QUALITY ASSURANCE AUDIT REPORT

For

GEOSCIENCES AND ENGINEERING DIVISION AUDIT 2007-1 Of NRC-FUNDED PROGRAMS CONDUCTED BY THE CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES

JUNE 5-8, 2007

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EXECUTIVE SUMMARY

The annual internal Quality Assurance (QA) audit for the Geosciences and Engineering Division (GED) of NRC-funded programs conducted by the Center for Nuclear Waste Regulatory Analyses (CNWRA) was performed June 5-8, 2007. The audit team, comprised of technical specialists and quality assurance auditors, determined that the GED QA program was being effectively implemented and provided adequate controls over technical product development. U.S. Nuclear Regulatory Commission (NRC) observers (QA, technical, and program management) observed the audit.

The GED staff was operating in accordance with the GED QA 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 being conducted in a satisfactory manner.

Concerns from the previous audit were adequately addressed and closed. Improvements noted during this annual audit included the manner in which trend analyses are conducted in the programmatic and technical areas to ensure adverse or potentially adverse trends are identified, captured and resolved. In addition, a more aggressive internal surveillance program has been implemented as an effective mechanism to provide value to the quality program through oversight activities of the programmatic and technical requirements. Aside from the trend analysis process, another good practice identified in the TPA Code Development evaluation included the process of technical authors working closely with software coders during development to ensure efficient knowledge transfer and to achieve the desired software performance.

Two minor nonconformances were identified and two minor nonconformances were corrected during the audit (CDA). The first minor nonconformance was identified in the evaluation of Airborne Transport of Radionuclides concerning Scientific Notebook (SN) 818 that contained post-it notes that was to be recorded in the SN at a later date. Secondly, the review of training documentation found that the record of training needs, Form QAP-11-1, could not be located for one consultant and one GED staff member. Two minor nonconformances CDA included a misplaced software development plan (SDP) for the (xFLO) computer code evaluation that was recovered, approved, and placed in the QA records. Also, SN 799E and SN 778E used in the Preclosure Safety Evaluation project were corrected to address minor concerns.

The results of the audit were discussed with the GED management and staff during daily management briefings and in the post-audit meeting held on June 8, 2007. As mentioned above, two minor nonconformance reports (NCR) were initiated and two minor nonconformances CDA were also documented in NCRs for trending purposes. The nature of the nonconformances identified was judged by the audit team to pose little risk to the quality of GED products. In addition, several opportunities for improvement were identified that may facilitate the GED maintaining and improving its quality program and technical products.

1 AUDIT SCOPE

The audit evaluated the GED quality assurance program to verify that it met the applicable requirements and was being effectively implemented. The audit was performance-based and evaluated programmatic requirements in light of their application to technical activities. In addition, the corrective action process was reviewed to determine the appropriateness of actions taken and implementation effectiveness.

2 PROGRAMMATIC ELEMENTS AUDITED

GED QA Program Criteria	Corresponding QAM Chapter
Organization	1
QA Program	2
Design Control	Not Applicable
Scientific Engineering Investigation and Analysis Control	3
Procurement Document Control	4
Instructions, Drawings, and Procedures	5
Document Control	6
Control of Purchased Material	7
Identification and Control of Items	8
Control of Special Processes	9
Inspection	10
Test Control	11
Control of Measuring and Test Equipment	12
Handling, Storage, and Shipping	13
Inspection, Test, and Operating Status	14
Nonconformance Control	15
Corrective Action	16
Records Control	17
Audits	18

Design-related activities are not performed by GED; therefore, Design Control requirements are not applicable. All QAM sections were addressed in this audit. The technical and QA program aspects of the audit were integrated to the fullest extent practicable.

3 AUDIT APPROACH

A performance-based approach to auditing was accomplished by direct evaluation of selected technical activities, assessment of products, discussions with key project staff, and the contributions of these processes to product quality. Teams composed of a programmatic auditor and a technical specialist performed the technical audits.

