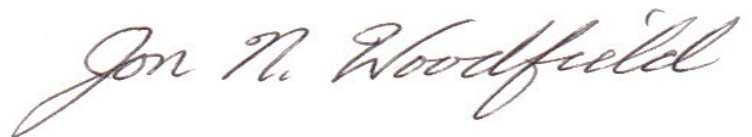


U.S. NUCLEAR REGULATORY COMMISSION STAFF OBSERVATION OF THE
CALENDAR YEAR 2022 GEOSCIENCES AND ENGINEERING DEPARTMENT
QUALITY ASSURANCE AUDIT, GED 2022-1

OBSERVATION AUDIT REPORT NO.: OAR-22-01

A handwritten signature in cursive script that reads "Jon N. Woodfield".

Jon Woodfield, Primary Observer
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Enclosure

1.0 INTRODUCTION

The Geosciences and Engineering Department (GED), formally known as the Center for Nuclear Waste Regulatory Analyses (CNWRA), of the Southwest Research Institute (SwRI) provides technical support to the U.S. Nuclear Regulatory Commission (NRC) staff through current NRC Charter Contract 31310018D0001 and Work-For-Others (WFO) Contract 31310018D0002. These Contracts require GED to meet the quality assurance (QA) requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities;" Part 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada;" Part 71, "Packaging and Transportation of Radioactive Material;" and Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste." On December 6-7, 2022, QA auditors and technical specialists from SwRI (auditors) conducted the audit GED 2022-1 of two NRC funded projects performed by GED in San Antonio, Texas. An NRC staff member (observer) from the Office of Nuclear Material Safety and Safeguards (NMSS) observed the whole audit virtually and was the primary observer. Other NRC staff observed virtually only parts of the audit sessions. The GED held a post-audit virtual meeting with the auditors, NRC primary observer, NRC Contracting staff for the two contracts, and other NRC staff on December 8, 2022.

The scope of the audit was to evaluate the GED QA program to determine whether it meets contractually mandated QA program requirements and is being effectively implemented for NRC sponsored activities by the GED. The objective of the NRC primary observer was to evaluate the effectiveness of the audit process and the implementation of the GED QA program.

Details of the audit are available in the January 3, 2023, SwRI report for GED, "Quality Assurance Audit Report for Geosciences and Engineering Department Audit, GED 2022-1" (Agencywide Documents Access and Management System [ADAMS] ML23017A148).

2.0 MANAGEMENT SUMMARY

The auditors evaluated the adequacy of applicable QA program elements and two technical tasks during this full-scope audit. During the audit, the auditors identified one minor nonconformance and four recommendations for improvements (see Section 9.0, Results). The primary observer verified that the auditors were qualified and independent of the activities and technical areas they audited.

The auditors determined that: (1) the GED QA program continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities; (2) the GED staff continues to operate in accordance with the GED Quality Assurance Manual, contracts, task-orders, project plans, technical operating procedures, QA procedures, and applicable administrative procedures; and (3) the technical staff was appropriately qualified through education, experience, and training with the technical work executed in a satisfactory manner.

The primary observer concluded that the audit process was well-planned, thorough, effective, and performed in a professional manner. The auditors developed and used audit checklists that were comprehensive and effective in providing guidance to the auditors. The Audit Team Leader provided ample opportunities for the primary observer to provide comments and ask questions throughout the audit process. The auditors and primary observer discussed potential findings with GED management during caucuses, audit debriefs, and at the post-audit meeting.

The primary observer determined that the audit achieved its objectives of evaluating the GED QA program to verify that it met applicable requirements and was effectively implemented. The primary observer determined that the audit was effective in reviewing, evaluating, and determining compliance with procedural requirements in the areas controlled by the QA program. The primary observer agreed with the auditors' conclusion that the QA program was effectively implemented.

