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Responses to Deficiencies and Suggestions, AIHA Site Assessment July 12-14, 2016

J. T. Bennett, R. N. Harding

August 15, 2016

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Lawrence Livermore National Laboratory

August 11, 2016
ESH-2016-057

Ms. Lauren Schnack
Quality Systems and Accreditation Specialist
AIHA Laboratory Accreditation Programs, LLC
3141 Fairview Park Drive, Suite 777
Falls Church, VA 22042

Subject: *Responses to Deficiencies and Suggestions, AIHA Site Assessment July 12-14, 2016*

Dear Ms. Schnack:

Attached please find responses to the deficiencies and suggestions found by Steve Lerman during the American Industrial Hygiene Association external site assessment carried out July 12-14, 2016 in the Analytical Services and Instrumentation Division Analytical Laboratory (Lab ID 101757).

Sincerely,

Ruth Harding, Assurance Officer
Environment, Safety & Health Directorate
Lawrence Livermore National Laboratory

Enclosure: Responses to Deficiencies and Suggestions, AIHA Site Assessment July 12-14, 2016

Copy:

Bennett, Jack
Merrigan, Jim
Sundsmo, Michele



Responses to Deficiencies and Suggestions

AIHA Site Assessment July 12-14, 2016 by Site Assessor Steve Lerman

Analytical Services and Instrumentation Division Analytical Laboratory (Lab ID 101757)

Lawrence Livermore National Laboratory

Jack Bennett, ALAB Technical Lead

Ruth Harding, ALAB Quality Assurance Coordinator

Deficiency 1

- 1) Statement of deficiency
 - a. The Lab does not have a written Quality Policy statement. (ISO 17025 Section 4.2.2)
- 2) Results of root cause analysis
 - a. There is a quality policy discussion in the overarching ES&H Directorate-Level Quality Assurance Plan that was not adequately referenced in the ALAB Activity-Level Quality Assurance Plan. The QAC and TL inadvertently failed to direct the auditor to the policy in the document.
- 3) Statement of action
 - a. A quality policy statement was added to the SOP WSH-IH-ALAB-DES-01 "Activity-Level Quality Assurance Plan" Section 1.1, including a reference to the overarching ES&H Directorate Quality Policy detailed in ESH-DES-001 "ES&H Directorate-level Quality Assurance Plan".
- 4) Proof of commitment
 - a. A revision to SOP WSH-IH-ALAB-DES-01 "Activity-Level Quality Assurance Plan" was completed.
- 5) Objective evidence of compliance
 - a. Attachment 1-1 shows the quality policy statement for the ALAB and Attachment 1-2 shows the quality policy statement for the overarching ES&H Directorate.

Attachment 1-1

Deficiency #1



1. Purpose

The Environment, Safety, and Health (ES&H) Directorate Analytical Laboratory (ALAB) provides analytical support to its clients for use in providing protection to workers and the environment at Lawrence Livermore National Laboratory (LLNL). To accomplish this, the analytical data produced by the ALAB shall be defensible and of known accuracy and precision.

The program described in this ALAB Quality Assurance Plan (QAP) addresses organization facilities, equipment, and materials, as well as procedures, practices, competency, documentation control, and data traceability.

This program provides specific procedures for meeting the guidelines of Institutional Program Description DES-0115, LLNL Quality Assurance Program, ESH-DES-001 ES&H Directorate-Level Quality Assurance Plan, International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005(E), American Industrial Hygiene Association – Laboratory Accreditation Program (AIHA-LAP), LLC, and Environmental Protection Agency (EPA) Manual for the Certification of Laboratories Analyzing Drinking Water.

The ALAB is accredited by AIHA-LAP, LLC to ISO 17025 and AIHA-LAP, LLC requirements. The State of California Environmental Laboratory Accreditation Program accredits the ALAB for waste water analysis.

1.1 Quality Policy

The ALAB's mission is to provide excellent service and quality analytical results while exceeding customers' expectations. The ALAB is committed to using quality practices that require all tests to be carried out in accordance with stated methods and customers' requirements. The ALAB's quality policy aligns with the overarching ES&H Directorate Quality Policy detailed in ESH-DES-001 ES&H Directorate-level Quality Assurance Plan.

2. Applicability

This QAP is applicable to work performed in Building 253 ALAB laboratories and associated offices and the Building 581 National Ignition Facility (NIF) Health Physicist (HP) Laboratory in support of Lawrence Livermore National Laboratory (LLNL) missions and provides an integrated approach to quality requirements associated with that work for beryllium analysis.

3. Exceptions

None

4. Prerequisites

None

DI

Attachment 1-2 pgl of 2
 Deficiency # 1



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ESH-DES-001
 Revision 4.0
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ES&H Directorate-Level Quality Assurance Plan

	ES&H Directorate PROGRAM DESCRIPTION DOCUMENT ES&H Directorate-Level Quality Assurance Plan			
	Doc ID:	ESH-DES-001 Rev 4	Effective Date	03/31/2015
	Supersedes:	ESH-DES-001 Rev 3	Next Review:	03/31/2016
Functional Area	Quality Assurance			
Topic:	Quality Assurance Program			
Subtopic:	Quality Assurance Plan			

1. Purpose and Scope

This Environment, Safety and Health (ES&H) Directorate-Level Quality Assurance Plan (EDLQAP) describes ES&H's mission, quality policy, objectives, requirements and controls that must be integrated into ES&H Directorate activities in support of the Lawrence Livermore National Laboratory (LLNL) mission. ES&H's implementation of the LLNL quality assurance program and its integration into ES&H processes and activities are described in section 4.0.

1.1 ES&H Mission, Quality Policy and Objectives

The ES&H Directorate's mission is to support LLNL's research and development activities and operations by providing ES&H policy and personnel in the areas of environmental management, occupational health, industrial hygiene, industrial safety and radiation safety. ES&H mission priorities include:

- Ensuring excellence in execution: delivering results of the highest quality, on schedule and on budget
- Ensuring excellence in operations: safety, security, environment, and state of the art business practices and processes
- Improving operational cost effectiveness
- Providing a first-class workplace environment to our employees
- Expanding LLNL's ES&H contributions to the local and national economy through partnerships with academia and industry

Approved By: alston7
 Approval Date: 03/27/2015



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ES&H Directorate-Level Quality Assurance Plan

ESH-DES-001

Revision 4.0

Page 4 of 34

ES&H is committed to using quality practices and principles to achieve its mission, meet customer requirements, enhance customer satisfaction and continually improve the effectiveness of work processes while meeting contractual requirements. ES&H objectives include:

- Applying quality principles throughout ES&H organization's activities
- Providing a process for continual improvement in all areas of ES&H performance
- Ensuring customer needs are met in a safe, environmentally sound, and cost effective manner
- Ensuring appropriate planning, organization, direction, control, and support are provided to achieve ES&H goals

ES&H policy is conveyed to staff through management communications, leadership, staff meetings and by example. The EDLQAP, implementing documents and processes listed in Appendices 1 and 2 form the foundation of the ES&H implementation of the LLNL quality assurance program with the objective of achieving quality in products, work processes and programmatic support, as well as soliciting and enhancing customer satisfaction.

