FINAL REPORT

EXTENT OF CONDITIONS REVIEW OF THE 222-S LABORATORY

Contract No. GS-10F-0093K
Order No. DE-AT27-03RV14541

Submitted to:

U.S. Department of Energy
Office of River Protection
P.O. Box 450
Richland, WA 99352

Submitted by:

SC&A, Inc.
6858 Old Dominion Drive
Suite 301
McLean, VA 22101

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1.0 BACKGROUND AND SCOPE

SC&A, Inc., was contracted by the U.S. Department of Energy's (DOE) Office of River Protection (ORP) to conduct an extent of condition (EOC) review of the 222-S Laboratory located at DOE's Hanford Site. This EOC was necessary because the 222-S Laboratory is being transitioned from the DOE Richland Office (DOE/RL) to the ORP. The purpose of the EOC review is to identify pre-existing conditions prior to the transition. This report describes the results of the EOC that was conducted at the Laboratory from July 14 through August 8, 2003.

The 222-S Laboratory, located on the southern edge of the 200 West Area of the Hanford site, consists of the 222-S complex of buildings and auxiliary buildings used for ventilation and electrical services, bulk material storage, and handling and transferring wastes to an onsite waste handling facility or offsite facilities.

The 222-S Laboratory performs analyses of high radioactivity samples and mixed wastes, and provides process technology support (e.g., methods development, process troubleshooting) for the site. Chemical process development at a bench scale is also performed. Cesium-137 and Sr-90 in quantities of hundreds of curies are the major radioisotopes used. Small quantities (less than the limit for "isolated facility") of plutonium are also used. The Laboratory has a broad range of capability for radiochemical, inorganic, and organic analyses, employing about 175 analytical methods to meet the diverse needs of site customers. Currently the Laboratory performs about 25,000 analyses per year, including those for tank characterization and closure, mission acceleration, treatment optimization and waste characterization.

The scope of the EOC was defined by the statement of work (SOW) contained in the contract and is included as Attachment A. SC&A developed a checklist consistent with the SOW to assure that all pertinent items were addressed during the site visit. This checklist is included as Attachment B. The EOC review was conducted by seven SC&A personnel who had specific expertise in the technical areas addressed by the SOW. These personnel visited the Laboratory to review pertinent procedures and documents, conduct interviews with appropriate Laboratory personnel, and observe operations and practices. These activities were directed to determining compliance of the Laboratory with its SOPs and recognized standards, procedures, and good practices; and to identifying deficiencies and proficiencies that ORP should consider in the transfer process.

222-S Laboratory Overview

The 222-S Laboratory is designed to process samples with relatively high radioactivity levels (up to 100 mrem/hr). A reported 70 percent of the samples come from the Hanford Tank Farm. The higher-level samples are processed through hot cells, where they are extracted from the sample container and in many cases diluted prior to transport to the chemistry laboratories for analysis. All the chemical and radiological laboratories are in a radiological control area where entry and egress is controlled according to radiological work practice (RWP). Workers in the controlled area wear shoe covers, gloves, and coveralls.

The 222-S Laboratory is one of two onsite laboratories operated by Fluor Hanford for DOE/RL. The other laboratory, the Waste Sampling and Characterization Facility (WSCF), accepts samples of lower radioactivity levels (<5 mrem/hr), whereas the 222-S Laboratory specializes in analyzing higher-level samples. Personnel assigned to WSCF and other external organizational entities provide many of the activities required for support to the 222-S Laboratory.

There are two primary groups performing analyses in the 222-S Laboratory. The Analytical Production group performs the more routine types of analyses for site entities. They mostly use established analytical protocols and apply them to meet the objectives of their particular client. The Accelerated Projects group conducts special studies designed to give clients project-specific solutions and answers. They may use established analytical protocols or ones that they develop to meet special needs. This group may also develop and validate methods for the Analytical Production group. In turn the Analytical Production group performs analyses for Accelerated Projects.

2.0 KEY FINDINGS

The findings from the extent of condition (EOC) review that relate to the SC&A checklist are contained in Attachment B. While the majority of the findings are classified as adequately addressing the specific requirement, there are many that are classified as deficient. Although the majority of findings are classified as adequate, these findings reflect our observations of the conditions existing at the time of the review. Those findings that appear to be most significant are discussed below. There are some items that are not addressed in Attachment B, but are addressed here, as they are not directly related to any of the questions or are better addressed in this section. The key findings are organized by the SOW categories:

- Laboratory Operations and Analysis
- Environmental, Health, Safety, and Quality
- Finance
- Infrastructure
- Customer Interface and Information Systems, Including the Laboratory Information Management System

2.1 Laboratory Operations and Analysis

Sample Tracking and Disposal

While the laboratory appears to be doing a good job in plan implementation, there have been many occasions in the past when excess samples have accumulated without a plan for disposition. In addition, on a recent matter, PNNL (Science and Technology) abandoned the LASER Ablation research and development project at the Laboratory without completing the required hot cell clean out in 11A. PNNL has been contacted to remove the material, but there was no action taken as of the site visit. It is important to carefully evaluate the disposal options for samples and residues prior to the initiation of new projects. Failure to do so can lead to significant costs and liabilities for the laboratory.

Personnel and Staffing

With the pending change in management of the 222-S Laboratory, persons in key positions have left those positions for others available to them on the Hanford Site. This decision was likely based on the uncertainty of the future disposition of the Laboratory and/or their desire to remain with the current management contractor. This trend will likely continue through the transfer of the Laboratory to ORP. Because of the current decreased workload, this may not be an immediate concern; however, the Laboratory anticipates an increase in the number of samples received in the coming fiscal year. If additional staff leaves, new personnel must be recruited and trained, plus, there could be a significant loss of institutional knowledge. The result could be that the efficiency and capacity of the Laboratory to perform the required analyses would be greatly reduced.

The effective operation of the 222-S Laboratory depends on significant support services provided by personnel who are not directly assigned to the Laboratory. These “matrixed” personnel provide services that are absolutely necessary to the Laboratory’s operation. It was not clear during the EOC assessment how or how effectively this external support will be provided

following the transfer of the Laboratory to ORP. This is a matter that must be carefully considered in the transfer process, because it has a major bearing on the ability of the Laboratory to function effectively.

Compliance with EMCAP Laboratory Standards

The 222-S Laboratory currently has no requirement to conform to EMCAP Laboratory standards. Given the current emphasis in DOE for laboratories to participate in this program and to conform to its requirements, there is a reasonable expectation that the 222-S Laboratory may be mandated to be part of the program in the future. The primary area where noncompliance with EMCAP was noted was in the radiation counting room operation. While a comprehensive evaluation of compliance with EMCAP was not performed, the following fundamental exemptions were noted:

- Periodic and scheduled calibrations are not performed on instruments.
- No stable and uninterruptible power source is provided for instruments.
- Alpha and beta measurements are not corrected for self-absorption.
- Daily performance checks are not performed on alpha spectrometry detectors or the liquid scintillation counters.
- Instrument run logs are not maintained.
- Alpha spectrometry detectors are not calibrated (this is not absolutely necessary if traceable radiochemical tracers are used; however, it is required for EMCAP).

This is by no means a comprehensive evaluation, but is an indication that significant operational changes might be required to bring the 222-S Laboratory into compliance with EMCAP requirements.

2.2 Environmental, Safety, Health and Quality

ALARA Awareness

On the surface, the ALARA program at 222-S appears to be active and effective. This is the conclusion one would reach by simply reviewing the available documents associated with the program. However, two things observed during the assessment bring into question the oversight of and commitment to the principles of the ALARA concept.

During the evaluation of the radiological laboratory area that is located in a controlled area, only one escort and one radiological technician were provided for the three auditors. This required that the auditors remain in one group, even though all three auditors were not required to observe all the laboratory areas. When one of the auditors attempted to remain in a hallway area where, presumably, the potential exposure was lower, he was directed to accompany the remaining auditors into an area of greater potential exposure. With preplanning, this situation could have

been avoided, but of more concern is that this potential additional exposure was not considered in planning or at the time that the auditor was directed to the potentially higher exposure area.

Of even greater concern is the second discovery. In reviewing the "Analytical Services–2002 and 2003 Area Dosimetry Results" (PBB03-EA530-023), it was noticed that one of the area thermoluminescent dosimeters (TLDs) had quarterly exposures of almost 500 mrem for two successive quarters. According to the report this location was "2SkellyConf." Upon examination, the location was further defined as 222-SH that contains a laundry holding area and what is listed as and appears to be a conference room. This building is just adjacent to the "Conex" areas H00083 and H00084, which are "hot" waste holding areas.

Questioning revealed that this is a "lounging" area for about four people who have keys for this location; however, it is apparently available to anyone desiring to enter it and the area is not routinely surveyed. While the total occupancy factor is probably low in the conference room, its existence in this area, particularly given that these area readings were known, again brings into question the monitoring of and adherence to ALARA principles.

Radiation technicians perform monitoring in the Conex area and its perimeters routinely and during significant activities; however, no record of the readings is maintained as long as the exposure readings are below 5 mrem/hr. This leaves no documentation to evaluate the actual exposures in this area. It is recommended that actual readings, in this and all other monitored areas, be recorded.

Criticality Safety

The Nuclear Criticality Safety (NCS) limits are given in the section on "Precautions and Limitations in the Laboratories" in the technical procedures. However, there are no explicit statements within the procedures that require that incremental additions of fissile material be checked for compliance with the limits. Such checks may be made by software, but such a function should be explicitly indicated as present. Samples from many sources at Hanford have a clear historical and well-documented basis from which the lab may establish an estimated fissile content. The waste from tank farms and irradiated, but unprocessed, fuel residues from reactor basins are examples where such a basis for estimation exists. The Plutonium Finishing Plant (PFP) also sends samples to the lab. There is communication between PFP personnel and lab staff, but there is no requirement for the formal documentation of the source and fissile content of the sample. Samples from the PFP normally are transmitted in very small containers (less than 100 ml.), however the lab has not imposed a requirement that such small containers be used. Without such a requirement the lab is not able to demonstrate that a multiple failures would be required for accidental criticality to result at the lab. If a failure occurred at PFP and significant quantities of fissile material were inadvertently sent to lab, subcriticality would still be assured if the sample size were small. Analysis of the sample would reveal the presence of higher than anticipated fissile materials.