3.0 PARTICIPANTS

3.1 Auditors

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|---------------|---|
| Colby Tate | Institute Quality Systems (IQS) – Audit Team Leader |
| Mark Ehnstrom | IQS – QA Auditor |
| Ross Cantu | IQS – QA Auditor |

3.2 Technical Specialists

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|------------------|---|
| Dave Turner, PhD | Environmental Assessment Saint Mary's University, San Antonio, Texas |
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| Biswajit Dasgupta, PhD | Geomechanics Engineering SwRI, San Antonio, Texas |
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3.3 NRC Observers

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| Jon Woodfield | Primary observer (NMSS/Division of Fuel Management/Inspection and Oversight Branch Inspector) |
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4.0 REVIEW OF AUDIT AND AUDITED ORGANIZATION

The GED provides technical support to NRC staff under NRC Contracts 31310018D0001 and 31310018D0002. These contracts require GED to meet the QA requirements of 10 CFR Parts 50, 63, 71, and 72. GED had the audit performed to determine whether its QA program meets contractually mandated QA program requirements and was effectively implemented for NRC sponsored activities at the GED. The primary observer evaluated the conduct of the audit to determine the adequacy of the audit process and the effectiveness of the QA program implementation. The auditors performed the audit following GED Quality Assurance Procedure 11 (QAP-011), "Audits." The observer evaluated the audit using the guidance of NRC Inspection Manual Chapter 2410, "Conduct of Observation Audits."

5.0 SCOPE OF AUDIT

The GED audit was both compliance and performance based. The auditors reviewed selected QA program elements to determine compliance with applicable procedures. The audit was also performance based in that the auditors reviewed completed technical products to determine compliance with GED QA control processes and procedures. GED risk-informed its selection of the technical topics for the audit based on the time since the previous audit of the areas and the importance of the activity, particularly regarding risk insights. The primary observer determined that the auditors achieved the audit scope.

6.0 CONDUCT AND TIMING OF THE AUDIT

The primary observer determined that the auditors were thorough, effective, and performed in a professional manner. The primary observer determined that the timing, length, and application of resources to complete this audit were appropriate for the current level and type of activities performed by GED under the NRC contract. The primary observer also determined that the auditors achieved the purpose of the audit.

7.0 AUDIT TEAM QUALIFICATION AND INDEPENDENCE

The audit team was composed of an Audit Team Leader, two additional QA auditors, and two technical specialists. The primary observer found the qualifications of the auditors to be acceptable and in compliance with the GED QA program. The primary observer also found the auditors to be independent of the activities they reviewed.

8.0 AREAS OF EXAMINATION

8.1 QA Elements

The auditors evaluated the following QA programmatic elements:

| <u>QA Programmatic Elements</u> | <u>Corresponding QA Manual* Chapter</u> |
|--|---|
| Organization | 1 |
| QA Program | 2 |
| Design Control | ** |
| Scientific/Engineering Investigation and Analysis Control | 3 |
| Procurement Document Control | 4 |
| Instructions, Procedures, and Drawings | 5 |
| Document Control | 6 |
| Procurement Control | 7 |
| Identification and Control of Items, Software, and Samples | 8 |
| Control of Processes | 9 |
| Inspection | 10 |
| Test Control | 11 |
| Control of Measuring and Test Equipment | 12 |
| Handling, Storage, and Shipping | 13 |
| Inspection and Test Status | 14 |
| Nonconformance Control | 15 |
| Corrective Action | 16 |
| Records Control | 17 |
| Audits | 18 |

*QAM - GED *Quality Assurance Manual*

**GED does not perform design-related activities.

The auditors addressed all the QA Manual chapters during the audit except for Design Control. The auditors used checklists during the audit for the assessment of the QA programmatic and technical elements. The auditors reviewed and evaluated material and documentation related

to the QA programmatic and technical elements and interviewed responsible personnel to determine the effectiveness of implementing procedures and technical processes.