2. Applicability

The EDLQAP applies to work performed by the ES&H Directorate in support of the Lawrence Livermore National Laboratory (LLNL) mission and to ES&H Directorate personnel and to personnel participating in activities performed by the ES&H Directorate.

The EDLQAP supports the LLNL Integrated Safety Management System and is integrated with the *LLNL Quality Assurance Program*, ES&H Document 41.1.

3. Exceptions

The EDLQAP does not apply to routine business activities such as staff performance appraisals and salary planning; or procurement of standard office supplies and equipment. These activities are performed in accordance with contract requirements and best business practices.

4. ES&H Implementation of the LLNL Quality Assurance Program

The ES&H Directorate relies on the ISO 9001 consensus standard, along with supplemental governing documents, to flow-down the requirements of the LLNL quality assurance program.

Approved By: alston7
Approval Date: 03/27/2015

Deficiency 2

- 1) Statement of deficiency
 - a. The Lab does not have a written procedure for document control. (ISO 17025 Sections 4.3.1, 4.3.2.2, 4.3.3.3, and 4.3.3.4)
- 2) Results of root cause analysis
 - a. There are overarching document control procedures in the ES&H Directorate-Level Quality Assurance Plan and ES&H Document Management procedure. These documents were not adequately referenced in the ALAB Document Control SOP. The author of the ALAB Document Control SOP was not available for interview due to retirement. The author inadvertently failed to specifically describe some procedures required by ISO 17025.
- 3) Statement of action
 - a. A major revision of SOP WSH-IH-ALAB-PRO-13 "Analytical Laboratory Document Control" Section 6.2 added specific procedures for document control in the ALAB aligning with the overarching ES&H documents. References to the overarching documents were also added.
- 4) Proof of commitment
 - a. A revision to SOP WSH-IH-ALAB-PRO-13 "Analytical Laboratory Document Control" was completed.
- 5) Objective evidence of compliance
 - a. Attachment 2-1 is the revised SOP WSH-IH-ALAB-PRO-13 "Analytical Laboratory Document Control" Section 6.2 Analytical Procedure Documents.

Attachment 2-1 page 1 of 2
Deficiency # 2



Analytical Laboratory
Document Control

WSH-IH-ALAB-
PRO-13
Revision 0
Page 3 of 8

6. Procedure

6.1 Instrument Manuals

6.1.1 Manuals for the major instruments are kept together with the Maintenance Records binders near the instrument. Manuals for smaller instruments and other lab equipment are kept in a file drawer in Room 1734A. The drawer is labeled "EQUIPMENT & INSTRUMENT MANUALS."

6.2 Analytical ~~Method~~ Procedure Documents

6.2.1 Document control policies and procedures in the ALAB align with the overarching ES&H Directorate and are detailed in ESH-DES-001 ES&H Directorate-Level Quality Assurance Plan and ESH-DIP-04-01 ES&H Document Management.

6.2.2 Originals of each current method Each ALAB procedure is reviewed and approved for use by authorized personnel (i.e., TL, QAC, and AS&I Manager) prior to issue. Original copies are kept by the Quality Assurance Coordinator (QAC). After 5 years the originals are archived with the sample documents. Any superseded/obsolete documents are marked as such.

6.2.3 The current, approved versions of procedures are posted on the internal Worker Safety and Health Functional Area website (coordinated by the QAC) and are available to all analysts. The electronic copy of the procedure is the controlled copy. An analyst may use printed bench copies footnoted with "Uncontrolled if Printed", but it is the analyst's responsibility to ensure that the copy in use is the latest version.

6.2.4 The master procedure list is on the Worker Safety and Health Website and also within the Universal Records Management (UCM) system. The UCM system also contains archived/superseded procedure versions in a separate folder from the current procedure versions. Immediately after a procedure revision is issued, the superseded version is moved to the archived procedure version folder and the current version is placed in the current procedure version folder. Any superseded procedure versions are also removed from the website to prevent inadvertent use of the outdated version (i.e., only the current version of each procedure is posted on the website).

6.2.5 All procedures are reviewed periodically per programmatic requirements and as needed by knowledgeable personnel (i.e., analysts, TL, and/or QAC) to ensure that they correctly describe the current practices. The time between procedure reviews shall not exceed three years for all procedures except for the Quality Assurance Plan, which is reviewed annually.

UNCONTROLLED IF PRINTED



6.2.6 If upon review it is determined that a procedure requires revision, the revisions are completed by knowledgeable personnel (i.e., analysts, TL, and/or QAC) and the new procedure version is reviewed and approved for use by authorized personnel (i.e., TL, QAC, and AS&I Manager) prior to issue.

6.2.7 In the interim between recognizing a procedure requires revision and the formal issuing of the revised procedure version, amendments may be made to procedures in writing (clearly marked, initialed, and dated) and distributed to all analysts (e.g., via email) by the TL for use until the revised version is formally issued. The amendment will also result in a memo to file in the same location as the procedure.

6.2.8 If a draft procedure version undergoing revision is used to analyze customer samples before the revised procedure version is formally issued (i.e., not just for procedure development) it will be documented in a memo to file by either the TL or QAC.

6.2.9 Revised versions of procedures retain the unique procedure identification number and iterate the revision number by whole numbers. An initial version of a new procedure is given revision number 0.

6.2.10 Technical basis documents from external sources are referenced within each procedure.

6.2.11 Procedures shall be maintained in accordance with DOE/LLNL records retention requirements as described in Schedule 10 of the LLNL Records Retention Schedule. Documents used to develop procedures shall be maintained as historical information and/or design development information. Procedures may be kept for a longer period if deemed appropriate.

6.3 Sample Records Documents

6.3.1 Records shall be maintained in accordance with DOE/LLNL records retention requirements as described in Schedule 10 of the LLNL Records Retention Schedule. Records may be kept for a longer period of time if deemed appropriate.

6.3.2 The sample documents for completed and reported analyses are kept together in folders in filing cabinets in Room 1734A. If more space is needed in the filing cabinets, some of the earlier document packages are transferred to cardboard filing boxes, which are later used for long-term storage. The boxes are temporarily stored in Rooms 1734, 1734A, 1734B and 1734C. The documents include worksheets, instrument printouts, LIMS QC reports, and final reports.

