, completeness, comparability, and representativeness. Of these, the precision, accuracy, and representativeness have direct impacts on data quality (see Section 11.0 for limitations associated with precision and accuracy). The client is responsible for ensuring that adequate sample material is available and that appropriate sampling techniques are administered in order to meet their data quality objective(s). The laboratory is responsible for using proper protective sample handling protocols. The laboratory and client share responsibility for selecting appropriate sample preparation and analysis.

The precision and accuracy requirements shall be agreed on by the laboratory and the client and should be based on the error tolerances of the sampling and analytical effort. The laboratory is responsible for providing precision and accuracy values obtained from the standards to the client. If the client has special requirements for precision and accuracy, the requirements must be identified in the agreement. If the client has no special requirement, HASQAP or normal laboratory performance may be specified.

4.2.1 Precision

Precision is defined as an agreement among a set of replicate measurements without assumption of knowledge of the true value. Precision is estimated by means of duplicate/replicate analyses and is expressed as the relative standard deviation (RSD). For very small data sets, relative percent difference between duplicate measurements is accepted. Precision is calculated based on the equations listed in Section 12.

Precision of analytical methods is estimated using the laboratory control samples over time. The precision of analytical methods indicates the variability for the analytical method that can be expected on the relatively simple matrices.

Acceptance criteria for precision shall be established for each project and agreed upon by the laboratory and the client. Acceptance criteria for each analyte or analyte method shall be listed in the project plan, characterization plan, or statement of work. The laboratory provides historical precision values to the client based on the measurements from the standards.

4.2.2 Accuracy

Accuracy is defined as the closeness of agreement between an observed value and an accepted reference value. Accuracy is calculated based on the equations listed in Section 12.

Accuracy of the actual sample is expressed as the percent recoveries of spiked samples. Spiking may not be applicable for analytes present in the samples in relatively high concentration ($> 0.1\%$). In these cases other laboratory control samples can be used to estimate the accuracy of the method. Acceptance criteria for sample accuracy shall be established for each project and agreed upon by the laboratory and the client. Acceptance criteria for each analyte or analyte method shall be listed in the project plan, characterization plan, or statement of work. The 222-S Laboratory provides historical values to the client based on the measurements from spiked samples or from the standards.

4.2.3 Comparability

Comparability is the confidence with which one data set can be compared to another. For each analyte, comparable precision and accuracy depend on the method and sample matrix. Factors such as analytical method selected, detection limits or uncertainty, precision, accuracy, and matrix effects should be taken into consideration when data is to be compared. A split sample or a known standard shall be used for comparability of different methods.

4.2.4 Completeness

Completeness is a measure of the total amount of usable/valid data obtained from a measurement system compared to the amount of data requested that was expected to be obtained under correct normal conditions. Completeness can be used to evaluate the amount of data produced that meets the client's requirements (e.g., accuracy, precision). Completeness is generally used by the client to measure laboratory performance.

4.2.5 Representativeness

Representativeness is defined as a degree to which data accurately and precisely represent a characteristic of a population, parameter variation at a sampling point, a process condition, or an environmental condition.

Representativeness of a population or an environmental condition depends on sampling and is outside the control of the laboratory.

Representativeness should be maintained by proper homogenization or appropriate subsampling (if different phases are apparently visible in the sample). Once subsampling occurs, identification of chemical/physical properties of subsamples, proper analytical protocol, and traceability of results to the original subsamples should be in place. Clients shall be consulted if unplanned subsampling appears necessary.

5.0 SYSTEMS QUALITY ASSURANCE

5.1 Software Systems

Laboratory software systems can be separated by application into two categories: administrative and technical. Administrative software systems manage the work flow or monitor performance against administrative requirements. Examples of administrative software systems are those that control sample tracking, procedure control, training, and reporting. Technical software systems control laboratory systems, and accumulate and reduce data. Examples of technical software systems are those that provide instrument interface, calculations, calibration control, and control charts.

5.1.1 Control Requirements

Software control requirements applicable to both commercial and laboratory-developed software shall be developed, documented, and implemented. Software systems shall be protected from unauthorized or inadvertent changes.

Software systems shall be documented under configuration control. For laboratory-developed software systems, a copy of the original program code shall be maintained, and all changes shall include a description of the change, authorization for the change, and test data that validates the change. Configuration control and acceptance test data shall be maintained for commercial software packages.

The following documents govern laboratory software system configuration control:

- WHC-SD-WM-CM-002, *Configuration Management Plan for LABCORE Program*
- WHC-CM-5-4, Section 8.3 and 8.6 for projects outside the scope of the LABCORE program as well as for any project that does not have a specific configuration management plan in place.

5.1.2 Acceptance Testing

Software systems shall be tested for acceptance when installed, after changes, and periodically during their use. The frequency of the test shall be based on the potential for adverse impact on the laboratory and the ease in which changes can be made to the computer code. Testing may consist of manually performing calculations, checking against another software system that has been previously tested, comparing output with previous output, or by analyzing standards.

Testing of LABCORE is performed in accordance with WHC-SD-WM-CSWD-058, *LABCORE Software Test Plan.*

The following procedures are used for laboratory-developed program/applications outside the scope of the LABCORE program as well as for any project that does not have a specific configuration management plan in place:

- LC-400-001, *FORTRAN Coding and Documentation Guidelines*
- LC-400-002, *Programmable Calculator Documentation and Coding Guidelines*
- LC-400-003, *Basic Coding and Documentation Guidelines*
- LC-400-006, *Spreadsheet Documentation Guidelines*
- LC-705-101, *ACE Program - Implementation and Operation of Spreadsheet and Computer Interface.*

Documentation of the testing shall include printouts of the data or results from data generated by the software for comparison, the name of the person performing the test, and the date the test was performed. The version and manufacturer of the software shall be documented.

5.1.3 Backups

Both software and data shall be backed up. The frequency of backup shall be based on the amount of data and the impact of the loss of data or software on the organization. The following procedures may be followed for software backups.

- LC-718-001, *Laboratory ADP Operations*, provides authority to use worksheets for routine operations (i.e., LABCORE or any project outside the scope of LABCORE). A specific worksheet "File System Backup Guide" is followed for LABCORE software and data backup. In addition, specific worksheets can be authorized to support laboratory instrument software and data backup if requested by the laboratory managers.

- LC-808-101, *Laboratory Computer System Operation*, provides authority to use worksheets for routine operations for the Data General[1] Systems in MO-037. Two specific worksheets "MV10000 Full Backup" and "Daily Morning Status" are followed for software and data backup.

5.1.4 User's Manuals

Procedure LC-708-001, *MULTI-LIMS Use in the Laboratory* provides user instructions on the use of MULTI-LIMS. In addition, two training classes are provided: "LABCORE Overview On-the-Job" and "LABCORE Job Specific On-the-Job".

LC procedures are issued when appropriate for an application (such as LCCS). If programs or applications for projects outside the scope of the MULTI-LIMS system are small or straight forward, a controlled manual or special training is not required (see WHC-CM-3-10, *Software Practices*, Section SP-3.4, "Small Job Development").

---

[1]Data General is a trademark of Data General Corporation.

5.1.5 Error Reporting

Data management software errors found during use are immediately reported to the system administrator of software. Errors and corrective actions shall be documented.

5.2 Administrative Systems

Westinghouse Hanford Company has established an administrative control system based on a hierarchy of controlled manuals (CM). These manuals provide documented interpretation of DOE orders and procedures for implementation. The 222-S Laboratory works to the administrative policies and directions published in Westinghouse Hanford Company Controlled Manuals (WHC-CM) In the WHC-CM system, a hierarchy exists in which Level I manuals provide direction from the President for implementation of key policy and administrative actions, Level II manuals are issued by company organizations for implementation of broadly applicable activities based on specific DOE orders (e.g., safety, quality assurance, and purchasing), and Level III manuals are provided for personnel at the working level, providing additional information not found in higher level documents. In addition to the administration directions listed in manuals, laboratory procedures are used for specific activities.

Control manual, WHC-CM-5-4, *Laboratories Administration*, a Level III manual provides the documentation describing and directing laboratory activities not sufficiently covered in Level II documents.

The following list identifies the documents that provide laboratory personnel with approved directions for various activities:

- Organization charts are published by the Director of Analytical Services
- Procurement controls are in the Level II manual WHC-CM-2-1, *Procurement Manual and Procedures*
- WHC-CM-5-4, *Laboratories Administration*
- Sample and waste disposal instructions are found in the series of laboratory procedures numbered LO-100-nnn
- Sample receiving and custodianship instructions are found in the series of laboratory procedures numbered LO-090-nnn.

5.3 Physical Facilities Systems

The WHC-SD-HIE-001 Rev. 0 describes facilities orientation and operation, hazards identification and evaluation, and operational safety limits. Table 5.1 lists physical facilities in the 222-S and 222-SA Laboratories.

The 222-S Laboratory is a two-story building with its main work areas on the first floor and a section of the basement. The 222-SA Laboratory is a five-wide modular building containing two laboratory work areas, a lunch room, and office.

The 222-S facility has emergency power service for ventilation and lighting. Critical computer systems are protected by uninterruptable power supplies.

Laboratory work areas are maintained at negative pressure with respect to atmosphere using a once through ventilation system. The air supply system is designed to distribute filtered air into the laboratory work areas. Samples are stored according to type of analysis, activity level, and to prevent cross contamination. Refrigerator temperature is monitored and maintained at the specified level.

Table 5.1 Physical Facilities in the 222-S and 222-SA Laboratories

Facility	222-S	222-SA
Sample Receiving Area	Yes	Yes
Sample Storage Area	Yes	No
Hot Cell for Sample Extrusion	Yes	No
Standard Preparation	Yes	Yes
Sample Preparation Organic:VOA[2], SV[3]	Yes	No
GC/MS[4]: VOA, SV, GC	Yes	No
Sample Preparation/Extraction Inorganic: ICP, AA[5]	Yes	No
Wet Chemistry	Yes	Yes
Preparation for Radiochemistry	Yes	No
Counting Room	Yes	No
Chemical Storage	Yes	Yes
Shipping Area	Yes	Yes
Waste Storage	Yes	Yes. Temporary storage
Flammable Gas Storage	Yes	Yes
Non-Flammable Gas Storage	Yes	No
Lunch Room	Yes	Yes
Offices	Yes	Yes
Change Room	Yes	No
Equipment	Yes	Yes
Equipment Storage	Yes	Yes
Quality Assurance Records Storage	Yes	Yes
Glass Shop	Yes	No
Computer Room	Yes	No

[2] VOA = volatile organic analyte (analysis)

[3] SV = semivolatile (organics)

[4] GC/MS = gas chromatography/mass spectrometry

[5] AA = atomic absorption

This page intentionally left blank.

6.0 SAMPLE CUSTODY AND HANDLING

6.1 Chain-of-Custody

The 222-S Laboratory is restricted to authorized personnel only. Admission to the 222-S Laboratory area requires special badging and personnel are checked before entering the Hanford sites. The entire 222-S Laboratory is considered a secured area. During the day, exit doors are either monitored by the personnel or locked if personnel are not present. Exit/entrance doors are locked during the night.

Chain-of-Custody is maintained as required between the sample collection and the laboratory receiving area by the client. Custody is transferred at the laboratory receiving area to the laboratory internal custody. The laboratory receiving area refers to sample receiving custody. Internal custody refers to maintaining custody as the sample is dispersed to various groups within the laboratory for analysis. Internal sample custody is maintained until disposal of the sample from the laboratory. The following procedures are for sample custody and handling:

- LO-090-101, *Sample Receiving and Custodianship-222-S Laboratory*
- LO-150-132, *Sample Storage, Rooms 2E and 2B, and 222-S Laboratory Hot Cells*
- LO-150-135, *Sample Disposal Criteria.*

6.2 Holding Times

The majority of work supporting RCRA and CERCLA requires adherence to holding time requirements. These holding times begin when the sample is collected. Holding time is understood to be the time between sample collection and preparation and/or final analysis.

Tables 6.1 and 6.2 list regulatory required holding times for both EPA or CLP for projects that have to comply with either RCRA or CERCLA. Projects that do not have regulatory holding times are not required to comply with the holding times listed in Table 6.1 and 6.2.

All holding time agreements should be either based on SW-846 or CLP specifications and shall be established between the Laboratory and client before sample analysis. If the Laboratory is unable to meet prescribed holding times, (e.g., due to sample radioactivity), the client must agree, in writing, as applicable, to this fact before work begins. The client is responsible for ensuring the timely delivery of samples to the Laboratory to enable laboratory personnel to meet holding time requirements.

Table 6.1 Holding Times for Aqueous Matrices: Based on SW-846 Regulatory Requirements

Analytes	Holding times
Chloride	28 days
Cyanide (Total & Amenable)	14 days
pH	24 hr
Chromium VI	24 hr
Mercury	28 days
Metals (Except Cr VI & Hg)	6 months
Nitrate	48 hrs
Sulfate	28 days
Sulfide	7 days, add zinc acetate
Organic carbon, total (TOC)	28 days
Radiological Test (Alpha, Beta, and Radium)	6 months

Table 6.2 Holding Times for Organic Analyses: Based on Regulatory Requirements

Analytes or Method of Extraction	CLP (OLM02.1) Contracted Holding Times Number of days for Extraction/ Number of Days for Analysis	SW-846 Holding times Number of Days for Extraction/ Number of Days for Analysis
Volatile organics	10 days for extraction and analysis after validated time of sample receipt (VTSR).	14 days for extraction and analysis.
Semi-Volatile Organics	Water samples: 5 days after VTSR/within 40 days after extraction. Soil samples: 10 days after VTSR/ within 40 days after extraction.	Water samples: 7 days/ within 40 days after extraction. Concentrated waste samples, soil/ sediments, and sludges: 14 days/ within 40 days after extraction.
TCLP[6] Extraction (Hazardous Waste Toxicity)	NA	7 days
Pesticides, chlorinated or organophosphorus (SW-846 method), PCBs[7] (SW-846 method)	NA	Water samples: 7 days/ analyze within 40 days after extraction. Concentrated waste samples, soil/ sediments, and sludges : 14 days/ analyze within 40 days after extraction.
Pesticides including PCBs (CLP method)	Water samples: 5 days after VTSR/within 40 days after extraction. Soil Samples: 10 days after VTSR/within 40 days after extraction.	NA

[6]TCLP = toxicity characteristics leaching procedure

[7]PCB = polychlorinated biphenyl

The project coordinator, sample custodian, and chemist are responsible for tracking and complying with the regulatory holding times. Holding times are recorded on the analytical card and tracked in the LABCORE system.

The holding times tracking system is dependent on electronic tracking systems and communications between the sample custodian and laboratory analysts. Holding times are recorded on the analytical cards (when in use) and on the LCCS. The new LABCORE can also track holding times and sample retention time in the laboratory. The project coordinator is responsible for identifying holding times with the clients and notifying the responsible manager, chemist, and sample custodian before sample arrival. The sample custodian is responsible for electronically notifying the laboratory personnel (responsible manager and chemists) upon receiving samples. After sample receiving, the responsible manager and chemist are responsible to meet the holding times requirements.

6.3 Sample Receiving Procedure

The laboratory sample custodian shall perform the following actions at sample receiving according to the LO-090-101 procedure.

- Document the common carrier that delivers samples to the laboratory. A copy of the shipping document shall become part of the permanent laboratory record.
- Check that the outer-most sample container(s) is not damaged.
- Check that the outer-most sample seal(s) is intact.
- Verify that the chain-of-custody documentation is accurate, complete, legible, and includes the following information:
  - Project name or number
  - Client name and client sample number
  - Date and time of sampling and sampling location for each sample
  - Container types, sizes, and number of containers
  - Sample preservation (when used)
  - Analyses requested (or referred)
  - Signature of the person receiving and relinquishing
  - Date and time of relinquishment and receipt
  - Descriptions of any deficiencies identified by previous custodians.

- Check and record incoming cooler temperatures where volatiles, acid/base neutral, pesticide, or cyanide analysis are requested; note any deviations from 4°C ±2°C. Certain conditions, such as sample containers (sample pig and cask), prevent a temperature check. Therefore, verification of the temperature shall be excluded under such conditions.

- Verify that client sample numbers on the chain-of-custody match those on the sample containers.

- Verify that collection date and date of laboratory receipt are within method- or project-specific holding time requirements.

- Notify laboratory staff as soon as possible when the sample holding time is less than 48 hours.

- Notify the client of sample receipt within 24 hours, by telephone, facsimile, or electronic mail. Notification documentation (e.g., copies of the telephone logs, facsimile, or electronic mail) shall be included in the report package if requested.

- Notify the client of nonconformance within 24 hours, by telephone, facsimile, or electronic mail. Nonconformance notification and client responses shall be documented by project coordinator and kept on file in the laboratory.

In the event that prompt client response (within two business days) is not received to a notification of nonconformance, the laboratory can proceed at its discretion to analyze the samples. All actions and decisions must be documented in the project file, and include a summary of the nonconformances and their actions in the case narrative accompanying the final report.

When sample receipt is completed, samples are then accepted for analysis. Upon acceptance of samples, the sample custodian shall sign the chain-of-custody and shall initiate internal chain-of-custody for analytical activities.

6.4 Sample Log-In And Tracking Procedure

Internal chain-of-custody is initiated by sample log-in (see LO-090-101) and remains unbroken until sample disposal is completed. The sample custodian(s) is responsible for maintaining custody of the samples during the log-in and distribution processes. The sample custodian is also responsible for ensuring that all records documenting that possession are properly completed and placed in the laboratory record system. Additional information such as radiation level should be provided by the field sampler and documented on the chain-of-custody form. The project coordinator is responsible for checking the information related to storage, preservation, holding time, and requested analysis to make sure it matches the work-authorizing document (e.g., Waste Analysis Plan).

The following activities are part of the sample log-in and tracking procedures.

- The samples are secured in refrigerated storage or storage cabinets as appropriate after sample log-in. Any safety hazards communicated by the client are identified.

- Either the LCCS or LABCORE is used to assign sample numbers. Subsamples generated at the sample preparation stage (e.g., hot cell) are recorded in the logbook. Each sample is given a unique identifier regardless of its re-sample status. Every sample, sample replicate, and subsample shall be labeled in a manner that allows traceability to the parent sample number.