Environmental Compliance

There are no outstanding environmental compliance violations with regulatory agencies; however, there are a number of issues that need to be monitored to assure that they do not become a problem.

First, the 222-S main stack, which received damage in 1996 due to system vibration, needs to be addressed. The DOE-RL FY-04 budget includes a request for $1 million for the repair of this stack. This expenditure is the largest line item in their proposed budget. If this funding is not approved, there is the potential for the facility to not maintain compliance with air emissions requirements. The facility has received a letter from the Washington Department of Health stating that all emission units, minor and major, are to be maintained and operated as designed and approved. The letter further states that if a failure of the design is detected, it is the owner's responsibility to make the needed corrections.

Another issue to monitor is related to polychlorinated biphenyl (PCB) fluorescent light fixtures. In January 2000, a shipment of ballasts, marked as "Non-Leaking PCB Ballasts," was sent to the central recycle area and was refused because some of the ballasts were leaking. It was later determined that the facility was not properly decontaminating and testing the light fixtures or other areas where PCBs may have leaked. Maintenance personnel replacing fixtures would turn off the power and wait until the ballast stopped leaking and consider it "non-leaking." It was determined that the releases were not necessarily decontaminated or cleaned up per Toxic Substances Control Act regulations.

Laboratory staff has previously submitted a funding request for the coating of the 207-SL Basin, which remains unfunded at this time. This request was made because the concrete basins are beginning to deteriorate and the coating would minimize any future leakage potential. There has been a concern that any leakage may be contaminated since the effluent has been above discharge levels in the past. This contamination may be the result of sludge that exists in the basin. There is an estimate of $50,000 in a paper titled "222-S Upgrades" to coat the basin. There was no backup provided for this, but depending on the sludge volume and its disposal requirements, the cost to perform this project could be higher. This issue should be further evaluated.

2.3 Finance

Scope of Work and Pricing

The Laboratory has various types of documents related to the analytical services they anticipate performing for their customers. One of the primary documents describing the future scope of work is the service level agreement (also more recently referred to as service level plan (SLP)) that is established between the facility and its customers. The facility provided a summary sheet, "222S Laboratory - SLPs Status," that lists the SLPs by customer/project and shows the projected analytical work by cost (unburdened and unescalated) for FY-04, FY-05, and FY-06. The projected values for FY-04, FY-05, and FY-06 are $9.7 million, $8.4 million, and $7.6 million, respectively. The list includes 14 non-CH2M HILL Hanford Group (CHG) SLPs and 5 CHG SLPs. The facility provided 16 of the 19 SLPs shown in the summary list. Some of the

SLPs were signed, while others were not. Not all the staff that should have had current copies of the SLPs had them. This process and its documentation should be improved.

The facility appears to have good systems in place to track costs. There are more than 20 cost accounts that have been established, with facility technical points of contact assigned and a budget analyst assigned to each account. Costs are distributed to customers based on the number of analyses performed and the published price per analysis. The facility has developed a model to estimate the "variable" costs associated with each of the analyses that forms the price per analysis. The cost information is documented within the Laboratory Information Management System (LIMS). According to the facility, the customers participate on an equity basis in any "over or under liquidation." What this means is that the customers share in any discrepancy between revenues received and the actual variable costs of the operation.

There is no attempt to recover "fixed or capital" costs, which appears to be the approach that has been taken historically. Therefore, the customers do not see the real cost per analysis. It is uncertain, without further analysis, what impact charging customers the real cost would have on the facility operations. The higher sample prices could cause some of the customers to rethink their sampling programs or look for alternative laboratory arrangements. The percentage of total costs recovered could decrease if the sample load declines.

Procurement Actions

Items for the laboratory are generally purchased on either an open purchase order basis or through a contract. The contracts are typically negotiated for a 1-year period from October 1 through September 30. The facility has seven maintenance agreements, two service agreements, and five agreements with other laboratories. It was mentioned by procurement that they have had some trouble negotiating equipment service agreements with manufacturers, since the manufacturers' staff is often not able to work directly on the equipment because of union issues. Procurement also mentioned that they have had trouble with one of their total inorganic carbon/total organic carbon (TIC/TOC) analyzers. There has also been an issue in obtaining follow-up training for one of their mass spectrophotometers. They have been working to resolve this issue. The Laboratory has developed a comprehensive spreadsheet presenting the status of all procurement actions. At the time of this report submittal, we had not been provided a copy of this spreadsheet.

CHG procurement staff should be working with the lab staff prior to September 30 to transfer these procurement contracts and agreements before they expire.

2.4 Infrastructure

Inventory of Equipment

The 222-S Laboratory has good systems in place for equipment inventory management. This system includes a comprehensive database and the "barcoding" of all equipment. However, it was not possible to confirm whether all equipment characterized as sensitive is being inventoried on an annual basis, as required by HNF-RD-11408, since it was not possible to view output from the database. A good inventory of equipment is important to the transition, since there have been

many occasions when equipment has been moved from the 222-S Laboratory to the WSCF laboratory.

2.5 Customer Interface and Information Systems, Including the Laboratory Information Management System

Computer Systems Disaster Recovery

The servers designated for disaster recovery currently are housed in the same room as the operational servers. In the case of an event affecting the server room, the backup servers could also be rendered unusable. This is in the process of being corrected. Going to site-compliant server configurations eases disaster recovery. The lab is in the process of upgrading the servers. All new servers will be based on site-standard configurations. This is expected to occur before the end of March 2004. At that point, there will be a large pool of available servers in the case of an event affecting the lab's servers.

ATTACHMENT A
STATEMENT OF WORK

STATEMENT OF WORK
DE-AT27-03RV14541

1.0 BACKGROUND

As directed by Congress, the U.S. Department of Energy (DOE) established the Office of River Protection (ORP) at the Hanford Site to manage the River Protection Project (RPP), which is the Department's largest and most complex environmental cleanup project. The mission of the RPP is to retrieve and treat Hanford's tank waste and close the tank farms to protect the Columbia River. The cleanup of the highly radioactive tank waste must occur in an environmentally sound, safe, and cost-effective manner.

The 222-S Laboratory located on the southern edge of the 200 West Area of the Hanford site consists of the 222-S complex of buildings and auxiliary buildings used for ventilation and electrical services, bulk material storage, and handling and transferring wastes to an onsite waste handling facility or offsite facilities.

The 222-S Laboratory performs analyses of high radioactivity samples and mixed wastes and provides process technology support (e.g. methods development, process troubleshooting) for the Site. Chemical process development at a bench scale is also performed. Cs-137 and Sr-80 in quantities of hundreds of curies are the major radioisotopes used. Small quantities (less than the limit for 'isolated facility' of plutonium is also used. The Laboratory has a broad range of capability for radiochemical, inorganic, and organic analyses, employing about 175 analytical methods to meet the diverse needs of Site customers. Currently the Laboratory performs about 25,000 analyses per year, including those for tank characterization and closure, mission acceleration, treatment optimization and waste characterization.

The 222-S Laboratory is being transitioned from the DOE Richland Office (DOE/RL) to the ORP. Under the assumptions of the transition plan, an extent of condition (EOC) review is needed. The EOC will be conducted under contract through the DOE/ORP. CH2M Hill will assist ORP by providing subject matter expert support (SME) for this review to the successful offeror. **The purpose of the EOC review is to identify pre-existing conditions prior to the transition.**

2.0 WORKSCOPE DESCRIPTION

The scope of this contract is to examine and provide reports per the schedule below. The NAICS code applicable to this scope of work is 541380.

Laboratory Operations and Analysis
ESH&Q
Finance
Infrastructure
Customer Interface and Information Systems, including the Laboratory Information Management System (LIMS)

The successful offeror will be provided facility specific safety/process training upon award.

Five main areas shall be reviewed for pre-existing conditions during the 222-S Extent of Condition Review: Laboratory Operations and Analysis; Environmental, Health, Safety, and Quality; Financial; Infrastructure; and, Customer Interface and Information Systems (including LIMS). Some key areas of concern have been identified for review. Additional areas may be added at the discretion of the ORP, upon warranted authorization provided in writing by the ORP Contracting Officer.

The workscope shall consist of planning for the Extent of Condition Review, documentation review, up to two weeks of an on-site laboratory field review (including filling out Pre-Existing Condition Forms), an oral out brief and final report listing areas reviewed, conditions and issues found.

