



SOUTHWEST RESEARCH INSTITUTE

QUALITY ASSURANCE AUDIT REPORT

For

GEOSCIENCES AND ENGINEERING DIVISION CONSOLIDATED AUDIT, GED 2016-1

November 29 – December 1, 2016

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EXECUTIVE SUMMARY

The annual internal quality assurance (QA) audit for the Geosciences and Engineering Division (GED) was performed November 29 - December 1, 2016. The audit team, comprised of technical specialists and QA auditors, determined that the GED QA program continues to be effectively implemented and provides adequate controls over technical product development and related quality affecting activities. U.S. Nuclear Regulatory Commission (NRC) representative observed the audit.

The GED staff continues to operate in accordance with the GED *Quality Assurance Manual* (QAM), operations plans, technical operating procedures (TOPs), QA procedures (QAPs), and applicable administrative procedures (APs). The technical staff was judged to be appropriately qualified through education, experience, and training. The technical work was determined to have been executed in a satisfactory manner.

The results of the audit were discussed with the GED management and staff as well as with the NRC representative during the post-audit meeting held on December 1, 2016. Two (2) open minor nonconformances and one (1) minor nonconformance corrected during the audit (CDA) were identified. All findings were issued in the SwRI® Quality Reporting System (QRS). The nature of the nonconformances identified was determined by the audit team to pose minimal risk to the quality of GED products. In addition, six (6) recommendations were identified that may provide opportunities for the improvement of the GED quality program and technical products.

1.0 AUDIT SCOPE

This internal audit evaluated the Geosciences and Engineering Division (GED) quality assurance program to determine whether it meets contractually mandated QA program requirements and is being effectively implemented. This included an evaluation of the Nuclear Regulatory Commission (NRC) sponsored activities of the Center for Nuclear Waste Regulatory Analyses (CNWRA®). This was a full-scope audit in which all QA program elements applicable were evaluated and three (3) technical tasks with associated reports were audited. In addition, the corrective action process was reviewed to determine its effectiveness.

2.0 PROGRAMMATIC ELEMENTS AUDITED

QA Program Criteria	Corresponding QAM* Chapter
Organization	1
Quality Assurance Program	2
Design Control	Not Applicable
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

Design-related activities are not performed by CNWRA®; therefore, design control requirements are not applicable. All other QAM sections were addressed in the audit.

3.0 AUDIT APPROACH

A performance-based approach to auditing was accomplished to the extent possible by direct evaluation of selected technical activities, assessment of products, discussions with key project staff, and the contributions of these processes to product quality. Interview teams, composed of a programmatic QA auditor and the assigned technical specialist, performed the technical audits of the activities. The NRC observer was present during the session relating to the NRC funded project and for portions of the other two (2) sessions.

In preparation for the audit, technical specialists and QA auditors reviewed applicable operation plans and proposals, the *Quality Requirements Application Matrix* (QRAM) for each project, procedures, other quality planning documents, and technical products. Technical checklists were prepared based on these reviews appropriate to each scope of work. A comprehensive QA programmatic checklist was prepared for application during the technical sessions and for the assessment of the programmatic elements.

The technical sessions were conducted through discussions with project management and key technical staff and review of objective evidence, which included document review packages and scientific notebooks (SNs). Technical and programmatic results were compiled for discussion and reporting. Programmatic activities were also conducted through review of objective evidence, evaluation of reports and SNs, discussions with project staff, and observation of laboratory activities.

4.0 TECHNICAL ACTIVITIES AUDITED

A risk-informed approach was applied in selecting the technical activities to audit. Technical and programmatic risks and the time since the previous audit of an activity were considered in selecting the areas for this audit, as follows:

- *R8637, Mechanical Stratigraphy and Natural Deformation in the Austin Chalk;*
- *19943, Analysis of Missile Impact Probability for Generic Tornado Hazard Assessments;*
- *19674.01.002, Electrical Resistivity Survey Bulverde Transmission Line.*

5.0 AUDIT TEAM

QA Auditors

Faye Brockwell	Institute Quality Systems (IQS) – Audit Team Leader (ATL)
Ross Cantu	IQS – Auditor
Mark Ehnstrom	IQS – Auditor

Technical Specialists

Thomas Gardner, PhD	Technical Specialist Geosciences	Trinity University, San Antonio
John McFarland, PhD	Technical Specialist SwRI Sr. Research Engineer Materials Engineering	Mechanical Engineering (18)
Dave Turner, PhD	Technical Specialist Environmental Assessment	St. Mary's University, San Antonio