- A cross-reference system is established to correlate the client sample number and the laboratory sample number using the chain-of-custody form or the LABCORE.

- The LABCORE system is used for tracking sample status and holding times. Regulatory holding times and sample log-in times are recorded in the LABCORE system and can be traceable. Sample retention times are also recorded in LABCORE; therefore the chemist can track the status of any particular sample using the LABCORE system. This system allows the laboratory managers to assess whether holding times will be met or exceeded.

- Sample turnover times (from the time the laboratory received samples to delivery of the data report to client) are tracked in the same manner as the regulatory holding times.

6.5 Laboratory Internal Chain-of-Custody

Procedure LO-090-101 addresses sample receiving and custodianship for the 222-S Laboratory. The internal chain-of-custody remains unbroken using a sample log-in and log-out system. Once samples are in the laboratory, sample custody is controlled by the sample custodian. The location of all samples and the person in control of the samples is traceable from the time samples are received at the laboratory until the analysis is completed and the sample is disposed of or returned to the client.

6.6 Sample Disposal

Sample disposal includes disposing of or returning the original samples to the client. The Hot Cell and Sample Preparation organization is responsible for disposing of client's samples that have been processed for analysis in the laboratory. The Hazardous Waste organization is responsible for disposing of samples that have been relinquished from the laboratory. The laboratory has procedures in place to meet the following requirements:

- Disposing of or returning samples to the client

- Maintaining records that identify the date of disposal

- Meeting all local, state, and Federal regulations

- Documenting the status of the sample in the chain-of-custody record (if samples are returned to the client, custody records shall document the return)

- Shipping documentation shall be maintained with the sample chain-of-custody by the sample custodian and shall meet Department of Transportation and applicable carrier requirements for transportation.

This page intentionally left blank.

7.0 CALIBRATION

This section describes the calibration practices used by the 222-S Laboratory. These practices include:

- Calibration of laboratory measurement systems
- Traceability and documentation of standards used in calibration
- Recordkeeping for calibration data
- Calibration of balances, thermometers, and pipettes.

The initial and continuing verification of laboratory measurement system calibration is described in Chapter 11.

7.1 Calibration Of Laboratory Measurement Systems (LMS)

The requirements for calibration of each LMS are included in the laboratory procedure(s) that govern its operation. These requirements include, at a minimum:

- Number and range of concentrations or activities to be used in the calibration
- Frequency of calibration
- Criteria used to accept calibration
- Actions to be taken if calibration fails acceptance criteria.

Any variances from the requirements included in the laboratory procedures must be based on an agreement between the Laboratory and the client (e.g., via letter of instruction, tank characterization plan, statement of work).

Calibration requirements in laboratory procedures used for regulatory-driven analyses must conform with calibration requirements specified in Section 7.4.1, 7.4.2, and 7.4.3 of the Hanford Analytical Services Quality Assurance Plan (HASQAP).

Instruments that fail acceptance criteria shall be investigated and re-calibrated. Instruments are not allowed to be used for sample analysis until they meet acceptance criteria. Appropriate corrective actions are described either in calibration procedures (for radchem) or in the LA procedures (for organic and inorganic groups).

A level of independence shall exist between the materials used for LMS calibration and those used for initial calibration verification (described in Chapter 11).

7.2 Specifications Of Standards Used In Calibration

The Standards Laboratory is responsible for the procurement and preparation of materials used for LMS calibration. When appropriate, these materials shall be traceable to a nationally or internationally recognized standard agency source (e.g., National Institute of Standards and Technology [NIST]) or measurement system. Alternatively, the Standards Laboratory will procure materials of known quality and will document the materials as described below.

The Standards Laboratory maintains records of procured reference materials which include, at a minimum:

- Source vendor
- Lot number
- Purity
- Date of preparation and/or expiration
- Certified concentration or activity of the standard material (including uncertainty if available).

In addition, for calibration standards prepared by the Standards Laboratory, the following information, at a minimum, is maintained on standard preparations and if possible placed on the label:

- Name of the preparer
- Date prepared
- Unique identification of the standard
- Dilution or other preparation performed (e.g., digestion or mounting)
- Final concentration or activity
- Expiration date or shelf life (standards with indefinite shelf life are so designated).

When these records are maintained, the final standard shall be considered traceable to the original standard reference material.

This traceability data is available from the Standards Laboratory upon request. Where beneficial, the Standards Laboratory can present this data as a certificate documenting the source of the standard reference material and its subsequent preparation for use as a calibration standard. Some standard materials that have long shelf life may be re-certified using the LO-120-101 procedure.

Calibration standards that have exceeded their expiration date or shelf life shall not be used for LMS calibration and shall be removed from the laboratory or clearly marked as unusable for calibration purposes unless re-certified as appropriate.

Some standards, such as radioactive materials, are verified by preparing mounts. The mounts are counted and compared to the calculated certified value. Some standards such as those for ICP are submitted to the analytical laboratory based on the traceable certified value; material is then checked against an independent standard by the analytical laboratory for verification. The data is documented in the data management system, (e.g., LMCS). Organic compounds used for calibration standards are procured by the Standards Laboratory, but are prepared by the chemists before calibration.

7.3 Calibration Records

The 222-S Laboratory maintains calibration records for all methods requiring LMS calibration. These records include raw data (e.g., instrument response values necessary to reconstruct the calibration; such as peak areas, counts, absorbance values, or emission intensity), the standard used, corresponding concentration or activity data, calculated calibration factors (e.g., regression results), criteria used to accept or reject the calibration (e.g., correlation coefficient), effective date of the calibration, and analyst's name or initials.

Calibration records are maintained in logbooks, notebooks, or electronic files as appropriate. When completed, these books are maintained in accordance with Section 10.0.

Results for sample analyses performed at the 222-S Laboratory shall include an analysis date. This date and the recorded effective calibration date permits traceability of the analysis to the most recent preceding LMS calibration. If ambiguity is possible because a calibration was performed after a sample analyses on the same date, either time-of-day information must also be recorded (for both calibration and analyses), or the date of the applicable calibration must accompany analysis results.

7.4 Balances, Thermometers, And Pipettes

7.4.1 Balances

As a component of the Hanford Site Component Based Recall System (CBRS) program, balance calibration checks are performed on a quarterly basis by an approved metrology organization. Balances not passing these checks are removed from service. In addition, laboratory staff verifies balance performance on a monthly basis. These calibration records include, at a minimum, the date of calibration, the initials of the person performing the calibration, a unique identifier for the balance, and the date the calibration expires. This information is affixed on or near the balance.

The calibration of balances used for quality-affecting measurements is verified, at a minimum, before use or on a daily basis, whichever is less frequent, by measurement of an

internal or external check weight (LQ-140-006, *Routine use of analytical balances*). The results of the check are logged in a notebook maintained in the same room as the balance. This notebook also contains acceptance criteria for each logged balance. If the check fails, the balance is taken out of service until it is recalibrated.

Balances that do not satisfy 222-S Laboratory calibration requirements are labelled and are not used for quality-affecting determinations.

7.4.2 Thermometers

Thermometers and thermocouples used for sample storage refrigerators are checked annually at a minimum against a nationally recognized standard (e.g., NIST certified thermometers).

If temperature measurements affect the quality of data obtained from specific laboratory measurement systems, the governing laboratory procedure shall include the steps required to ensure sufficient temperature accuracy and precision.

7.4.3 Pipettes

Daily or before-use volume checks of mechanical pipettes or dispensers is impractical for economic or practical reasons. Volume checks by weight for mechanical pipettes and dispensers located in the radiologically controlled hoods would require an analytical balance in each hood. This is economically impractical and space is often not available. The alternative is to remove the mechanical pipettes or dispensers out of the hood to an analytical balance outside the hood. The radiological controls necessary for removing pipettes and dispensers from a Contamination Area (the hood) into a Radiological Buffer Area (outside the hood) and performing the volume checks on a daily basis also make this alternative impractical.

The 222-S Laboratory has adopted the following program to ensure accuracy of volume measurements:

- The calibration of mechanical pipettes and dispensers used for quality-affecting determinations is checked by weight bi-monthly by 222-S Laboratory staff. The results of these checks are documented chronologically per pipette. A calibration sticker indicating its calibration status is attached to each mechanical pipette and dispenser. Devices found to be out of calibration are removed from service. This process is documented in the following procedures:

    - LQ-510-113, *Calibration of Volumetric Dispensers*
    - LQ-510-114, *Calibration of Motor-Driven Burets*
    - LQ-510-123, *Calibration of Pipettors used in 222-S Laboratory*.

- Pipette and dispenser performance is also monitored on a batch-wise basis through their use for preparation of laboratory control samples (LCS) or blank spikes. Individual mechanical pipettes or dispensers are assigned to the analytical procedure, generally

located where the analytical procedure is performed, and considered as part of this analytical procedure device. Performance of the LCS is monitored by a data management system (e.g., LABCORE) and also monitored by control charting. Acceptable performance of LCS ensures that the pipettors and/or dispensers used for the test are performing adequately. A failure of LCS results in an investigation of mechanical pipette and dispenser accuracy, validity of standards, instrument calibration, analyst practices, and other causes and properly documented.

Other WHC documents that contain calibration guidelines or policies include the following:

- WHC-CM-4-2, *Quality Assurance Manual*
  QR 12.0 "Control of Instruments"
  QI 12.2 "Operator Calibrated Measuring and Test Equipment"
  QI 12.3 "Calibration of Plant-Installed Instrumentation"
  QI 12.4 "Calibration Control of Measuring and Test Equipment"
  QI 12.5 "Statistically Controlled Analytical Instruments"
  QI 12.6 "Determinately Controlled Laboratory Instruments"
  QI 12.7 "Assuring Availability of Laboratory Instruments"

- WHC-CM-5-4, *Laboratories Administration*
  8.2 "Laboratory Instrument Calibration Control Program".

This page intentionally left blank.

8.0 LABORATORY PROCEDURES

Laboratory activities are directed and controlled by approved procedures. Each has a unique identification code based on an approved numbering system (WHC-CM-5-4, Section 3.9).

Each procedure code includes a two letter identifier which denotes the general task category; e.g., LA represents analytical procedure, LC for computer, LO for operating procedure, LQ for quality control, LT for laboratory technology, LR for laboratory reference material.

8.1 Procedures And Supporting Documents

A standard format is used for each procedure as guided by the *Writer's Guides for Technical Procedures*, DOE-STQ-1029-92 and in WHC-CM-5-4 Section 3.9.

Procedures for each laboratory analysis and/or activity are prepared by chemists or other technically qualified personnel.

The procedure is reviewed by technical organizations or individuals for technical correctness. Reviewers document their comments using a Procedure Review and Approval Form (PRAF). The procedures shall be approved before use in accordance with WHC-CM-3-5 Manual, Section 12.7 and 4.0.

The approved procedure is issued as a performance "goldenrod" copy with an identification code (document number, revision/modification number), release date, official release stamp, author, author's manager, and the title. Up-to-date procedure distribution is done by Procedure Administration. White-copies of procedures are uncontrolled copies and are used for reference only.

During development of new procedures, a user test should be performed under the direction of the author and recorded on the User Test Approval Form or issued as a supporting document (only for a new analytical method).

Active procedures have no fixed expiration date, but are required to be reviewed every 24 months for accuracy and adequacy by technically qualified personnel. The review is documented on the PRAF and maintained by Procedure Administration.

A procedure can be inactivated or removed by the responsible scientist or engineer, using the PRAF or other signed notification with management approval.

8.1.1 Preparation And Review Of Supporting Documents

Supporting documents (SDs) are used to document Quality Assurance Program Plans (QAPPs), Quality Assurance Project Plans (QAP$_j$Ps), basic laboratory practices, technical project plans, and laboratory test plans. Laboratory SDs do not have a specific format.

These documents provide a combination of administrative guidance, technical direction, and quality requirements. They are reviewed internally and externally based on the topic and application. The Supporting Document Release Station assigns identification numbers for all SDs.

The responsible manager (approval authority) for each SD identifies the reviewers within WHC organizations. The approval of the SD is documented on the Engineering Data Transmittal (EDT) form (BD-7400-127) by the reviewers.

An SD can be canceled and recalled by use of an internal letter.

8.2 Change Control

8.2.1 Supporting Document Changes

An SD can be revised by the author using an Engineering Change Notice (ECN). There are two types of ECN changes: direct or supplemental changes. For direct changes, the ECN summarizes the change description and is the authorization for a new revision of the document to be issued. For supplemental changes, the ECN delineates the change details and becomes a part of the current document. Supplemental ECNs are incorporated into the document in the next revision. Both methods are detailed in Procedure EP 2.2 in WHC-CM-6-1. Approval signatures are obtained from the author and the author's manager. EDC release-stamps the ECN/document, and Information Resource Management Document Control distributes the complete document revisions or documents with a supplemental ECN incorporated to the same (or officially revised) recipients as the original document.

8.2.2 Procedural Changes

The laboratory makes changes to procedures (both regulatory and internally developed procedures) for a variety of reasons. The Procedure Change Authorization (PCA) (form A-6400-242) or PRAF is used for documenting and issuing procedural changes described in the following. Three categories of changes are used based on the HASQAP concept.

8.2.2.1 Definition Of Procedural Changes

Substitution is an adjustment in a procedure that has no significant effect on final results. This would be clearly evident in the quality control data associated with the final results.

Deviation is divergence from the original procedure that does not adversely impact the analyst's ability to meet the precision, accuracy, detection limit, selectivity, and quality control criteria of the procedure. Therefore, the decision to deviate shall be based on published literature (e.g., alternate methods) and/or known sample chemistry. For documentation requirements, see Section 8.2.2.2.

Modification changes the character of a method, and thereby, potentially limits a method's capability to meet the originally stated precision, accuracy, detection limit,

selectivity, and quality control criteria. Because the impact of such a modification cannot be ascertained before implementation, it must be demonstrated by application. For documentation requirements, see Section 8.2.2.2.

8.2.2.2 Control Of Procedural Change

Because substitution does not impact the method performed, no documentation of change is required (see Section 8.2.2.1 under substitute). Only the documentation necessary to allow reproducibility of results is required.

Deviation requires documenting the changes made to a procedure. Documentation of deviations made shall be included in the final report narrative. Justification of the deviation should be evident in the acceptable performance associated with the final results and should also be addressed. Acceptable performance shall be demonstrated by the analyst's ability to meet or exceed the original method's precision, accuracy, detection limit, selectivity, and quality control criteria. Whenever possible, the client should be notified of deviations before starting work. When a deviation is used routinely, it shall be incorporated into the procedure.

Modification requires the procedure to be qualified (see Section 8.5), documented, approved by laboratory management, and agreed on with the client before work. Requirements for implementation and personnel training shall apply as necessary to all laboratory procedures. Justification of the modification should be evident in the quality control data associated with the final results and should also be addressed. A modification with long-term applicability should be developed into a new laboratory procedure that is issued with a new title and code.

8.3 New Analytical Methods

The EPA, DOE, and consensus methods (e.g., American Society for Testing Materials [ASTM], standard methods) are recommended where the technique is applicable to the sample matrix and the overall objective of the analysis.

New analytical method procedures shall be qualified before use (see Section 8.5). New methods are defined as methods used for the first time whether based on published, well-understood procedures or developed in the laboratory. The following protocol is followed as applicable for developing new analytical methods. The first stage is to conduct and document the performance using simple standard materials and to establish the following parameters as appropriate:

- Accuracy/precision
- Detection limits
- Individual interference studies
- Parameter variable studies
  - Linear ranges
  - Effect of interferences (chemical)

- Effect of reagent concentrations
- Effect of instrument parameters
- Kinetic effects.

The performance shall be verified using the following parameters as appropriate:

- Complex standards, if available or prepared simulated
- Matrix standards, if reasonable
- Spikes or method standard addition on actual samples
- Independent analytical method
- Sample exchange programs with other laboratories
- Comparison with standard or accepted methods on actual samples.

8.4 Modification Of Required Regulatory Methods

The following procedures shall be used when modifying required regulatory methods. These procedures shall be followed only when the precision, accuracy, detection limits, and/or quality control criteria of approved methods might be impacted (positively or negatively). Method qualification requirements are in Section 8.5.

8.4.1 Justifying Modification

The citation of the original, required regulatory method shall be provided. All modifications to the required regulatory method shall be specifically described by providing a synopsis (or direct quotation) of the regulatory method requirement and a description of all changes made. The reason(s) why the requirement cannot be met and/or the technical, health and safety, environmental, and/or waste disposal merits of the modification(s) shall be provided.

8.4.2 Documenting The Modified Method

In cases where changes are restricted to specific sections of the required regulatory method, the text of the modification shall be provided (e.g., different instrument configuration, different spike or surrogate compounds). A complete copy of the modified method shall be provided when extensive modifications are necessary. The modified method shall be managed as a controlled document, subject to the necessary review and approval.

The impact of the changes on the published precision, accuracy, and/or detection limit of the modified method shall be established by experiment. Any modification to the approved quality control procedures for the method shall be described and the acceptance criteria specified (e.g., using special surrogates and/or spikes, detection limit). See Section 8.5 for the approach required for method qualification.

Implementing the final modified method as a production method in the laboratory requires signatures of approval that all requirements have been met. Approval signatures are required from the laboratory quality assurance representative and a representative of laboratory

management from the section where the method is to be performed. Modifications to the regulatory-required methods also require program, DOE-RL, approval for use.

All original laboratory test data shall be retained on file to enable retrospective examination of the method should the need arise.

8.4.3 Reporting Results From Modified Regulatory Methods

All modified methods shall be issued with unique identification codes to notify the data user that the method has been modified. To the extent practical, modified methods shall retain a method reference (identifier) to the original method.

8.4.4 Acceptance Criteria For Modified Methods

Modified methods shall include the acceptance and performance criteria for precision, accuracy, calibration, and detection limit established during the qualification experiments.

8.5 Qualification Of Analytical Methods

Qualification is the process of determining the suitability of a measurement system (preparative or analytical) for providing useful analytical data. Performance parameters of the method are compared with the requirements for the analytical data. Several approaches may be used to qualify a method and include the following.

- When suitable reference materials are available to adequately test method performance versus matrix effect, performance is demonstrated quite easily. This test consists of analyzing a sufficient number of reference samples and comparing the results obtained to that quoted for the particular material. A simulated matrix may be the closest performance indicator available.