The following deliverables are anticipated:

a) Pre-existing Condition Forms documenting areas reviewed and issues found during the review. These forms are to be turned in following review

b) An oral out brief review summarizing conditions found to be performed immediately the field review for representatives of DOE and its contractors

c) A Final Report summarizing areas reviewed and conditions found

2.1 LABORATORY OPERATIONS AND ANALYSIS

The following systems shall be reviewed for adequacy (compliance to requirements), effectiveness, ease of use and pre-existing conditions

- **Sample Tracking and Disposal**
  - Verification that Laboratory has a tracking system that will track samples from receipt to disposal
  - Verify that a plan is in place to ensure all excess samples are disposed or returned to customer prior to transition
  - Verify whether or not there are samples without a disposal pathway

- **Laboratory Data Records**

  Verify analytical data are stored as quality records. Analytical data should include:
  - Raw and supporting data
  - Electronic instrument files
  - Logbooks
  - Certificates for reference materials
  - Sample shipping records/ Chain of custody records
  - Subcontractor data with required quality control information

- **Laboratory Procedures**

- Ensure technical procedures are adequately reviewed and tested by technical staff prior to implementation
- Verify procedure reviews of active procedures take place on a routine basis
- Verify a documented change control process exists for procedure updates
- Obtain a backlog of current procedure changes that are in process

- **Measuring and Testing Equipment**
  - Verify calibration and maintenance of equipment and instruments used for measuring and testing
  - Verify documentation of major, preventative, and daily equipment maintenance
  - Verify a documented inventory of critical spare parts and/or equipment necessary to minimize measurement downtime
  - Verify equipment is connected to a stable power source, surge protection is used, and UPS backup exists
  - Verify equipment is calibrated, adjusted and maintained at prescribed intervals or prior to use according to nationally recognized standards. If nationally recognized standards to not exit, verify documentation of basis for calibration
  - Verify that balances, pipets, refrigerators, ovens and other laboratory equipment are accurate and that performance is monitored and documented
  - Determine method of equipment transfer

- **Laboratory Instrumentation**
  - Listing of Major Instrumentation/Date of Purchase
  - Maintenance Records/ Logbook Review
    - Routine maintenance and inspections conducted and documented
    - Significant corrective actions documented
    - Annual review of instrument maintenance records
    - Spare parts inventories are documented if applicable

- **Training & Qualifications**
  - Verify Qualification Card compliance
  - Verify Training Matrix
  - Verify that all training is current
  - Verify that an analyst certification program is in place and that analysts are recertified on a designated basis (not to exceed 2 years)

- **Management/Organization**
  - Verify that current organizational charts are available and accurate
  - Verify that adequate staffing exists to meet compliance and production requirements
  - Estimation of Production Capability for Inorganics, Organics and Radiochemistry

- **Maintenance and Preventative Maintenance Programs DOE Order 4330.4B**
  - Report on backlog of maintenance work orders (preventive and corrective)
  - Verify that there is adequate maintenance staffing
  - Verify that preventative maintenance program implement and adequate
  - Review work packages for adequacy and completeness
  - Review scheduling and planning process for work control
  - Verify adequate staffing or matrix staffing to support facility maintenance requirements

- **Engineering**
  - Verify adequate implementation of site engineering standards
  - Verify adequate staffing or matrix staffing to support facility engineering requirements

- **Corrective Actions and Tracking Programs**
  - Verify program implementation
  - Verify corrective action tracking system exists which tracks corrective action to completion
  - Verify for significant corrective actions have completed root cause analyses
  - Review Price Anderson- issues and determine resolution adequacy
  - Review Occurrence Reporting – issues and determine resolution adequacy
  - Review Critique process

- **DOE Order 5480.19 – Conduct of Operations**
  - Verify compliance matrix
  - Verify implementation

2.2 ENVIRONMENTAL, HEALTH, SAFETY AND QUALITY

- **Safety, Industrial Hygiene, ISMS**
  - Verify ISM Implementation (DOE P 450.4)

- Verify ISM Work Control implementation
- Appropriate hazard analysis has occurred prior to work
- Planning has considered all aspects of worker safety
- Verify ISM Implementation
- Verify work control
- Verify records of employee monitoring including both radioactive and chemical exposure
- Ensure safety inspection program exists and corrective actions have been completed
- Ensure adequate safety showers and eye wash stations
- Verify emergency exits are well marked and not blocked
- Verify employee health and safety training is current
- Verify adequacy of housekeeping

- **Quality**
  - Verify Quality Assurance Program Plans flowdown 10 CFR 830.120 requirements
  - Verify independent assessments have been conducted. Review issues and actions for adequacy
  - Verify Quality program implementation

- **Chemical Management**
  - Verify chemicals are managed in accordance with OSHA 1910.1450 and SARA (Community Right-to-Know)
  - Assure chemicals are stored with compatible materials
  - Verify adequacy of laboratory standards program

- **Environmental/Waste**
  - Review environmental documentation for issues and resolution adequacy (e.g. RCRA and other permit compliance; settlements and commitments for Washington Department of Ecology)
  - Verify required environmental reporting has been completed on time and is on schedule for the current year

- **Radiological Control**
  - Verify Radiological equipment is properly maintained
  - Review ALARA, independent and Facility Evaluation Board assessments, NTS and Occurrence reports for issues and actions
  - Verify Radiological Control Program is in accordance with 10 CFR 835

- **Authorization Basis/Criticality Safety**
  - Review new Documented Safety Analysis, Technical Safety Requirement (TSR) and Fire Hazards Analysis (FHA) documents that are currently pending approval
  - Verify TSR, FHA and DSA documents are current and implemented or implementation is in progress.
  - Review of process and validation of inventory control for Authorization Basis limits
  - Assure adequate criticality procedures are in place and implemented

- **Emergency Preparedness**
  - Review spill records and ensure cleanup documentation is detailed and complete
  - Verify Emergency Preparedness Plan is current, appropriate information posted
  - Verify Emergency Preparedness drill documentation is available and complete
  - Determine status of in-progress or planned repair/maintenance fire systems
  - Determine status of fire system upgrades/modifications for facility

2.3 FINANCIAL

- **Controls/Baseline**
  - Scope, schedule and cost baseline information is available and accurate
- **Contracts and services**
  - Listing of current contracts and services is available and up to date
- **Procurements**
  - Review most recent procurement assessment for issues and actions

2.4 INFRASTRUCTURE

- **Property management**
  - Inventory is properly controlled and accounted for
- **Safeguards and Security**
  - Safeguards program for special nuclear material
  - Security program in place
  - Training and qualifications current

2.5 CUSTOMER INTERFACE, INFORMATION SYSTEMS & LIMS

- **Computers and Software**

- Verify software change control documentation is maintained and readily available
- Verify documentation for verification of software validity is maintained
- Verify software historical files of all version of software programs exist and include dates that software was placed into and removed production
- Verify computer security system includes password changes, virus protection, and physical access
- Verify regularly scheduled maintenance is performed and documented
- Verify system backups and disaster recovery processes are in place

- **LIMS**
  - Verify that a description of the LIMS design and capacity is documented and maintained
  - Documentation of updates and changes to the LIMS exists and is maintained
  - Native files (original code) are available
- **Records Management**
  - Records management program exists and is implemented
  - Quality records are clearly identified and properly maintained
  - Verify that laboratory has an adequate document control system in place
  - Verify procedures, policies, and manuals reflect current operations and have been reviewed on a designated frequency
  - Verify that records storage meets federal and DOE guidelines
- **Services Level Agreements (SLA)**
  - SLA current and signed off for all customers
  - Tracking of actual work received vs. SLA

3.0 SCHEDULE & DELIVERABLES

3.1 Schedule of Review Activities

The scope of work is scheduled for completion by August 25, 2003. Documents will be available for review July 14, 2003. In-field review shall begin on July 21. The final report is due not later than August 25, 2003.

3.2 Deliverables

The final report shall be submitted to the Contracting Officer in hard copy and electronically, with a copy provided to the technical point of contact.

ADDITIONAL TASK ORDER TERMS AND CONDITIONS

ATTACHMENT B
HANFORD 222-S AUDIT CHECKLIST

HANFORD 222-S AUDIT CHECKLIST

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-1	2.1 Laboratory Operations and Analysis-Sample Tracking and Disposal	LABCORE	Laboratory has a tracking system that will track samples from receipt to disposal.	**Verified** **Adequate**	The laboratory relies on its laboratory information management system (LABCORE) to track samples from receipt to disposal. This system, combined with the work of the project coordinators, allows for the quick identification of samples in the laboratory.
2-2	2.1 Laboratory Operations and Analysis-Sample Tracking and Disposal	LO-100-151—Laboratory Waste Generation ASP-310, Section 2.9, 222-S Sample Disposal	A plan is in place to ensure all excess samples are disposed or returned to the customer prior to transition.	**Verified** **Adequate**	The laboratory's analytical procedures contain procedures for sample and residual disposal. The waste management personnel and laboratory technicians are responsible for monitoring the laboratory for excess samples and following LO-100-151.
2-3	2.1 Laboratory Operations and Analysis-Sample Tracking and Disposal	LO-100-151—Laboratory Waste Generation	The plan is followed and documented.	**Verified** **Deficient**	While the laboratory appears to be doing a good job in plan implementation, there have been many occasions in the past where excess samples have accumulated without a plan for disposition. In addition on a recent matter, PNNL (Science and Technology) abandoned the LASER Ablation R&D project at the lab without completing the required hot cell clean out in 11A. The cost of this clean out is estimated at $65,000 to $70,000 for removal of the equipment and to prepare it for disposition. Disposition costs are not included in this estimate. PNNL has been contacted to remove the material, but there was no action taken as of the site visit.
2-4	2.1 Laboratory Operations and Analysis-Sample Tracking and Disposal	HNF-PRO-052 Corrective Action Management	The plan contains provision for corrective actions and incidents have been followed up by documented corrective actions.	**Verified** **Adequate**	Corrective Action Management System (CAMS) uses a Deficiency Tracking System (DTS) to document deficiencies and track corrective actions. The facility has a CATRAX system that incorporates the DTS findings and also is used for administrative requirements. Several deficiencies were evaluated and the appropriate corrective actions had been taken.
2-5	2.1 Laboratory Operations and Analysis-Sample Tracking and Disposal		Are there samples without a disposal pathway?	**Verified** **Deficient**	See remarks above under Item 2-3. Other than this specific item, samples appear to have a defined pathway.
2-6	2.1 Laboratory Operations and Analysis-Laboratory Data Records	EMCAP	Analytical Data Records include raw and supporting data.	**Verified** **Adequate**	An extensive analytical data package was reviewed in its entirety. The package included the raw data in both hardcopy and electronic (.pdf) format.