8.2 Technical Activities

The auditors selected the technical products for the audit based on the level of activity, technical and programmatic risks involved, and the time since each technical area was last audited. The auditors evaluated the following technical products:

- Technical Assistance on DOE Non-HLW Determinations - Experimental Program
The objective of this task area is to provide NMSS with Technical Assistance for the Review of the U.S. Department of Energy's (DOE) Non-High-Level Waste (Non-HLW) Determinations. Specifically, the Task Area 3, Subtask 1 (23700.04.020) project is focused on conducting laboratory experiments that independently evaluate performance aspects of waste forms proposed by DOE for tank cleanup activities at the Savannah River Site in South Carolina. (Task Order 31310018F0077 Under NRC Contract 31310018D0001) (GED Project 23700.04)
- Seismic Liquefaction Model Development
The objective of this task order is to provide the NRC Office of Nuclear Regulatory Research and the U.S. Bureau of Reclamation with technical assistance for the development of new models relating to triggering seismic liquefaction. Specifically, task area 2c is focused on the status report of the next generation liquefaction case history database, Task 4, a technical letter documenting preliminary probabilistic liquefaction models, and Task 5b focusing on the effects of overburden and initial static shear stresses on liquefaction. (Task Order 31310019F0030 Under NRC Contract 31310018D0002) (GED Project 24009)

The auditors used a performance-based approach to evaluate the effectiveness of the QA program in ensuring product quality. The auditors implemented the performance-based approach by using sub-teams of technical specialists and QA auditors who evaluated activities from their individual technical perspectives and evaluated implementation of procedures and plans associated with product development.

9.0 RESULTS

The results (findings) of the 2021 CNWRA annual audit (Report CNWRA 2021-1) were reviewed by a member of the 2022 audit team prior to the 2022 audit under follow-up Southwest Research Institute Surveillance Report 2022-SR-0312, approved November 2, 2022. There were two good practices and four recommendations for improvements identified during the 2021 audit. It was documented in Surveillance Report 2022-SR-0312 that the four recommendations had been closed since the 2021 audit with no 2022 audit follow-up action required. Preventive Action Requests (PARs) 2021-PAR-0159, 2021-PAR-0160, 2021-PAR-0161, and 2021-PAR-0162 written to address the 2021 audit recommendations were found to be adequately closed.

For the GED 2022-1 audit as listed below, the auditors identified one minor nonconformance and four recommendations for improvement.

The minor nonconformance identified by the auditors was:

- Programmatic

Information from Form QA-016 is not being entered into the Electronic Record Library (ERL) per QAP-012, *Quality Assurance Records Control*, section 3.4.5. (Reference Nonconformance Report 2022-NCR-0659 written to address the issue)

The four recommendations for improvements identified by the auditors are:

- Programmatic

Recommendation 1: The division should evaluate keeping initial training records in the Division 01 electronic training system for ease of access. [Reference Preventive Action Request [PAR] 2022-PAR-0141. Note: This PAR was incorrectly identified as 2022-PAR-0144 in the SwRI GED 2022-1 Audit Report (ML23017A148)]

- 23700.04.032 Technical Assistance on DOE Non-HLW Determinations-Experimental Program

Recommendation 2: GED should document key vertical technical decisions made along with personnel involved and the date. (Reference 2022-PAR-0142)

Recommendation 3: Notebook 1321E should be updated to reference notebook 1320. (Reference 2022-PAR-0143)

- 24009 Seismic Liquefaction Model Development

Recommendation 4: The introduction paragraph for reports should contain more detail to prepare the reader as to content (i.e., executive summary). (Reference 2022-PAR-0144)

The auditors determined that the QA program applied by the GED continues to be adequate and effectively implemented and the recommendations identified provide opportunities for improvements which may reduce the potential to adversely affect products in the future or enhance the products.

10.0 NRC STAFF FINDINGS/CONCLUSIONS

The NRC observer concluded that the audit process was well-planned, thorough, effective, and performed in a professional manner. The NRC observer also concluded that the auditors developed and used audit checklists that were comprehensive and effective in providing guidance to the auditors. The SwRI Audit Team Leader provided ample opportunities for the NRC staff to provide comments and ask questions throughout the audit process. The auditors and NRC observers discussed findings with GED management during the post-audit meeting.

The NRC observers determined that the audit achieved its objectives of evaluating the GED QA program to verify that it met applicable requirements and was effectively implemented. The NRC observers determined that the audit was effective in reviewing, evaluating, and determining compliance with procedural requirements in the areas controlled by the QA program. The NRC observers agreed with the auditors' conclusion that the QA program was effectively implemented.