- When suitable reference materials are not available, two other approaches are considered reasonable. The first involves comparing the new method against a known, well-established (laboratory-approved or regulator-recognized) method; the second involves inter-laboratory comparisons. In limited cases, matrix spikes and/or surrogates may be used; this is the least desirable because of the limitations associated with preparing spike and/or surrogate materials. Also, spikes and/or surrogates may behave differently than the actual sample in the process investigated.

Generally accepted standards dictate using a minimum of four replicates for each test case. Whenever possible, seven replicates should be used. This data should then be used to establish statistical control on an advisory basis until sufficient data are acquired, typically considered to be 30 data sets.

A method must also be evaluated for its overall effectiveness in the areas of sensitivity, linear range limitations, matrix or analytical precision, accuracy, and counting statistics

(radiochemistry), as applicable to the method and/or analyte. Method testing includes the following:

- Method detection level determination and/or minimum detectable activity (according to Section 12.0)
- Method blank evaluation
- Precision and accuracy determination
- Counter performance, if applicable
- Uncertainty
- Determination of method interferences as appropriate to the method (i.e., preparative versus determinative).

These studies shall be documented in the procedure or in the referenced document.

9.0 DATA COLLECTION, REDUCTION, AND REPORTING

Data collecting and reporting processes include proper sampling (client's responsibility), correct chain-of-custody, collection of raw data, data reduction and calculations, and transferring results to a final form for reporting.

9.1 Data Collection

Raw data are generated by either manual or electronic means in the 222-S Laboratory. Manual collection is done by the analyst and recorded on either laboratory cards, work sheets, or log books according to applicable procedures. Raw data is defined as data that can not be easily derived or recalculated from other information. Raw data is collected and maintained based on the method or instrument. For instruments that have a built-in integration or detector signal processing software, the instrument controller output is considered the raw data.

Information used in sample preparation (e.g., weight or volume of sample used, percent dry weight for solids, dilution factor used) and in the calculations (e.g., raw data or detector signal data, calibration, tuning records, interference check results or correction factors, blank or background correction values) shall be maintained, if available, in order to enable reconstruction of the final results at a later date.

The cognizant chemist is responsible for designating raw data filing system. Raw data can be filed by project, batch, or by filing chronologically. Raw data is controlled by the laboratory and may be reviewed by the client upon request.

Most of the analytical systems in the Laboratory are computer controlled and have the capability to generate and report both hard copy and electronic data. In these cases laboratory cards are not used for data recording and calculations.

Each individual generating data or information is responsible for identification of data entry errors, sample identification errors, and calculation errors. The person entering the raw data is responsible for checking the integrity between raw data and entered data. Any of these entries must be legible, understandable and reproducible with a standard photocopier.

Results are calculated from raw data, then transferred to LABCORE or LCCS. Analysis of standards and matrix spikes are manually entered into the Laboratory Information Management System (LIMS) or LABCORE.

Data entry errors shall be corrected by one line drawn through the error that is then dated and initialed. Data changes shall be marked by one line drawn through the change that is then dated, initialed, and explained, as appropriate.

Only authorized personnel have access to the laboratory information management systems. Users are screened by their job functions and categories. Only selected laboratory personnel have the full range of data management privileges for data entering and screening.

Final data is controlled by the laboratory. Data records are dispositioned according to the laboratory Record Inventory and Disposal System (RIDS) (See Section 10.0).

9.2 Data Reduction

Data from sample analysis should be reduced according to applicable procedures. Data reduction includes activities that convert analytical measurements and instrument responses into reportable results. These activities may involve calculations, changes to the units or the data values, statistical and mathematical analysis, as well as correction of final results for appropriate backgrounds and/or interference (e.g., Compton effects for gamma energy analysis [GEA] and inter-element correction for ICP). Data reduction shall be documented.

Calculations that are used for generating a final result are described in the procedures and documented on the analytical card or on the Analytical Card Enhancement (ACE) form. The laboratory leader or chemist is responsible for calculating and checking the accuracy of the final results. The laboratory QC personnel are responsible for randomly checking calculations.

Computer programs used for data reduction shall be verified with known results before use to ensure calculation and data manipulation programs perform properly.

9.2.1 Significant Figures

Data reduction procedures on significant numbers, rules for rounding, and reporting rules are provided in LO-150-127. Vendor-supplied software may not meet the general rules for significant figures; the laboratory should work with the client to determine the best way to report results, based on the project needs.

Once the number of significant figures obtainable from a type of analysis is established, data resulting from such analyses are reduced according to set rules for rounding off (see Section 9.2.2).

Reported values should contain only significant figures and the exponential notation should be used.

9.2.2 Rounding-Off Methods

The rounding-off method is used when an observed or calculated value needs to be reported in a limited number of significant figures for determining conformance with specifications. Rounding off numbers shall be performed at the end of a series of calculations (see LO-150-127).

9.3 Data Review

Data review refers to the process of determining whether data conform to specified requirements. The data review system is described in the following in accordance with laboratory-established procedures to review data before data reports are prepared.

The technologists, chemists, or laboratory leaders can perform data entry and calculate results and/or QC parameters (precision or accuracy). These calculated results or data are reviewed by either the chemists, by the supervisor, and/or by the laboratory QC staff. The data review activities are briefly described by the following.

- The person who is responsible for calculating data shall check calculations against laboratory procedures.

- The supervisor or chemist is responsible for checking the calculations performed by the analyst, checking calibration information to ensure the stability and accuracy of the instrument, and checking administrative records or documents to ensure the calculated results are associated with the appropriate samples and final reports.

- The chemist is responsible for reviewing data against applicable QC criteria to verify that the analytical system is performing acceptably (see Section 11.0 for details). If QC criteria did not meet QC requirements, data within the batch shall be evaluated to determine if there were any adverse effects on the data; the sample shall be re-run or the data shall be reported with qualification(s), which will be detailed in the narrative as appropriate to the condition.

- Sample identification during sample collection and preparation, and certain raw data records are transferred manually and are checked by the analyst, chemist, and/or by the manager.

- Laboratory QA/QC staff is responsible for performing independent spot checks on QC parameters, calculations, administrative information, and checking that data are accurately transcribed. The frequency of data review by the laboratory QA/QC staff depends on the type of project, ranging from 5% to 100%.

The project coordinator is responsible for checking compliance with the request for analysis.

Errors detected in the review process shall be referred to the appropriate responsible party for corrective action (see Section 15.0).

Final data on the laboratory cards and worksheets are then entered into either the LCCS or the LABCORE after calculations are performed and data are reviewed.

9.4 Data Reporting

Measured parameters, the details of analysis, and the data values are reported in accordance with the requirements of the end-user as specified in the agreement between the laboratory and the client. The type of information, level of approval, data reporting format, and means of delivery shall be discussed and agreed upon between the laboratory and the client (see 9.4.1 for information required in the reporting documentation). The inorganic or organic results are reported as numeric values. If the value is less than the instrument detection limit (IDL) or method detection limit (MDL), it is reported as the numerical detection limit proceeded by a less than symbol. If the detection limit is reported else where, the results may be reported as undetectable (e.g. "N.D"). Appropriate data qualifiers are used either with the results or discussed in the case narrative to provide information on the confidence level of the results (see Section 12.5).

Radiochemical results shall be reported based on calculated concentration or activity values (whether negative, positive, or zero) using the appropriate blank for each nuclide. The measured activity or concentration should be reported with estimates of the associated counting uncertainty and total propagated uncertainty but without comparison to the estimated *a priori* minimum detectable concentration (MDC). The MDC should not be reported to the client *in lieu* of low-level measurements.

The 222-S Laboratory provides various types of data reporting systems ranging from a simple printout of the LMCS/LCCS or LABCORE or letter reports to a completed data package. In addition, telephone reporting is acceptable for emergency situations and shall be agreed upon between the laboratory and the client. The LMCS tracks results of QC samples (e.g., laboratory control samples, preparation blanks, and standards for verifying instruments or analytical performances). The LCCS is a database that is used to record sample results. The LABCORE is a database that contains both sample and QC data.

The Program Support organization is responsible for preparing data packages. After the analytical results are entered into LCCS/LABCORE, the analytical batches are signed out in the project coordinators's logbook by Data Handling personnel.

When review is completed by the chemist and necessary corrections are made, the analytical batches are checked out and transferred to project coordinators. The data is assimilated and the narrative is written by the project coordinator into the data package format required by the specific project plan. Concurrent with the project coordinator's review the batch sets are reviewed by Laboratory QC personnel. The QC personnel primarily review the calculations for accuracy, precision, and QC checks against the established QC criteria. Those items found deficient or requiring further explanation are written onto QA comment forms, requiring timely response from the responsible chemist.

After data handling review, QC review, and project coordinator review the case narrative, summary tables, and analytical data are compiled into the reporting format requested in the work request. Upon completion of all corrections, the data is sent to Data Packaging where the formal data package is completed. If the data package requires data validation, the entire package is sent to an appropriate organization for validation.

9.4.1 Data Reporting Documentation

The reporting documentation shall include the following information:

- Laboratory name and address
- Sample information including unique laboratory identifier cross-referenced to client identification, sample collection date and time, date of sample receipt, and date(s) of sample preparation and analysis
- Analytical units and results, reported with an appropriate number of significant figures
- Report uncertainty for radiochemical analysis
- Detection limits
- Method reference
- Identification of any amended test results; signature and title of person accepting responsibility for the report contents; and identification of subcontracted results if applicable
- Appropriate QC results (correlation with sample batch shall be traceable and documented)
- Appropriate data qualifiers with definitions and a narrative on the quality of the results if applicable
- Additional data reporting (i.e., the percent of moisture/solid or correction for equivalent dry weight may be included if requested by the client).

9.4.2 Preliminary Reporting

A preliminary data reporting system shall be established between the client and the laboratory to address emergency situations. The type of information, level of approval, data reporting format, and means of delivery shall be discussed and agreed upon between the laboratory and the client. The emergency situation may include, but is not limited to, screening activities for safety issues, critical analytes, or limiting sample amount.

For example, the action level of radionuclides of interest is established in the analysis plan for potential health hazards reasons. Sample results that show a radionuclide of interest exceeding this action level require an immediate report to the client to initiate a proper response. A preliminary report does not go through the routine data review and verification cycle. The immediate supervisor and chemist are responsible for reviewing the data before reporting to the client.

This page intentionally left blank.

10.0 RECORDS

The quality records include, but are not limited to the following:

- Procurement documents
- Training records
- Calibration records
- Maintenance records
- Chain-of-custody forms.

Information Resource Management (IRM) is responsible for the quality records system based on WHC-CM-3-5 Sections 5 and 9. Specifications, preparation, review, approval, and maintenance of quality records are governed by the WHC-3-5 Sections 5 and 9. A computer system is used to maintain and access quality records including electronic media to ensure the records are useable and retrievable.

10.1 Generation Of Quality Records

Documents and data referenced by final reports shall be retrievable from the records system, except for readily available references (e.g., national codes and standards).

10.2 Receipt Control

The Program Management and Integration organization is responsible for maintaining the Laboratory Technical Information Center and for coordinating retrieval of the record copy that is maintained in the laboratory. The IRM is responsible for receiving the records and implementing a system of receipt control of the records for permanent and temporary storage. Information Resource Management has the capability to do the following:

- Designate the required records
- Identify records received
- Receive and inspect incoming records
- Submit completed records to the records-holding facility without unnecessary delay.

10.3 Records Validation

Records considered valid shall be signed, initialed, stamped, or otherwise authenticated, and dated by the document's originator (WHC-CM-3-5, Sections 9, 4 of 14). Electronic records shall be validated by signing and dating a paper copy of the first page of the record. These records may be originals or copies. Handwritten signatures are not required if the record is clearly traceable to the person or organization who created the record.

10.4 Correcting Records

Correction to the quality records system is described in WHC-CM-3-5, Section 9, 5.4. The correction of technical or quality related information shall have an appropriate review and approval by an authorized person of the originating organization that was responsible for the approval of the in-process document. The name of the person authorized to issue the correction and the date of correction shall be marked on the quality record.

10.5 Records Identification And Indexing

Records are cataloged and tracked on a database and can be retrieved through a variety of topics including project or activity identification. Record retention times are controlled by the Records Inventory Disposition Schedule (RIDS) system. Location of the record is indexed on the Record Holding Area - Management Information System (RHA-MIS).

10.6 Maintenance And Retention Of Records

Control manual WHC-CM-3-5 Sections 5 and 9 describes the maintenance of active records for transmittal, distribution, retention, protection, preservation, traceability, accountability, disposition, and retrievability.

Section 9 describes the criteria for lifetime records and nonpermanent records. The appropriate quality record retention time is monitored by the RIDS system. Expired records are destroyed after reaching the scheduled retention time.

10.7 Access Control

Access to the quality records system is limited only to the authorized personnel (WHC-CM-3-5, Section 5). Access to the electronic media quality records is limited to hard copies of this information.

10.9 Replacement, Restoration, or Substitution of Records

Lost or damaged records shall be replaced, restored, or substituted when applicable (WHC-CM-3-5, Section 9).

10.10 Records Turnover To Client

Records turned over to the client are copies of the original records. Original records are kept at WHC and controlled according to the appropriate record requirements defined in WHC-CM-3-5.

11.0 QUALITY CONTROL

This section describes the quality control measures used for analyses performed at the 222-S Laboratory. The following areas of Quality Control (QC) are addressed:

- Laboratory QC
- Preparation QC
- Analytical QC.

The degree of QC required for analysis is determined through negotiations with the client. It is based on the end-use of the data. It may not violate, however, the specific QC protocols of EPA analytical methods.

11.1 Laboratory Quality Control

The QC described in this section represents the basic environment surrounding the analytical operation.

11.1.1 Reagent Water

Reagent water is prepared using reverse osmosis (RO) followed by ion exchange using a mixed-bed ion exchanger and final submicron filtering. Water used for some organic analyses may be additionally treated by UV oxidation.

The quality of the water is measured by the following:

- A resistivity check using a built-in meter or indicator on the ion exchanger. A minimum resistivity of 10 megohm-cm at 25°C is required (the corresponding conductivity is 0.1 uS/cm at 25°C).
- Assessment of sample blank data (e.g. analytes in water shown to be below detection limits).

Documentation of the water quality data (resistivity, conductivity, or blank data) is kept in tabular format in a notebook or binder near each reagent water station.

11.1.2 Compressed Gases/Reagents

Percent purity levels necessary for quality analysis are listed in each analytical procedure. The quality of gases or reagents is monitored by the performance of the preparation blank.

11.1.3 Labware

When affecting quality, and if available, only Class A glassware will be used for laboratory operations. Plasticware can be used for qualitative measurements where the volume used does not affect the data. Labware will be cleaned according to operating procedure LO-080-116.

11.1.4 Housekeeping

Each employee is responsible for maintaining their work area in a neat and orderly manner. Housekeeping inspections are performed and corrective actions documented in accordance with LO-150-105. Housekeeping inside fume hoods is performed using operating procedure LO-190-101.

11.1.5 Control Charts

Control charts provide a useful tool in assessing trends in system performance. Monitoring these trends by the technical staff will help them do the following:

- Ensure their analytical system is in control
- Recognize problems and address them before the system goes out of control
- Document conditions or corrective actions that fix particular performance problems (for future reference)
- Demonstrate continuous quality improvement as they refine the system and the practices.

At a minimum, control charts are maintained for a parameter or parameters that monitor both the preparative process (if any) and the analytical measurement. Normally this requirement can be fulfilled by charting the laboratory control sample (LCS) recovery percent.

Control limits will be set either at 3 sigma or based on environmental regulatory requirements. The LMCS and LABCORE control limits are calculated by the statistics department using the classical standard deviation approved by the cognizant chemist. The LABCORE database has the option of using either standard deviation or average and moving range. Formulas used for calculation of the control chart are provided by the statistics department for the database systems. See LQ-150-001 Section 7.0 for control chart requirements.

Any data point that falls outside the upper or lower control limit or fails other test rules of trends and patterns shall require chemist investigation.

The cognizant chemist may choose (and is encouraged) to chart other parameters that assist in monitoring instrument or preparative procedures. Such examples include internal

check standards, instrument control standards, signal intensities, lamp energies, or background levels.

The control charts will be maintained in such a way that they are readily available to the laboratory technologist, cognizant chemist, QA/QC representatives, or management. Control charts shall be kept current for immediate use and may take the form of at-the-bench manually updated charts, on-line electronic displays (e.g., generated by the LIMS or by application software), or hardcopy printouts generated periodically as close to real-time as practical.

The technical staff will be trained on the maintenance and use of control charts. The technical staff is expected to use them for system monitoring and early trend detection as described above and to be able to use them to demonstrate that their measurement system is in control.

11.2 Preparative Techniques

Preparative techniques are used to prepare a sample for analysis. This may include sample digestion, dissolution, extraction, and/or leaching. Selection of preparative technique should be based on client data quality requirements.

11.2.1 Batch

A batch is a group of samples with similar matrix processed (at the sample preparation step) together. The batch contains all quality control samples required for sample analysis.

11.2.2 Preparation Blanks

The sample preparation blank is generated by using reagent water or a material that contains none of the analytes of interest and is similar to the sample. The preparation blanks are subjected to the same sample preparation, treatments, and analysis as the sample in a batch. Blank results may be used to assess the quality of subsequent analysis. Blank results provide the information on contamination of the method analysis. Preparation blanks are prepared as required by the analytical procedures. All affected samples in the preparation batch are re-prepared and re-analyzed if contamination of the preparation system is suspect.

Preparative blank results are not subtracted from sample results unless client data requirements specify otherwise.

11.2.3 Laboratory Control Sample

The laboratory control sample (LCS; either a LCS prepared from a suitable matrix or a blank spike) is used to monitor the effectiveness of the entire analysis process or an analytical system. The analyte or isotope of interest of known concentration is added to a suitable matrix and carried throughout the analysis. A blank spike is normally used when an appropriate laboratory control sample is unavailable. In the case of organic compounds, a

typical blank spike can be considered the method blank that is spiked with surrogate compounds.

Laboratory control sample control is demonstrated when target analytes or isotopes are within established control limits. Control limits are established by one of the following:

- Specifications by vendor
- Specified by regulatory requirement
- Statistically determined by multiple analysis over time.