HANFORD 222-S AUDIT CHECKLIST

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-7	2.1 Laboratory Operations and Analysis-Laboratory Data Records		Analytical Data Records include electronic instrument files.	**Verified** **Deficient**	Data packages include a .pdf file of hardcopy printouts; however, instrument analysis files are not electronically transferred to the LIMS system. Hand-entered data is independently verified; however, direct transfer of instrument data is preferred.
2-8	2.1 Laboratory Operations and Analysis-Laboratory Data Records	EMCAP	Analytical Data Records include logbooks. Logbooks are reviewed by laboratory management. Logbooks are identified and controlled.	**Verified** **Adequate**	Logbooks are controlled and periodically reviewed by laboratory management.
2-9	2.1 Laboratory Operations and Analysis-Laboratory Data Records	NELAC EMCAP	Analytical Data Records include certificates for reference materials.	**Verified** **Adequate**	Certificates for radioactive standards are available; however, the organization of the file drawer where they are contained is poor.
2-10	2.1 Laboratory Operations and Analysis-Laboratory Data Records		Analytical Data Records include sample shipping and chain of custody records.	**Verified** **Adequate**	The analytical data package reviewed contained sample shipping and chain of custody records.
2-11	2.1 Laboratory Operations and Analysis-Laboratory Data Records		Analytical Data Records include subcontractor data with required quality control information.	**N/A**	Subcontracts with outside laboratories are in place but rarely used for the level of work performed in 222-S.
2-12	2.1 Laboratory Operations and Analysis-Laboratory Procedures	ASP-200, Various Procedures EMCAP	Are technical procedures adequately reviewed and tested by technical staff prior to implementation?	**Verified** **Adequate**	A procedure validation and review process is in place and appears to be followed and tracked. Methods are validated and reviewed.
2-13	2.1 Laboratory Operations and Analysis-Laboratory Procedures	ASP-200, Various Procedures EMCAP	Are procedures reviewed on a periodic basis? Is there a procedure that requires and defines this review?	**Verified** **Adequate**	A procedure validation and review process is in place and appears to be followed and tracked. The first procedure in ASP-200 Section 1.01 discusses the administrative process for controlling procedures.
2-14	2.1 Laboratory Operations and Analysis-Laboratory Procedures		Obtain a listing of current procedure changes that are in progress.	**Obtained**	Method reviews and assessments are tracked in the 222-S and WSCF Assessments Planning System. This is an ongoing process.
2-15	2.1 Laboratory Operations and Analysis-Measuring and Test Equipment	EMCAP and NELAC	All instruments are calibrated and with NIST traceable standards.	**Verified** **Adequate**	Instruments are calibrated with NIST traceable standards. This fact was tracked from calibration records to the standard certificate used in the calibrations.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-16	2.1 Laboratory Operations and Analysis-Measuring and Test Equipment	EMCAP	Verify documentation of major, preventative, and daily equipment maintenance.	**Verified** **Adequate**	The maintenance and preventative maintenance program for radiation counting instruments is performed in a timely and well-documented fashion.
2-17	2.1 Laboratory Operations and Analysis-Measuring and Test Equipment		Verify a documented inventory of critical spare parts and/or equipment necessary to minimize measurement downtown. (Verify adequate number of instruments to accommodate workload.)	**Verified** **Adequate**	There is not a large inventory of spare radiation counting instrument parts; however, this is not a critical item since they are usually available overnight from the instrument manufacturer. Although, since some of the equipment is fairly old, this could be an issue in the future, as parts may not be readily available.
2-18	2.1 Laboratory Operations and Analysis-Measuring and Test Equipment	EMCAP	Verify that instruments are connected to a stable power source, surge protection is used, and UPS backup exists.	**Verified** **Deficient**	The radiation counting instruments are not powered by a surge-protected source with UPS backup. This should be remedied soon. Temporary interruption of power results in loss of counting data and longer outages prevent the processing of analyses. EMCAP requires protection of instruments from short-term power failure.
2-19	2.1 Laboratory Operations and Analysis-Measuring and Test Equipment	EMCAP	Verify that equipment is calibrated, adjusted and maintained at prescribed intervals or prior to use according to nationally recognized (NELAC, EMCAP) standards.	**Verified** **Deficient**	Calibrations are performed "as required" on radiological equipment as opposed to a set frequency, i.e. annually, as required by most analytical protocols. EMCAP requires that alpha spectrometers be calibrated monthly and that gamma spectrometers and proportional counters be calibrated annually. All portable survey instruments observed were in calibration and a system is in place to assure that they are calibrated annually. Daily instrument checks to verify operability and continuing calibration are performed and documented.
2-20	2.1 Laboratory Operations and Analysis-Measuring and Test Equipment	EMCAP NELAC	Verify that balances, pipettes, refrigerators, ovens, and other lab equipment are accurate and that performance is monitored and documented. How are the accuracy and performance verified on a continuing basis?	**Verified** **Deficient**	Calibration records for the balances in the radiation control area were requested and hand entries are questionable. Balance LE-BAL-015 was calibrated on November 4, 2002, but the calibration sheet was signed on December 5, 2002. Data on the sheet was changed and the changes dated December 5. What prompted these changes and where was the new data recorded that prompted the changes one month after the calibration? Balance LE-BAL-028 was also calibrated on November 4, 2002 with some corrections made on December 9, the day it was signed.
2-21	2.1 Laboratory Operations and Analysis-Laboratory Instrumentation		Obtain a listing of Major Instruments and Purchase Date.	**Unavailable**	This list was requested but was not provided. Thus, it is not possible to ascertain the age of the major instruments.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-22	2.1 Laboratory Operations and Analysis-Laboratory Instrumentation	EMCAP	Routine maintenance and inspections conducted and documented.	**Verified** **Adequate**	Maintenance, both routine and preventative, is performed in a timely and professional manner. Records are readily available to verify the adequacy of the program.
2-23	2.1 Laboratory Operations and Analysis-Laboratory Instrumentation	EMCAP	Failures are documented and corrective actions taken and documented. Instruments are tagged out of service when failure is discovered.	**Verified** **Adequate**	Radiation detection instrument failures are well documented and are tagged out of service upon failure of the daily calibration verification. Corrective actions are clearly indicated in the maintenance records.
2-24	2.1 Laboratory Operations and Analysis-Laboratory Instrumentation	EMCAP	Review of maintenance records is documented at least on an annual basis.	**Verified** **Adequate**	The instrument maintenance program is well run and documented.
2-25	2.1 Laboratory Operations and Analysis-Training & Qualifications		Verify Qualification Card compliance.	**Verified** **Adequate**	Qualification Card requirements were reviewed and are appropriate. Compliance with the requirements is difficult to evaluate, but there are no indications of noncompliance.
2-26	2.1 Laboratory Operations and Analysis-Training & Qualifications		Verify Training Matrix. (Listing of personnel and their training.)	**Verified** **Adequate**	The training record for each individual is available in a computer directory. The contents of two individual records were matched to the master training database maintained by the current contractor.
2-27	2.1 Laboratory Operations and Analysis-Training & Qualifications	EMCAP	Verify that an analyst certification program is in place and that analysts are recertified on a designated basis (not to exceed 2 yrs.)	**Verified** **Adequate**	Analysts are recertified biennially. EMCAP requires an annual recertification.
2-28	2.1 Laboratory Operations and Analysis-Management and Organization	Organizational Charts	Verify that current organizational charts are available and accurate.	**Verified** **Deficient**	The organizational chart provided was not current due to the recent departure of several personnel.
2-29	2.1 Laboratory Operations and Analysis-Management and Organization		Verify that adequate staffing exists to meet compliance and production requirements.	**Verified** **Adequate**	The current staffing, while hard to evaluate with a short-term evaluation, appears to be adequate because the workload is below the capacity. However, a major concern is that, due to the transition and uncertainty about the ultimate fate of the laboratory, key people have left and may continue to leave. This could result in a staff that is deficient in numbers and experience. If the workload increases, as is anticipated (see next item), this could present a problem because of the short time available for hiring and training new people, not to mention the loss of experienced personnel and institutional knowledge.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-30	2.1 Laboratory Operations and Analysis-Management and Organization		Estimate Production Capacity for Inorganics, Organics, and Radiochemistry.	**Verified** **Adequate**	It is difficult to estimate the production capacity because of the type of samples processed and the availability of production records. Data generated by a computer model to estimate future workloads were reviewed. There is general agreement, based on personnel interviews and the model, that the current workload is well below its maximum capacity and that there will be a significant increase in the workload in the coming fiscal year.
2-31	2.1 Laboratory Operations and Analysis-Maintenance and Preventative Maintenance Programs (DOE Order 4330.4B)	DOE Order 4330.4B	Report on backlog of maintenance work orders (preventative and corrective).	**Obtained**	The current backlog and schedule of upcoming maintenance were available and appeared to be complete. This list is available electronically and is updated daily and addresses both preventive and corrective maintenance.
2-32	2.1 Laboratory Operations and Analysis-Maintenance and Preventative Maintenance Programs (DOE Order 4330.4B)	DOE Order 4330.4B	Verify that there is adequate maintenance staffing.	**Verified** **Adequate**	Sufficient maintenance staffing is available. Additional support is utilized from Central Maintenance Group for support on crafts such as welding, which are seldom performed. The Fire Department maintenance group conducts all maintenance of fire protection systems.
2-33	2.1 Laboratory Operations and Analysis-Maintenance and Preventative Maintenance Programs (DOE Order 4330.4B)	DOE Order 4330.4B	Verify that preventative maintenance program is implemented and adequate.	**Verified** **Adequate**	The laboratory conducts and tracks all PM's on all systems. The Engineering Group reviews procedures and DOE reviews Vital Safety Systems (VSS). The Fire Department maintenance group maintains fire systems and the Fire Protection System Engineer reviews preventive maintenance procedures.
2-34	2.1 Laboratory Operations and Analysis-Maintenance and Preventative Maintenance Programs (DOE Order 4330.4B)	DOE Order 4330.4B	Review work packages for adequacy and completeness.	**Reviewed** **Adequate**	Work packages are comprehensive with required permits and PPE requirements. Reviews are performed using an Automated Job Hazard Analysis (AJHA) program. This program requires extensive input from several different organizations prior to issuing work packages. Attended pre-job briefing for repairs of preheat coils on air handling units. An extensive review was conducted with all affected personnel who perform the maintenance activities or support roles.
2-35	2.1 Laboratory Operations and Analysis-Maintenance and Preventative Maintenance Programs (DOE Order 4330.4B)	DOE Order 4330.4B	Review scheduling and planning process for work control.	**Reviewed** **Adequate**	Scheduling and planning of work is reviewed at daily meetings prior to work packages being performed. Observed planning for sanitary water outage to support replacement of piping and valves that supply water to emergency eyewash and showers. All affected personnel were well aware of schedule. Work was scheduled to ensure the least impact to daily operations. Announcements were comprehensive and timely.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-36	2.1 Laboratory Operations and Analysis-Maintenance and Preventative Maintenance Programs (DOE Order 4330.4B)	DOE Order 4330.4B	Verify adequate staffing or matrix staffing to support facility maintenance requirements.	**Verified** **Adequate**	Sufficient maintenance staffing is available. Additional support is obtained from the Central Maintenance Group for support on crafts such as welding, which are seldom performed. The Fire Department maintenance group conducts all maintenance of fire protection systems.
2-37	2.1 Laboratory Operations and Analysis-Engineering		Verify adequate implementation of site engineering standards.	**Verified** **Adequate**	Good lockout, tag-out (LO/TO) procedures and good implementation. Also reviewed Hanford electrical safety program. DOE has reviewed and approved procedures on VSS (Vital Safety System) equipment.
2-38	2.1 Laboratory Operations and Analysis-Engineering		Verify adequate staffing or matrix staffing to support facility-engineering requirements.	**Verified** **Adequate**	There is sufficient staffing in this function based on interviews with the group staff.
2-39	2.1 Laboratory Operations and Analysis-Corrective Actions and Tracking Programs	CATRAX	Verify program implementation.	**Verified** **Adequate**	Other than the item noted in Issue 2-41, several corrective action activities were reviewed and it appears they are being conducted as planned.
2-40	2.1 Laboratory Operations and Analysis-Corrective Actions and Tracking Programs	HNF-PRO-052, Deficiency Tracking System (DTS) and CATRAX	Verify corrective action tracking system exists which tracks corrective action to completion.	**Verified** **Adequate**	A corrective action tracking system exists (CATRAX) and appears to be well received by facility personnel.
2-41	2.1 Laboratory Operations and Analysis-Corrective Actions and Tracking Programs	EMCAP	Verify that significant corrective actions have completed root cause analyses.	**Verified** **Deficient**	A review was conducted of a corrective action for a failure on a PE (QAP 57) sample from the Environmental Measurements Laboratory Quality Assessment. The corrective action assessment was inadequate, since no root cause was investigated. The reason given was that these analyses passed on the previous test.
2-42	2.1 Laboratory Operations and Analysis-Corrective Actions and Tracking Programs	Price Andersen Act	Review Price Anderson issues and determine resolution adequacy.	**Verified** **Adequate**	PAA Compliance Officer reviews all items relative to requirements in the Federal Acquisition Regulations (FAR). PAA evaluation system appears comprehensive and effectively implemented. The last PAA issue occurred in FY-2001/2002. There are no current issues and no outstanding issues.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-43	2.1 Laboratory Operations and Analysis-Corrective Actions and Tracking Programs	CATRAX	Review critique process.	**Verified** **Adequate**	Attended critique conducted on LO/TO occurrence. Critique was conducted as per procedure. Several senior staff members were in attendance to address LO/TO procedural questions. The leader of the review appeared to lack experience in conducting critiques. He had a copy of the critique procedure to follow.
2-44	2.1 Laboratory Operations and Analysis-Corrective Actions and Tracking Programs	CATRAX	Review laboratory audits by outside parties.	**Verified** **Deficient**	"True" outside audits are not generally performed. There are reviews by the Facility Evaluation Board, but this board is made up of Fluor staff.
2-45	2.1 Laboratory Operations and Analysis-DOE Order 5480.19-Conduct of Operations	DOE Order 5480.19	Verify Compliance Matrix.	**Verified** **Adequate**	Obtained matrix, which was updated on 6/22/2000 and accepted by DOE on 6/28/2000.
2-46	2.1 Laboratory Operations and Analysis-DOE Order 5480.19-Conduct of Operations	DOE Order 5480.19	Verify Implementation.	**Verified** **Adequate**	Verified matrix and procedure in place. The procedures are followed. Daily turnover meetings are conducted and timely orders and nine standing orders are in place. Short-term orders are used as needed. Appropriate procedures are in place.
2-47	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify ISM Implementation (DOE P 450.4)	**Verified** **Adequate**	The FY 2003 Safety Improvement Plan for 222-S Laboratory, which was prepared by the 222-S Zero Accident Council, includes a matrix that correlates VPP and ISM sections.
2-48	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify ISM work Control Implementation.	**Verified** **Adequate**	The FY 2003 Safety Improvement includes strategies, person responsible for actions, and status as of 6/25/03. The matrix identified one weakness in the area of Management of Field Presence. Corrective action was for managers and leads to spend more time in the field with employees.