In preparation for the audit, technical specialists and auditors reviewed applicable operation plans, procedures, quality planning documents, and technical products. Technical checklists were prepared based on these reviews appropriate to the scopes of work. QA programmatic checklists were prepared for application during the technical audits and for QA systems (i.e., document control, records control, nonconformance and corrective actions, etc.) assessments.

The audit sessions were conducted through discussions with project management and technical staff, review of objective evidence (including review packages and scientific notebooks), and when appropriate, observation of laboratory activities. Technical and programmatic findings were compiled by the audit teams for discussions and reporting.

Daily caucuses for the audit team and NRC observers and daily meetings between the audit team leader and CNWRA management were conducted.

4 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:

- Flow Paths in the Unsaturated Zone
- Volcanic Disruption of Waste Packages
- Airborne Transport of Radionuclides
  - Field Work
- Degradation of Engineered Barriers
  - Laboratory activities
- Performance Confirmation
  - xFLO Development
- TPA Code Development
- Preclosure Safety Evaluation
  - Interim Staff Guidance-01 & 02 Example problems
- Mechanical Disruption of Engineered Barriers
- Fuel Cycle Projects
- Methodology and Overall System Performance
  - Postclosure Seismic/Faulting Scenario Analysis
- Redistribution of Radionuclides in Soil
  - Field work
- Waste Incidental to Reprocessing
  - Generic Issues and Guidance Task

5 AUDIT TEAM

Thomas Trbovich	Audit Team Leader (ATL)	Institute Quality Systems (IQS)
Christopher Hobson	QA Auditor/ATL in Training	IQS
Ashley Smith	QA Auditor	IQS
Donald Dunavant	QA Auditor	IQS
Joseph Brewer	Technical Specialist, Analysis and Monitoring	SwRI
Ewan Grantham	Technical Specialist, Software	SwRI
Edgar Oelkers	Technical Specialist Safety Analysis	SwRI
Kurt Schrader	Technical Specialist, Structural Engineering	SwRI
James Dante	Technical Specialist, Material Sciences	SwRI
Dr. Diane Smith	Technical Specialist, Geosciences	Trinity University
Dr. Alan Dutton	Technical Specialist, Hydrogeology; Aqueous Geochemistry	University of Texas San Antonio

6 APPLICABLE REQUIREMENTS DOCUMENTS

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

- Title 10 CFR Part 50, Appendix B [by reference in 10 CFR Part 60, Subpart G and10 CFR 70.22(f)]
- Title 10 CFR Part 71, Subpart H
- Title 10 CFR Part 72, Subpart G
- Title 10 CFR Part 63, Subpart G
- ANSI/ASME NQA-1-1986
- GED QAM
- GED QA Procedures (QAPs)
- GED Technical Operating Procedures (TOPs)
- GED Administrative Procedures (APs)

7 U.S. NUCLEAR REGULATORY COMMISSION (NRC) OBSERVERS

Tom Matula	Observer Team Lead
Deborah DeMarco	Program Management Observer
Frank Jacobs	QA Observer
Jack Gwo	Technical Observer
Rosemary Reeves	Technical Observer

8 AUDITED ACTIVITIES

8.1 Flow Paths in the Unsaturated Zone

Audit Team
Dr. Alan Dutton, Thomas Trbovich

Task Description
The project addresses various topics associated with hydrogeology of the unsaturated zone at Yucca Mountain. The quality of these complex and multi-component studies was sampled by reviewing and discussing documents describing: (1) hydrogeologic characterization of tuffs near Bishop, California, studied as natural analogs to volcaniclastic units located adjacent to a potential waste repository horizon in Yucca Mountain; (2) experimental analysis and numerical modeling of thermal and hydrological conditions inside a simulated waste-storage drift; and (3) the hydrogeologic role of the Paintbrush nonwelded unit (PTn) as a natural barrier to flow in the unsaturated zone above a potential repository at Yucca Mountain.