If the LCS or BS fails to meet the acceptance criteria, re-preparation of the batch for failed analytes is required.

11.2.4 Matrix Spike

The matrix spike is used to monitor method performance in a specific matrix. The matrix spike is an aliquot of the sample spiked with the analyte(s) of interest and processed similar to the original sample.

When the sample concentration is unknown, spiking is typically performed at one of the following levels:

- Equivalent to the regulatory threshold
- Specified in the method
- One to five times the estimated quantitative limits (EQL).

Otherwise, spiking should be performed at a level equivalent to that of the sample or at least 25% of the sample.

Matrix spike control is demonstrated when target analytes are within established control limits. Control limits are established by one of the following:

- Regulatory requirement
- Client via data quality requirements for a particular project or program
- Laboratory performance.

The recommended target level for matrix spike analysis is 75% - 125% recovery. Control limits are not applicable to spikes that are <25% of the analyte concentration in the sample. Spike recoveries outside this range will be flagged and explained in the narrative, not necessarily generating an automatic re-analysis. Re-preparation and/or re-analysis should be conducted as necessary based on the data quality objectives/data quality requirements.

Minimum spike frequency will be 5%, one per matrix if less than 20 samples are analyzed per matrix, or as requested by client.

A matrix spike may not be applicable if the analyte concentration in the sample is very large (>0.1%) where addition of large amounts of spikes are not practical because of solubility concerns. Other methods of evaluating method performance, such as serial dilution or post-digestion spike, may be used.

11.2.4.1 Inorganic Chemistry

The recommended criteria for most inorganic analysis is recovery within 75% - 125%.

11.2.4.2 Organic Chemistry

Acceptance criteria for organic compounds are based on the *USEPA Methods for Evaluating Solids, Physical/Chemical Methods* (SW-846). For compounds of interest not covered by SW-846, the Laboratory shall establish spike compounds and acceptable levels according to Section 8.0.

11.2.4.3 Radiochemistry

In radiochemistry, the matrix spike represents the addition of a known quantity of the isotope of interest to an aliquot of sample. Radiochemical analysis may include either a matrix spike or a post-digestion spike (see Section 11.3.8); the decision is based on the activity level present in the sample. Spiking additional activity into a sample that already exhibits high activity is not justifiable. In such cases, spiking is generally performed after preliminary sample preparation, but before any additional sample handling except large dilution. However, activity levels in such cases should always meet or exceed the decision or action limit to provide sufficient count rate that the counting error for the spike is significantly lower than the data recovery requirements. Radiochemical techniques typically employ either a tracer, carrier, or matrix spike, or a combination of a matrix spike with a tracer or carrier.

11.2.5 Sample Duplicate Or Matrix Spike Duplicate

Duplicates are used to assess the precision of the preparation process. Although more replicates can be requested, typically duplicates are required as a minimum. Duplicates are two aliquots of the same sample that are taken through the entire sample preparation and analytical process. Matrix spike duplicates are two spiked aliquots of the same sample that are taken through the entire sample preparation and analytical process. Precision is estimated by calculating the relative percent difference (RPD). To the degree possible, the laboratory and the client should agree upon the use of sample duplicates versus matrix spike duplicates before starting work.

Minimum frequency for sample duplicates will be 5% or one per matrix type, whichever is greater.

11.2.5.1 Inorganic Chemistry

Typically, inorganic preparations include a sample and a sample duplicate because a high probability exists that the analyte(s) of interest will be detected in the sample.

Inorganic duplicate RPD criteria is normally set at 20%; this criteria shall only be applied to samples with analyte concentrations greater than 10 times the instrument detection level.

11.2.5.2 Organic Chemistry

Organic preparations usually rely on a matrix spike or matrix spike duplicate to determine precision, because commonly, a low probability exists that the analyte(s) of interest will be detected. In this case, precision is determined from the analytes spiked into the matrix spike and the matrix spike duplicate.

Organic matrix spike/spike duplicate RPD criteria control is demonstrated when target analytes are within established control limits. Control limits are established as follows: 1) specified by regulatory requirement, or 2) specified by the client via the Data Quality Objectives (DQOs) for a particular project or program. In general, the limits quoted by SW-846 are used. For compounds of interest not covered by SW-846 or the Contract Laboratory Program, the Laboratory shall establish acceptable precision criteria according to Section 8.0.

11.2.5.3 Radiochemistry

Typically, radiochemical preparations include a sample and sample duplicate because a high probability exists that the analyte(s) of interest will be detected in the sample.

A radiochemical duplicate RPD criteria of 20% can also be achieved provided the isotopic activity or concentration has an uncertainty, or counting error, less than 20%. When uncertainty or counting error exceeds 20%, the duplicate results shall be evaluated based on statistical comparability.

In all cases (i.e., inorganic, organic, radiochemistry) if the RPD falls outside the established limits the results are flagged and explained in the narrative. It does not automatically trigger re-analysis.

11.2.6 Surrogate

A surrogate is a compound or analyte that is added to all samples during preparation. The surrogate is typically similar in chemical composition to the compound or analyte being determined, yet not normally encountered in most samples. Criteria for selection and recovery of surrogates is generally specific to the method and compounds being detected. Each method that uses surrogates shall specify instructions for surrogate introduction and use. Surrogate recoveries are normally reported as measured on overall method performance in the matrix/matrices (i.e., no sample recovery corrections are performed based on surrogate recovery).

11.2.6.1 Inorganic Chemistry

Surrogates are typically not applied.

11.2.6.2 Organic Chemistry

Most, if not all, organic techniques employ surrogates; in this case, surrogates are also added to all standards and QC samples. The criteria is based on (1) regulatory requirement, (2) laboratory performance, three standard deviations, (3) or client via data quality requirements for a particular project or program.

11.2.6.3 Radiochemistry

Surrogates are typically not applied.

11.2.7 Tracer -- Radiochemistry Only

A tracer is used to correct method performance in a specific sample. A tracer represents the addition to an aliquot of sample of a known quantity of an radioactive isotope that is different from that of the isotope of interest but expected to behave similarly. Criteria for selection and recovery of tracers shall be specified in each method, as use may be considered unique to the specific isotope being determined. Sample results are normally corrected based on yield recovered on a tracer.

The tracer added to the sample shall be well mixed in the sample in order to reach an equilibrium between the tracer and the isotope of interest. Otherwise, the recovery of a tracer does not represent performance of the isotope of interest. Activity of the tracer should exceed the decision or action limit to provide sufficient counts. The tracer recovery is calculated and is used to correct sample results based on the tracer recovery.

11.2.8 Carrier -- Radiochemistry Only

A carrier is used to monitor method performance in a specific matrix. A carrier represents the addition to an aliquot of sample of a known quantity of a stable isotope that is expected to behave similarly to the isotope of interest. Criteria for selection and recovery of carriers shall be specified in each method, as use may be considered unique to the specific isotope being determined. Sample results are normally corrected based on the yield recovered on a carrier. Radiochemical techniques typically employ a matrix spike (Section 11.2.4), tracer (Section 11.2.7), carrier, or a combination of a matrix spike with a carrier or tracer.

11.3 Analytical Techniques

11.3.1 Analytical Run Or Sequence

An analytical run or sequence is defined as a group of samples analyzed together that may include one or more preparation batches (Section 11.2.1). Analytical QC is used to define the boundary of each analytical run. The analytical run typically starts with either calibration or confirmation that the calibration is still valid.

11.3.1.1 Inorganic Chemistry

For most inorganic analyses, the run ends based upon continuing calibration performance.

11.3.1.2 Organic Chemistry

For organic analyses by gas chromatography/mass spectrometry, the run ends based on analytical clock expiration. For gas chromatography, the run ends based upon continuing calibration performance.

11.3.1.3 Radiochemistry

For radiochemistry, the analytical sequence or run is defined as those samples counted on any specific detector in a period of time between counter control counts. The analytical run starts after the counter control source is counted and ends when the following counter control source is counted. As a matter of good technique, the sequence of samples counted on a detector where the detector face is directly exposed to the sample should be traceable.

11.3.2 Initial Calibration Verification (ICV)

The ICV is a standard used to confirm acceptability of the most recent calibration. Standards for ICV are prepared from a source other then that used to prepare the calibration standard.

Analytical measurement systems that are calibrated frequently and for which calibration standards are routinely prepared normally follow the initial calibration with an ICV.

Analytical measurement systems for which calibration applies over an extended period of time (e.g., months for some GC/MS methods to years for many radiochemical methods) normally use the ICV only at the time of initial calibration. Subsequent, routine performance checks are made using the equivalent of a continuing calibration verification (CCV) (See Section 11.3.3).

Calibration of counting instrumentation used in support of radiochemical measurements often applies over extended periods of time (e. g., years). Only one calibration verification needs to be performed after instrument calibration per geometry. Instrument stability, and thus calibration stability, is monitored by counter control standards (the equivalent of a continuing calibration verification, see Section 11.3.3).

The concept of calibration verification is accomplished in radiochemistry by using one of four methods: independent standards, use of independent measurements, multiple calibration curves, and/or data analysis.

Acceptance criteria will be (1) as defined in the specific methods, (2) as described in DQO process, or (3) as stated in SW-846. Failure of the initial calibration verification indicates instrument and/or standard problems that must be evaluated and corrected before any client samples are processed for the analytes of interest.

11.3.3 Continuing Calibration Verification

The CCV is used to monitor instrument stability over time. Acceptable performance demonstrates the continued appropriateness of the calibration, indicating that the measurement system is still in control. The CCV may be prepared from any reliable source.

11.3.3.1 Inorganic Chemistry

Each inorganic analytical system shall include periodic checks on the stability of the instrument. For unstable analytical systems, these checks will be performed every 10 samples and at the end of the analytical run. Failure indicates that the analytical system has drifted out of control and requires corrective action for the analytes of interest. If CCV failure occurs, all samples analyzed after the last acceptable CCV shall be re-analyzed. Re-analysis applies to specific analyte failure. In limited cases, isolated analyte failures may be tolerated if sample results still meet the client data quality requirements. Reporting results in such cases requires justification in the report to the client.

11.3.3.2 Organic Chemistry

Organic analysis by GC/MS is limited by analytical run time. Each run is defined by a 12-hour clock that cannot be exceeded. In this case, periodic CCVs are not required. The analyst shall rely on internal standard and surrogate performance to ensure that the sample run ended in control. Corrective action, such as reanalysis of all samples demonstrating unacceptable internal standard performance, shall be taken. Analytical runs for organic analysis such as gas chromatography typically can extend anywhere from several hours to several days. Regular CCV checks are required based on their specific methods.

All samples analyzed after the last acceptable continuing calibration verification shall be re-analyzed.

11.3.3.3 Radiochemistry

Many radiochemical analyses are limited by the samples that can be analyzed in one run. In such cases, periodic CCVs are impractical. However, each analytical sequence shall be followed by an acceptable CCV during the next analytical sequence. Failure warrants corrective action and applies to all samples run since the last acceptable check. If no additional standard or spike information is present at the end of the preceding run, all data generated since the last acceptable standard or QC sample shall be considered suspect and

investigated. The CCV is commonly referred to as the counter control standard in radiochemistry (see also Section 7.0). For example, daily calibration checks are made on GEA using a pre-prepared check standard.

11.3.4 Initial And Continuing Calibration Blanks

Initial and continuing calibration blanks monitor affects such as contamination and instrument drift. The initial and continuing calibration blank can be replaced by an instrument check blank.

11.3.4.1 Inorganic Analysis

Blank analysis should always follow standard analysis to identify any carry-over effects.

11.3.4.2 Organic Analysis

Calibration blank analysis is accomplish using the instrument or method blank. The calibration blank is run after the continuing calibration verification standard. Periodic calibration blanks are not performed. In the case of analysis by gas chromatography, periodic blanks are recommended.

11.3.4.3 Radiochemistry

Most radiochemical techniques use instrument background count measurements at least daily. Background counts are a measure of system and/or environmental contributions and a fundamental aspect of the minimum detectable activity determination. Background counts are collected when the instrument is not in use for sample analysis. Background counts on alpha/beta counters are subtracted from all subsequent sample counts. These may be either daily or window average (stated windows duration) after determining the daily value is within accepted limits. Gamma spectroscopy uses a fixed background (subtracted), with daily monitoring to determine acceptability. Radiochemical background counts are similar to that of the initial calibration blank.

11.3.5 Internal Standards

Internal standards are used in the ICP spectrometry analysis although they may be appropriate to other types of analysis, when multiple analytes are being analyzed together.

Internal standards can be used to correct for analytical problems such as instrument drift, pipetting variation, and injection technique.

Selecting appropriate internal standards shall be method- and compound-list specific because all results are normalized based on internal standard performance. Laboratory procedures shall specify requirements for internal standards and acceptance criteria. Internal standards are added after sample preparation and before analysis.

11.3.6 Low-Level Standard

The low-level standard is used to monitor instrument performance in the region at or just above the EQL (see 12.4.1.3). When sample dilution is required, it is preferable to adjust sample size so that results are mid-range on instrument calibration curves.

11.3.7 Interference Check Standards

Interference check standards are typically used only in ICP spectrometry systems. The interference check normally consists of two standards. The first standard contains known concentrations of the interfering elements that will provide an adequate test of correction factors. The second standard contains both the major interferents and the majority of other analytes tested. The major interferents are spiked into the standards at significant concentrations that are expected to produce an interference effect. All other analytes are spiked at relatively low levels. Data from both standards, when corrected, should recover between 80% and 120% for all analytes tested or interelement interference is considered inadequate. The first standard, containing only the primary interferents of concern, should produce no analyte concentrations in excess of the EQL. Instruments capable of showing negative results do not require the second standard that contains both interferents and additional analytes tested. If significant interferences are observed the instrument inter-element correction factors should be re-evaluated.

11.3.8 Post Digestion Spike

A post-digestion spike is a spike added to the sample after preliminary preparation, usually just before analysis. If a matrix spike is used, the sample spiked would be that sample on which a matrix spike was originally performed. The post-digestion spike is used for indication purposes. It provides the analyst with information regarding matrix-related interferences on the analytical system that may or may not still be present in the sample following digestion. Acceptable recovery is generally 75% to 125% for this spike. The analyst should use caution when interpreting recovery failure; such failure could also be the result of spectral interferences. This technique is typically used for ICP spectrometry analysis but is appropriate to other techniques as well.

11.3.9 Serial Dilution -- Inorganic Only

Many inorganic techniques such as ICP spectrometry use a serial dilution. The serial dilution analysis is typically used when new or unusual matrices are encountered. When the sample analyte concentration is less than 50 times the instrument detection limit, an analytical spike should be used instead. Although not specially required, serial dilution can be used for other techniques.

Serial dilution is simply a five-fold dilution of a sample followed by analysis. This technique is another indicator of potential matrix-related interferences associated with an analysis. Serial dilution is only performed when a sufficient number of analyte concentrations exceed 50 times the instrument detection limit. The sample concentration should, therefore, be a minimum of 10 times the EQL before performing the 1 to 5 dilution.

A percent difference of 10% or less indicates acceptable performance. The sample dilution is not applicable to analytes whose concentrations are reduced to an instrument detection limit (IDL) < 10 when diluted.

The serial dilution is not meant to replace a sample dilution necessary to maintain a sample in optimum instrument performance range. The serial dilution is designed to indicate potential problems such as high solids. In these cases, results would begin to vary beyond the 10% criteria because of sample aspiration and the subsequent effect on the analyte species detected.

11.3.10 Analytical Spike - Graphite Furnace - Atomic Absorption

An analytical spike is similar to a post-digestion spike (See Section 11.3.8) in that a spike is added to the sample just before analysis. Typically, a very small quantity of spike is added so no significant change occurs in sample volume or matrix results. The concentration spike should equal 50% to 100% of the sample analyte concentration or approximately two times the EQL if no analyte is expected or the concentration is unknown. The analytical spike is applied to every sample. Recoveries outside of 85% to 115% warrant investigation and corrective action. Corrective action may consist of dilution followed by reanalysis, repreparation of the sample followed by reanalysis, or in extreme cases the use of standard additions.

11.3.11 Method Of Standard Additions

The method of standard additions involves adding known amounts of a blank and standard to aliquots of the sample. The method of standard additions is meant to compensate for a sample effect that enhances or depresses the analyte signal. A method of standard additions can be used *in lieu* of instrument calibration because each sample essentially has its own calibration. The standards used should be approximate 50%, 100%, and 150% of the expected sample concentration. When the method of standard additions is employed, instrument calibration and periodic calibration verification using standards and blanks is <u>not</u> required.

The method of standard additions or analytical spike is required for all Extraction Procedure Toxicity and Toxicity Characteristic Leaching Procedure samples.

12.0 PROCEDURES TO ASSESS DATA QUALITY

This section provides various formulas that are typically used to compute quality assurance parameters that are used to assess data quality.

12.1 Precision

Precision has been defined in Section 4. Precision for the sample is estimated by using duplicate and/or replicate, or matrix-spike duplicate. Samples used to calculate precision should contain the concentrations of analytes above the method detection limit (MDL). The precision of test results is expressed as the relative standard deviation (RSD) or the relative percent difference (RPD). The precision of a method in a given matrix is expressed as the RSD or the RPD among matrix spike duplicates.

12.1.1 Relative Standard Deviation

The RSD is used when at least three replicate measurements are performed on a given technique. The RSD is computed using the following equation:

$$RSD = \frac{S}{\bar{x}} * 100$$

where

s = Standard deviation with n - 1 degrees of freedom
n = Total number of observed values
$\bar{x}$ = Mean of observed values.

12.1.2 Relative Percent Difference

The RPD is used when two measurements exist. The RPD is generally used to express the precision of matrix duplicate or matrix spike duplicate samples. The RPD is computed using the following equation:

$$RPD = \frac{|x_1 - x_2|}{\bar{x}} * 100$$

where

$x_{1,2}$ = Observed values
$\bar{x}$ = Mean of observed values.

12.2 Accuracy

12.2.1 Method Accuracy Based On Sample Spike

Accuracy has been defined in Section 4. Accuracy for the sample is expressed as the percent recovery (%R) of a matrix spike (or matrix spike duplicate) sample. The percent recovery is calculated based on the following equation:

$$\%R = \frac{(SSR - SR)}{SA} * 100$$

where:

SSR = Spiked sample result
SR = Sample result
SA = Spike added.