2-49	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify that appropriate hazard analysis occurs prior to work.	**Verified** **Adequate**	The Automated Job Hazard Analysis (AJHA) system is used which reviews risks and generates appropriate permits. Once the package is completed, an additional formal review is conducted prior to work being performed.
2-50	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify that planning has considered all aspects of worker safety.	**Verified** **Adequate**	The AJHA system is used which reviews risks and generates appropriate permits.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-51	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify records of employee monitoring including both radioactive and chemical exposure.	**Verified** **Adequate**	Industrial hygiene surveys are conducted and a medical monitoring program is in place with annual physicals conducted. Baseline Hazard Assessment conducted in June of 2003. The report includes the location of the hazard, description of hazard, controls currently in place, additional abatement if required, and relevant standard/procedure to issue.
2-52	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	ASP 200 Section 1.13	Verify that safety inspection program exists and corrective actions have been completed.	**Verified** **Adequate**	Health and safety self-inspections are conducted. Reviewed checklists dated 5/15/03 and 6/19/03. Procedure ASP 200 Section 1.13 is in place and is being utilized.
2-53	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Ensure adequate safety showers and eye wash stations exist.	**Verified** **Adequate**	Safety showers and eyewashes are adequate. Piping, which had degraded and supplies the system, was being repaired on 8/1/03.
2-54	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify emergency exits are well marked and not blocked.	**Verified** **Adequate**	Emergency exits were well marked, illuminated and not obstructed or blocked. An ICR has been submitted for egress route concerns from equipment room on second level.
2-55	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS	DOE P 450.4	Verify employee health and safety training is current.	**Verified** **Adequate**	Qualification-cards were reviewed and a system is in place to prevent entry into areas without the proper training. No data entries can be made without being current on training.
2-56	2.2 Environmental, Health, Safety, and Quality-Safety, Industrial Hygiene, ISMS		Verify adequacy of housekeeping.	**Verified** **Adequate**	Housekeeping inside and outside the buildings was good.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-60	2.2 Environmental, Health, Safety, and Quality-Quality	10 CFR 830.120	Verify Quality Assurance Program Plans flowdown 10 CFR 830.120 requirements.	**Verified** **Adequate**	There are two QA Programs pertinent to the operation. Laboratory operations are addressed under Quality Assurance Program Plan QAPP-016, Revision 7, and facility QA is addressed under PLN-03 QP-001. This is somewhat confusing and it is not entirely clear which requirements cover a specific activity. There is also the four-volume HASQARD (Hanford Analytical Services Quality Assurance Requirements Document) that addresses analytical aspects; Volumes 1 & 2 pertain to the 222-S Laboratory. The requirements of 10 CFR 830 do not flow down to QAPP-016; PLN-03-QP-001 contains the requirements of 10 CFR 830 generally, but needs to be updated for full flowdown. PLN-03 QP-001 does not adequately represent all eighteen elements of NQA-1; in some cases it appears adequate, but there was insufficient time to completely evaluate this aspect. There is considerable documentation relative to the QA program and the program generally appears active and effective as far as could be ascertained during this evaluation. All analytical work is assigned a specific set of Quality Control procedures prospectively, i.e., prior to beginning work; default criteria from HASQARD are used in the absence of client-specified criteria. It is not clear that planning for analytical work that occurs under the heading of Technology Development is adequately captured under the 222-S QA Program. The QA hierarchy relevant to 222-S operations is more complicated than can be easily represented here. There appear to be adequate QA programs in place, but the interfaces among all organizations were difficult to assess in the time span provided. For example, there is redundancy in that all site organizations must follow selected Hanford PRO series procedures irrespective of whether the activities are addressed in laboratory specific documents (ASP 200 or ASP 310 Series). Additionally, the 222-S QA lead was absent the entire week of this activity, preventing as thorough an evaluation as the team would have liked.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-61	2.2 Environmental, Health, Safety, and Quality-Quality	CATRAX	Verify independent assessments have been conducted. Review issues and actions for adequacy.	**Verified** **Adequate**	There are good systems in place to track corrective actions, including the personnel responsible for completing actions and the schedule. A minor deficiency was noted in that the root cause of HVAC exhaust ducting cracks had not been documented or was not presented during the audit.
2-62	2.2 Environmental, Health, Safety, and Quality-Quality		Verify Quality Program Implementation.	**Verified** **Adequate**	This evaluation was limited in scope and time and therefore was limited to a sample of all activities. The activities the team evaluated, the personnel interviewed and records examined indicate the following regarding the 222-S Quality Assurance Program. The program is adequate relative to the appropriate upper-tier requirements and the program is generally implemented. The organizational nature of the laboratory operations makes assessment difficult. Several key functions/individuals are matrixed to a few site organizations and have different reporting responsibilities, e.g., DOE/RL or Fluor-Hanford. While there is nothing inherently wrong with this configuration, it adds levels of complexity that requires excellent communication among all parties for proper functioning, and provides obstacles when communication is poor or absent.
2-63	2.2 Environmental, Health, Safety, and Quality-Chemical Management	HNF-PRO 10468 & LO-150-063	Verify Chemicals are managed in accordance with OSHA 1910.1450 and SARA (Community Right-to-Know)	**Verified** **Adequate**	The facility has a strong chemical management program and systems. Systems include the site-wide Chemical Inventory Tracking System (CITS), which is supplemented by "add-ons" developed by Cheryl Neff. There are designated "Laboratory Room Owners" to implement the program at specific locations within the complex.
2-64	2.2 Environmental, Health, Safety, and Quality-Chemical Management		Assure chemicals are stored with compatible materials.	**Verified** **Adequate**	The standards laboratory, which stores roughly half of the facility chemicals, does an excellent job of separating the chemicals. Each major type of chemical is stored separately in the standards laboratory.
2-65	2.2 Environmental, Health, Safety, and Quality-Chemical Management		Verify adequacy of laboratory standards program.	**Verified** **Adequate**	The laboratory standards program is strong, potentially "best in class."
2-66	2.2 Environmental, Health, Safety, and Quality-Environmental/ Waste		Review environmental documentation for issues and resolution adequacy (e.g. RCRA and other permit compliance; settlements and commitments for Washington Department of Ecology).	**Verified** **Adequate**	There are no outstanding violations with regulatory agencies and based on the review, the facility appears to be in compliance with regulatory requirements. There are several environmental items in CATRAX that need to be addressed, but none of them has been determined to be "out of compliance." New Documented Safety Analysis (DSA) was obtained and reviewed. DOE approved the DSA.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-67	2.2 Environmental, Health, Safety, and Quality-Environmental/ Waste		Verify required environmental reporting has been completed on time and is on schedule for the current year.	**Verified** **Adequate**	Clean Air Act reporting is being performed and will be attested to with the 9/30/03 certification of compliance that Fluor will provide. Hazardous waste reporting has been completed. Other reporting has been performed by laboratory or support organizations (e.g., preparation of SARA Title III report).
2-68	2.2 Environmental, Health, Safety, and Quality-Radiological Control	10 CFR 835	Verify Radiological equipment is properly calibrated and maintained.	**Verified** **Adequate**	All survey and radiation control equipment reviewed were within calibration. A computer program prompts and tracts the calibration.
2-69	2.2 Environmental, Health, Safety, and Quality-Radiological Control	ALARA	Review ALARA, independent and Facility Evaluation Board assessments, NTS and Occurrence reports for issues and actions.	**Verified** **Adequate** **Deficient**	Occurrence reports were reviewed. There was only one report for the current fiscal year. It was appropriately addressed and assessed. Follow-up was complete and documented. The ALARA program is active, publicized, and documented. It appears from composite exposure records that overall exposure is decreasing. It is unclear if this is related to the reduced workload or the results of ALARA actions. However, two findings bring into question the program effectiveness and commitment to applying ALARA principles. These are addressed in greater detail in Section 2 of this report. **(Adequacies and deficiencies noted)**
2-70	2.2 Environmental, Health, Safety, and Quality-Radiological Control	10 CFR 835	Verify Radiological Control Program is in accordance with 10 CFR 835	**Verified** **Adequate**	The overall Radiological Control Program is in compliance with 10 CFR 835. The basis for DOE radiological control programs is established in 10 CFR 835 and the 222-S program addresses all the requirements.
2-71	2.2 Environmental, Health, Safety, and Quality-Authorization Basis/ Criticality Safety		Review new Documented Safety Analysis, Technical Safety Requirement (TSR) and Fire Hazards Analysis (FHA) documents that are currently pending approval.	**Verified** **Adequate**	New Documented Safety Analysis was obtained and reviewed. DOE approved the DSA.
2-72	2.2 Environmental, Health, Safety, and Quality- Authorization Basis/ Criticality Safety		Verify TSR, FHA, and DSA documents are current and implemented or implementation is in progress.	**Verified** **Adequate**	See Item 2-71 above.
2-73	2.2 Environmental, Health, Safety, and Quality- Authorization Basis/ Criticality Safety		Review of process and validation of inventory control for Authorization Basis limits.	**Verified** **Adequate**	New Documented Safety Analysis was obtained and reviewed. DOE approved the DSA. New procedure to explain inventory control is in the final development stages.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-73a	2.2 Environmental, Health, Safety, and Quality- Authorization Basis/ Criticality Safety	ASP-310, 1.12, Administration of 222-S Laboratory Complex Criticality Safety; LO-180-105, Operation of the MBAs at 222-S Laboratory and Transfer of Nuclear Material; LO-090-101, 222-S Laboratory Sample Receiving & Custodianship; LO-180-107, Radiological Sample Inventory Control	Assure adequate criticality procedures are in place and implemented.	**Verified** **Deficient**	The Nuclear Criticality Safety (NCS) limits are given in the section on Precautions and Limitations in the procedures. However, there are no explicit statements within the procedure that require that incremental additions of fissile material be checked for compliance with the limits. Such checks may be made by software, but such a function should be explicitly indicated as present. Samples from many sources at Hanford have a clear historical and well-documented basis from which the lab may establish an estimated fissile content. The waste from tank farms and irradiated, but unprocessed, fuel residues from reactor basins are examples where such a basis for estimation exists. The Plutonium Finishing Plant (PFP) also sends samples to the lab. There is communication between PFP personnel and lab staff, but there is no requirement for the formal documentation of the source and fissile content of the sample. Samples from the PFP normally are transmitted in very small containers (up to 100 ml.), however the lab has not imposed a requirement that such small containers be used. Without such a requirement, the lab is not able to demonstrate that a multiple failures would be required for accidental criticality to result at the lab. If a failure occurred at PFP and significant quantities of fissile material were inadvertently sent to lab, subcriticality would still be assured if the sample size were small. Analysis of the sample would reveal the presence of higher than anticipated fissile materials.
2-74	2.2 Environmental, Health, Safety, and Quality-Emergency Preparedness		Review spill records and ensure cleanup documentation is detailed and compete.	**Verified** **Adequate**	Incident records were reviewed and were detailed and complete.
2-75	2.2 Environmental, Health, Safety, and Quality-Emergency Preparedness		Verify Emergency Preparedness Plan is current, appropriate information is posted	**Verified** **Adequate**	Emergency Preparedness Plan is current and contains names of key personnel. One of the key personnel left for a new position on Monday of the audit. Sufficient coverage still exists.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-76	2.2 Environmental, Health, Safety, and Quality-Emergency Preparedness	HNF-SD-PRP HA-005 S.03.00D_ ANALLAB _005	Verify Emergency Preparedness drill has been conducted in the last year and that documentation is available and complete, including corrective actions.	**Verified** **Adequate**	FY 2003 Emergency Preparedness/Operational Drill Program Plan that was submitted in Dec. 2002 was reviewed. The program was current through June. The July drill was delayed and will be conducted in August. Reviewed HNF-SD-PRP-HA-005, 222-S Laboratory Complex Hazards Assessments, to ensure drills are structured around risk identified in hazard assessment. S-03-OOD-ANALLAB-005 was completed in March of 2003. The review confirmed that the EP coordinator, Rich Allen, who was hired in October of 2002, corrected previous concerns.
2-77	2.2 Environmental, Health, Safety, and Quality-Emergency Preparedness	HNF-SD-CP-FHA-007	Determine status of in-progress or planned repair/maintenance fire systems.	**Verified** **Adequate**	Interviewed the System Engineer for the fire protection systems. The System Engineer maintains a notebook for the fire protection systems, since they are designated as Vital Safety Systems. The Fire Hazard Analysis, HNF-SD-CP-FHA-003, was reviewed. This document was incorporated in the DSA.
2-78	2.2 Environmental, Health, Safety, and Quality-Emergency Preparedness	HNF-SD-CP-FHA-003	Determine status of fire system upgrades/modifications for facility.	**Verified** **Adequate**	See response to Item 2-77.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-79	2.3 Financial-Controls and Baseline		Scope, schedule and cost baseline information is available and accurate	**Verified** **Adequate** **Deficient**	The facility has relatively good information on the scope, schedule and cost associated with their near-term sampling activities. The scope information is included in several different forms. One of the primary documents describing future scope is the service level agreement (SLA) (discussed in Item 2-80). In addition to the SLAs, the facility often receives a Statement of Work (SOW), which is the most similar of the documents to a contract, from its customers. CHG, the largest customer, is the most consistent in preparing a SOW. The SOW describes more specifically than the SLA the scope of work to be performed. The document providing the most specificity in sampling requirements is referred to by many names including the "Data Quality Objectives" document, Technical Sampling and Analysis Plan, Sampling and Analysis Plan or Letter of Instruction. It was mentioned that CHG is the only customer that typically involves the laboratory in the development of these specific documents. The laboratory uses Primavera Project Planner™ for scheduling that is supplemented by the LIMS. These tools allow the facility to track samples and evaluate sample load. The facility appears to have good systems in place to track costs. There are more than 20 cost accounts with facility technical points of contact assigned and a budget analyst assigned to each account. Costs are distributed to customers based on the number of analyses performed and the published price per analysis. The facility has developed a model to estimate the "variable" costs associated with each of the analyses that forms the price per analysis. There is no attempt to recover "fixed or capital" costs, which appears to be the case historically. Therefore, the customers do not see the real cost per analysis. It is uncertain, without further analysis, what impact charging customers the real cost would have on the facility operations. The cost information is documented within the LIMS. Customers share in any discrepancy between revenues received and the actual variable costs of the operation. **(Adequacies and deficiencies noted.)**