Deficiency 3

1) Statement of deficiency

- a. QM 6.9.8 states that all complaints are to be recorded in the Lab's non-conformance system. A complaint is discussed in the management review, but there is no record of this complaint in the Lab's non-conformance system. (ISO 17025 Section 4.8)

2) Results of root cause analysis

- a. The ALAB TL was interviewed as he heard the complaint at a weekly IH meeting and documented it in the Annual Management Review Report for CY 2015. He developed a corrective action, implemented it, and communicated it to the customers, however, he failed to complete the procedure outlined in ALAB QAP 6.9.8 by not documenting the complaint on the "Client Complaint" form and in the NCR system. The TL had documented training on the ALAB QAP. As the TL was recently hired into the position and since complaints are relatively rare (the last ALAB complaint was in 2012), he inadvertently did not complete all of the procedure.

3) Statement of action

- a. The Client Complaints procedure in SOP WSH-IH-ALAB-DES-01 "Activity-Level Quality Assurance Plan" Section 6.9.8 was revised to remove the requirement to record all complaints in the NCR system. The revised procedure was completed by documenting the complaint on a Client Complaint form. The QAC re-trained the TL on the revised Client Complaints procedure.

4) Proof of commitment

- a. A revision to SOP WSH-IH-ALAB-DES-01 "Activity-Level Quality Assurance Plan" was completed. The QAC re-trained the TL on the revised Client Complaints procedure and documented it on the Safety and General Laboratory Training Documentation Form.

5) Objective evidence of compliance

- a. Attachment 3-1 is the revised Client Complaints procedure, Attachment 3-2 is the completed Client Complaint form, and Attachment 3-3 is the training documentation form for the TL.

Attachment 3-1

Deficiency #3



The investigation may include but not be limited to checks for calculation and data transfer errors, use of the correct method, aliquoting or dilution errors, incorrect instrument behavior, unusual sample behavior during processing, and other possible sources of error. The investigation may include a repeat of sample, blank, duplicate and/or spike analyses.

After the investigation is completed, the LTL shall select and implement the corrective action(s) most likely to eliminate a reoccurrence. Corrective actions shall be taken immediately.

The LTL is responsible for determining if an extended condition investigation is required.

6.9.5 Documentation

The results of the investigation shall be documented using the NCR form in ALIMS. The investigation includes a description of the root cause(s) of the out-of-control results, the corrective action(s) taken and the steps that shall be followed to prevent a reoccurrence of the out-of-control situation. A copy of the completed form shall be filed with the paperwork associated with the samples.

6.9.6 Implementation and Monitoring of Corrective Actions

The LTL is responsible for implementation of corrective actions. The QAC is responsible for monitoring corrective actions.

6.9.7 Preventative Action

Preventative actions are proactive and initiated to prevent future NCRs. Corrective actions which prevent future NCRs are preventative actions. The preventative action may be in response to an NCR or observation. All ALAB team members shall seek opportunities for preventative action. Any possible preventative actions determined shall be communicated to the LTL. The LTL is responsible for selecting and implementing preventative actions. The QAC is responsible for monitoring preventative actions.

6.9.8 Client Complaints

Client complaints shall be documented on the Client Complaint form, Attachment

1. ~~The complaint shall be treated as an NCR.~~ The results of the investigation and the corrective actions shall be reported to the client in a timely manner.

6.9.9 Continuous Improvement

The processes will be continuously improved using input from NCR causal analysis, assessment findings, lessons learned and review of updated guidance and method development from outside sources.

03

Attachment 3-2
Deficiency # 3

CCR# 6

LLNL HAZARDS CONTROL LABORATORY
Client Complaint Report

Directions: Complete report sign, date and take immediately to the Subject Matter Expert.

Client Name: Diana Larson / All ITHs Phone Number: 35468

L-Code: 382 Date of Complaint: 11.4.15

Describe Complaint:

The ITHs would prefer that samples are sent to the subcontract labs multiple times per week rather than once per week, as is current practice.

Signature: Diana Larson

Date: 8/3/16

Describe Corrective Actions:

The ALAB Technical Lead met with the ITHs & agreed that if the ITHs identify samples that can't wait until the send-out day that ALAB will send them out when they are submitted. This is now the current practice.

Review and Approval:

Approved by SME: [Signature]

Date: 8/3/16

Approved by QCC: [Signature]

Date: 8.3.16

Use additional pages as required.

Attachment 3-3
Detraency #3



Safety and General Laboratory Training Documentation Form
Analytical Laboratory (ALAB)
Analytical Services and Instrumentation

Trainee name: Jack Bennett

Laboratory Safety Training			
Item	Trainee	Trainer	Date
Personal Protective Equipment (PPE)			
Eye wash locations and usage			
Safety shower locations and usage			
Hood alarm locations and usage			
Emergency exits and assembly area			

General Laboratory Training			
Item	Trainee	Trainer	Date
Electronic pipettes			
Analytical balance, XS205, Mettler Toledo			
Analytical balance, AT261, Mettler Toledo			
Top loading balance, PM 4800, Mettler Toledo			
Quality Assurance Plan	JB	RH	8.3.16

Notes:

Re-training on QAP Section 6.9.8 Client Complaints

Deficiency 4

- 1) Statement of nonconformity
 - a. There is a Pb outlier (201506882, 5/4/15, 13.3% recovery) for which there is no record of any review made or action taken. (ISO 4.9.2 and 5.9.2)
- 2) Results of root cause analysis:
 - a. The primary analyst was interviewed. The analyst indicated that their understanding was that the QA Manager was responsible for review of lead recoveries. There was no evidence that the review occurred. Further investigation was impossible because the former QA Manager had retired.
- 3) Statement of Action:
 - a. We have programmed the instrument software to evaluate the % Recovery of the spike samples for lead paint. The recovery will be reviewed prior to release of the data.
- 4) Proof of commitment:
 - a. Attachment 4-1 is a screenshot of the instrument software changes.
- 5) Objective evidence of completion:
 - a. Attachment 4-2 is a copy of the reviewed instrument printout.

Attachment 4-1

Detecency #4

The screenshot displays the WinLab32 ICP Commission software interface, which is used for controlling and monitoring an ICP-MS system. The interface is divided into several main sections:

- Automated Analysis Control:** This panel shows the progress of sample analysis and provides buttons for 'Analyze All', 'Calibrate', 'Analyze Samples', and 'Repeat Sequence'. It includes a table listing sample sequences, locations, IDs, and their analysis status.
- Plasma Control:** This panel allows for manual control of the plasma system, including 'On/Off' buttons and various parameter sliders for flow rates and power.
- Sample Information Editor:** This panel provides details for the current sample, including the Batch ID (160729 Pb Part 1), Analyte Name (CPG), and Volume Units (mL). It also includes a 'File Description' field.
- Method Editor:** This panel shows the 'Analyte Concentrations Added to Recovery Check' table, which lists various analytes and their concentrations. A handwritten 'D4' with an arrow points to the first row of this table.
- Parameters That Vary By Sample:** This panel displays a detailed table of parameters for each sample, including Sample No., A/S Location, Sample ID, Inital Sample Wt, Sample Prep. Vol, Matrix Check, Analyte QC's Below, and Sample Units.