12.2.2 Method Accuracy Based On Standard

The accuracy of an analytical method is expressed as the percent recovery of a standard (%R). The percent recovery of a standard is calculated according to the following equation:

$$\%R = \frac{A_m}{A_k} * 100$$

where

A_m = Measured value of the standard analyte
A_k = Known value of the standard analyte.

12.3 Yield Recovery (Radiochemistry only)

Yield percent recovery (%Y) of a tracer or carrier in the radiochemical analysis is a measure of effectiveness of separation methods for some radionuclides. It is expressed as the percent recovery and is generally used to correct the analyte recovery in the sample for radiochemical analysis. Yield percent recovery is calculated according to the following equation:

$$\%Y = \frac{T_m}{T_k} * 100$$

where

T_m = Measured value of the tracer or carrier
T_k = Known value of the tracer or carrier.

Yield percent recovery should be controlled and evaluated per method to monitor the effectiveness of radionuclide separation method. Tracer or carrier when used is added to each sample. Correction is performed based on corresponding sample yield recovery.

12.4 Measures Of Agreement

12.4.1 Percent Difference

The percent difference (%D) is often used to compare one reference point to another. The percent difference is calculated using the following equation:

$$\%\ D = \frac{|\ I - C\ |}{I} * 100$$

where

I = Observed value used as the reference point
C = Compared value.

12.4.2 Bias

Bias (B) is often used to measure the deviation of a measured value from a known value or accepted reference value. Bias can be assessed by comparing a measured value to an accepted reference value in a sample of known concentration or by determining the recovery of a known amount of contaminant spiked into a sample. Thus, the bias caused by the matrix effects based on a matrix spike is calculated using the following equation:

$$B = (X_s - X_u) - K$$

where

X_s = Measured value (e.g., spiked sample)
X_u = Miscellaneous contribution (e.g., sample contribution). If no miscellaneous contributions exist, X_u would be zero.
K = Known value (e.g., true spiked value).

12.5 Detection Limit Considerations

12.5.1 Inorganic And Organic Methods

12.5.1.1 Method Detection Limit

The MDL is defined as "the minimum concentration of a substance that can be measured and reported with 99% confidence that the value is greater than zero" (SW-846, consistent with the requirements specified in 40 CFR 40 Appendix B to 40 CFR 136) and is briefly described in the following text.

The concentration of the MDL for the analyte of concern can be estimated by using one of the following:

- Instrument signal-to-noise ratio within the range of 2.5 to 5
- Region of the standard curve where there is a significant change in sensitivity (i.e., a break in the slope of the standard curve).

When determining the MDL, a minimum of **three** analyses are required in a matrix spiking with the analyte of interest at a concentration three to five times the estimated MDL. Whenever possible, the matrix should be similar to the sample matrix. When not possible, the matrix will be water. All sample processing steps of the analytical method shall be included in the final determination of the MDL.

Variance (S^2) is determined from the replicate measurements, as shown:

$$S^2 = \frac{1}{(n-1)} \left[\sum_{i=1}^{n} (X_i - \bar{X})^2 \right]$$

where

X_i = With measurement of the variable X
$\bar{X}$ = Mean of observed variable X.

The MDL should be determined by the following equation:

$$MDL = t\ (n-1,\ \alpha = .99) * (s)$$

where

$t_{(n-1,\ \alpha=.99)}$ = One-sided t-statistical value appropriate for the number of samples used to determine standard deviation
s = Standard deviation obtained from the MDL replicate measurements.

12.5.1.2 Instrument Detection Limit

Instrument detection limit (IDL) is determined by spiking reagent water with each analyte of concern. The following considerations apply to the selection of the IDL standard.

- Concentration of the IDL standard should be at least equal to or in the same concentration range as the estimated IDL.
- Concentration of the IDL standard should be in the region of the standard curve where there is significant change in sensitivity.

A minimum of seven aliquots of the IDL standard are required to determine the IDL. The IDL standards are run through the analytical process only. The IDL is calculated the same as the MDL.

Ideally each analytical method should have data supporting a MDL for the specific matrix of each sample. If this is not practical, MDL on generic matrices (e.g., deionized water, ground water, soil) can be used to estimate the sample specific MDL. If MDL can not be determined, at a minimum, IDL information will be available and can be used.

12.5.1.3 Estimated Quantitation Limit

The estimated quantitation limit (EQL) has been defined by RCRA as the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. The analyte concentration at the estimated quantitation limit is determined using the following guidance: 1) 5 to 10 X MDL or IDL, or 2) the lowest non-zero standard in the calibration curve. In some cases, sample dilutions affect the quantitation limit. The quantitation limit for this sample is calculated as dilution factor times the EQL as defined above.

The quantitation limit can be used to qualify the sample results or used to compare the data quality requirements from the end-user of the data during DQO process. When results are less than the quantitation limit or detection limit, sample results should be reported with appropriate qualifier. Results that are less than the IDL or MDL are reported as the numeric limit proceeded by a less than symbol. If the detection limit is reported else where, the result may be reported as undetectable. Results falling between the IDL (or MDL) and the EQL can be reported with appropriate qualifier or discussed in the case narrative.

12.5.2 Radiochemistry Methods

12.5.2.1 Decision Level Count Rate

The decision level count rate (DLR) is defined as a 95% confidence limit for a critical decision level. This level is used for making a decision as to whether a sample emits radiation above the appropriate blank background level. The decision should be based solely upon whether the net count rate observed for that sample exceeds this DLR. The DLR is calculated as shown below:

$$DLR = 1.65 * \sqrt{(\frac{R_b}{T_b}) * (1 + \frac{T_b}{T})}$$

where

R_b = Background count rate
T_b = Background count time
T = Sample count time

When counting a sample containing no analyte (radionuclide) of interest, R_s is assumed to be equal to R_b. The DLR can be simplified as shown below:

$$DLR = 1.65 * (S_b) * \sqrt{2}$$

where

S_b = Standard deviation of background (or appropriate blank) count rate for the counting time (T).

12.5.2.2 Minimum Detectable Activity

The minimum detectable activity (MDA) has been defined as a level of activity that is practicably achievable by a measurement system. The sample MDA generally is applied as the mean (expected) activity of samples having a 5% probability of escaping detection and 5% probability of false detection. The MDA is calculated based on Currie's (Currie, 1968) formula and is simplified to the following two equations when the counting time in the sample is the same as in the background. It must be recognized that the background may, and normally is, affected by the components of the sample. Therefore, the MDA value is an (*a posteriori*) estimate for comparative purposes.

$$MDA = [(\frac{2.71}{T}) + (2 * DLR)] / K$$

or

$$MDA = [(\frac{2.71}{T}) + (4.65 * S_b)] / K$$

where

T = Sample count time
K = Detector calibration factor (e.g., $min^{-1}/\mu Ci$ or $s^{-1}/\mu Ci$)
S_b = Standard deviation of background count rate for the counting time (T).

When T_b is not equal to T_t, MDA is calculated as shown below.

$$MDA = \frac{2.71 + 3.3\sqrt{(R_b * T_b) * \left[1 + \frac{T_b}{T_t}\right]}}{e * b * L_T * k}$$

where

R_b = Background count rate
T_b = Background count time
T_t = Sample count time
e = Counting efficiency
b = Abundance
L_T = Elapsed live time (background counting time = T_b)
k = Conversion factor (e.g., 37,000 disintegrations/second/μCi).

The minimum detectable concentration (MDC) is defined as the mean concentration of samples having a 5% probability of escaping detection and 5% probability of false detection.

$$MDC = \frac{MDA}{q * Y * decay}$$

where

q = Sample quantity (e.g., g or mL)
Y = Chemical yield
decay = Decay factor (correction for radioactive decay to reference date).

Software provided by vendors may have variations of the above formula. A vendor-provided software or data reduction package is adequate for data calculation.

12.6 Uncertainty

Uncertainty is expressed as the range of values within which the true value is estimated to lie. The uncertainty estimate consists of two components, systematic and random variability. Each contributing source of uncertainty is expected to be distributed over its range. Each systematic component can be estimated in terms of the measurement result for the contributing source of uncertainty.

The analytical systematic component can be estimated using standard or spike recovery. The random analytical component can be estimated from replicate measurements of a sample.

The total uncertainty is calculated as the square root of the sum of the squares of random and systematic variabilities as shown in the following equation. The component of uncertainty has to be expressed in the same unit designation (e.g., concentration percentage).

$$\text{Total uncertainty} = \sqrt{(s_x^2) + \sum_{j=1}^{q} \delta_j^2}$$

where

s_x = Standard error
q = Number of systematic uncertainty components
δ = Systematic uncertainties.

Uncertainty is used in the radiochemical analyses to express method and counting error. The total random uncertainty is obtained by propagating the individual variance (s_i^2) and is expressed as the standard error based on multiple determinations of x. However, the typical radiochemical methods used are not sufficient to separate systematic and random uncertainties such that biases can be corrected. Uncertainty will be measured, or uncertainty will be estimated if it cannot be measured.

13.0 AUDITS

A quality assurance program can only be effective if systems are in place to continuously monitor or assess the laboratory's ability to conform to program requirements. The systems are a collection of QA audits and assessments that do the following:

- Measure the degree of conformance with the laboratory's QA program
- Determine the effectiveness of the QA program
- Permit continuous improvement of the quality of products or services the laboratory provides.

To achieve this goal, personnel who perform independent assessments shall be technically qualified and have sufficient authority and freedom from the line organization to carry out their responsibility. The independent assessment process shall incorporate a performance-based approach with emphasis on the results of work process and compliance to requirements.

The QA program consists of management system audits, technical systems audits, performance audits, data quality audits, and external audits. The format and distribution of internal assessment results are described in WHC-CM-5-4 Sections 8.5 and 8.5A.

Results from the external audits are tracked by HATS. Corrective actions are initiated by the Operations Assurance and Support staff and distributed to the affected manager and staff. The Operations Assurance and Support staff are responsible for tracking the implementation of corrective actions.

13.1 Management System Audits

Management system audits are directed by laboratory management. These audits are required to be conducted annually, at a minimum. The purpose of these audits is to assess the following:

- Systems for developing technical procedures
- Quality and applicability of current management systems (e.g., QA manual, administrative procedures)
- Procedures for the design and conduct of audits
- Systems for tracking quality adherence (i.e., performance indicators)
- Degree of management support as well as current roles and responsibilities.

13.2 Technical Systems Audits

Technical systems audits consist of a review of laboratory operations, procedures, and documentation. Laboratory QA/QC personnel or matrixed QA/QC personnel are responsible for coordinating and evaluating technical systems audits. Technical systems audits are performed quarterly. Each systems audit focuses on a particular aspect of laboratory operation. Aspects of technical systems shall be audited once per year. Any deficiencies and/or deviations shall be documented and provided to that laboratory management for corrective action initiation.

The laboratory managers shall be responsible for documenting that corrective actions have been initiated, for follow-up verification of corrective action and closeout of deficiency document, and for maintaining all completed responses on file to the QA representative.

13.3 Performance Audits

Laboratory QA staff is responsible for coordinating and evaluating performance audits. Performance audits consist of laboratory analyses of standard materials that are used to evaluate the analyst and the method proficiency. Performance audits may be driven either externally or internally.

Washington State requires all laboratories performing water quality analyses, in the state, to be accredited laboratories and to participate in the USEPA Environmental Monitoring Systems Laboratory-Cincinnati Semi-Annual Water Pollution Study Program. The Laboratory is a DOE (government) Laboratory performing mixed/hazardous waste analyses but does participate in this EPA Region 10 coordinated performance evaluation program.

The EPA and Washington State require laboratories analyzing samples from CERCLA-Superfund sites to participate in the USEPA Contract Laboratory Program Quarterly Blind Performance Evaluation Program. The Laboratory is a DOE (government) Laboratory and cannot be a Contract Laboratory but will participate in this performance evaluation program until a more suitable matrix sample (standard) program is made available.

The Laboratory participates in one or more of the following Blind QC Standard or Performance Evaluation Programs:

- USEPA Environmental Monitoring Systems Laboratory-Las Vegas Quarterly Blind Inorganic/Organic Performance Evaluation
- USEPA Environmental Monitoring Systems Laboratory-Cincinnati Semi-Annual Inorganic/Organic Water Pollution Performance Evaluation Studies
- USEPA Environmental Monitoring Systems Laboratory-Las Vegas Radiological Performance Evaluation Studies

- DOE Environmental Measurements Laboratory - New York Semi-Annual Radiological Quality Assessment Program -
- DOE Radiological and Environmental Sciences Laboratory - Idaho Falls Pilot Mixed Waste Radiological/Inorganic Performance Evaluation Program (MAPEP)
- WHC/PNL Sample Exchange Evaluation Program-Richland Pilot Radiological/Inorganic Sample Exchange Performance Evaluation Program
- Laboratory QA Blind Studies (e.g. ERA, APG as determined).

All noted deficiencies shall be investigated, resolved, and documented by the appropriate laboratory personnel. All documentation of corrective action shall be maintained in accordance with program protocol. In addition, the Office of Quality Assessment is responsible for establishing and maintaining an assessment data base for tracking and trending from the annual assessments (WHC-CM-5-4, Section 8.5).

13.4 Data Quality Audits

Laboratory QA/QC or matrixed QA/QC staff are responsible for performing data quality audits (also known as data quality reviews). The 222-S Laboratory performs data quality audits on each data package. The objective is to determine if adequate information and documentation exist within a given data package to support an assessment of its quality. Furthermore, the degree of conformance to client data quality requirements shall be evaluated and documented.

13.5 External Audits

External audits of the laboratory are performed by agencies or groups that are not under the control of laboratory management. External audits may consist of inspections, interviews, and/or evaluations that focus on the laboratory's ability to meet client, program, and/or regulatory requirements. Laboratory management shall be responsible for initiating, tracking, following-up, and documenting all corrective actions that are required as a result of external audits.

This page intentionally left blank.

14.0 PREVENTIVE MAINTENANCE

Preventive maintenance of laboratory instrumentation helps to ensure its availability for analytical measurements by reducing downtime and avoiding inconsistencies in instrument performance.

The Laboratory has a Instrument Preventive Maintenance Program. This program is described in Section 10.1 of WHC-CM-5-4.

Significant components of this program include the following:

- Instrument preventive maintenance (IPM) schedules for each instrument

  These schedules are developed by the cognizant scientist and are based on manufacturer's recommendations, operational experience, and usage. Typical components of schedules include periodic instrument checks (e.g., daily, weekly, or monthly), activity-based checks (e.g., analysis of instrument check standards or control chart trends), routine service requirements, and sources of service (e.g., analytical troubleshooting by the cognizant scientist, instrument troubleshooting and repairs by instrument technologists, on-call vendor service, or vendor service contracts). An example of a preventive maintenance checklist is provided in Figure 14.1.

- IPM logbooks

  These logbooks contain definitions of the schedules and a running log of IPM activities actually performed. For example, a filled out reproduction of the checklist shown in Figure 14.1 may be signed, dated, and inserted in the notebook on a daily basis (or whenever the instrument is used).

Other activities related to preventive maintenance may include:

- Spare parts inventories

  These inventories may be day-to-day consumable or other known-to-fail parts maintained at the discretion of the cognizant scientist.

  Spare parts may be formally maintained in the WHC spare parts inventory, administered at the Laboratory by the AS Laboratory Engineering group. The current status of this inventory can be queried through the Hanford Inventory Program (HIP), available on the Hanford Local Area Network (HLAN) through Soft Reporting.

  Alternatives to spare parts inventories that help ensure minimal loss of analytical capacity include the following:

  - Overnight parts availability from suppliers

  - Availability of back-up instrumentation (see "Redundant Capacity" below)

- Vendor service contracts.

- Redundant capacity

  For most technologies, the 222-S Laboratory has multiple units of equivalent instruments available. Also, Pacific Northwest Laboratories (PNL) has similar instrumentation in many areas. Both these resources can minimize the impact of downtime required for instrument maintenance.

WHC documents that include preventive maintenance guidelines or policies:

- WHC-CM-4-2, *Quality Assurance Manual*
  - QR 12.0 "Control of Instruments"
  - QI 12.7 "Assuring Availability of Laboratory Instruments"

- WHC-CM-5-4, *Laboratories Administration*
  - 10.1 "Instrument Preventive Maintenance Program".

Figure 14.1 Sample Preventive Maintenance Checklist

SAMPLE PREVENTIVE MAINTENANCE CHECKLIST

Instrument Maintenance Log for PE2380 (Procedure #: LA 325-104)

Analyst:_____ Date:_____

Instrument Shutdown Maintenance: (Refer to procedure for details.)

Clean Exterior of MHS-20: Date_____ Initials_____

Flush System: ___Acid: 5% HCl
___Q-water
Other_____ Date_____ Initials_____

Troubleshooting Maintenance: (Refer to procedure to determine necessity, or contact chemist.)

____ No Maintenance Required (All date and initial spaces can be left blank.)
____ Maintenance Required (If some maintenance items are not performed, those spaces can be left blank.)

Check Windows: CLEAN / REPLACE / OK (circle one) Date_____ Initials_____

Check Cell: CLEAN / REPLACE / OK (circle one) Date_____ Initials_____

Rinse and Dry Transfer Tubing: ___ Acid: 2% HNO_3
___ Q-water Date_____ Initials_____

Rinse Valves (1-4) on MHS-20: Date_____ Initials_____ *NOTE: Contact chemist first.*

Check reductant flow rate: ___OK
___Adjust (should be 10 mL / 30 sec.) Date_____ Initials_____

Other Information: (To be entered at start of analysis.)

Lamp serial #:_____

Lamp energy stability: ___Stable
___Small Fluctuation (notify chemist)
___Large Fluctuation (notify chemist)

Action Taken: ___New lamp installed: New Lamp Serial # _____
___Chemist Notified (see 'comments' for troubleshooting details)

Comments:_____

Figure 14.1 Sample Preventive Maintenance Checklist

This page intentionally left blank.

15.0 CORRECTIVE ACTION AND CONTINUOUS QUALITY IMPROVEMENT

The corrective action process consists of the identification of an adverse condition or deficiency, root cause analyses, determination of corrective action, and documentation. When fully implemented, this process is the basis for continuous improvement. The laboratory will follow guidelines from the WHC-CM-1-3 MRP 5.1, WHC-CM-4-2 QI 16.0-16.2, and/or WHC-CM-5-4 Sections 6 and 8.