Products and Associated Documents Reviewed

- Lithological, Structural, and Hydrological Characteristics of Reworked Tuffaceous Sedimentary Rock and Interbedded Ashfall Deposits near Bishop, California: Implications for Lateral Flow Technical Report—Manuscript for journal submission
- Letter Report Resubmittal of Evaluation of In-Drift Heat Transfer Processes
- Revised Letter Report, 4/19/2007 Resubmittal, Flow Paths in the Unsaturated Zone, The Nature of Flow in the Faulted and Fractured Paintbrush Nonwelded Hydrogeologic Unit

8.2 Volcanic Disruption of Waste Packages

Audit Team
Dr. Diane Smith, Donald Dunavant

Task Description
The task consisted of evaluating Department of Energy (DOE) documents to improve understanding of the DOE assumptions, technical bases, data, and models for features, events, and processes relating to future igneous events. The review consisted of interviews with project management and two technical staff involved. In addition the qualification of the personnel, including consultants, was evaluated and one scientific notebook reviewed.

Products and Associated Documents Reviewed

- Operations Plan for Volcanic Disruption of Waste Packages
- Review of Two Electric Power Research Institute Technical Reports on the Potential Igneous Process Relevant to the Yucca Mountain Depository
- Report on the Eruption of Wet Basaltic Magma

8.3 Airborne Transport of Radionuclides

Audit Team
Dr. Diane Smith, Donald Dunavant

Task Description
The objective of this task is to support preparation for a review of a potential DOE license application by evaluating DOE documents to improve understanding of the DOE site descriptions, assumptions, technical bases, data, and models related to features, events, and processes related to airborne transport of radionuclides. The audit consisted of interviews of the project management and principal investigator, review of a scientific notebook, review of sample identification and control, and personnel qualifications. One minor nonconformance was documented in the incomplete content of scientific notebook 818.

Products and Associated Documents Reviewed

- Operations Plan for Airborne Transport of Radionuclides
- Status Report of Field Observation from Sunset Crater, AZ
- Modeling Potential Tephra Disposal at Yucca Mountain, NV

8.4 Degradation of Engineered Barriers

Audit Team
James Dante, Christopher Hobson

Task Description
The primary objective of the Integrated Subissue on Degradation of Engineered Barriers is to support preparations to review the potential DOE license application by (i) evaluating available documents and participating in meetings with DOE to improve understanding of DOE assumptions, technical bases, data, and models related to features, events, and processes that may affect degradation processes for the engineered barrier system; (ii) preparing license application review strategies to facilitate a timely and efficient review of the license application; (iii) supporting refinements and documentation of analysis tools such as the TPA code, which are anticipated to be important to the license application review; and (iv) conducting independent analyses and evaluations to facilitate a better understanding of processes important to waste isolation.

Products and Associated Documents Reviewed

- Corrosion Behavior of Alloy 22 in Concentrated Nitrate and Chloride Salt Environments at Elevated Temperatures – Presentation at CORROSION 2007, NACE, Nashville
- Crevice Corrosion Propagation Behavior of Alloy 22 in Extreme Environments – Presentation at CORROSION 2007, NACE, Nashville
- Understanding Conditions for Localized Corrosion and Stress Corrosion Cracking of Alloy 22 in Repository Settings – Presentation to the 3rd International Workshop on Long Term Prediction of Corrosion Damage in Nuclear Waste Systems, State College, PA, May 14-19, 2007

8.5 Performance Confirmation: xFLO Development

Audit Team
Dr. Alan Dutton, Ashley Smith

Task Description
The computer code xFLO is intended as a replacement for MULTIFLO and is expected to feature modular software components that will be more easily used to simulate drift-scale and repository-scale coupled thermal and hydrological processes for performance confirmation oversight. The new xFLO code has a flexible design that should allow new physics-based models to be added and thus keep pace with evolving understanding of the physical processes that may affect long-term repository performance.