D4



Analyte	Conc. Units	Recovery Set 1	Recovery Set 2	Recovery Set 3	Recovery Set 4
Fe 253 535	mg/L				
Pb 228 353	mg/L	2			
As 208 215 AR	mg/L				
Al 306 113 AR	mg/L				
Fe 273 958 AR	mg/L				
Ti 334 940 AR	mg/L				
Ti 336 121	mg/L				

Sample No.	A/S Location	Sample ID	Inital Sample Wt	Sample Prep. Vol	Matrix Check Samples	Analyte QC's Below *	Sample Units	Wt.
1	15	130C0763	0.1379	50			wt% (percent)	g
2	16	SPM 2580	0.1044	50			wt% (percent)	g
3	17	130C2759	0.1038	50			wt% (percent)	g
4	18	130C0760	0.1027	50			wt% (percent)	g
5	19	130C0762	0.1033	50			wt% (percent)	g
6	20	201609979	0.1037	50			wt% (percent)	g
7	21	201609980	0.1045	50			wt% (percent)	g
8	22	201609987	0.1068	50			wt% (percent)	g
9	23	201609988	0.1096	50		2.6	wt% (percent)	g
10	24	201609989	0.1053	50			wt% (percent)	g
11	25	201609989_D	0.1062	50	Duplicate # 10		wt% (percent)	g
12	26	201609989_S	0.1049	50	Recovery 1 of 10		wt% (percent)	g
13	27	201609981_0	0.1059	50			wt% (percent)	g
14	28	201609981_1	0.0995	50			wt% (percent)	g
15	29	201609981_2	0.1079	50			wt% (percent)	g
16	30	201609981_3	0.1058	50			wt% (percent)	g
17	31	201609981_4	0.1049	50			wt% (percent)	g
18	32	201610045	0.105	50			wt% (percent)	g
19	33	201610045	0.1022	50		2.6	wt% (percent)	g
20	34	201610074	0.1019	50			wt% (percent)	g

Attachment 4-2 Deficiency #4

d: EnvPb Paint

Page 11

Date: 7/29/2016 11:31:44 AM

361.383	95.5	98.4	1.088	%	2.9
259.939	1.43	1.39	0.001	mg/L	2.4
220.353	0.0091	0.0101	0.002	mg/L	10.5
308.215 Alt	11.9	14.0	0.078	mg/L	16.5
336.121	1.099	1.473	0.016	mg/L	29.1

Sequence No.: 27
 Sample ID: 201609809 S
 Analyst: ICP6
 Initial Sample Wt: 0.1048 g
 Dilution:
 Wash Time: 20

Autosampler Location: 26
 Date Collected: 7/29/2016 11:26:31 AM
 Data Type: Original
 Initial Sample Vol:
 Sample Prep Vol: 50 mL
 Auto Dilution Factor: 1

Nebulizer Parameters: 201609809 S

Analyte	Back Pressure	Flow
All	199.0 kPa	0.60 L/min

Mean Data: 201609809 S

Analyte	Mean Corrected Intensity	Conc. Units	Calib. Units	Std.Dev.	Sample Conc. Units	Std.Dev.	RSD
Sc 361.383	688742.9	94.7	%	1.83			1.93%
Sc 361.383 Rad	23124.3	95.1	%	1.54			1.61%
Fe 259.939†	98316.6	1.71	mg/L	0.019	0.082 wt%	0.0009	1.12%
Pb 220.353†	5460.0	1.767	mg/L	0.0332	0.0843 wt%	0.00158	1.88%
Al 308.215 Alt†	128971.5	22.2	mg/L	0.36	1.06 wt%	0.017	1.63%
Al 396.153 Alt Rad†	25726.3	23.6	mg/L	0.04	1.13 wt%	0.002	0.17%
Fe 273.955 Alt Rad†	507.3	1.74	mg/L	0.000	0.083 wt%	0.0000	0.01%
Ti 334.940 Alt Rad†	4312.9	1.06	mg/L	0.011	0.051 wt%	0.0005	1.04%
Ti 336.121†	172804.7	1.052	mg/L	0.0261	0.050 wt%	0.0012	2.48%

Matrix Recovery Check: 201609809 S

Analyte	Expected Conc.	Measured Conc.	Std. Dev.	Units	Recovery (%)
Pb 220.353	2.009	1.767	0.033	mg/L	87.9

OK
h/h

Sequence No.: 28
 Sample ID: 201609810
 Analyst: ICP6
 Initial Sample Wt: 0.1069 g
 Dilution:
 Wash Time: 20

Autosampler Location: 27
 Date Collected: 7/29/2016 11:28:48 AM
 Data Type: Original
 Initial Sample Vol:
 Sample Prep Vol: 50 mL
 Auto Dilution Factor: 1

Nebulizer Parameters: 201609810

Analyte	Back Pressure	Flow
All	198.0 kPa	0.60 L/min

Mean Data: 201609810

Analyte	Mean Corrected Intensity	Conc. Units	Calib. Units	Std.Dev.	Sample Conc. Units	Std.Dev.	RSD
Sc 361.383	711424.1	97.9	%	0.66			0.68%
Sc 361.383 Rad	23953.9	98.5	%	0.68			0.69%
Fe 259.939†	58382.8	1.02	mg/L	0.000	0.048 wt%	0.0000	0.02%
Pb 220.353†	23.3	0.0075	mg/L	0.00185	0.0004 wt%	0.00009	24.50%
Al 308.215 Alt†	45358.8	7.82	mg/L	0.015	0.366 wt%	0.0007	0.19%
Al 396.153 Alt Rad†	9308.4	8.53	mg/L	0.374	0.399 wt%	0.0175	4.39%
Fe 273.955 Alt Rad†	291.4	1.00	mg/L	0.027	0.047 wt%	0.0012	2.67%
Ti 334.940 Alt Rad†	5339.5	1.32	mg/L	0.013	0.062 wt%	0.0006	0.95%
Ti 336.121†	209878.8	1.277	mg/L	0.0010	0.060 wt%	0.0000	0.08%

Sequence No.: 29
 Sample ID: 201609811
 Analyst: ICP6
 Initial Sample Wt: 0.0995 g
 Dilution:

Autosampler Location: 28
 Date Collected: 7/29/2016 11:31:44 AM
 Data Type: Original
 Initial Sample Vol:
 Sample Prep Vol: 50 mL

Deficiency 5

- 1) Statement of nonconformity
 - a. There are no records of effectiveness follow-up for corrective action. (ISO 4.11.4)
- 2) Results of root cause analysis:
 - a. Section 6.9.4 of the Quality Manual says "The LTL is responsible for determining if an extended condition investigation is required". That is unclear. Because of the lack of clarity, effectiveness follow-up was not performed.
- 3) Statement of action:
 - a. Section 6.9.4 of the Quality Manual was revised to clearly state the need for effectiveness follow-up.
- 4) Proof of commitment:
 - a. Attachment 5-1 shows the revised section of the Quality Manual in track changes.
- 5) Objective evidence of completion:
 - a. Attachment 5-2 is a NCR report with effectiveness follow-up.