6.0 APPLICABLE REQUIREMENTS DOCUMENTS

The following criteria formed the basis of the audit conduct and the generation of audit checklists:

- Title 10 CFR Part 50, Appendix B
- Title 10 CFR Part 60, Subpart G
- Title 10 CFR Part 63, Subpart G
- Title 10 CFR Part 71, Subpart H
- Title 10 CFR Part 72, Subpart G
- NQA-1-1986
- GED QA Manual (QAM)
- GED QA Procedures (QAPs)
- GED Administrative Procedures (APs)
- GED Technical Operating Procedures (TOPs)

7.0 U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVER

Jon Woodfield	Observer
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8.0 AUDITED ACTIVITIES**8.1 *Mechanical Stratigraphy and Natural Deformation in the Austin Chalk (R8637)*****Audit Team**

Dr. Thomas Gardner (*Technical Specialist*)

Ross Cantu (*QA Auditor*)

Task Description

The purpose of this task was to investigate the mechanical properties and fracture system development in the Austin chalk in the San Antonio region. Analysis of stress evolution was performed using the in-house 3DStress model.

Products and Associated Documents Reviewed

- Mechanical Stratigraphy and Natural deformation in the Austin Chalk: Final Report, August 2016.
- Scientific Notebook 1273, Pages 1 – 6 (scanned).
- QRAM for R8637

8.2 Analysis of Missile Impact Probability for Generic Tornado Hazard Assessments (19943)

Audit Team

Dr. John McFarland (*Technical Specialist*)

Mark Ehnstrom (*QA Auditor*)

Task Description

The purpose of this task was to evaluate the applicability of the Missile Impact Probability as a general means for assessing tornado risks to nuclear facilities, including assessment of the limitations of the approach.

Products and Associated Documents Reviewed

- Report: Analysis of Missile Impact Probability For Generic Tornado Hazard Assessments, June 24, 2016.
- Analysis Missile Impact Probability Generic Tornado Hazard Assessments June – multiple Excel files.
- QRAM for 19943.01.001

8.3 Electrical Resistivity Survey Bulverde Transmission Line (19674.01.002)

Audit Team

Dr. David Turner (*Technical Specialist*)

Ross Cantu (*QA Auditor*)

Task Description

The purpose of the task was to perform an electrical resistivity survey of the right-of-way tower locations for a planned electrical transmission line along Bulverde Road and U.S. Highway 281 on the north side of San Antonio, Texas. The survey was designed to evaluate the potential for subsurface voids at each of the 32 tower locations identified by the client.

Products and Associated Documents Reviewed

- Electrical Resistivity Survey Bulverde Transmission Line San Antonio, Texas, May 2016.
- Scientific Notebook 1188, Pages 1 – 102 (scanned)
- QRAM for 19674.01.002

8.4 Programmatic QA

QA Auditors

Ross Cantu, Mark Ehnstrom, Faye Brockwell

Audit Approach

Those elements that were not likely to be covered in the technical sessions or project reviews (topics including nonconformance control, document control, purchasing, QA records control, etc.) were assigned to the QA auditors. Applicable programmatic elements were also evaluated in each technical session, including *Scientific Notebook Control*; *Review of Documents, Reports, and Papers*; *Quality Planning*; *Documentation and Verification of Scientific and Engineering Calculations*; etc. Following are the QA procedures reviewed during the audit and the results that corresponded to that specific programmatic element.

Quality Procedures Reviewed

- **QAP-001, *Scientific Notebook Control***
The entire audit team was involved in reviewing the scientific notebooks in two (2) of the technical sessions. Each notebook was evaluated to determine conformance with the requirements of the procedure. One (1) recommendation was identified under this programmatic element.
- **QAP-002, *Review of Documents, Reports, and Papers***
The entire audit team was involved in reviewing documents associated with their assigned technical areas. Project reviews performed by all audit team members included verifying conformance with the QAP. No concerns were identified under this programmatic element.
- **QAP-004, *Surveillance Control***
The surveillance program implemented by GED continues to be a value-added process. No concerns were identified under this programmatic element.
- **QAP-005, *Quality Indoctrination and Training***
Records of training, training notifications and the database were reviewed during the technical sessions for the personnel involved in the activities. No concerns were identified under this programmatic element.
- **QAP-008, *Document Control***
Evaluation of this programmatic topic included control of documents, issue of controlled and uncontrolled documents, control of documents of external origin, and control of sensitive/ proprietary information. One (1) recommendation was identified under this programmatic element related to the process for scanning hard copy notebooks.
- **QAP-009, *Nonconformance Control***
A sample of NCRs generated since the previous audit were reviewed and found to be thorough, complete, and the corrections were deemed effective. No concerns were identified under this programmatic element.
- **QAP-010, *Corrective Action***
There were no corrective actions initiated since the last audit. No concerns were identified under this programmatic element.
- **QAP-011, *Audits***
The results of GED annual audits 2015-1 and 2015-AR-0018 were reviewed prior to this audit under the follow-up surveillance, 2015-SR-0454, and any remaining items were addressed during this audit. No concerns were identified under this programmatic element.
- **QAP-012, *Quality Assurance Records Control***
Examination of archived quality records verified conformance to this procedure with the exception of one (1) minor nonconformance. In addition, one (1) recommendation was identified under this programmatic element.