Products and Associated Documents Reviewed

- Software requirements description for xFlo, an extensible flow model for use in U.S. NRC performance confirmation oversight) (pc report 1.pdf)
- xFlo version 1.0β User's manual (pc report 2.pdf)

8.6 TPA Code Development

Audit Team
Ewan Grantham, Ashley Smith

Task Description
The TPA code is being modified to create version 5.1. The task includes code development and validation testing. The activities are conducted in accordance with TOP-018, *Development and Control of Scientific and Engineering Software*.

Products and Associated Documents Reviewed

- Software Validation Plan for TPA Code Version 5.1
- Letter report: Summary of Planned Changes to TPA Version 5.1 Beta to Address Issues Identified by NRC
- TPA Version 5.1 Draft Users Guide Chapters 8, 11, 13, and 16

8.7 Preclosure Safety Evaluation

Audit Team
Edgar Oelkers, Donald Dunavant

Task Description
The primary objective of the Pre-closure Safety Evaluation Integrated Subissue is to support NRC staff preparation to review the adequacy of design of structures, systems, and components for the surface and subsurface facilities in the potential DOE license application. The emphasis of the interviews was on clarification of the statistical analysis and risk assessments performed. The review covered qualifications of the staff and consultants and scientific notebooks documenting the effort. Eight GED management and technical staff were interviewed. Two minor discrepancies in scientific notebook entries were CDA.

Products and Associated Documents Reviewed

- Excerpts from the CNWRA Operations Plans for the High-Level Waste Repository Program, Pre-closure Safety Evaluation, Section 2.19
- HLWRS-ISG-01, Review Methodology for Seismically Initiated Event Sequences
- HLWRS-ISG-02, Pre-closure Safety Analysis-Level of Information and Reliability Estimation

8.8 Mechanical Disruption of Engineered Barriers

Audit Team
Kurt Schrader, Thomas Trbovich

Task Description
The primary objective of the Integrated Subissue on Mechanical Disruption of Engineered Barriers is to prepare for the review of a potential DOE license application. The preparation will pursue the following activities during this fiscal year: (i) evaluation of available DOE documents to improve understanding of the DOE assumptions, technical bases, data, and models related to features, events, and processes related to the disruptive events; (ii) evaluation of DOE studies on the response of the engineered barrier subsystem to the disruptive events; (iii) staff independent analyses and evaluations; (iv) update of the abstractions to be used in the mechanical degradation (MECHFAIL) module; and (v) support of the TPA code development and documentation.

Products and Associated Documents Reviewed

- Report: A Literature Review of Low Temperature ($<0.25T_{mp}$) Creep Behavior of α, α-β, and β Titanium Alloys
- Report: Summary of Current Understanding of Drift Degradation and Its Effect on Performance at a Potential Yucca Mountain Repository
- Report: Structural Performance of Drip Shield Subjected to Static and Dynamic Loading

8.9 Fuel Cycle Projects

Audit Team
Kurt Schrader, Donald Dunavant

Task Description
This task provides on-call technical assistance to the NRC staff in reviewing Integrated Safety Analysis summaries in areas related to the characterization of natural phenomena hazards and the associated accident sequences. The audit consisted of review of the two documents listed below, and interview of project management and the scientist involved. It was recommended that the technical reports evaluated be re-reviewed to correct minor editorial errors.

Products and Associated Documents Reviewed

- Operations Plan for Fuel Cycle Projects
- Final Review Plan for Seismic, Tornado, and High-Wind Hazards and Structural Design Assessments of American Centrifuge Plant in Piketon, OH

8.10 Methodology and Overall System Performance

Audit Team
Edgar Oelkers, Donald Dunavant

Task Description
The primary objective of this task is to prepare for the review of a potential DOE license application. The audit was conducted through the review of two documents listed below, though interviews with the project manager and scientists conducting the work. The qualifications of the personnel involved were evaluated and one electronic scientific notebook was reviewed. The primary focus of the interviews was on clarification of the statistical analyses techniques applied.

