Department of Energy

Idaho Operations Office
1955 Fremont Ave.
Idaho Falls, Idaho 83415

June 4, 2013

Mr. Ted Carter
U. S. Nuclear Regulatory Commission
Office of Nuclear Materials Security and Safeguards
MS T-7-F-27 TWFN
Washington, D. C. 20555

SUBJECT: Transmittal of 2013 Audit Report for the ORISE Laboratory (IS-RESL-13-055)

Dear Mr. Carter:

Please find enclosed the report of the May 14-15, 2013, Audit of the ORISE Laboratory. This report has been prepared as a deliverable under JCN J5142 Task 2.

The Audit Team concludes that except where noted, the programmatic and technical components of the ORISE Laboratory quality assurance program are generally quite effective. Specific Findings and Observations are detailed in the enclosure.

Please contact me at (208) 526-0784 if you have any questions regarding the report or if you need any additional information.

Sincerely,

Steven Bohrer
Audit Team Leader

Enclosure

cc: Wade Ivey, ORISE
Sarah Roberts, ORISE
Ann Payne, ORISE

Nuclear Regulatory Commission
Radiological Measurements Assurance Program

Audit Report for
Oak Ridge Institute for Science and Education
ORISE

May 14-15, 2013

Steven Bohrer
Lead Technical Auditor
Radiological and Environmental Sciences Laboratory
Idaho Operations Office
U.S Department of Energy
Idaho Falls, Idaho

Audit Scope:
The quality audit of the Oak Ridge Institute for Science and Education (ORISE) was performed in accordance with the audit plan submitted and referenced in the April 16, 2013 letter to ORISE.

The following documents were evaluated during the audit:

- Quality Program Manual for the Independent Environmental Assessment and Verification (IEAV) Program
- Laboratory Procedures Manual for ORISE/IEAV
- The content of various project files maintained by ORISE/IEAV to store sampling information, raw analytical data and measurement results reported to the U.S. Nuclear Regulatory Commission and other customers
- Training files of ORISE/IEAV personnel who performed that work
- Records of controlled document distributions
- Revisions to specific ORISE/IEAV quality assurance and technical procedures
- Review comments of those procedures made by ORISE/IEAV personnel
- ORISE/IEAV sample storage locations
- Assigned hard copy ORISE/IEAV Laboratory Manuals.
- Electronic procedure manuals (iPad).

This quality audit evaluated both the ORISE quality assurance and technical systems for conformance to established quality requirements and the effectiveness of implementation. Measurement systems were evaluated based on their ability to produce technically valid data.

During the audit, the audit team considered how the quality requirements specified in the current revision of the *ORISE/IEAV Quality Program Manual* are reflected in the *ORISE/IEAV Laboratory Procedures Manual* and in other appropriate ORISE implementing procedures. Additionally, the assessment team evaluated how effective the implementation of the ORISE quality program has been in producing quality data.

The technical portion of the audit focused on laboratory implementation of the ORISE/IEAV quality program, the ORISE/IEAV Laboratory Procedures Manual and the technical adequacy of the work processes being performed, and included the following:

- Implementation of corrective actions for the deficiencies identified previously by the quality audit performed May 15-16, 2012.

- An evaluation and discussion of the performance of ORISE/IEAV on recent external Performance Evaluation (PE) programs;

- Preparation, storage and use of standard solutions and other solutions that affect the quality of the result;

- Use, knowledge, adherence to and implementation of written procedures;

- A comparison of the steps in the written procedures describing the work with the steps of the processes actually being performed in the laboratory;

- Evaluation of calibrations and other quality indicators associated with the instrumentation used in the laboratory;

- An evaluation of the training and knowledge of staff relative to their duties.

Personnel Contacted:
From ORISE/IEAV: Dale Condra, Ann Templon, Paige Benton, John Cox, Roxanne Nagle, Wade Ivey, and Forrest Smith.

Audit Performance and Conditions Observed:
Each item of the audit checklist was evaluated to be either satisfactory, a deficiency or finding, or an observation. The specific evaluations of the pertinent checklist items are detailed in the narrative summary. Noteworthy conditions are indicated as such.

Audit Reporting and Conclusions:
General conclusions from the audit are described in the Executive Summary. Detailed explanations of the specific findings, observations and noteworthy practices observed during the audit for each of the major quality assurance areas are described in the narrative summary. The executive and narrative summaries provide the audit sponsor and the ORISE laboratory personnel with the essential audit results.

Audit Checklist Basis:
This audit checklist is based on the *ORISE Quality Assurance Manual for the Environmental Survey and Site Assessment Program Rev. 20* dated September 1, 2007. This checklist and audit plan were approved for use by the audit sponsor: Office of Nuclear Materials Safety and Safeguards, Division of Waste Management, NRC Technical Monitor.

Audit Requirements Documents:

- *ORISE/IEAV Quality Program Manual*
- *ORISE/IEAV Laboratory Procedures Manual*

Instructions for the Laboratory:
Please address each deficiency (finding) documented by the audit team and reference each deficiency by assigned number. Please respond in writing to the audit team lead within 30 days from the date of receipt of the formal audit report. The observations listed do not need to be addressed by the laboratory. However, they may be the subject of further evaluation on subsequent audits.

Audit Team:

Steven Bohrer	Team Lead / Technical
Shane Steidley	Technical
Donald Warner	Programmatic / QA

Executive Summary:

One Finding, three Observations, and three Noteworthy Practices were identified during the 2013 audit.

The audit team verified the effective implementation of corrective actions for the Findings and Observations identified during the 2012 audit.

The laboratory performed within acceptance limits on nearly all Intercomparison Test Program (ITP) results submitted for the year. For those results outside of acceptance limits, the audit team verified that corrective actions were developed and implemented. The laboratory continues to perform well on Mixed Analyte Performance Evaluation Program (MAPEP) samples.

On-Site Assessment Narrative Summary

Finding 2013-1: Procedure QCP1 defines the requirements for analysts to be qualified to perform analytical procedures. The QPM Sec. 3, 4.4.2 states "Training must be completed before a procedure is performed for direct project activities." The individual analyst certification files contain up to date qualification data and signatures for the Analytical Procedures (APs) the analysts are authorized to perform. There are no defined criteria for a staff member to be qualified to perform the Quality Control Procedures (QCPs) and Sample Preparation (SPs) procedures. There are also no records of which staff members are authorized to perform the QCPs and SPs.

Observation 2013-1: QCP3 and CP2 have been revised to address U-232 ingrowth in the Pu-236 tracer. However, there is no requirement to update the correction factor on a periodic basis.

Observation 2013-2: IEAV chemists have been working with the AP-11 procedure to include curium. As of this date, the procedure has not been updated to include the minor modifications to the current procedure.

Observation 2013-3: The audit team recommends that a review of the NRC Scope of Work is included in the internal assessment schedule.

Noteworthy Practice: The IEAV staff has made a considerable effort to compile crosswalks between their procedures and other quality standards, such as NQA-1, and DOE QSAS.

Noteworthy Practice: The IEAV staff has prepared special checklists for use during the reporting of proficiency testing results. The spreadsheets include expected values, nuclides, activity ranges, etc. which are useful in identifying data that may be erroneous due to typographical or other errors.

Noteworthy Practice: IEAV staff has begun including a revision history at the end of procedure documents. Revisions have been marked in the past, but the revision history gives context and further information regarding the reasons for the changes.