- **QAP-013, *Quality Planning***
Quality planning was considered by each member of the audit team during the review of the technical documentation as well as through the project reviews. The Quality Requirements Application Matrix (QRAM) for each technical topic was used to verify implementation and conformance to this procedure. No concerns were identified under this programmatic element.
- **QAP-014, *Documentation and Verification of Scientific and Engineering Calculations***
The entire audit team was involved in reviewing scientific and engineering calculations associated with each SN generated for the technical areas audited and the project reviews. No concerns were identified under this programmatic element.
- **QAP-016, *Procurement***
Purchase requisitions initiated in the previous twelve months for quality-affecting material were reviewed. No concerns were identified under this programmatic element.
- **QAP-017, *Drawing Control***
A drawing control process is established and no concerns were identified under this programmatic element.
- **QAP-018, *Procedure for Confirmatory Analysis***
The applicability of this procedure was reviewed during each technical session. No concerns were identified under this programmatic element.
- **QAP-019, *Control of Measuring and Test Equipment***
Measuring and test equipment was evaluated in the laboratories of Building 57. Calibration of equipment in use was verified to be current or evidence of calibration verification was documented in the scientific notebooks. One (1) minor nonconformance CDA was identified under this programmatic element.
- **AP-001, *Source Selection and Evaluation***
The entire audit team was involved in reviewing the applicability of this procedure in each technical session to determine if this process is being followed. One (1) minor nonconformance was identified under this programmatic element.
- **TOP-012, *Identification and Control of Samples and Chemical Reagents and Standards***
Laboratory controls implemented in Building 57 were reviewed. No concerns were identified under this programmatic element.
- **TOP-018, *Control, Development and Modification of Scientific and Engineering Software***
A sampling of controlled software was evaluated. These requirements were also evaluated during the technical sessions. No concerns were identified under this programmatic element.

9.0 SUMMARY OF RESULTS

Each technical activity was audited by a team of at least one technical specialist knowledgeable in the field of study and a programmatic QA auditor. Based on review of deliverables produced in the period since the last audit in December 2015, checklists were created specific to each technical task in addition to a general programmatic checklist addressing the QA requirements. Detailed checklists were used containing a total of one-hundred thirty (130) items which resulted in eighty eight (88) satisfactory items, three (3) minor nonconformances, one (1) of which was CDA, and thirty nine (39) judged to be not applicable (NA) or that could not be evaluated (NE) due to lack of use or execution of the particular item. As the technical specialist evaluated the technical qualifications of involved personnel, rigor of the science or engineering involved, and thoroughness of supporting documentation, the programmatic auditor confirmed the presence of required documentation supporting the processes involved and their conformance to QA procedural requirements. This programmatic evaluation included review and approval of quality documents, SN controls, training and qualification of the personnel involved in the activity. The following is a detailed description of the audit results including the technical task or programmatic topic from which the results were noted. Two (2) minor nonconformances; one (1) minor nonconformance CDA and six (6) recommendations are described below.

9.1 Minor Nonconformances

1. AP-001, Evaluating, Selecting, and Engaging Labor Resources

Conflict of interest determinations were not current for the IQS auditors and for one subcontractor used on technical project 19674.

Requirement: AP-001, *Evaluating, Selecting, and Engaging Labor Resources*
(Reference 2016-NCR-0460)

2. QAP-012, Quality Assurance Records Control

QA records are not being submitted and are not being examined to ensure completeness.

Project 19943

- Form QAP-012 available through QA records missing editorial review completion date and evidence of technical review for several required areas. Note: a completed version of the form was presented by the P.I.
- Form QAP-019 missing the signature and date for the person performing the calculation verification.

Project 19674

- Hard copy review comments were not submitted as a record.
- Scanned pages from notebook 1188, covering the period from February 2016 to May 2016 were not available for review.