Products and Associated Documents Reviewed

- Methodology and Overall System Performance Operations Plan
- Report: Exploratory Modeling of Extreme Peak Ground Accelerations
- Presentation at Seismological Society of America meeting 2007, Kona, HI 4/12/2007

8.11 Redistribution of Radionuclides in Soil

Audit Team
Joseph Brewer, Christopher Hobson

Task Description
The first objective of the Integrated Subissue on Redistribution of Radionuclides in Soil is to prepare for the review of a potential DOE license application. The Redistribution of Radionuclides in Soil staff will pursue the following tasks with the highest priority during this fiscal year: (i) document the results of field investigations and laboratory analyses to measure airborne particle concentrations at the Sunset Crater volcanic analog site; (ii) prepare a draft user's guide chapter for the TPA code; and (iii) develop a review strategy for the Redistribution of Radionuclides in Soil Integrated Subissue and update the status of review issues based on new DOE information. These high-priority tasks are categorized under the seven general activities associated with Redistribution of Radionuclides in Soil. Planned proactive work also supports the primary objective to prepare for the review of a license application.

Products and Associated Documents Reviewed

- Journal Article: Measurement of Airborne Particle Concentration near the Sunset Center Volcano, Arizona.

8.12 Waste Incidental to Reprocessing

Audit Team
Donald Dunavant

Task Description
The main objective of this task is for the GED staff to provide technical assistance to support the NRC in consulting with the DOE on non-high-level waste determinations and disposal strategies at the Savannah River Site and the Idaho National Laboratory. These tasks include evaluation of information provided by DOE to support its non-high-level waste determination, including site

characterization data and performance assessments developed to demonstrate compliance with the criteria in the National Defense Authorization Act, development of requests for additional information (if applicable), and documentation of its review. The audit was conducted through review of the three documents listed below and through interviews with the project management and with the report author conducting the work. The review included document and verification of participant and consultant qualification. One recommendation was made concerning documentation of NRC requests and actions taken.

Products and Associated Documents Reviewed

- Operational Plan for Technical Assistance in Evaluating Non-High-Level Waste Determinations for the U.S. Department of Energy Facilities in South Carolina and Idaho
- Letter report: Summary of Technical Assistance in Evaluating Non-High-Level Waste Determination for the U.S. Department of Energy Facilities in South Carolina, and Idaho, Reactive Tasks 1-5 Activities for January – March of Fiscal Year 2007
- Letter report: Summary of Technical Assistance in Evaluating Non-High-level Waste Determination for the U.S. Department of Energy Facilities in South Carolina and Idaho, Reactive Tasks 1-5 for Activities October – December Fiscal 2007

8.13 Programmatic QA

Auditors
Donald Dunavant, Christopher Hobson, Ashley Smith, Tom Trbovich

Quality Procedures Reviewed

- QAP-001, *Scientific Notebook Control*
  The entire audit team was involved in reviewing the scientific notebooks in each technical session. One minor nonconformance and one minor nonconformance CDA were identified under this programmatic element. Each notebook was evaluated to determine conformance with the requirements of this procedure.

- QAP-002, *Review of Documents, Reports, and Papers*
  The entire audit team was involved in reviewing documents associated with their assigned technical areas. Each technical document was verified to have the proper form completion and comment/resolution sheets with appropriate signatures and acceptance.

- QAP-004, *Surveillance Control*
  The surveillance schedule was reviewed and noted that the planned surveillances had been performed within the month indicated. Surveillance reports were reviewed and found to contain detailed summaries with some discrepancies noted and documented in NCRs. A much more aggressive surveillance program has been implemented in the last year and evidence of the effectiveness of this process was demonstrated.