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-80	2.3 Financial-Contracts and Services		Ensure that current contracts and services listing are available and current.	**Verified** **Deficient**	One of the primary documents describing future scope is the service level agreement (also more recently referred to as service level plan (SLP)) that is established between the facility and its customers. A summary list of 19 SLPs was provided. The list includes 14 non-CH2M HILL Hanford Group (CHG) SLPs and 5 CHG SLPs. The facility provided the actual SLPs for 16 of the 19 shown in the summary list. Several of the SLPs did not have signatures and 3 of the 19 could not be provided. This system needs improvement, so that both the financial and client services staff has current contracts.
2-81	2.3 Financial-Procurements		Review most recent procurement assessments for issues and actions.	**Verified** **Deficient**	Items for the laboratory are generally purchased on either an open purchase order basis or through a contract. The contracts are typically negotiated for a 1-year period from October 1 through September 30. The facility has seven maintenance agreements, two service agreements, and five agreements with other laboratories. It was mentioned by procurement that they have had some trouble negotiating equipment service agreements with manufacturers, since the manufacturers' staff is often not able to work directly on the equipment because of union issues. Procurement also mentioned that they have had trouble with one of their total inorganic carbon/total organic carbon (TIC/TOC) analyzers. There has also been an issue in obtaining follow-up training for one of their mass spectrophotometers. They have been working to resolve this issue. CHG procurement staff should be working with the lab staff prior to September 30 when the procurements will be expiring.
2-82	2.4 Infrastructure-Property Management	HNF-RD-11408, Property Management Requirements	Inventory is properly controlled and accounted for.	**Verified** **Deficient**	The systems and procedures for inventory control are comprehensive. There were conflicting responses on what percentage of the equipment is inventoried on a quarterly and annual basis. The responses ranged from 100% to a majority of the equipment; the latter response appears to be correct. There is a requirement in HNF-RD-11408 that requires the annual physical inventory of tagged sensitive property. This was not possible to confirm, given that much of the information in the system has restricted viewing.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-83	2.4 Infrastructure-Safeguards and Security	HNF-99-00056	Verify a safeguards program is in place for special nuclear material.	**Verified** **Adequate**	A vulnerability assessment was performed for the lab in 1999 (ref: HNF-99-00056). The level of protection present is consistent with the current DOE guidance for a Category IV Material Balance Area (MBA). The vulnerability assessment will be revised before April 2004 using the revised DOE Design Basis Threat.
2-84	2.4 Infrastructure-Safeguards and Security		Verify security program is in place for all material.	**Verified** **Adequate**	The 222-S material is protected at the appropriate level and is consistent with DOE guidance for Category IV MBAs. The lock and key program, used to control access to areas where material is kept, was observed to be effective.
2-85	2.4 Infrastructure-Safeguards and Security		Training and qualifications are current.	**Verified** **Adequate**	Access to MBAs where material is kept and processed is under the control of MBA custodians. A computer-based system is used for maintaining training records. Security training records were reviewed for one of the MBA custodians. The training and qualification were found to be current. The MBA custodians were found to be knowledgeable regarding operations, safety, and security in their respective areas.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-86	2.5 Customer Interface, Information Systems & LIMS-Computers and Software	HNF-PRO-052, Corrective Action Management; LC-700-003, LIMS Problem Reporting and Change Request Procedure; HNF-15156, Software Management and Quality Assurance Plan for Computer Software Management; ASP-200 Section 1.21, Laboratory Configuration Control	Verify software change control documentation is maintained and readily available.	**Verified** **Deficient**	Change control is being managed through the Laboratory Configuration Control Board (LCCB) and the LABCORE Control Board (LCB). Online and hardcopy files and documentation supporting change control for all major LIMS systems were observed. There is little documentation for LABCORE during this calendar year. This appeared to be due to the new development effort. Fewer changes are being made to the existing systems and more resources are being applied to the new development effort. Change requests usually initiate within the problem reporting systems used by the laboratory. There are several problem-reporting systems used, which vary by system and by problem severity. CITS has a problem reporting function built directly into the product. LABCORE uses its own reporting system. C14/OmniLIMS is currently under development and problem reporting is documented within the Mortice-Kern Software (MKS). In each of these cases, the problem report/change request is the basis for recording problem analysis, corrective actions, and other impacts on the systems. The resulting materials are kept in physical files or within the MKS. Lab personnel have access to and were aware of higher-level problem reporting systems. In general, internal systems are being used for problems of limited impact, such as errors not systematically affecting final results. There is a development effort underway to implement a Laboratory Configuration Control Board Database, (LCCBDB), which would track changes to software configurations as well as hardware. A draft requirements specification has been written which references a system called “Revised_LCCDB,” built in Microsoft Access, which is used to track software in laboratories. No one interviewed, however, seemed to be aware of this system.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-87	2.5 Customer Interface, Information Systems & LIMS-Computers and Software	HNF-PRO-309, Computer Software Quality Assurance Requirements; HNF-15410, Analytical Services Software Test Plans; ASP-200 Section 1.22, Documentation of Laboratory Quality Affecting Software	Verify documentation for verification of software validity is maintained.	**Verified** **Adequate**	Operational programs have been introduced in the laboratory over a period of many years. In some cases, the lab is using software that was written, in part, over 20 years ago. The documentation associated with the verification of software validity largely follows the age of the system. However, partially compensating for the lack of documentation, the older systems have extensive validation though operational use. For new systems development, such as C14/OmniLIMS and CES, the lab is following HNF-PRO-309. Within this framework, systems are rigorously tested during the implementation phase. The test procedure includes documented test plans, test results, and sign-offs at various levels. Documentation supporting software validity is being maintained within MKS for all current contractor development efforts, including C14/OmniLIMS and the inventory control database LCCDB. For recent in-house development efforts, such as the ACES, CITS, Volumetric Dispenser Database, and the IC Standards Calculation Spreadsheet, a similar process is being followed (but without the oversight of the LCCB). Documentation supporting software validity is being maintained within MKS. For modifications to existing systems, software validity is established through regression testing and through beta testing by users with a direct interest in the correctness of the systems. Beta testing of pre-release versions of applications is built into the LABCORE system as a main menu choice. The systems that were developed to control or interface to the lab equipment (Alpha Spec I/F, CAAF, and ABCS) have been peer reviewed. In the case of the Alpha Spec I/F, the software has been placed in the public domain. The lab has published papers on the Alpha Spec I/F and on CAAF, and again, this provides one level of peer review helping to ascertain and document software validity.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-88	2.5 Customer Interface, Information Systems & LIMS-Computers and Software	ASP-200 Section 1.21, Laboratory Configuration Control	Verify software historical files of all versions of software programs exist and include dates that software was placed into and removed from production.	**Verified** **Deficient**	In general, information regarding when systems were put in place was kept on an ad hoc basis. For newer systems this is being controlled and documented though the LCCB. Previous versions of software are available on the MKS for all new system development (e.g., C14/OmniLIMS) and some other systems (CES, CITS, Volumetric Dispenser Database, IC Standards Calculation Spreadsheet, K-Basin Sand Filter Backwash Line Spreadsheet). No evidence of systematic archiving of non-COTS software was observed within the lab—either on a routine, time-based schedule or on a per-version schedule. As such, when systems change, historical files of all versions of the software programs are not readily, if at all, available. In some instances, such as with LABCORE, records documenting the changes exist so the system could (theoretically) be reconstructed.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-89	2.5 Customer Interface, Information Systems & LIMS-Computers and Software	HNF-RD-11626, Unclassified Computer Password Generation, Protection, and Use; HNF-PRO-592, Unclassified Computer Security Control Program Management Control Process	Verify computer security systems include password changes, virus protection, and physical access.	**Verified** **Adequate**	The lab enforces the Hanford standard for passwords at the network server and all workstations. Periodic password changes on all workstations are not required, but networked-based workstations utilize a password timeout scheme that forces periodic password changes. All servers utilize passwords that periodically timeout. In addition, non-spreadsheet applications (LABCORE, CES, and CITS) utilize a password challenge to gain access to the underlying data. The user's logon determines the functions that are available. In other words, only authorized personnel have access to administrative functions within each application. All laboratory software that is used in a network environment (i.e., not the instrument interfaces), resides on network shares on the servers. The servers provide a granulated level of privileges to users based on each user's role. Each account on the system is granted certain roles, which gives them read-only, read-write, etc., access to the shares. A similar granulated rights system is available, and is being actively used within the MKS system and in major applications such as LABCORE, CES, CITS, and VDD. Computer virus protection resides on each workstation on the Hanford Wide Area Network. Virus protection is managed over the network. Each workstation automatically checks for updates to the virus protection program (or virus definition files) each time a user logs onto the workstation. Standalone workstations have virus protection programs (and updates) on an ad-hoc basis. The site controls physical security. All servers are housed in code-key locked rooms. Master copies of software and documentation are contained in the Software Control Cabinets (MO-037, Room 8). The cabinets are well identified and are kept locked. Documentation is checked out via an honor system sign-out sheet.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-90	2.5 Customer Interface, Information Systems & LIMS-Computers and Software	HNF-PRO-309, Computer Software Quality Assurance Requirements; ASP-200 Section 1.4, Analytical Services Laboratory Record Systems	Verify regularly scheduled maintenance is performed and documented.	**Verified** **Adequate**	Regularly scheduled maintenance is being performed and documented for all systems and COTS packages, except where systems have been purposely frozen. Operating system upgrades and patches are performed by in-house personnel for the server systems, and by a contractor for workstations on the LAN. Lab personnel update standalone workstations on an ad-hoc basis, and these updates go undocumented, except possibly within the system files on the computer itself. For most Ingres-based applications, the system hardware configurations are frozen (i.e., no upgrades or maintenance patches are being applied). This was done based on the recommendation of the vendor. LABCORE hardware maintenance is provided through a contract with IBM. Their recommendation for systems this old is to not run any routine hardware maintenance, but only respond to problems. They feel shutting the systems down for maintenance will cause more problems than it will fix. Lab personnel expressed that their experience is similar. For LABCORE software systems, the LMSI contractor supporting software patches, upgrades, and maintenance has several worksheets (stored in a notebook in his office) describing routine tasks that need to be done. Lab management signs off on these worksheets. They include system backup and restore, system power-down and power-up procedures, user setup and removal, outage notification, security patches, and print management.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-91	2.5 Customer Interface, Information Systems & LIMS-Computers and Software	ASP-200 Section 1.23, LABCORE Post-Disaster Recovery Plan	Verify system backups and disaster recovery processes are in place.	**Verified** **Deficient**	All data stored on the network shares are backed up routinely. This includes all system files and database files. Nightly incremental backups are kept on the premises. Backup databases are maintained offsite at WSCF. Complete backups and database checkpoints are routinely run weekly and the tapes are kept for 90 days. Systems in the downtown offices are routinely backed up via the high speed Hanford Wide Area Network and the files are maintained offsite. Currently, the servers designated for disaster recovery are housed in the same room as the operational servers. In the case of an event affecting the server room, the backup servers could also be rendered unusable. This is in the process of being corrected. Going to site-compliant server configurations eases disaster recovery. The lab is in the process of upgrading the servers. All new servers will be based on site-standard configurations. This is expected to occur before the end of March 2004. At that point, there will be a large pool of available servers in the case of an event affecting the lab's servers.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-92	2.5 Customer Interface, Information Systems & LIMS-LIMS	HNF-PRO-309, Computer Software Quality Assurance Requirements; HNF-15156, Software Management and Quality Assurance Plan for Computer Software Management; ASP-200 Section 1.22, Documentation of Laboratory Quality Affecting Software	Verify that a description of the LIMS design and capacity is documented and maintained.	**Verified** **Deficient**	No documentation was observed about the intended or actual capacity of the LIMS. Laboratory personnel stated that the current LIMS can reach 90% of its throughput capacity near the end of each fiscal year. The limiting factor is the 2GByte hard drive size on the servers. The system currently contains a large amount of historical data that could be archived and purged from the operational system. It was estimated that this would reduce the size of the databases by as much as two thirds. It is not anticipated that this will be required before the new system comes online. No similar size constraint is expected with the new C14/OmniLIMS system. The standard configuration of this system does not have the 2GByte limit. **C14/OmniLims—**C14/OmniLIMS is an ongoing development effort that will replace the existing LABCORE software systems. Detailed descriptions of the C14/OmniLIMS requirements, functionality, and design are documented. This documentation is being managed within the MKS system. **LABCORE—**The LABCORE systems consist of a set of applications and utility programs that implement the essential processing of the 222-S LIMS. LABCORE includes MultiLIMS, Ingres Shell, ACES, TCD I/F, LTS, and various utilities. MultiLIMS stores and manages data that pertains to sample analysis tracking and to the management aspects of the laboratory operations, work assignments, sample status, final reporting, personnel training, and equipment status. MultiLIMS collects and compiles specific sample data to provide summary laboratory reports. MultiLIMS is an Ingres-based application. No detailed design documentation supporting the Ingres Shell was observed. Use of MultiLIMS is briefly documented in LC-708-001, MultiLIMS use in the Laboratory. The Ingres Shell is used to upload data from instruments that generate import files containing sample analysis results. No detailed design documentation supporting the Ingres Shell interfaces were observed. Calculations (such as yield) are documented in the Laboratory Analytical Procedures and in the Lab QA Manual (HASQUAD Vol. IV).