The external sources that may initiate corrective actions are clients such as (Tank Farms and Evaporator) or regulatory agencies such as (DOE and EPA).

The corrective action process shall ensure that laboratory personnel at all levels are responsible for initiating corrective action when conditions may adversely impact laboratory systems (e.g., administrative, analytical, operations).

Examples of conditions where corrective action shall be implemented are included in the following:

- Documentation errors
- Adverse trends in the analysis of standards
- Failure to comply with approved procedures
- Failure to follow the preventive maintenance program
- Failures in the instrument systems
- Failures in performance evaluation sample analysis
- Non-compliance issues identified by audits, surveillances and assessments
- Validation and/or verification issues negatively impacting reported results
- Failure to follow client analytical requests and/or data quality objectives (DQOs) - this condition may be addressed as part of the narrative in the data package report.

15.1 Evaluating Impact

The corrective action processes listed above describe the provisions for 1) determining the significance of the problem and 2) taking effective corrective action based on the potential impact on the data quality. The process can be initiated by submitting a fact sheet, critique, unusual occurrence report, non-conformance report, or letter of observation.

The LMCS generates an Off-Standard Condition Report (OSCR) automatically when a quality control parameter is outside the control limits. The LABCORE also can generate an

OSCR. When certain QC results fail to meet the control limits, the responsible chemist or manager is required to override data entry to the LABCORE. Sample results from the same batch associated with this failing QC result shall be entered. In this case, sample results shall be flagged with appropriate qualifiers or samples shall be re-analyzed depending on the types of QC failure.

Implementation of corrective actions shall be verified as appropriate. When corrective actions involve a measurement system, the corrective response will be fulfilled when the flagging is complete and the narrative documents the QC problems.

In order to promote timeliness and efficiency in the laboratory, corrective actions are made at the lowest management level possible.

- First Level Managers shall review all reports of problems generated in their respective units. The first level managers are responsible for the resolution of problems and ensuring that QA/QC objectives are met.

- Responsible Scientists/Engineers shall assist unit managers in the resolution of problems relating to their area of responsibility.

- Section Managers provide overall coordination of laboratory operations.

- Operations Assurance and Support Manager is responsible for the overall corrective action database (HATS).

- Laboratory Quality Assurance Officer or QA/QC representatives are responsible for ensuring that reported problems are closed out and corrective actions have been completed.

15.2 Recurring Conditions Adverse To Quality

These processes are established in the procedure used to correct the problem. The measures to eliminate or minimize recurrence of quality problems shall be established using the following provisions. These determinations shall include but not be limited to the following.

- Determine the events leading to the adverse condition.

- Understand the technical and work activities associated with the quality problem.

- Ascertain the quality problem's generic implications.

- Determine the extent to which similar quality problems (or precursors to the problem) have been recognized.

- Determine the effectiveness of any corrective actions that were taken.

- Determine the impacts on the completed work.
- Recommend actions that can be taken by the responsible organization to preclude recurrence.
- Determine if stopping the work associated with the activity is necessary.

15.3 Trend Analysis

Analysis of quality-related information shall include, where possible, identifying common work processes for quality problems, conducting cause-and -effect analyses, and determining effective corrective and preventive actions from internal sources, including other DOE facilities or sites.

Quality related information to be analyzed shall include, but are not limited to, the following, as appropriate:

- Performance data
- Audit reports
- Surveillance reports
- Non-conformance reports
- Quality-related information from external sources (not limited to one type of work, one facility, or one contractor)
- Performance indicators.

15.4 Root Cause Analysis

The extent of the root cause analysis shall be commensurate with the importance or significance of the problem (see WHC-CM-1-4 for reference).

15.5 Continuous Quality Improvement

Quality improvement is a continuous process and is designed to reduce the variability of every process that influences the quality of the product. This concept is used throughout this quality assurance program. Laboratory activities, analytical measurements and results, and QA/QC activities are documented and are traceable for evaluation. For example, management or personnel can analyze the performance indicators, control charting, corrective actions, or assessment to identify actions as a means of continuous quality improvement. In addition, information obtained from lessons learned evaluations, HATS, or peer reviews also are used for management planning and problem prevention as a means of continuous quality improvement.

REPORTS	AUTHOR	APPROVED	FREQUENCY	DISTRIBUTION	CORRECTIVE RESPONSIBILITY	TYPE OF DOCUMENT
Open OSCR Report	OQA Staff	N/A	Weekly	Lab Manager Key Scientist	Lab Manager Key Scientist	Electronic Communication
LMCS Status	OQA Staff	N/A	Monthly Quarterly	Lab Management WHC-QA	Lab Management	Internal Letter
QA Status	LQAO[1] Staff	N/A	Monthly	Lab Management	Lab Management	Internal Letter
Topic Audit Ext. Assessment	OQA Staff	OQA Manager	Annual	Lab Management	Lab Management	Internal Letter
Topic Audit Int. Assessment	OQA Staff	OQA Manager	Quarterly	Lab Management WHC-QA	Lab Management	Internal Letter
QA Data Review	QA/QC Staff	N/A	Ad hoc	Lab Management Technical Staff	Lab Management	Internal Form
Responses Data Review	Technical Staff & Management	LQAO Staff	Ad hoc	Lab Management	N/A	Internal Form
Letter of Observation	QA/QC Staff	N/A	Ad hoc	Lab Management	Lab Management	Internal Form
Case Narrative	Technical Staff	PC[2]	1/Data Package	Data Package	N/A	N/A
Case Summary	PC	PS[3] Manager	1/Data Package	QA File	N/A	Internal Forms
External Audit/Assessment	Auditor	N/A	Ad hoc	Lab Management	Lab	Internal/External Letter
External Surveillance	AEQA[4] Staff	AEQA Manager	Quarterly	Lab Management WHC-QA	Lab	Internal Letter

[1]LQAO = Laboratory Quality Assurance Officer
[2]PC = Project Coordinator
[3]PS = Project Support
[4]AEQA = Analytical Environmental Quality Assurance

This page intentionally left blank.

17.0 DATA VALIDATION

The project requirements must be defined in the specific Quality Assurance Program Plan, along with the systematic process to be used in verification or validation of project data. In cases where data must be validated, a specific set of acceptance criteria must be defined that provides ensurance that the data generated are adequate for their intended use. The acceptance criteria reflect the requirements generated during the DQO planning process. The validation process will consist of data editing, screening, checking, auditing, verification, flagging, and review. The Laboratory will not perform data validation; validation is independent of laboratory data review.

Acceptance criteria for validation purposes may include the following:

- Holding times
- Preservative methods and container types
- Minimum required sample size, for analysis
- Calibration criteria and requirements (initial and continuing)
- Detection limits
- Accuracy and precision definitions and requirements
- Field blank and preparation blank requirements
- Surrogate recoveries for organic compounds
- Tracer/carrier recovery requirements for radiochemical analysis.

This page intentionally left blank.

18.0 PROCUREMENT CONTROLS

The 222-S and 222-SA Laboratories follow the WHC-CM-2-1 (*Procurement Control and Manual*) and WHC-4-2 QR 4.0 "Procurement Document Control" to ensure the procurement process is documented and controlled. The controls ensure procured items and/or services can do the following:

- Conform to established specifications
- Meet acceptable quality
- Perform as expected.

The subcontractor shall include organizations that provide services and supplies.

When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to laboratory management for appropriate action (e.g., subsequent reporting to the U.S. Department of Energy Office of the Inspector General).

18.1 Procurement Planning

Procurement activities shall be planned according to WHC-CM-2-1 and documented to ensure a systematic approach to the procurement process.

18.2 Control Of Subcontractors

18.2.1 Subcontractor Selection

Subcontractors shall be selected based on their capability to provide items or services in accordance with the requirements of the procurement documents. Their capability shall be evaluated before the purchase order is awarded.

Provisions for evaluating and selecting procurement subcontractors (and the results thereof) shall be documented and shall include one or more of the following:

- Subcontractor's history of providing an identical or similar product or service that performs or has performed satisfactorily in actual use. This history shall reflect current capability.

- Subcontractor's current record, supported by documented qualitative and quantitative information that can be evaluated objectively

- Subcontractor's technical and quality capability as determined by the following:

  - Direct evaluation of the subcontractor's facilities and personnel (e.g., participation in performance evaluation program)

  - Implementation of their quality system (e.g., pre-award audit).

18.2.2 Subcontractor Performance Evaluation

The purchaser of items and services shall establish provisions to communicate with the subcontractor and to verify the subcontractor's performance as deemed necessary by the WHC technical representative. These verification provisions shall include the following:

- Establishing and documenting an understanding between the technical representative and subcontractor of the procurement documents' provisions and specifications
- Reviewing subcontractor documents that are generated during activities that fulfill procurement requirements
- Identifying and processing necessary change information
- Establishing a method of document information exchange between the purchaser and the subcontractor
- Establishing the extent of source surveillance and inspection activities.

These verification activities shall be conducted as early as practicable. Westinghouse Hanford Company's verification activities, however, shall not relieve the subcontractors of their responsibility to verify quality achievement.

18.2.3 Content Of Procurement Documents

Procurement documents issued at all tiers of procurement shall include the following technical documentation as deemed necessary by the technical representative:

- Scope of work
- Technical requirements
- Quality system requirements
- Rights of access
- Documentation requirements
- Subcontractor nonconformance
- Spare and replacement parts.

18.2.4 Review And Change Control Of Procurement Documents

The procurement documents, and changes thereto, shall be reviewed. The review shall ensure that the documents transmitted to the prospective subcontractor(s) include appropriate provisions to ensure that items or services meet the specified requirements. Reviews shall be

performed and documented to provide objective evidence of satisfactory evaluation of procurement documents. This will be done before the purchase order award.

Procurement document changes shall be subject to the same degree of control used in preparing the original documents. Reviews of procurement document changes and their effects shall be completed before the purchase order award.

18.2.5 Acceptance Of Items Or Services

Provisions shall be established and implemented to ensure that purchased items or services that are furnished by the subcontractor conform to established specifications, are of acceptable quality, and perform as expected.

18.2.6 Control Of Subcontractor Nonconformances

A system for documenting subcontractor nonconformance shall be developed and implemented for nonconforming items and services.

18.3 Purchase Of Commercial-Grade (Off-The-Shelf) Items

The following requirements are an acceptable alternative to requirements discussed in Section 18.2.1 with regard to commercial-grade (off-the-shelf) items.

- Verify that the item shall perform the intended function and shall meet requirements applicable to both the replaced item and its application. This verification shall be done by the analyst.

- Complete source evaluation and selection, where determined necessary by purchaser, based on complexity and importance to safety.

- Identify commercial-grade items in the purchase order by the manufacturer's published product description (e.g., catalog number).

- Inspect the following before receipt of items:

  - Damage during shipment

  - Item received was item ordered

  - Item conforms with the manufacturer's published requirements

  - Documentation (e.g., certificates of cleanliness, traceability to National Institute for Standards and Technology) was received and is acceptable.

- Develop controls to inspect and verify conformance of the measuring and test equipment with the manufacturer's specifications and any requirements specified in the procurement documents (see next paragraph for details).

Controls are developed by fully exercising the equipment's range of capabilities and features once the equipment is installed in the analytical contractor's facility. The controls will be based upon criteria derived from the manufacturer's published specifications and the required data quality that is specified contractually. The controls will include the following:

- Number of quality control samples to be run
- Number of data points to be collected
- Initial calibration
- Necessary adjustments to allow correct operation in the analytical contractor's unique environment.

The necessary controls and results shall be documented and retained for each procured piece of measuring and test equipment.

19.0 REFERENCES

10 CFR 830.120, 1994, "Quality Assurance Requirements," *Code of Federal Regulations*, Title 10, Part 830.120, U.S. Environmental Protection Agency, Washington, D.C.

40 CFR 136, 1994, "Guidelines Establishing Test Procedures for the Analysis of Pollutants," *Code of Federal Regulations*, Title 40, U.S. Environmental Protection Agency, Washington, D.C.

Clean Air Act of 1977, 42USC 7401 et seq.

Clean Water Act of 1977, 33 USC 1251 et seq.

Comprehensive Environmental Response, Compensation, and Liability Act of 1980, 42 USC 9601 et seq.

Currie, L.A., 1968, "Limits for Qualitative Detection and Quantitative Determination," *Analytical Chemistry*, 40(3):586-593.

David, Howard, 1984, *Guidelines for Screening National Pollution Discharge Elimination System Permits*.

DOE, 1991, *Quality Assurance*, DOE Order 5700.6C, U.S. Department of Energy, Washington, D.C.

DOE, 1992, *Writer's Guides for Technical Procedures*, DOE-STQ-1029-92, U.S. Department of Energy, Washington, D.C.

Ecology, EPA, DOE, 1994, *Hanford Federal Facility Agreement and Consent Order*, Vol. 1 and 2, Washington State Department of Ecology, Olympia, Washington; U.S. Environmental Protection Agency and U.S. Department of Energy, Washington, D.C.

EPA, 1977, *Environmental Protection Agency National Emission Standards for Hazardous Air Pollutants*, U.S. Environmental Protection Agency, Office of General Enforcement, Washington, D.C.

EPA, 1980, *Guidelines and Specifications for Preparing Quality Assurance Program Plans*, EPA QAMS-004/80, U.S. Environmental Protection Agency, Washington, D.C.

EPA, 1980, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans*, EPA QAMS-005/80, U.S. Environmental Protection Agency, Washington, D.C.

EPA, 1991, *USEPA Contract Laboratory Program, Statement of Work for Organics Analysis*, OLM02.1, U.S. Environmental Protection Agency, Washington, D.C.

EPA, 1992, *Test Methods for Evaluating Solid Waste: Physical/Chemical Methods, SW-846*, U.S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, washington, D.C.

Meznarich, H.K., 1993, *Quality Assurance Program Plan for Laboratory Analyses and Process Testing*, WHC-SD-CP-QAPP-003, Rev 1, Westinghouse hanford Company, Richland, Washington.

Moss, S.S., 1992, *Quality Assurance Project Plan for the Chemical Analysis of Highly Radioactive Samples in Support of Environmental Activities on the Hanford Site*, WHC-SD-CP-QAPP-002, Westinghouse Hanford Company, Richland, Washington.

Occupational Safety and Health Act of 1970, 21 USC 651 et seq.

Resource Conservation and Recovery Act of 1976, 42 USC 6901 et seq.

Rich, H.S., 1995, *Configuration Management Plan for LABCORE Program*, WHC-SD-WM-CM-002, Westinghouse Hanford Company, Richland, Washington.

Taylor, L.H., 1993, *Analytical Chemistry Services Laboratories Quality Assurance Plan*, WHC-SD-CP-QAPP-001, Westinghouse Hanford Company, Richland, Washington.

Taylor, L.H., 1994, *Quality Assurance Project Plan for the Chemical Analysis of Highly Radioactive Samples in Support of Environmental Activities on the Hanford Site*, WHC-SD-CP-QAPP-002 Rev 0B, Westinghouse Hanford Company, Richland, Washington.

Weaver, L.L., 1992, *Laboratory Facilities Hazards Identification and Evaluation*, WHC-SD-HIE-001, Rev. 0,E, Westinghouse Hanford Company, Richland, Washington.

Westinghouse Hanford Company Analytical Services procedures:

LC-400-001, *FORTRAN Coding and Documentation Guidelines*

LC-400-002, *Programmable Calculator Documentation and Coding Guidelines*

LC-400-003, *Basic Coding and Documentation Guidelines*

LC-400-006, *Spreadsheet Documentation Guidelines*

LC-705-101, *ACE Program - Implementation and Operation of Spreadsheet and Computer Interface*

LC-708-001, *MULTI-LIMS Use in the Laboratory*

LC-718-001, *Laboratory ADP Systems Operations*

LC-808-101, *LMCS/LCCS LINR System User Manual*

LO-080-116, *Glassware Cleaning for Standards Laboratory*

LO-090-101, *222-S Laboratory Sample Receiving and Custodianship*

LO-120-101, *Proper Labeling and Recertification of Chemicals, Standards, and Reagents at 222-S*

LO-140-004, *Routine use analytical balances*

LO-150-001, *Laboratory Measurement Quality Control Using Laboratory Measurement Control System (LMCS)*

LO-150-002, *Response to Off-Standard Condition Reports and Precision Reports*

LO-150-105, *Safety and Housekeeping Inspections of the 222-S Laboratory Complex*

LO-150-127, *Mathematic Aspects of Checking and Reporting Results*

LO-150-132, *Sample Storage, Rooms 2E and 2B, and 222-S Laboratory Hot Cells*

LO-150-135, *Sample Disposal Criteria*

LO-190-101, *Hood Decontamination - 222-S Analytical Laboratory*

LQ-150-001, *Laboratory Measurement Quality Control*

LQ-510-113, *Calibration of Volumetric Dispensers*

LQ-510-114, *Calibration of Motor-Driven Burets*

LQ-510-123, *Calibration of Pipettors used in 222-S Laboratory*

Westinghouse Hanford Company Control Manuals:

WHC-CM-1-3, *Management Requirements and Procedures*

WHC-CM-1-4, *Corrective Action Management Manual*

WHC-CM-2-1, *Procurement Manual and Procedures*

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

WHC-CM-3-10, *Software Practices*

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

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

WHC-CM-6-1, *Standard Engineering Practices*

WHC, *Configuration Management Plan for LABCORE Program*, WHC-SD-WM-CM-002, Westinghouse Hanford Company, Richland, Washington. (to be released)

WHC, *LABCORE Software Test Plan*, WHC-SD-WM-CSWD-058, Westinghouse Hanford Company, Richland, Washington.