- QAP-005, *Quality Indoctrination and Training*
  Records of training, training notification, training and database were reviewed. With the exception of one record that could not be located for one consultant and one GED staff member as noted below, the indoctrination and training processes are in accordance with QAP-005.

- QAP-007, *Professional Personnel Qualification*
  Qualification records are being effectively managed; files are complete and are readily available. The position descriptions, qualifications, and other information, as required by this procedure, are complete and appropriate in the records reviewed. Reviews are performed to ensure personnel meet the requirements of the position and annual reviews are being conducted and documented accordingly.

- QAP-008, *Document Control*
  Documents are being maintained and controlled effectively through the use of the *Electronic Library Facility* (ELF). Files are being maintained in a storage vault, environmentally protected, and access limited. Sensitive and proprietary information is identified in ELF and controlled in accordance with AP-020, *Managing Sensitive Unclassified and Export-Controlled Information*. Uncontrolled copies generated by the document control clerk are being stamped as *Uncontrolled.*

- QAP-009, *Nonconformance Control*
  A sample of NCRs was reviewed during this audit. Section 5 of QAP-009 requires an annual trend analysis of the nonconformances. The comprehensive trend analysis generated for 2006 was identified as a good practice. NCRs were categorized based on technical and programmatic areas to ensure adverse trends are identified, captured and resolved. One trend identified for sample control resulted in the generation of a corrective action request (CAR) indicating that the process is working as intended.

- QAP-010, *Corrective Action*
  CARs written since the last audit were reviewed. The actions taken to address the documented findings were appropriate and thorough. Follow-up action included verification by QA personnel that actions taken had addressed all proposed corrective actions.

- QAP-011, *Audits*
  The results of the 2006 annual audit were reviewed and the corrective actions were evaluated to ensure implementation and effectiveness. Recommendations were addressed and each had either been implemented or a justification provided as to why the recommendation was not accepted. These recommendations were also documented and tracked to closure.

- QAP-012, *Quality Assurance Records Control*
  Examination of the quality records archived verified conformance to this procedure. The use of ELF facilitates the archival process.

- QAP-013, *Quality Planning*
  Quality planning was considered by each member of the audit team during the review of the technical documentation. The *Quality Requirements Application Matrix* (QRAM) was used in many cases to verify implementation and conformance to this procedure.

- 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 scientific notebook generated for the technical areas audited. The verification of these calculations was determined to be in conformance with the requirements based on the justification identified in the review comments of each technical report, as applicable.

- QAP-016, *Procurement*
  Purchase requisitions generated electronically in the *Forms Manager* application were reviewed and found to be in conformance with procedural requirements. QA reviews are performed and proper quality codes are identified for purchases with quality requirements.

- QAP-017, *Drawing Control*
  Limited evidence of drawing control was observed during this audit. In the laboratory evaluation, several drawings were reviewed. These drawings were controlled and approved in accordance with the procedure.

- QAP-018, *Procedure for Confirmatory Analysis*
  Evidence of conformance was observed during the laboratory evaluation. Confirmatory analysis was identified for steel wire procured from a non-Approved Supplier List (ASL) vendor. The wire was analyzed and results were provided for review from Staveley Services Materials Testing, an approved vendor for chemical and materials testing.

- QAP-019, *Control of Measuring and Test Equipment*
  Calibration of equipment was verified during the laboratory evaluation. Twenty-five pieces of equipment were verified as being within the calibration interval and that these were included in the Institute Calibration Laboratory recall system. All equipment was found to be in conformance with the requirements.

- AP-005, *Obtaining Subcontract Services*
  The entire audit team was involved in verifying whether subcontractors were used on the projects reviewed in the technical sessions. Appropriate training documentation was available for review in those instances where subcontract services were employed.

- AP-006, *Obtaining Consultant Services*
  The entire audit team was involved in verifying whether consultants were used on the projects reviewed in the technical sessions. Appropriate training documentation was available for review in those instances where consultant services were employed.

