

**U.S. Department of Energy
Laboratory - Sample Control and Information Management**

Line of Inquiry and source	Compliance			Findings/observation	Comments
	No	Yes	N/A		
1.0 Building Security					
1.1 Physical controls exist in all laboratory areas to ensure that sample chain of custody (COC) is not broken during periods when laboratory staff are not present. <i>[Analytical Support Agreement Terms and Condition (ASA T&C), Article V; Contract Laboratory Program (CLP), Exhibits F 1.2 and 3]</i>					
1.2 Physical or administrative controls exist to ensure that sample COC is not broken during periods when laboratory staff are present. (ASA T&C, Article V; CLP, Exhibits F 1.2 and 3)					
1.3 Visitor access to controlled areas is maintained by strict physical or administrative controls. (ASA T&C, Article V; CLP, Exhibits F 1.2 and 3)					
1.4 A controlled list of authorized staff has been defined that has access to areas of sample storage during periods when sample custodians may not be present. (ASA T&C, Article V; CLP, Exhibits F 1.2 and 3.4)					

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	No	Yes	N/A		
2.0 Sample Receiving, Log-in, and Transfer					
2.1 Written/controlled procedures are available at each workstation. [U.S. Department of Energy (ASME NQA-1)]					
2.2 Conditions of samples as received are checked and documented, including cold preservation, unusual conditions, COC seals, completeness of delivery per the sample request sheet or COC form. (Laboratory quality assurance plan; CLP, Exhibit F 1.3 SW-846 4.3.1)					
2.3 Nonconformances during sample receiving are documented and, in instances where sample integrity may be compromised, the customer is immediately notified of problems. (ASME NQA-1, CLP, Exhibit F 1.3.7)					
2.4 COC is maintained while samples are in initial storage in the sample receiving area during all hours of the day, on weekends, holidays, etc. (CLP, Exhibits F 3.5 and 3.6)					
2.5 Sample refrigeration practices ensure and document that conditions remain within an acceptable range ($4 \pm 2^{\circ}\text{C}$). (SW-846, Chapter 1, 4.3.1; CLP, Exhibit D Section II; CLP Exhibit A, Section 4.3.3.2)					

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2.6 Monitoring for volatile cross contamination is performed routinely for volatile organics sample storage refrigerators (i.e., frig. blanks). (CLP, Exhibit D, Section 1.2)					
2.7 Sample segregation practices are in place for waste and environmental (or high and low concentration) samples and for radioactive and nonradioactive samples? (SW-846, Chapter 1, Sections 4.1 and 4.3.1)					
2.8 Data from 2.7 are routinely assessed and evaluated by sample receiving room staff. Data are available for presentation to the auditor. (CLP, Exhibit D, Section 12)					
2.9 Copies of completed COC forms are available for inspection. (CLP, Exhibit F 2)					
2.10 COC is transferred to the analytical laboratories using a documented sign-off process? (CLP, Exhibit F 3.7)					
2.11 A sample receiving logbook is present that documents the chronological sequence and volume of samples processed through sample login. (CLP, Exhibit F 1.4)					
2.12 Logbooks are well maintained and legible? (CLP, Exhibit B, Section II)					

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2.13 Controlled SOPs exist to cover sample control operations. (ASME NQA-1; CLP, Exhibit F 3.3)					
2.14 Employee training is routinely conducted on sample control operations? (ASME NQA-1)					
2.15 Sample receiving/transfer logbooks are reviewed and initialed by the reviewer on a regular frequency? (CLP, Exhibit F 3.7;ASME NQA-1)					
2.16 Sample receiving/transfer records are dispositioned to protected or redundant storage? (ASME NQA-1, CLP Exhibit F 3.7)					
3.0 Laboratory Information Management Systems (LIMS) for Log-in/Sample Control					
3.1 Controlled SOPs are present at the workstation for LIMS log-in/sample control operation. [Good Automated Laboratory Practices (GALP), Sect. 8.3.2]					
3.2 Training is performance-based. (ASME NQA-1)					

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3.3 A sample log-in and tracking system ensure that the sample retains a unique and traceable identity as it is processed through the laboratory. (CLP, Exhibit F 3.3)					
3.4 Sample log-in screens capture customer-supplied information concerning sample date and time, required analyses, number of containers received, field sample ID number, and billing information. (CLP, Exhibit F 1.3)					
3.5 Sample log-in to LIMS is permitted only by restricted password control. (GALP, Sect. 8.2)					
3.6 An automated sample reporting system exists for analytical backlog.					
3.7 LIMS can track to whom and at what time a sample was transferred for analysis. (CLP, Exhibit F 1.4)					
3.8 Positive methods exist for minimization of transcription errors. (ASME NQA-1)					
3.9 The number of data entry screens does not appear to be burdensome to the data entry clerk.					

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3.10 The system speed does not appear to be restrictive to effective processing of workloads.					
3.11 Records are maintained of all database changes and maintenance activities. (GALP, Sect. 8.4.5)					
3.12 Database changes are permitted only by authorized staff. (GALP, Sect. 8.4.5)					
3.13 System backups are made at a regular frequency. (GALP, Sect. 8.6.6)					
3.14 System backup tapes/disks are protected in the event of a disaster. (GALP, Sect. 8.6.6)					
3.15 LIMS can track the status of sample material entering the laboratory for analysis to the point of sample return, archival, consumption, or disposal. (ASA T&C, Article VI 4.f)					
3.16 All logbooks/logsheets are reviewed for accuracy by independent staff at a regular frequency and are initialed and dated. (ASME NQA-1)					

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3.17 All important records are dispositioned to protected or dual storage. (ASME NQA-1)					
4.0 Maintenance of Sample Control During Analytical Operations					
4.1 Individual laboratory areas have access-controlled doors or access-controlled sample storage areas. (ASA T&C, Article V)					
4.2 Sample receipt to and from log-in is documented on a sample transfer record.					
4.3 At the completion of a work cycle, samples that are not in process are returned to secure storage. (GLP Chap. 15, "Chain of Custody")					
4.4 If unanalyzed samples are returned to the sample receiving area, this transfer is noted in a tracking system.					
4.5 Laboratory areas are not left unattended or unsecured during the course of auditor inspection. (Laboratory quality assurance plan)					
4.6 Laboratory sample refrigerators are monitored for proper temperature ($4 \pm 2^{\circ}\text{C}$) for samples requiring cold preservation. (Standard Methods 9030B.11 and 12)					

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4.7	Sample segregation practices are in place for waste and environmental (or high and low concentration) samples and for radioactive and nonradioactive samples.					
4.8	Monitoring for volatile organic cross contamination is performed routinely for volatile organics sample storage refrigerators (i.e., refrigerator blanks)					
4.9	Data from (4.8) are routinely assessed and evaluated by sample receiving room staff. Data are available for presentation to the auditor.					
4.10	Soil samples (or other unpreserved media) awaiting digestion, extraction, or other initial processing are not left unrefrigerated for extended periods. (Samples can be left out for 1-2 hours to allow for stabilization to room temperature).					
4.11	Waste sample disposition is documented.					
4.12	Waste samples are not stored in laboratories but are promptly returned to the sample receiving area (or other central area) for dispositioning.					
4.13	If the sample is entirely consumed, documentation is made of this fact and communicated to sample receiving or the responsible waste management group.					

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4.14	Old unused samples or excess samples are not stored in the laboratory areas.					
4.15	The volatile organics analysis laboratories have a positive mechanism for controlling the influx of solvent-laden air into their work areas (e.g., separate air handling system). (SW-846, Chap. One, Sect. 4.1)					