Requirement: QAP-012, *Quality Assurance Records Control*, sections 3.4.1 and 3.4.4
(Reference 2016-NCR-0459)

9.2 Minor Nonconformance Corrected During the Audit

1. QAP-019, Control of Measuring & Test Equipment

The calibration date listed on the certificate of calibration was not consistent with the date on the equipment status label for balance, AN 010225. The calibration certificate

stated the calibration was performed 31 October 2016 yet the calibration sticker showed calibration on 28 October 2016. The date of calibration was verified and the certificate revised to include the correct date. Data for all 8 balances calibrated on 28 October 2016 was reviewed and no other errors were noted.

Requirement: QAP-019, *Control of Measuring & Test Equipment*

9.3 Recommendations

During the course of the audit activities, six (6) recommendations were made, which if acted upon, may prevent future nonconformances or will support continuous improvement of the GED quality program. These recommendations include the following:

Analysis of Missile Impact Probability for Generic Tornado Hazard Assessments

1. The basis and/or limitations for claims made in the report to support the conclusions should be clearly stated.
 - Section 2.1 of the report states “differences are most likely statistical artifacts” but does not provide any basis for this.
 - Additional qualitative and/or quantitative evidence for claims, such as a simple numerical example (even with hypothetical numbers) to illustrate the points being presented should be included.
 - Address or note potential limitations/assumptions associated with the conclusion based on the nature of the models/data used in the analysis.

(Reference 2016-PAR-0178)

Electrical Resistivity Survey Bulverde Transmission Line

2. Consider including references in the report to previous successful applications of the methodology, approach and likelihood ranking to provide a more sound technical basis.
3. Capture important technical expert reasoning in the scientific notebook. Areas to address include reasoning used in establishing the survey area and electrode spacing, and in establishing the contouring of the data.

(Reference 2016-PAR-0179)

QAP-012, Quality Assurance Records Control

4. QAP-012, *Quality Assurance Records Control*, section 3.4.4, should be revised to allow the division's QA Representative to sign Form QAP-16 when processing quality planning documents such as the QRAM. Additionally, Form QAP-16 should be revised to add a QA signature block.

(Reference 2016-PAR-0180)

QAP-001, Scientific Notebook Control

5. Evaluate the requirement for scanning hard copy notebook information. Consider adding “as soon as practicable at the end of a project or not to exceed 6-months”. Currently the

requirement is "not to exceed 6-month intervals".
(Reference 2016-PAR-0181)

QAP-008, Document Control & QAP-012, Quality Assurance Records Control

6. Review procedures to ensure references to ELF are still appropriate and accurately describe the processes being followed within the Division. Consider implementing a procedure describing the process for electronic record retention and retrieval.
(Reference 2016-PAR-0182)

10.0 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, with the exception of the nonconformances noted, the QA program applied by the GED continues to be adequate and effectively implemented. The recommendations identified provide opportunities for improvements and, if implemented, may reduce the potential to adversely affect products in the future.

PERSONS CONTACTED

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
GED Staff and Consultants			
Patrick, W.			X
Wittmeyer, G.	X		X
Ferrill, D.	X	X	X
Pensado, O		X	X
Green, R.		X	
Prikryl, J.		X	X
Bertetti, P.		X	
Neill, L.		X	X
Poerner, M.		X	
Howard, L.			X
NRC Observer			
Woodfield, J.			X
Audit Team and Others			
Barberino, C.	X	X	X
Brockwell, F.	X		X
Cantu, R.	X		X
Ehnstrom, M.	X		X
Gardner, T.	X		
McFarland, J.			
Turner, D			
Lewis, M.			X

APPROVAL SIGNATURES



Faye Brockwell
Audit Team Leader (ATL)

Dec 13, 2016

Date



Ross Cantu
QA Auditor

12/13/2016

Date



Mark Ehrstrom
QA Auditor

12/13/16

Date



for Dr. Thomas Gardner
Technical Specialist

Dec 13, 2016

Date



Dr. John McFarland
Technical Specialist

12/14/2016

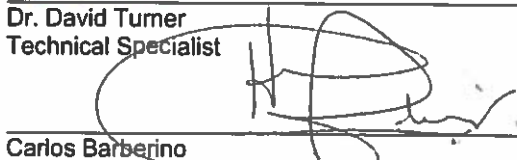
Date



for Dr. David Turner
Technical Specialist

Dec 13, 2016

Date



Carlos Barberino
Senior QA Scientist, GED QA Staff Support

13 Dec 2016

Date