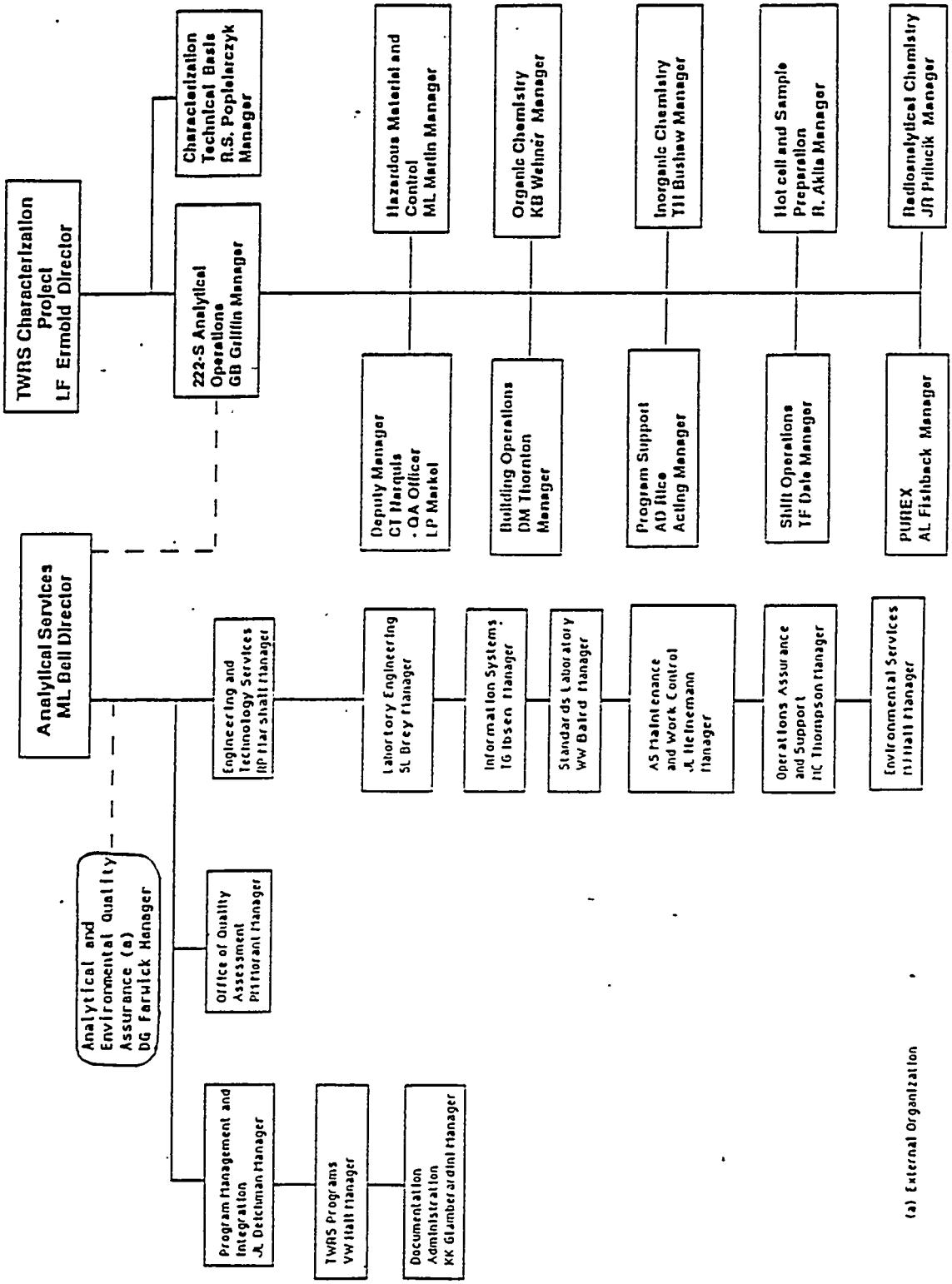
APPENDIX A QUALITY ASSURANCE INDEX

QUALITY ASSURANCE REQUIREMENTS	DOCUMENTS - WHC	PROCEDURES - LABORATORY
1. Introduction	NA	NA
2. Organization and Responsibility	WHC-CM-4-2, QI 2.1	
3. Personnel Qualification and Training	WHC-CM-4-2, QI 2.6	WHC-CM-5-4, Sec. 4.0
4. Quality Assurance Objectives 1. Data quality objectives 2. Client data quality requirements		 Client's QAPjP, State of Work
5. Systems Quality Assurance 1. Software systems 2. Administrative systems 3. Physical facilities systems	 WHC-CM-4-2, QR19.0 WHC-CM-5-4 WHC-SD-HIE-001	 WHC-SD-WM-CM-002 Specific LC procedures WHC-CM-5-4 Specific LO procedures
6. Sample Custody and Handling 1. Chain of custody definition 2 Holding times 3. Sample receiving procedure 4. Sample log-in and tracking procedure 5. Laboratory internal chain-of-custody 6. Sample disposal		 L0-090-101 L0-090-101 L0-090-101 LO-090-101 Specific LO Procedures
7. Calibration	WHC-CM-4-2, QR 12.0, QI12.0, 12.2, 12.3, 12.4, 12.5, 12,6, 12.7	Specific LQ procedures
8. Laboratory Procedures 1. Procedures and Supporting Document(s) 2. Change Control 3. New Analytical Methods 4. Modification of Required Regulatory Methods		 WHC-CM-5-4, Sec 3.9 WHC-CM-5-4, Sec 3.10
9. Data Collection, Reduction, and Reporting 1. Data collection 2. Data reduction 3. Data review 4. Data reporting		 Specific LA procedures Specific LQ procedures
10. Records	WHC-CM-3-5, Sec 5.0 and 9.0	

QUALITY ASSURANCE REQUIREMENTS	DOCUMENTS - WHC	PROCEDURES - LABORATORY
11. Quality Control 1. Laboratory Quality Control 2. Preparative Techniques 3. Analytical Techniques		 Specific LO or LQ procedures Specific LA procedures Specific LA procedures
12. Procedures to Assess Data Quality		Specific LA procedures
13. Audits	WHC-CM-4-2, QR18.0	
14. Preventive Maintenance		WHC-CM-5-4, Sec. 10.0
15. Corrective Actions	WHC-CM-4-2, QR16.0, QI16.0 -16.2	WHC-CM-5-4, Sec 6.0 & 8.0
16. Quality Assurance Reporting		
17. Data Validation		
18. Procurement Planning	WHC-CM-2-1 WHC-CM-4-2, QR 4.0	

APPENDIX B ANALYTICAL OPERATIONS ORGANIZATION AND QUALITY INTERFACE

Appendix B: Analytical Operations Organization and Quality Interface



This page intentionally left blank.

APPENDIX C GLOSSARY

accuracy	the degree of agreement of a measurement (or an average of measurements of the same thing), X, with an accepted reference or true value, T, usually expressed as the difference between the two values, X - T, or the difference as a percentage of the reference or true value, 100 (X - T)/T, and sometimes expressed as a ratio, X/T. Accuracy is a measure of the bias in a system.
analyst	a person performing a measurement.
analyte	the element, isotope, specie, or characteristic of a measurement.
anomalies	something different, abnormal, or peculiar, not easily classified.
assessment	the act or instance of assessing (appraisal); the act of reviewing, inspecting, testing, checking, conducting surveillance, auditing, or otherwise determining and documenting whether items processes or services meet specified requirements. The terms assessment and verification as used in DOE Order 5700.6C are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organizations. For data, assessment encompasses verification and validation. Data assessment (verification and/or validation) can be performed within the laboratory and/or by an independent review agency at the discretion of the client to the criteria of the project.
client	the person or organization submitting work.
comparability	expresses the confidence with which one data set can be compared to another.
completeness	a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions.
consensus standard	a procedure, protocol, or guidance document issued by a professional organization based on extensive testing and peer review.
continuous quality improvement	a program or system that monitors performance, evaluates trends, and implements changes based on trends.

false negatives	a term that identifies the acceptance of a test or condition as false, when in fact it is true.
false positive	a term that identifies the acceptance of a test or condition as true, when in fact it is false.
matrix	the component or substrate (e.g., surface water, drinking water) that contains the analyte of interest.
nonconformance	a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.
out-of-control (QC Failure)	a system is said to be out-of-control when it fails to meet preselected performance criteria.
precision	a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is best expressed in terms of the standard deviation. Various measures of precision exist depending upon the "prescribed similar conditions."
preventive maintenance	a program of instrument care based on scheduled activities and spare parts inventory designed to minimize instrument downtime.
qualify	to qualify laboratory staff or a subcontractor is to provide evidence of meeting a performance standard for fitness by training skill or ability for a designated purpose. To qualify analytical procedures or computer programs is to provide evidence of performance to meet the required standard criteria.
quality assurance	the total integrated program for ensuring the reliability of monitoring and measurement data. Quality assurance is a system for integrating the quality planning, quality assessment, and quality improvement efforts to meet user requirements.
reagent quality	an analysis or industry-accepted grade that denotes purity or applicability for application.
regulatory procedures	those methods published or promulgated for laboratory use to meet the requirement of a law or government rule.
representa-tiveness	expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.
traceable	a document trail that identifies the history of a sample, standard, or other material.

valid	having legal efficacy or force, well grounded, or justifiable being at once relevant, meaningful, logically, and correct, appropriate to the end in view.
validation	an act, process, or instance of validating. For data, validation is the process by which the data and quality control information is assessed or compared against the client's requirements.
verification	act or process of verifying. For data, verification is the process of comparing the reported data with the required information.
verifying	to establish the truth, accuracy, or reality.

This page intentionally left blank.

APPENDIX D 222-S LABORATORIES QUALITY ASSURANCE IMPLEMENTATION PLANS

The 222-S Laboratories quality assurance implementation plans are grouped based on the organizational structure: Hot Cell and Sample Preparation, Inorganic, Organic, Radioanalytical Chemistry, and the Standards Laboratory. The following tables list the implementation plans for each group including information on section numbers, implementation items and actions, and target date to complete each implementation item. The implementation plans are developed by each group. The sections that are not listed may not require any implementation actions.

The target date is set up either by a specific date or by a specific time period. The specific target date is the date that the Laboratory declares compliance with these quality assurance requirements. However, certain implementation actions could not be implemented until new or revised procedures or documents (e.g., WHC-CM-5-4) are issued. Under this circumstance, the target date is set by estimating the time required to complete the implementation. The date that the procedure or document is issued shall be used as day 0 and the final target date will be calculated thereafter.

The completion status of the 222-S Laboratory quality assurance implementation will be assessed and issued.

The following procedures have been updated by the Information Systems:

- LC-400-001, *FORTRAN Coding and Documentation Guidelines*
- LC-400-002, *Programmable Calculator Documentation and Coding Guidelines*
- LC-400-003, *Basic Coding and Documentation Guidelines*
- LC-400-006, *Spreadsheet Documentation Guidelines*
- LC-705-101, *ACE Program - Implementation and Operation of Spreadsheet and Computer Interface.*

The following procedure has been updated by the quality assurance officer but is not yet issued:

- LQ-150-001, *Laboratory Measurement Quality Control*

The following procedure has been updated:

- LO-150-002, *Response to Off-Standard Condition Reports and Precision Reports.*

Implementation Plan for Hot Cell and Sample Preparation

Sections not listed do not require implementation actions for the Hot Cell and Sample Preparation group.

Section Number	Items	Responsible Person	Completion Date
3.3	Provides continuing improvement in the awareness and proficiency of all employees Each group of technologists within the Hot Cell and Sample Prep organization has a specific list of procedures to train on. Each of the chemists and plant engineers have their training plans reviewed yearly at the time of their performance appraisal.		1. 07/12/95 2. COMPLETE
3.3	Revise WHC-CM-5-4 Section 4, Training to reflect TMX. 1. Define the criteria for individual re-training Hot Cell/Sample Prep: TMX has been done for each category of jobs in the group and a matrix made. 2. Re-training requirements in the individual annual training plan: a. In the individual annual training plan. b. routine re-qualification tickler from the training department HOT CELL/SAMPLE PREP: TMX has the routine re-training courses listed for each category of job in this group. The Training Department has still been sending out notices that training is due and needs scheduling or are scheduled for us. 3. Continuous improvement needs. HOT CELL/SAMPLE PREP: this is on-going, since it is continuous, development plans are discussed with each individual yearly during their appraisal.		1. June 15, 1995 2. COMPLETE 3. COMPLETED

Section Number	Items	Responsible Person	Completion Date
3.4	222-S personnel's orientation training on HASQAP requirements and 222-S LABQAP (WHC-QAPP-016). HOT CELL/SAMPLE PREP: When LABQAP is issued (officially), a basic overview will be conducted of the key objectives and requirements that we must operate under.		06/15/95
3.4.4	Managers obtain appropriate management training courses. HOT CELL/SAMPLE PREP: training courses are determined by upper level management with minor input of the individual managers. This is an on-going professional and personal development process among all managers.		ON-GOING
3.6	Do we have checklist covers training to all laboratory operating and analytical procedures. Review WHC-CM-5-4, Section 4.4 OJT for the topics list in the 222 LABQAP HOT CELL/SAMPLE PREP: a list of operating procedures is being developed for each job category within this group. The topics listed in Section 4.5 is general and is updated as needed with regulations and managerial mandates.		07/12/95
3.7	1. Update individual resumes for exempt employees. HOT CELL/SAMPLE PREP: competency reports were submitted in lieu of resumes. I will still keep a copy of current resumes in my personal file. 2. What is the status on keeping the employee's training records? HOT CELL/SAMPLE PREP: according to our RIDS, we keep training records for all of employees in the field, and must keep them for at least a year after they leave the job. 3. Bargaining unit employees training records. HOT CELL/SAMPLE PREP: current training records are kept in a binder for each employee, and are stored in a cabinet in the secretary's office.		1. May 1, 1995 2. ON-GOING 3. ON-GOING

Section Number	Items	Responsible Person	Completion Date
4.1.1	Set up a communication system for notification of unique data quality requirements Client complaints and resolution	Program support Program support	
6.1	1. Identify the samplers that deliver samples to 222-S Lab HOT CELL/SAMPLE PREP: Still needs to be done. 2. Identify regulatory holding times, HOT CELL/SAMPLE PREP: most of the regulatory holding times have been identified and are in LABQAP in table. 3. Train sample custodian on regulatory holding times HOT CELL/SAMPLE PREP: the sample custodians have been informed that they will have know the specific analyses that have holding times and will have to inform the appropriate people when these samples come in. They do not have a chart available that lists those analyses that require holding times. An operator aid has been installed in Room 2A listing analytes with critical holding times. 4. Re-enforce holding times tracking system HOT CELL/SAMPLE PREP: when the job requirements are listed, the sample custodians and their delegates will be informed, trained, procedures updated (some are already updated).		1. May 5, 1995 2. COMPLETED 3. June 20, 1995 4. Procedure issue date

Section Number	Items	Responsible Person	Completion Date
6.2	1. Identify the samplers that deliver samples to 222-S Lab HOT CELL/SAMPLE PREP: still needs to be done. 2. Inform the cooler temperature measurement requirements for VOA, SVOA, and Cyanide. HOT CELL/SAMPLE PREP: need the list of customers before informing them of this requirement. One group (Mobile Samplers) has already been informed and are currently doing temperature measurements upon delivery.		1. May 5, 1995 2. May 30, 1995
6.2	Does the LABCORE tracking sample system describe in the procedure LO-090-101? HOT CELL/SAMPLE PREP: no, still not sure what the sample custodians have to do.		May 1, 1995
6.6	What is the status on the Sample Disposal Program? HOT CELL/SAMPLE PREP. this is on-going problem that is being worked on in several different ways: 1. All samples that can go back to the customer are sent back. 2. Permission to dump samples must have approval from the customer, which takes time and effort to coordinate. 3. Listed waste codes are being worked on by the HMC, at this time.		DUE DATE: ON-GOING
7.1	Verify the calibration procedures include 1. Number and range of concentrations or activities to be used 2. Frequency of calibration 3. Criteria used to accept calibration 4. Actions to be taken if calibration fails acceptance criteria 5. Is it a regulatory method? HOT CELL/SAMPLE PREP: the calibration procedures do not mention every one of the above criteria, and will have to have a cognizant person input this criteria into each analytical procedure.		Procedure issue date

Section Number	Items	Responsible Person	Completion Date
7.4.1	1. Issue a procedure for operating balances including a verified step for balances used for quality-affecting measurements and documented. HOT CELL/SAMPLE PREP: a procedure has been identified and written but not issued yet. 2 Incorporate acceptance criteria in the notebook for each balance logged HOT CELL/SAMPLE PREP: a logbook has not been issued for each balance in the organization. SAMPLE PREP has a logbook. HOT CELLS record data on worksheet.	DUE DATE: when procedure has been issued requiring a logbook.	03/30/95 Trained 04/20/95 Complete 07/17/95
7.4.2	Thermometers check annually against NIST certified thermometers HOT CELL/SAMPLE PREP: thermometers used for in refrigerators for temperature storage requirements: 1. are purchased with NIST documentation 2. are sent to PNL and calibrated according to NIST standards 3. are on a data base where the thermometers are tracked for expiration of calibration		DUE DATE: ON-GOING
7.4.3	Volume checks on mechanical pipettes daily or before use. Issue a procedure? Notebook for recording volume check HOT CELL/SAMPLE PREP: a decision whether a procedure is needed is still being decided. The procedure will specify how a daily volume check will be made and documented, and training on the procedure will be documented after issuance.	R. Akita	LO-150-172, issued 06/14/95 LQ-510-123, issued 06/19/95 June 15, 1995
8.5	Establish qualification of analytical methods. Establish database. HOT CELL/SAMPLE PREP: sample prep procedures follow SW-846 methods.		DUE DATE: COMPLETED 02/28/95

Section Number	Items	Responsible Person	Target Date
11	Verify analytical procedures on QC frequency, QC criteria? - where to list the client's QC criteria: precision, accuracy, prep blank, SAMPLE PREP: procedures are not specific on QC frequency: this is determined by the protocol of the specific sample requirements of the customer.		DUE DATE: ON-GOING
14.	Spare part list HOT CELL: Dennis Sovy of Rob Marshall's group maintains a spare parts inventory based on usage of selected parts. This inventory is monitored for high usage material and parts.		DUE DATE: COMPLETED
15.2	Trend Analysis HOT CELL/SAMPLE PREP: trend analysis is a continuing process of evaluating how we do. We check out sample prep by evaluating how the inorganic group performs on the various performance evaluation samples (we consider this a joint effort) to determine how we operate, by the score they receive.		DUE DATE: ON-GOING
15.3	Root cause analysis HOT CELL/SAMPLE PREP: when the scores from the inorganic performance evaluation samples come back with a less than acceptable rating, sample prep evaluates our preparation techniques and start corrective actions to mitigate the situations from happening again.		DUE DATE:ON-GOING
15.5	Continuous quality improvement HOT CELL/SAMPLE PREP: this is an on-going doctrine whereby we look at all of our performance data, audit findings, corrective actions and suggestions to improve how we do our work.		DUE DATE: ON-GOING

Implementation Plan for Inorganic Chemistry

Note: Sections not listed do not appear to require implementation activities by the 222-S Inorganic Chemistry group.