Attachment 5-1 page 1 of 2
Deficiency # 5



6.8.4 Data Entry, Review

After completion of the analyses, the analyst reviews the analytical data. If no problems are evident, the analyst transmits the data to the ALIMS database.

6.8.5 Final Report

An approved final report is generated through ALIMS and signed or initialed by the LTL or designee. An e-mail with the report attached or an electronic report is sent to the requester. The final report lists the laboratory analytical method number and the reporting limit for each result.

If a correction is made to a report after the original has been sent to the requester, the requester is notified and sent a corrected report. The corrected report is identified as a supplement with a note identifying the original report. Copies of both the original report and the corrected report are kept with the data package for that set of samples.

6.8.6 Filing

All papers and documents relating to a particular sample batch are collated and filed in a hard-copy file.

Sample data is also retained in ALIMS files that are backed up daily.

The filing guidance and procedure is defined and described in WSH-IH-ALAB-PRO-13, Analytical Laboratory Document Control.

6.9 Control of Analytical Performance

6.9.1 Accuracy and Measurement Uncertainty

Accuracy and measurement uncertainty are determined using WSH-IH-ALAB-PRO-20, Control Charting and Uncertainty Estimation.

6.9.2 Quality Control

Quality control (QC) requirements are included in each procedure.

6.9.3 Nonconformance Reports

When quality control results are not acceptable, an NCR shall be initiated to determine the root cause(s) and to make appropriate corrections. NCRs for out of limits QC data may be generated by the ALIMS QC utility. When the NCR is not automatically generated, the ALIMS nonconformance utility shall be used to manually generate a nonconformance.

6.9.4 Investigation, Corrective, and Preventative Actions

A root cause(s) investigation shall be performed and the significance of the NCR shall be evaluated.



The investigation may include but not be limited to checks for calculation and data transfer errors, use of the correct method, aliquoting or dilution errors, incorrect instrument behavior, unusual sample behavior during processing, and other possible sources of error. The investigation may include a repeat of sample, blank, duplicate and/or spike analyses.

After the investigation is completed, the LTL shall select and implement the corrective action(s) most likely to eliminate a reoccurrence. Corrective actions shall be taken immediately.

~~The LTL is responsible for determining if an extended condition investigation is required. The QAC will review NCRs at least quarterly and determine if effectiveness follow-up is required for any particular NCR. If effectiveness follow-up is required, the results of the follow-up will be recorded on the NCR.~~

D5

6.9.5 Documentation

The results of the investigation shall be documented using the NCR form in ALIMS. The investigation includes a description of the root cause(s) of the out-of-control results, the corrective action(s) taken and the steps that shall be followed to prevent a reoccurrence of the out-of-control situation. A copy of the completed form shall be filed with the paperwork associated with the samples, and timely notification about the NCR will be made to the QAC.

6.9.6 Implementation and Monitoring of Corrective Actions

The LTL is responsible for implementation of corrective actions. The QAC is responsible for monitoring corrective actions.

6.9.7 Preventative Action

Preventative actions are proactive and initiated to prevent future NCRs. Corrective actions which prevent future NCRs are preventative actions. The preventative action may be in response to an NCR or observation. All ALAB team members shall seek opportunities for preventative action. Any possible preventative actions determined shall be communicated to the LTL. The LTL is responsible for selecting and implementing preventative actions. The QAC is responsible for monitoring preventative actions.

6.9.8 Client Complaints

Client complaints shall be documented on the Client Complaint form, Attachment 1. ~~The complaint shall be treated as an NCR.~~ The results of the investigation and the corrective actions shall be reported to the client in a timely manner.

Attachment 5-2 Deticiency #5

hcl282rr

NCR # : 10001728

NCR Dt: 28-JUN-16

NCR Initiator: BENNETT, JOHN T

Worklist Name: 160613143639

Sample #: 1111111

Batch #: 111111

NCR Action:

CLIENT CONTACTED LAB ABOUT ARSENIC IN FIELD BLANKS IN CASE 50071, AND REQUESTED LAB TO LOOK INTO IT.

NCR Cause:

THE FIELD BLANKS WERE RE-RUN AND THE ARSENIC WAS BELOW THE REPORTING LIMIT. LOOKED AT THE DATA FROM THE ORIGINAL RUN, AND THESE TWO SAMPLES WERE RUN AFTER A SAMPLE THAT HAD 340 PPM OF ARSENIC. CARRYOVER WAS THE LIKELY CAUSE OF THE ARSENIC DETECTIONS IN THE FIELD BLANKS. FURTHER REVIEW OF THE DATA SHOWED THAT THREE ADDITIONAL SAMPLES COULD HAVE SOME SLIGHT CARRYOVER. THEY ARE SAMPLES 201607802, 803 AND 804. THEY WILL BE RE-RUN

CAP Strt Dt:

CAP ID:

CAP Close Dt:

CAP Comnt:

REPORT RESULTS OF THE RE-RUNS IN A REVISED REPORT. IN THE FUTURE, ANY SAMPLES AFTER A SAMPLE WITH CONCENTRATIONS OF ANY ELEMENT OVER 50 PPM WILL BE REVIEWED FOR POTENTIAL CARRYOVER. IF THE SAMPLE FOLLOWING THE ELEVATED SAMPLE HAS OVER THE RL FOR THE OVERCAL ELEMENT, IT WILL BE RE-RUN TO VERIFY THE RESULT.

NCR Type:

QA Name : BENNETT, JOHN T

QA Aprv Dt: 28-JUN-16

QA Comnt:

AGREE

SME Name: BENNETT, JOHN T

SME Aprv Dt: 28-JUN-16

SME Comnt:

AGREE

Effectiveness Follow up:

Sample 201608803 had (C) above the calibration curve.
Sample 201608804, which was run just after the prior sample had (C) above the RL. It was re-run in the same batch with a similar result, confirming no carryover

JB 7/15/16

Deficiency 6

- 1) Statement of nonconformity;
 - a. The Lab's last completed internal audit report cites two (2) non-conformances for which there are no records of corrective action. (ISO 4.14.2 and 4.14.4)
- 2) Results of root cause analysis:
 - a. The ALAB QA Manager and Technical Manager who were responsible for the internal audit have retired and are not available for interview. A review of the quarterly report for the second quarter of 2015 showed the two deficiencies, however no NCR number was assigned for tracking purposes. Section 6.11.1 of the Quality Manual indicates that deficiencies found shall be documented as an NCR, but does not indicate who is responsible for performing the documentation.
- 3) Statement of action:
 - a. Section 6.11.1 of the Quality Manual was revised to clarify that the Quality Manager is responsible for initiating the NCR.
- 4) Proof of commitment:
 - a. A revision to the Quality Manual was created, and NCR's for the deficiencies were created.
- 5) Objective evidence of completion:
 - a. Attachment 6-1 shows the revised section of the Quality Manual in track changes.
 - b. Attachment 6-2 is NCR's created for the deficiencies.