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-92 Cont.					The Laboratory Training System (LTS) is an Ingres-based system used to track lab personnel training by procedure. This data is used by LABCORE to control who can be reported as doing each specific analysis. We observed no design documents supporting the LTS. The Analytical Card Enhancement System (ACES) consists of spreadsheets that are used to generate results for analysis that do not have an associated import file. The majority of the spreadsheets are implemented as Borland Quattro 5 spreadsheets, with a few developed as Excel spreadsheets. ACES is documented in the ACE Upgrade Plan (submitted to the LCCB, but not yet assigned a document number). The TCD Interface is an Ingres application that generates and uploads a standard electronic format file for the Tank Characterization Data Loader. The interface file contains both analytical results and sample descriptions. The interface is documented in HNF-3638, Standard Electronic Format Specification for Tank Characterization Data Loader, Version 3.5.
2-93	2.5 Customer Interface, Information Systems & LIMS-LIMS		Verify documentation of updates and changes to the LIMS exists and is maintained.	**Verified** **Deficient**	This item was addressed in Item 2-86.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-94	2.5 Customer Interface, Information Systems & LIMS-LIMS	ASP-200 Section 1.21, Laboratory Configuration Control	Native files (original code) are available.	**Verified** **Deficient**	The first step in determining whether all native files were available was to identify all files required to operate the laboratory. This was not entirely possible. Major systems are documented within the site-level HISI system, but not at the file level. The requirements specification for the planned LCCDB states that there is an existing system called "Revised_LCCDB" built in Microsoft Access that is used to track software in the laboratories. However, as noted previously, no one was aware of this system. In addition, there is a list of software contained in a spreadsheet (named "Software Control Sheet 222s.xls" and stored within the MKS), but due to personnel turnover, it was about 2 years out of date. There is a Paradox database that contains an indexed listing of the S/W cabinets, but due to recent upgrades to Microsoft XP, the database is not currently or readily accessible. Most of the information obtained on native file locations came from direct knowledge of the lab personnel responsible for the systems. Copies of COTS software are contained in the Software Control Cabinets and systems software is maintained in the server rooms. For each major application all native files required by the application were able to be located. Copies of all software are stored in machine-readable media (tape, floppies, CD-ROM), along with their relevant documentation. This material resides in the Software Control Cabinets (MO-037, Room 8) and its contents are listed on Software Control Check-In Sheets. Access is maintained though an honor-system sign-out/sign-in logbook. For newer development efforts, native files are stored (and access controlled) by the MKS Source Integrity Enterprise System. This was observed for C14/OmniLIMS, CES, CITS, Volumetric Dispenser Database, IC Standards Calculation Spreadsheet, and the K-Basin Sand Filter Backwash Line Spreadsheet.

Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-95	2.5 Customer Interface, Information Systems & LIMS-Records Management		Records management program exists and is implemented.	**Verified** **Adequate**	The lab has a good records management program. As an example of the records management review, the analytical logbooks used for the preparation of stable (non radioactive) analytical standards and reagents of varying concentrations were observed. All preparations were addressed under controlled copy of formal, written procedures that were readily available and appropriately maintained. The analyst was observed preparing solutions and documenting work. Certificates for all standards were appropriately maintained and accessible as needed. The supervisor reviews logbooks and the review is documented by the reviewer's signature and date. Entries are legible and organized. All analytical samples are maintained under Chain-of-Custody (COC); COC records appear adequate.
2-96	2.5 Customer Interface, Information Systems & LIMS-Records Management		Quality Records are clearly identified and maintained.	**Verified** **Adequate**	The activities evaluated, the personnel interviewed and records examined indicate the following regarding the Quality Assurance Program: the program is adequate relative to the appropriate upper tier requirements and the program is generally implemented. As an example of one set of quality records, the current practice is to perform data validation of 100% of the analytical data packages from the laboratory's main client, which amounts to approximately 80% of the packages generated; validation is performed on 10% of the remaining (approximately 20%). Data validation is conducted in accordance with formal, written procedures and all reviews are documented in Data Package Review Book. Reviews are conducted by two (2) individuals on the QA staff, as well as by a subcontractor. All issues identified during the validation process are tracked and closure of each issue is documented. QA Lead (Glen Clark) was absent for the duration of this evaluation, which made certain aspects difficult to evaluate.
2-97	2.5 Customer Interface, Information Systems & LIMS-Records Management	ASP-GD-003	Verify that laboratory has an adequate document control system in place.	**Verified** **Adequate**	There are multiple systems maintained by the laboratory or available to the laboratory for document management. These systems have been described elsewhere in this report. Overall, document management looks good.
2-98	2.5 Customer Interface, Information Systems & LIMS-Records Management	ASP-200:1.01, Administrative Procedure Control Process	Verify procedures, policies, and manuals reflect current operations and have been reviewed on a designated frequency.	**Verified** **Adequate**	The procedures, policies, and manuals that were reviewed were generally revised in the last year and appear to be up to date.

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Item	Category	Reference (SOP, DOE, or National Stds.)	Requirement	Assessment	Remarks
2-99	2.5 Customer Interface, Information Systems & LIMS-Records Management		Verify that records storage meets Federal and DOE guidelines.	**Verified** **Adequate**	Several types of records were reviewed and all of these records met storage requirements per Federal and DOE guidelines.
2-100	2.5 Customer Interface, Information Systems & LIMS-Service Level Agreements (SLA)		SLA current and signed off for all customers.	**Verified** **Deficient**	A summary table was provided that showed 19 Service Level Plans (SLPs, formerly called Service Level Agreements). Sixteen of the 19 SLPs were provided for review, some of which were not signed. This process needs to be improved so that both financial and customer relations staff have current and signed-off copies of the SLPs.
2-101	2.5 Customer Interface, Information Systems & LIMS-Service Level Agreements (SLA)		Tracking of actual work received vs. SLA	**Verified** **Deficient**	The tracking of actual work received versus the SLP is done more on an ad hoc basis versus through a computerized system. The combination of SLPs, sampling plans, statements of work, and the LIMS track this information at different confidence levels. However, these systems are not integrated.