SECTION	PREREQUISITES TO INORGANIC IMPLEMENTATION	INORGANIC IMPLEMENTATION ACTIVITIES	INORGANIC COMPLETION DATE
Chapter 2: Organization and Responsibility			
2.1	Implementation of policies outlined here are detailed in other sections of LABQAP.	Staff familiarization with LABQAP document.	LABQAP document to be distributed in late February/early March; also see 2.3.
2.2.1	222-S management needs to determine if technical groups are responsible for data package level narratives.	"...preparing case narrative..." is a specified responsibility. Current practice, but not at the data package level.	n/a
2.3	LABQAP Orientation training or procedure for familiarization needs to be developed.	Staff needs to become familiar with LABQAP requirements.	06/12/95
Chapter 3: Personnel Qualification and Training			
3.1	Minimum qualification requirements for each position need to be reviewed, revised, or established.	Mgr: Assist in establishing minimum requirements with respect to technical skills. Evaluate staff with respect to established requirements and prepare remedial training plans, if required.	08/31/95
3.3	WHC-CM-5-4, Section 4.5 needs to be updated to reflect LABQAP requirements.	Develop employee specific training plans for staff.	
3.4.1	HASQAP/LABQAP General Requirements training program/course needs to be developed.	Staff needs to complete the program/course.	Depends on course frequency and availability.
3.4.3	Procedure Author Training course needs to be updated to reflect new requirements of HASQAP/LABQAP.	Staff needs to complete training course.	
3.7	Establish common format (minimum content) for resumés. (?)	Resumés for exempt employees need to be collected and placed in personnel files. Annual training plans (see 3.3 above) need to be placed in personnel files.	09/01/95

SECTION	PREREQUISITES TO INORGANIC IMPLEMENTATION	INORGANIC IMPLEMENTATION ACTIVITIES	INORGANIC COMPLETION DATE
Chapter 4: Quality Assurance Objectives			
4.1.2	Program Support group needs to establish mechanism for documenting issues, complaints, and resolutions from clients.	Staff needs to be educated on Client Complaint and Resolution documentation mechanism (for those issues, minor or technical, that they coordinate).	1 month after mechanism established.
4.2	None	Staff needs to have accuracy and precision data for their methods (from standards) readily available (or documented in the procedures). This data is normally available from LMCS or LABCORE.	Procedure issue date
Chapter 5: Systems Quality Assurance			
5.1.1	Software control requirements need to be developed and documented. This is particularly an issue with respect to instrument-controlling software.	The control requirements will have to be implemented for instrument-controlling software used within the Inorganic Chemistry group.	LO-150-172, issued 06/14/95
5.1.2	None (?)	For each instrument-controlling software system, an "Acceptance Test" will have to be developed (or current practices will have to be documented). Where required, an initial "test" will have to be performed.	Procedure issue date
5.1.3	222-S management needs to develop a policy/procedure with respect to software backups covering "office" PCs, LABCORE systems, and instrument-controlling computers.	Staff will have to become familiar with this policy/procedure and apply it to the systems for which they are responsible.	1 month after policy established and promulgated.
Chapter 6: Sample Custody and Handling			
6.2	A method for tracking holding times needs to be designed and implemented. (LABQAP states "Holding times are recorded on the analytical card and tracked in the LABCORE system.")	Staff needs to maintain awareness of holding times, when applicable, and establish analysis priorities accordingly.	04/19/95

SECTION	PREREQUISITES TO INORGANIC IMPLEMENTATION	INORGANIC IMPLEMENTATION ACTIVITIES	INORGANIC COMPLETION DATE
Chapter 7: Calibration			
7.1	None	Procedures must be revised, where needed, to include the calibration information specified: • Number and range of concentrations • Frequency • Acceptance criteria • Failure actions These must conform to HASQAP if procedures are used for regulatory-driven analyses.	Procedure Issue Date
7.3	None	Where not presently in compliance, logbooks or notebooks need to be set up for maintaining calibration records. Completed books will be turned over to the Laboratory Technical Information Center for storage. Procedures need to be reviewed and updated, if needed, to ensure they specify how calibration data is linked to analytical results.	
7.4.1	A procedure for daily balance calibration checks needs to be written.	Staff needs to be trained on this balance-check procedure and to begin working to this procedure.	LO-140-006, issued 03/30/95 (mod 06/07/95) 04/18/95
7.4.2	None	Identify which analyses are influenced by temperature and review and update, if needed, the procedures to ensure that the LMS maintains sufficient temperature accuracy and precision.	Procedure issue date
7.4.3	A procedure for daily or before-use pipette volume checks needs to be written.	Staff needs to be trained on this volume-check procedure and to begin working to this procedure. Volume-check equipment may need to be procured depending on the governing procedure and the location of the pipettor.	LQ-510-123, issued 06/19/95

SECTION	PREREQUISITES TO INORGANIC IMPLEMENTATION	INORGANIC IMPLEMENTATION ACTIVITIES	INORGANIC COMPLETION DATE
Chapter 8: Laboratory Procedures			
8.1	Has a "User Test Approval Form" (UTAF) been designed and implemented? Management needs to determine what constitutes "qualification" of a method and the information that needs to go into the UTAF or a Supporting Document (SD).	Chemist staff needs to become familiar with (trained on?) the mechanism for qualifying a new procedure (use of the UTAF or preparation of a Supporting Document). Are existing procedures "grandfathered"?	1 month after mechanism is in place; applied to new procedures and revisions.
8.2.2	None	When procedures are based on regulatory methods, they need to reference that method and to document any deviations (as defined by HASQAP) from that method. For such procedures, a determination needs to be made whether differences are "deviations" or "modifications." If "modifications," the procedure needs to be qualified (Section 8.5).	Procedure issue date
8.3 / 8.5	See 8.1	Staff needs to be educated on requirements for procedure qualification for new methods.	See 8.1.
8.4	None	Procedures that are implementations of regulatory methods must be reviewed and updated, if needed, to include documentation of any variances from the regulatory method. (This is required ONLY IF precision, accuracy, detection limits, and/or QC criteria might be affected by these variances.)	Procedure issue date
Chapter 9: Data Collection, Reduction, and Reporting			
9.1	Laboratory management needs to define what constitutes "raw data."	The requirement for retention of "raw data" (based on the definition) needs to be interpreted for each AMS and implemented.	06/30/95
9.2	222-S management needs to determine if calculations performed by instrument controllers need to be included or just those required to convert "finished" instrument results into "customer-ready" results.	Analytical procedures need to be reviewed and updated, if needed, to include calculations required to produce final results.	Procedure issue date

SECTION	PREREQUISITES TO INORGANIC IMPLEMENTATION	INORGANIC IMPLEMENTATION ACTIVITIES	INORGANIC COMPLETION DATE
Chapter 11: Quality Control			
11.1.1	System for monitoring and logging Q-Water quality needs to be revised to reflect LABQAP requirements (monthly Q-water checks and data access near delivery points).	Staff must be trained on requirement to check Q-water conductivity prior to delivery and availability of analysis results for review.	I.O-150-060, issued 06/19/95 08/02/95
11.1.2	None	Procedures need to be reviewed and updated, if needed, to include minimum or required purity levels for gases and reagents.	Procedure issue date
11.1.5	A procedure is being written to provide guidance/requirements for the use of control charts.	Staff must be trained on the control charting procedure and the requirements specified in LABQAP (ready access, ability to maintain, and their use to demonstrate system control).	1 month after release of governing procedure.
11.2.4	None	Review QC Protocol sections of procedures and update, if needed (based on HASQAP requirements), to include matrix spike information (levels, frequency, acceptance criteria, and failure actions).	Procedure issue date
11.2.5	None	Review QC Protocol sections of procedures and update, if needed (based on HASQAP requirements), to include duplicate and/or matrix spike duplicate information (frequency, acceptance criteria, and failure actions).	
11.3.2 11.3.3 11.3.4	None	Review QC Protocol sections of procedures and update, if needed (based on HASQAP requirements), to include ICV, CCV, ICB, and CCB information (frequency, acceptance criteria, and failure actions).	Procedure issue date
11.3.5 11.3.6 11.3.7 11.3.8 11.3.9	None	Review QC Protocol sections of procedures and update, if needed (based on HASQAP requirements), to include Internal Standard, Low-Level Standard, Interference Check Standards (ICP only), Post Digestion Spike, and Serial Dilution information (frequency, acceptance criteria, and failure actions).	

SECTION	PREREQUISITES TO INORGANIC IMPLEMENTATION	INORGANIC IMPLEMENTATION ACTIVITIES	INORGANIC COMPLETION DATE
Chapter 12. Procedures to Assess Data Quality			
12.4.1.1	None	Although not specifically required by LABQAP, MDL guidance (measurement method) and typical values should be added to procedures, if not already present. LABQAP recommends using a matrix similar to the "sample" for MDL determinations.	June 15, 1995 (part of procedure review process).
12.4.1.2	None	Although not specifically required by LABQAP, IDL guidance (measurement method) and typical values should be added to procedures, if not already present.	
12.4.1 3	None	Procedures should include an EQL estimation (a multiple of the IDL, the MDL, or the lowest calibration standard).	June 15, 1995 (part of procedure review process).
Chapter 14: Preventive Maintenance			
	None	Ensure compliance with Section 10.1 of WHC-CM-5-4, "Instrument Preventive Maintenance Program"	April 15, 1995.
	222-S management needs to decide (once and for all) how to handle spare parts inventories. WHC-CM-4-2 requires controlled critical spare parts inventories for analytical measurement systems. LABQAP suggests that alternatives to spare parts inventories may be acceptable.	Implement management policy. This may require developing critical spare parts inventories for each AMS and maintaining them in controlled documents.	05/19/95
Chapter 18: Procurement Controls			
18.3	Instrument Acceptance Test procedure or guidance for technical staff should be developed and communicated.	Staff needs to be trained on the requirements for developing controls to inspect and verify operation of new analytical instrumentation (acceptance tests). The results of these tests needs to be documented.	06/14/95

Implementation Plan for Organic Chemistry

Section Number	Implementation Actions	Implementation Completion Date
3.0	Check personnel qualifications	To be completed
3.7	Set up training records and file	To be completed
5.1	Participate in developing policy on vendor software configuration control Implement and document instrument software control based on the outcome of instrument software control policy	06/14/95 To be completed
7.4	Implement the procedure addressed daily operation of balance	05/16/95
7.4.3	Implement the procedure addressed volume control of pipette	N/A*
8.2.2.2	Only applicable, when additional requirements are issued in the HASQAP or LABQAP	One week per procedure per matrix
8.4 and 8.5	Only applicable, when additional requirements are issued in the HASQAP or LABQAP	One week per procedure per matrix

*N/A - Volume control of mechanical pipets is performed by one person based on LQ 510-123, "Calibration of Pipettors Used in the 222-S Laboratory."

Implementation Plan for Radioanalytical Chemistry

Section	Implementation Actions	Implementation Completion Date
3.3	Develop job specific training plans for all radchem employees	06/16/95
3.4.1	Radchem Training to LQAP/HASQAP	06/21/95
3.7	Update competency records for all exempt radchem personnel	08/04/95
5.0	Software control requirements	2 month after availability of the procedure
7.0	Calibration Procedure Review. Must include number of standards and activities to be used, acceptance criteria, corrective action for failed calibrations, and frequency of calibration required.	04/18/95
7.0	Calibration Procedure Updates.	07/13/95 07/13/95
7.0	Liquid Scintillation: Instrument control standard limits to be set at 3 sigma or +/- 3% whichever is greater.	04/05/95
7.4	Implement the procedure addressed daily operation of balance	06/14/95
7.4.3	Implement the procedure addressed volume control of pipette	N/A[a]
8.5	Retrieve method qualification data (if required) from existing data management system (LMCS, LCCS, or LABCORE). Set up and maintain method qualification records file.	1. 05/17/95 2. 06/15/95
9.3	Report radchem data as calculated concentrations with uncertainties (i.e., counting and total propagated uncertainty). Set up Data Validation & Deliverable software to accomplish this.	September 1, 1995[b]
11.1.5	Method Control Charting will be accomplished via the use of LABCORE to meet all requirements.	As LABCORE is implemented for all methods
11.2 11.3	Issue a radchem QC procedure to define all radchem QC, frequencies required, and criteria.	07/20/95

a: Volume control of mechanical pipettes is performed by one person based on LQ-510-123, "Calibration of Pipettors Used in the 222-S Laboratory."
b: Implementation date is scheduled based on estimation of the time required to procure the software and its installation.

Implementation Plan for Analytical Services Standards Laboratory

Section	Implementation Actions	Resolution	Implementation Completion Date
7.2	Expiration date for the calibration standards prepared by standards lab must be in the logbook.		June 1, 1995
7.4.2	All sample storage refrigerator temperature monitors must be checked against a NIST thermometer annually	The organic storage refrigerator monitors need to be checked against NIST thermometers once a year; a tickle file needs to be created to ensure the check is done	March 1, 1995
7.4.3	All mechanical pipets need to be verified prior to use	Baseline operation of the mechanical pipets needs to be documented, specifications for acceptable deviations need to be determined and a procedure written and implemented.	N/A*
9.2.1	Significant figures only should be reported	OJT on LQ-150-127 for all standards lab personnel	March 20, 1995
11.1.1	Laboratory water quality is to be checked and documented monthly	LQ-150-060 needs to be rewritten to reflect the LABQAP requirements and then implemented. Questions regarding the types of analysis required need to be resolved.	June 15, 1995
11.3.2	ICV standards must be prepared from a source other than that used to prepare the calibration standards	Responsibility to ensure this needs to be delegated, any exceptions need to be communicated.	May 19, 1995

*N/A - Volume control of mechanical pipets is performed by one person based on LQ-510-123, "Calibration of Pipettors Used in 222-S Laboratory."

Implementation Plan for 222-S Analytical Operations

LABQAP Section	Implementation Actions	Implementation Completion Date
2.4	Define data security and confidentiality in the WHC-CM-5-4	07/28/95
3.0	Revise training sections in WHC-CM-5-4	Procedure issue date
5.0	Revise and issue procedures on software system control	Procedure issue date
5.1	Establish instrument/vendor software control	06/14/95
6.2	Establish tracking regulatory holding times in LABCORE and train proper personnel on tracking holding times	04/19/95
8.0	Establish method performance/ qualification program	To be completed by 08/31/95
13.0	Revise WHC-CM-5-4 and procedures for QA/QC activities	To be completed
14.0	Evaluate and comply WHC-5-4 instrument Preventive maintenance program	May 29, 1995
15.5	Define continuous quality improvement policy in LABQAP	06/08/95
18.3	Define instrument acceptance test criteria for procurement	06/14/95

This page intentionally left blank.

9554116

ATTACHMENT 2

Draft Form Letter

Consisting of 1 page

Mr. Roger F. Stanley, Director
Tri-Party Agreement Implementation
State of Washington
Department of Ecology
P.O. Box 47600
Olympia, Washington 98504-7600

Mr. Douglas R. Sherwood, Manager
Hanford Project Manager
U.S. Environmental Protection Agency
712 Swift Blvd., Suite 5
Richland, Washington 99336

Dear Messrs. Stanley and Sherwood,

THE WESTINGHOUSE HANFORD COMPANY 222-S LABORATORY QUALITY ASSURANCE/QUALITY CONTROL PROGRAM

Enclosed please find the Westinghouse Hanford Company document "222-S Laboratory Quality Assurance Plan (LABQAP)," WHC-SD-CP-QAPP-016, Revision 1. This is the document which describes the 222-S Laboratory's Quality Assurance/Quality Control Program. The program is designed to be consistent with Hanford Analytical Services Quality Assurance Program (HASQAP), Revision 2, and is being submitted for informational purposes.

The 222-S Laboratory is currently in transition for compliance with this document. Compliance is anticipated to be declared on or before August 31, 1995. Note that Chapter 19 is an action schedule which outlines final activities necessary at 222-S Laboratory for transition to compliance with the first 18 chapters of LABQAP.

All questions should be directed to _____.

Sincerely,

Thomas K. Teynor
Director

Enclosure

9554116

ATTACHMENT 3

Table

Consisting of 1 page

Subjects that are listed in the HASQAP, Revision 2, and may conflict with 222-S Laboratory QAP, Revision 1, are as follows:

No	Section	Subject	Action
1.	5.1.2	Second paragraph. Commercially - available software shall be accepted as supplied by the vendor.	The "shall" should change to "may." For certain vendor developed softwares (e.g., data management type of software), acceptance testing may be performed by the lab.
2.	7.4.3	Page 7-19. Second paragraph. All systems incorporating a gas chromatograph (GC) shall have the retention time window specifications established each time the GC system parameters (carrier gas flow, temperature profile, etc.) are changed and whenever a new column is installed.	This window specification has been identified as a deviation for GC. The 222-S believes retention times are sufficiently controlled with current practice.
3.	8.6	Page 8-6. Fourth paragraph. Technical procedures shall include the acceptance and performance criteria for precision, accuracy, calibration, and detection limit (as appropriate) established during the qualification experiments.	The 222-S includes such information either in the procedure or in a reference document. It is not necessary to specify that this information shall be included in the procedures per se.
4.	11.2.5	Page 11-7. Third paragraph. In cases where the sample is not expected to contain concentrations of target analytes sufficient to produce relatively small counting errors, a matrix spike duplicate should be used.	We currently are not performing matrix spike duplicates in this case. Customer defined specifications do not currently require.
5.	11.5.9	Re-analysis of samples using different preparation and/or measurement procedures should be considered by the lab if alternative procedures are available, which in judgement of qualified chemists, offer a reasonable solution to the problems. Results shall be flagged.	Our LABQAP does not require 222-S to "flag" the data, but alternate method must be discussed in the report narrative along with other anomalies.