Attachment 6-1

Deficiency #6



6.9.9 Continuous Improvement

The processes will be continuously improved using input from NCR causal analysis, assessment findings, lessons learned and review of updated guidance and method development from outside sources.

6.9.10 Performance Evaluation Samples

Performance evaluation (PE) samples shall be performed for all analyses where performance evaluation samples are available. Where not available, internally generated PE samples shall be used to evaluate performance.

6.10 Quality Assurance Reports

The QAC shall report quarterly to the IH Section Leader and the ALAB LTL on the state of quality in the laboratory. The reports shall as a minimum contain information on the following areas:

- The overall state of quality in the laboratory
- Procedural reviews and revisions Internal and External Reviews and Assessments
- Inter-laboratory comparisons
- Corrective actions
- Non conformances and resolutions

6.11 Audits/Reviews

6.11.1 Audits

The QAC is responsible for planning and coordinating annual internal audits. The program shall address all requirements of ISO 17025, AIHA-LAP, LLC and California, Environmental Laboratory Accreditation Program requirements.

Deficiencies found on the audits shall be documented as an NCR by the QAC. The LTL is responsible for performing corrective actions on audit findings on a timely basis. The QAC is responsible for verifying corrective actions are completed.

Internal assessments are conducted and documented according to the Institutional Procedure PRO 0053, Management Observations, Verifications, & Inspections (MOVI).

6.11.2 Management Reviews

The IH Section Leader shall conduct an annual review of the analytical activities. The review shall as a minimum include:

- Overall laboratory objectives

Db

Attachment Le-Z Deficiency #6 page 1 of 2

hcl282rr

NCR # : 10001761

NCR Dt: 03-AUG-16

NCR Initiator: BENNETT, JOHN T

Worklist Name: 11111

Sample #: 11111

Batch #: 11111

NCR Action:

2015 INTERNAL AUDIT DEFICIENCY 1 - SEVERAL PIPETS IN THE 548 LAB DID NOT HAVE "AS FOUND" VALUES ON THE CALIBRATION CERTIFICATES

NCR Cause:

"AS FOUND" TESTING WAS NOT REQUESTED.

CAP Strt Dt:

CAP ID:

CAP Close Dt:

CAP Comnt:

"AS FOUND" TESTING NOW REQUESTED AND IS ON THE CALIBRATION CERTIFICATES.

NCR Type:

QA Name : BENNETT, JOHN T

QA Aprv Dt: 03-AUG-16

QA Comnt:

AGREE

SME Name: BENNETT, JOHN T

SME Aprv Dt: 03-AUG-16

SME Comnt:

AGREE

Attachment 6-2 Deficiency #6 page 2 of 2

hcl282rr

NCR # : 10001762

NCR Dt: 03-AUG-16

NCR Initiator: BENNETT, JOHN T

Worklist Name: 11111

Sample #: 11111

Batch #: 1111

NCR Action:

2015 INTERNAL AUDIT DEFICIENCY 2 - NCR'S ARE NOT BEING GIVEN TO THE QAC IN A TIMELY FASHION; NCR DOCUMENTATION IS NOT INCLUDED WITH THE FINAL REPORTS AND CORRECTIVE ACTIONS MAY NOT BE PERFORMED IN A TIMELY FASHION

NCR Cause:

UNABLE TO INVESTIGATE BECAUSE THE ALAB TL AND QAC HAVE RETIRED.

CAP Strt Dt:

CAP ID:

CAP Close Dt:

CAP Comnt:

ADDED TIMELINESS REQUIREMENT TO SECTION 6.9.5 OF ALAB QAP; NCR FINAL REPORTS ARE NOW INCLUDED IN DATA PACKAGE, AND CORRECTIVE ACTIONS ARE PERFORMED IN A TIMELY FASHION.

NCR Type:

QA Name : BENNETT, JOHN T

QA Aprv Dt: 03-AUG-16

QA Comnt:

AGREE

SME Name: BENNETT, JOHN T

SME Aprv Dt: 03-AUG-16

SME Comnt:

AGREE

Deficiency 7

- 1) Statement of nonconformity:
 - a. There is no time-scale for the action items cited in the Lab's last management review report. (ISO 4.15.2)
- 2) Results of root cause analysis:
 - a. The management review was conducted according to the format used in prior years. The format did not have timelines established for action items, so no timelines were established for the calendar year 2015 management report. Section 2A4.15 (ISO 4.15.1) was reviewed to ensure that the necessary items were covered in the review, but Section 4.15.2 (which addresses timelines) was overlooked.
- 3) Statement of action:
 - a. Section 6.11.2 of the Quality Manual was revised to include that timelines for action items are required.
- 4) Proof of commitment:
 - a. Attachment 7-1 shows the revised section of the Quality Manual in track changes.
- 5) Objective evidence of completion:
 - a. Attachment 7-2 is a copy of the calendar year 2015 management review with timelines added.

Attachment 7-1 page 1 of 2
Deficiency #7



6.9.9 Continuous Improvement

The processes will be continuously improved using input from NCR causal analysis, assessment findings, lessons learned and review of updated guidance and method development from outside sources.

6.9.10 Performance Evaluation Samples

Performance evaluation (PE) samples shall be performed for all analyses where performance evaluation samples are available. Where not available, internally generated PE samples shall be used to evaluate performance.

6.10 Quality Assurance Reports

The QAC shall report quarterly to the IH Section Leader and the ALAB LTL on the state of quality in the laboratory. The reports shall as a minimum contain information on the following areas:

- The overall state of quality in the laboratory
- Procedural reviews and revisions Internal and External Reviews and Assessments
- Inter-laboratory comparisons
- Corrective actions
- Non conformances and resolutions

6.11 Audits/Reviews

6.11.1 Audits

The QAC is responsible for planning and coordinating annual internal audits. The program shall address all requirements of ISO 17025, AIHA-LAP, LLC and California, Environmental Laboratory Accreditation Program requirements.

Deficiencies found on the audits shall be documented as an NCR by the QAC. The LTL is responsible for performing corrective actions on audit findings on a timely basis. The QAC is responsible for verifying corrective actions are completed.

Internal assessments are conducted and documented according to the Institutional Procedure PRO 0053, Management Observations, Verifications, & Inspections (MOVI).