- TOP-012, *Identification and Control of Samples and Chemical Reagents and Standards*
  The laboratory controls implemented in Buildings 51 and 57 were reviewed. Control of *Alloy 22* samples was demonstrated in the Corrosion Laboratory. Understanding of this process was demonstrated at all levels of the organization, even though the individual responsible for this area was on travel during the audit. Reagents and standards were appropriately labeled and stored.

9 SUMMARY OF RESULTS

Each activity was audited by a team of at least one technical specialist knowledgeable in the field of study and a programmatic auditor. Based on review of deliverables produced in the period since the last audit in June 2006, checklists were created specific to each technical task in addition to a general programmatic checklist addressing the QA requirements. As the technical specialist evaluated the qualification 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. The following is a detailed description of the audit results including the technical task

from which the results were noted. Two minor nonconformances, two minor nonconformances CDA documented as NCRs for trending purposes, and eight recommendations are described below.

9.1 Good Practices

TPA Code Development
The process of technical authors working with software coders during development ensures efficient knowledge transfer and desired software performance.

Programmatic QA
Detailed trend program established to provide valuable information in programmatic and technical areas to ensure adverse trends are captured and addressed.

9.2 Minor Nonconformances

Airborne Transport of Radionuclides

QAP-001, *Scientific Notebook Control*, Section 3.2.5, requires that entries document specific conduct of technical activity and results. SN 818 was found to contain data on numerous post-it notes to be recorded in the SN at a later time. In addition, approximately twenty pages were left blank before starting a separate task. Individual responsible for this notebook is no longer with GED.

Programmatic QA

QAP-005, *Quality Indoctrination and Training*, Section 3.2.1, requires documentation of training needs for personnel on Form QAP-11-1. The record could not be located for one consultant and one GED staff member.

9.3 Corrected During Audit (CDA)

Performance Confirmation (xFLO)

TOP-018, *Development and Control of Scientific and Engineering Software*, Section 5.3, requires the generation of a SDP describing activities necessary to develop or modify software. Original SDP had been misplaced. SDP was recovered, approved and placed in QA records.

Preclosure Safety Evaluation

QAP-001, *Scientific Notebook Control*, Section 3.3.4, requires that pages be sequentially numbered and Section 3.4.9 requires statement by the manager indicating review of the completed notebook.

- SN 799E was not paginated after page 28; and
- SN 778E contained incorrect statement on SN management review.

9.4 Recommendations

During the course of the audit activities, eight 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:

Mechanical Disruption of Engineered Barriers
Technical reports should be reviewed further for errors identified during discussions to determine importance of missing data, incorrect figures and footnote issues. Any references to previous models or analyses should be explicitly identified in reports.

Waste Incidental to Reprocessing
Formal documentation of NRC requests and actions taken should be considered to provide objective evidence of task understanding and completion.

Airborne Transport of Radionuclides
Identification on outside of storage boxes for samples contained within should be considered to ensure ease of retrieval. (Bldg 57, Trailer 52)

TPA Code Development

- TOP-018, *Development and Control of Scientific and Engineering Software*, should provide better guidance regarding software change request (SCR) accountability and management.
- A mechanism should be established to search software surveillance reports by project, subject or title.

Redistribution of Radionuclides in Soil
Techniques utilized could have been improved or industry reference methods used to measure airborne particulate in both total and size-fractioned samples. Recommendations include the following:

- Provide more detail within the journal article to describe how samples were collected and the chronology of collection and analytical steps.
- Spend more time in the planning stage to ensure critical processes are identified and documented controls are provided to participants.
- Whenever possible, even if it costs more time, consider the use of referenced methodology.
- Ensure cost and schedule are not driving factors in study. Consider a smaller scope if cost and schedule are an issue.

Flow Paths in the Unsaturated Zone

- Consider adding requirements for *metadata files*, *readme files* and *<dir.lis> list files* on data CDs included in scientific notebooks.
- Texas Water Development Board (TWDB) has exemplary contract specifications that could be adapted as specifications for metadata or QA requirements or both.