6.11.2 Management Reviews

The IH Section Leader shall conduct an annual review of the analytical activities. The review shall as a minimum include:

- Overall laboratory objectives

Attachment 7-1 page 2 of 2
Deficiency # 7



Activity-Level Quality Assurance Plan

WSH-IH-ALAB-DES-01
Revision 1
Page 16 of 26

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventative actions
- Assessments by external bodies
- The results of inter-laboratory comparisons or proficiency tests
- Changes in the volume of work
- Client feedback
- Complaints
- Other relevant factors, such as quality control activities, resources and staff training

Management assessments are conducted and documented according to the Institutional Procedure PRO 0053, Management Observations, Verifications, & Inspections (MOVI). **Any actions assigned as a result of the management review will have a completion date assigned.**

D7

6.12 Review and Revision

This plan and all procedures are to be reviewed annually by the QAC and the ALAB LTL for the continued applicability and correctness of contents, and for necessary additions. If any changes are made, a revision is issued. The revision shall show the date and revision number on the title page and on each subsequent page. A copy of the superseded document is maintained in the obsolete procedure file.

6.13 Waste Handling and Minimization

6.13.1 Waste Handling

Waste handling shall comply with all applicable environmental, safety, and LLNL requirements.

6.13.2 Waste Minimization

ALAB waste is minimized since generally no more chemicals and reagents are used than is necessary to perform the required analyses.

Analytical procedures are chosen to minimize chemical usage and waste.

6.14 Service to Clients

Clients are encouraged to visit the laboratory and are assisted in interpretation of data.

Attachment 7-2 page 1 of 5
Deficiency #7

Annual Management Review Report January to December 2015 (Revision 1)

Date: 4/18/16

Attendees: Jack Bennett (organizer), Diana Larson, Michele Sundsmo, Jim Merrigan, Ruth Harding

- 1 Safety:
 - a. There are no known pending safety issues in the ALAB.
 - b. Ergonomic status- last evaluation of ALAB staff working in the lab was performed on 5/20/2014 and new chairs were ordered. Do we need/want to schedule another ergonomic evaluation? Typically done every three years, so put it on the list for next year.
- 2 Open items from previous management reviews:
 - a. A copy of the meeting minutes from the 2015 management review is attached (Appendix A). There was one action item from that meeting, which was to update the Quality Manual with a definition for "timely" in reference to the completion of NCR's. That was not completed.
- 3 Customer related issues:
 - a. Complaints:
 - i. The IH's would prefer that samples are sent to the subcontract labs multiple times per week rather than once per week, as is current practice. The ALAB Technical Manager met with the IH's and agreed that if the IH's identify samples that can't wait until the send-out day that ALAB will send them out when they are submitted.
 - b. New requirements:
 - i. None.
- 4 Internal or external audit reports completed during the review period:
 - a. Annual internal assessment (2015)
 - i. Two Findings: Pipettes not being calibrated properly (no certificates) and NCRs not being evaluated in a timely manner. A pipette send out schedule was developed and an NCR policy will be developed by the ALAB Technical Lead and the QA Manager. A copy of the report is attached (Appendix B).
 - b. AIHA External Assessment.
 - i. Next assessment will be in July 2016. Compliance to response of findings from 2014 audit will be reviewed in Q2 of calendar year (CY) 2016.

Attachment 7-2 page 2 of 5
Outreach # 7

5 Quarterly Reports:

- a. The quarterly reports are attached (Appendix C). The format should be reviewed to determine if it can be made more useful or if the current format is adequate.

6 Review of PT Results (Appendix D):

- a. The IHPAT had "Acceptable" ratings on all four rounds. The data appeared to be approximately normally distributed in three rounds, but had a negative distribution to the data in the fourth round.
- b. The BePAT had "Acceptable" ratings in all four rounds. The data had a slightly high data distribution, but all results were within 10% of the acceptable value.
- c. The ELPAT – Lead in Air had "Acceptable" ratings in all four rounds. The results had a slightly negative data distribution in all the rounds.
- d. The ELPAT – Paint and Dust had "Acceptable" ratings in three rounds, and a "Not Acceptable" rating in one round. The "Not Acceptable" rating was caused by LLNL not submitting data. Investigation showed that the receiving department sent the PT samples back because they were addressed to Rohit. An NCR was not generated for this. The Paint results generally had a negative data distribution.
- e. The cause of the negative data distribution for lead in paint and air should be investigated.

7 Status of processes:

- a. Summary review of non-conformances and corrective actions
 - i. Non-conformances not being evaluated in a timely manner is a major problem. There was discussion about ways to track NCR's better (e.g. manual entry into ALIMS, spreadsheet, ITS). Jack will show Ruth the tracking report in ALIMS.
 - ii. Review of the non-conformances revealed several trends, which are listed below.
 - i) There were multiple instances of QC unknowns being out of criteria, with the cause being identified as a problem preparing the QC unknown.
 - ii) There were multiple instances of QC limits in ALIMS not being updated.
 - iii. QA should review what is considered to be a non-conformance and provide training to the lab, especially for instances where the non-conformance reports are not automatically generated by ALIMS.
- b. Resolution of outstanding corrective actions that require management intervention
 - i. Non-conformances not being routed in a timely manner

- i) QA should meet with ALAB staff to determine current process flow, and discuss ways to improve processes and/or timeframes for completion of each step.
- c. Decisions related to corrective actions requiring significant resources
 - i. None
- d. Preventative Actions
 - i. No evidence of preventative actions taken during the review period.

8 Training:

- a. Training files for ALAB personnel are inconsistent in content required by the current training SOP. QA will review the files to attempt to bring them up-to-date and will also review the SOP to see if it needs to be updated. There was significant discussion on remediation strategies, including development of a memorandum to include in the training file for tests where the records can't be reconstructed. Subsequent to this meeting, the ALAB Technical Manager and the ALAB QA Manager met and decided on the following changes to the training requirements:
 - i. There is data in the laboratory from as far back as 2013, so those records will be used to reconstruct the training file. Data from PT challenges and routine operations will be used.
 - ii. The Environmental Lead Program has specific training requirements which will be followed.
 - iii. All other training for analytical testing will have these general requirements (based on National Environmental Laboratory Accreditation Conference Standards), which will be fleshed out in the revision to the SOP:
 - i) After initial training, the analyst will perform an independent run consisting of four spiked samples.
 - ii) The results of the analysis, calculated as % recovery, will be compared to pre-established recovery limits (to verify accuracy) and pre-established RPD limits (to verify precision).
 - iii) The QA manager will document that the analyst has met those criteria, and will provide the analyst with the documentation for inclusion in their training records.
 - iv) Continuing demonstration of competence data will be evaluated every six months using data from routine QC sample analysis.

9 Equipment issues:

- a. Performance or downtime issues: None

Attachment 7-2 page 4 of 5
Deficiency #7

- b. Maintenance: all maintenance is being performed on time. All major instruments have service contracts.
- c. Replacement of existing equipment: One centrifuge was replaced because of concern that the motor bearing was exhibiting symptoms of wear.
- d. New equipment requirements:
 - i. No new analytical equipment is required, however one ICP is approaching 10 years old.
 - ii. ALIMS is ageing, and a path forward should be considered. An ALIMS replacement project should get onto Steve Harris's list for requested equipment funding.

10 Quality Policies and Objectives:

- a. The quality policy and objectives have not changed.
- b. Even though the Quality Manual is updated annually, it should be reviewed to see if it is fit for purpose and needs revision
- c. The format of this report should be reviewed to determine if it can be made more useful or if the current format is adequate.

11 Changes in work volume and type of work:

- a. ALAB received about 19,000 samples in 2015. The mix of work was consistent with past years.

12 Allocation of resources for the organization being reviewed:

- a. Resources are adequate

13 Assessment of whether scope, objectives, and targets should be adjusted:

- a. There was discussion about whether ALAB (and RML) should continue to perform radiochemistry testing for the sewer shack.
- b. ALAB scope needs to be spelled out in the quality manual. Use institutional documents as a starting point for content as well as formatting. Also make quality manual language mirror new Bioassay Lab and other AS&I quality plans for consistency throughout the program.

14 Procedure reviews:

- a. All SOP's are within review dates, with several being updated and/or revised in the past year.
- b. Several SOP's should be considered for revision for clarity and to enhance quality control sections (e.g. add acceptance criteria for all QC samples). Focus on revising administrative SOPs (e.g. training, quality manual) first.

Attachment 7-2 page 5 of 5
Deficiency # 7

- c. ALAB should investigate changing its lead wipe procedure from using Pace Wipes to Ghost Wipes to improve laboratory efficiency.

15 Overall Laboratory Objectives:

- a. There are no significant changes in the overall laboratory objectives.

16 Assignment of actions:

07

- a. Diana to see if she can find the 2015 Management Review Report. (completed)
- b. Jack to show Ruth the ALIMS NCR tracking report. (by 5/15/16) (completed)
- c. Michele to provide copy of memo about "grandfathered" training used for DOECAP. (by 7/1/16) (completed)
- d. Michele to continue discussions with appropriate people about radiochemistry testing. (by 9/30/16) (completed)
- e. Jack and Ruth to develop update to training requirements. (completed)
- f. Jack to update training SOP. (currently in draft form) (by 6/30/16) (completed)
- g. Ruth and Jack to improve capture of different types of NCR's and have discussions with ALAB staff. Ruth also to talk to Lori about this. Lori said to talk to Dave Hickman about how he captures NCR tracking within his meeting minutes. (by 11/4/16)
- h. Jack to see if he can find contact information for Russ Stimmel. Russ's cell phone number is 925-321-1898, Ruth spoke to him and he plans to retain the number and is willing to help with problems. Ruth asked Russ about the training records, and there are not any more records that we haven't already found. (completed)
- i. Jack to write up an NCR detailing the training records deficiency and the path forward. (completed) (Appendix E)
- j. Michele needs to put an ALIMS replacement onto Steve Harris's list for when equipment funding becomes available. (by 7/30/16) (completed, actually talked to Frances Alston)


8/3/16

Laboratory: LLNL ASI		Laboratory ID: 101757		
Site Assessor: Steve Lerman		Site Assessment Dates: 7/12-14/2016		
AIHA-LAP, LLC Policy Module Reference	ISO/IEC 17025: 2005 Reference	Suggestion	#	Response
2A.4.2.1	4.2.2	The Lab should add a Table of Contents to its Quality Manual.	1	The Lab agrees and will add a table of contents to the QM.
	4.3.2.1	The Lab's document management system does not organize external documents well. They should improve this system so that it harmonizes with the way they organize internal documents.	2	The Lab will investigate ways to accomplish this.
	4.3.2.1	The Lab has a Master Document List in a spread-sheet. They also have a web page index. The web page index appears to make the spread-sheet unnecessary. The Lab should consider whether they need to maintain the spread-sheet.	3	The Lab is in the process of transitioning to a new document management system. As the transition occurs, we will evaluate if the new system will be able to serve as the Master Document list.
	4.6.1	The Lab's Quality Manual mentions that Reference Material Producers must have ISO 17025 accreditation. It should say ISO 17034 accreditation.	4	The Lab will make that change.
	4.6.1	SOP WSH-IH-ALAB-PRO-16 on procurement focuses on reagents and standards. They should also include more on other consumables and supplies.	5	The Lab will consider this during the next SOP update.
	4.6.4	The Lab's Approved Vendor List mentions ISO certification for various vendors, but does not state specifically which certification (ISO 9001, ISO 17025, ISO 17034, ISO 17043). It should.	6	This has been implemented.
	4.7.2	The Lab seeks feedback from clients(Field IH staff) at weekly IHmeetings, but this is an informal process. The Lab should formalize this process, and keep better records on the feedback.	7	The Lab has asked the IH Section Leader to periodically put "Feedback for Lab" as an agenda item for the weekly IH meeting.
	4.11.1	QM 6.9.4 states that all OOT results and complaints be treated as non-conformances. This may be excessively severe and be taking up too much time. The Lab should evaluate the merit of this policy.	8	The Lab agrees, and has removed the requirement that complaints are treated as NCRs from the QM. OOTs are currently captured as NCRs by the LIMS system, but will be marked as OOTs in the quarterly QC report.
	4.11.3	The Lab's root-causes as recorded in their CARs are somewhat superficial. The Lab should dig deeper into these issues to better determine true root cause.	9	The QA Manager will take training on root cause analysis and help the Lab develop a better understanding of the process.
	4.12.1	The Lab records preventive action opportunities informally in a Lab notebook. They should formalize this process and record more details of these activities.	10	The Lab will now use one page per opportunity to leave space for added information.
2A.4.14.2	4.14.1	The Lab's internal audit for 2015 used the AIHA R11 checklist. The 2016 audit is using the R14 checklist. The Lab should be very attentive to this issue so that it does not happen again in the future.	11	The Lab agrees and will make sure to use the proper version of the checklist.
	4.15.2	Some of the Lab's management review action items are more like tasks and don't address improvement or effectiveness. The Lab should look to make these items more relevant to improvement.	12	The Lab will consider this suggestion.
App. H, 5.8		The Lab's procedure for calibration should have more detail regarding scheduling, what equipment is being calibrated, and how to handle an as-found OOT.	13	The Lab will consider this suggestion.
	5.10.2k	The Lab has decided that a statement on test reports to the effect that the results relate only to the items tested is not relevant to their test reports. They may want to re-think this decision.	14	The Lab will discuss this with the LIMS support group.