10 QUALITY ASSURANCE PROGRAM EFFECTIVENESS

As determined by this annual audit, the QA program applied by the GED was being effectively implemented. The nature of the nonconformances identified in the audit did not pose a significant potential to adversely affect products or the overall effectiveness of the program. However, the recommendations identified provide opportunities for improvements and, if implemented, may reduce the potential to adversely affect products in the future.

11 PERSONS CONTACTED

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
GED Staff and Consultants			
Adams, G.		X	
Adams, N.		X	X
Axler, K.	X	X	
Basagaoglu, H.			X
Basu, D.		X	X
Benke, R.			X
Bradbury, K.		X	
Brettmann, B.			X
Brient, R.	X	X	X
Chiang, K.			X
Chowdhury, A.	X	X	X
Das, K.		X	X
Dasgupta, B.		X	X
Dinwiddie, C.		X	
Durham, J.		X	X
Ferrante, F.		X	
Folck, R.	X	X	X
Galloway, A.			X
Ghosh, A.		X	
Green, S.		X	
He, X.	X	X	X
Hooper, D.		X	X
Howard, L		X	X
Hsiung, S.		X	X
Huyse, L.		X	
Ibarra, L.		X	X
Ibrahim, B.			X
Janetzke, R.	X	X	X
Jung, A.			X
Kazban, R.		X	X
Lenhard, R.		X	
Mackin, P.	X		X
Manepally, C.		X	X
McMurry, J.			X
Mintz, T.			X
Mohanty, S.	X		X
Myers, J.			X
Padilla, M.		X	
Painter, S.		X	X
Pan, Y.		X	X
Patrick, W.	X		X
Pearcy, E.	X		X
Pensado, O.		X	X
Sagar, B.			X
Selvey, L.			X
Shukla, P.			X

	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Simpson, J.			X
Simpson, M.	X		X
Smart, K.		X	X
Stamatakos, J.	X	X	X
Street, B.			X
Turner, D.	X	X	
Walter, G.		X	X
Wilt, T.		X	X
Winterle, J.	X	X	X
Wittmeyer, G.	X		
Yang, L.		X	X
NRC Observers/OIG			
DeMarco, D.	X		X
Gwo, J.	X		X
Jacobs, F.	X		X
Matula, T.	X		X
Reeves, R.	X		X
Stetson, K.			X
Woodward, R.			X
Audit Team and Others			
Brewer, J.	X		X
Dante, J.	X		X
Dunavant, D.	X		X
Dutton, A.	X		X
Grantham, E.	X		X
Hobson, C.	X		X
Holt, A.			X
Mabrito, B.			X
Oelkers, E.	X		
Schrader, K.	X		X
Smith, A.	X		
Smith, D.	X		X
Trbovich, T.	X		X

APPROVAL SIGNATURES

Thomas C. Trbovich
Audit Team Leader (ATL)
Date: 7/19/07

Christopher D. Hobson
Auditor, ATL-In-Training
Date: 7/20/2007

Don W. Dunavant
Auditor
Date: 23 July 07

Ashley H. Smith
Auditor
Date: 7/19/07

Ewan Grantham
Technical Specialist, Software
Date: 7/20/07

Dr. Diane Smith
Technical Specialist, Volcanology
Date: 7/20/07

James Dante
Technical Specialist, Material Science
Date: 7/20/07

Dr. Alan Dutton
Technical Specialist, Aqueous Geochemistry, Hydrogeology
Date: 7/20/07

Edgar Oelkers
Technical Specialist, Safety Analyses/Risk
Date: 7/20/07

Kurt Schrader
Technical Specialist, Structural Engineering
Date: 7/20/07

Joseph Brewer
Technical Specialist, Environmental Monitoring
Date: 7/20/07

Robert D. Brient
Director of Quality Assurance, GED
Date: 7/24/2007