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April 18, 2003
Contract No. NRC–02–02–012
Account No. 20.06002.01.041

U.S. Nuclear Regulatory Commission
ATTN: Mr. Ted Carter
Two White Flint North
11545 Rockville Pike
Mail Stop 7 F3
Washington, DC 20555

Subject: Predecisional Observation Report of the Performance-Based Audit of Data Integrity Conducted at the Bechtel SAIC (BSC) Facility—Las Vegas, Nevada [Intermediate Milestone (IM) 20.06002.01.041.302]

Dear Mr. Carter:

Enclosed is the predecisional NRC Observation Audit Report on the BSC activities for the performance-based audit conducted at the BSC facility in Las Vegas, Nevada, OQAP–BSC–03–05, performed on March 17–27, 2003. An electronic version of this predecisional input is included and can be used in developing the final U.S. Nuclear Regulatory Commission (NRC) Observation Audit Report. This submittal fulfills IM 20.06002.01.041.302. Prior to NRC sending out the final Observation Audit Report, it is our understanding the team members will be afforded an opportunity to review the final version of the report and will sign the Observation Audit Report indicating their acceptance.

These NRC observations of U.S. Department of Energy (DOE) audits are to ensure that the DOE audits and surveillances are accomplished in an effective and adequate manner, and the DOE quality assurance program has been satisfactorily implemented in the areas being evaluated.

If you have questions regarding this description of the activity, please contact me at 210.522.5149. Your cooperation in this matter is appreciated.

Sincerely,

Bruce Mabrito
Director of Quality Assurance

BM:jg
Enclosure
cc: M. Leach, E. Whitt, B. Meehan, D. DeMarco, J. Greeves, T. Carter, W. Reamer, K. Stablein, T. Matula, R. Latta, J. Schlueter, D. Esh, B. Schlapper, W. Patrick, B. Sagar
CNWRA Directors (letter only)
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PREDECISIONAL

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Subject: NRC Observation Audit Report No. OAR–03–02, "Observation Audit of Bechtel SAIC (BSC) Activities for the Performance-Based Audit of Data Integrity Conducted at the BSC Facilities in Las Vegas, Nevada, Audit No. OQAP–BSC–03–05"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC) Observation Audit Report No. OAR–03–02. The audit was conducted by the Department of Energy Office of Quality Assurance (OQA) on March 17–27, 2003, regarding the input data integrity supporting technical products for the Yucca Mountain Project License Application.

The OQA audit team (hereafter, audit team) performed a limited scope performance-based audit to evaluate BSC's implementation of the Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description Document, DOE/RW–0333P, Revision 12, and associated implementing procedures pertaining to BSC's development of selected Analysis/Model Reports and the integrity of input data used in the reports.

The NRC observers (hereafter, observers) determined that the U.S. Department of Energy (DOE) audit of BSC was not fully effective in identifying potential deficiencies and recommending improvements for the reviewed BSC activities. The audit team determined that the audit was limited in scope because of the small number of technical products available for evaluation, and was limited in its determination of the overall adequacy, appropriateness, and suitability of the supporting data. During the audit, both the audit team and the observers independently reviewed applicable quality assurance procedures, and activities within the audit's scope.

The audit team identified three potential deficiencies, and five potential Quality Observations. The observers initiated one Audit Observer Inquiry. The Audit Observer Inquiry pertains to the identification of trends associated with data-related deficiency reports written in the last 4 years. BSC management has indicated that a corrective action request (CAR) will be issued regarding this review of previous deficiencies. The inquiry requests that DOE provide the outcome of this CAR evaluation, the results of the root cause analysis, the associated corrective action plan, and actions to be taken. The audit observer inquiry is described in Section 5.3 of the enclosed report.

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The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit meeting on March 27, 2003.

A written response to this letter and the enclosed report is not required. The staff will continue to interface with OCRWM and follow the action that BSC is taking to address the issues identified during this audit. If you have any questions, please contact Ted Carter of my staff at 301.415.6684.

Sincerely,

Janet Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report No. OAR–03–02, "Observation Audit of Bechtel SAIC (BSC) Activities for the Performance-Based Audit of Data Integrity Conducted at the BSC Facilities in Las Vegas, Nevada, Audit No. OQAP–BSC–03–05"

cc: See attached list.

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Letter to R. Milner from J. Schlueter dated _____

cc:

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J. Larson, White Pine County
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R. Anderson, NEI
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S. Kraft, NEI
J. Kessler, EPRI
D. Duncan, USGS
R. Craig, USGS
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N. Rice, NV Congressional Delegation
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A. Johnson, Eureka County, NV

A. Remus, Inyo County, CA

M. Yarbro, Lander County, NV

I. Zabarte, W.S.N.C.

C. Anderson, Las Vegas Paiute Tribe

J. Birchim, Yomba Shoshone Tribe

L. Jackson, Timbisha Shoshone Tribe

C. Meyers, Moapa Paiute Indian Tribe

V. Miller, Fort Independence Indian Tribe

A. Bacock, Big Pine Paiute Tribe of the Owens Valley

R. Quintero, Inter-Tribal Council of Nevada (Chairman, Walker River Paiute Tribe)

M. Bengochia, Bishop Paiute Indian Tribe

J. Egan, Egan & Associates, PLLC

W. Briggs, Ross, Dixon & Bell

J. Reynoldson, NV Congressional Delegation

S. Joya, NV Congressional Delegation

J. Pegues, City of Las Vegas, NV

R. Bahe, Benton Paiute Indian Tribe

C. Bradley, Kaibab Band of Southern Paiutes

R. Joseph, Lone Pine Paiute-Shoshone Tribe

L. Tom, Paiute Indian Tribes of Utah

E. Smith, Chemehuevi Indian Tribe

J. Charles, Ely Shoshone Tribe

D. Crawford, Inter-Tribal Council of Nevada

H. Blackeye, Jr., Duckwater Shoshone Tribe

D. Eddy, Jr., Colorado River Indian Tribes

J. Leeds, Las Vegas Indian Center

PREDECISIONAL

NRC OBSERVATION AUDIT REPORT NO. OAR–03–02, "OBSERVATION AUDIT OF BECHTEL SAIC (BSC) ACTIVITIES FOR THE PERFORMANCE-BASED AUDIT OF DATA INTEGRITY CONDUCTED AT THE BSC FACILITIES IN LAS VEGAS, NEVADA, AUDIT NO. OQAP–BSC–03–05"

4/ /03
Ted Carter
Performance Assessment Section
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Thomas Matula
Repository Site Section
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Center for Nuclear Waste Regulatory Analyses

Reviewed and Approved by:

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N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

1.0 INTRODUCTION

Staff from the U.S. Nuclear Regulatory Commission (NRC) Division of Waste Management, observed the DOE Office of Quality Assurance (OQA) performance-based limited scope audit of Bechtel SAIC Company, LLC (BSC), implementation of the Office of Civilian Radioactive Waste Management (OCRWM) quality assurance (QA) program related to input data integrity supporting technical products for the Yucca Mountain Project license application. The audit was conducted on March 17–27, 2003, at the BSC facility in Las Vegas, Nevada.

The objective of the audit was to verify data integrity related to selected technical products. Specific Analysis Model Reports (AMRs) were assessed against established measurement criteria in accordance with the audit plan. In addition, data-related deficiencies identified during the previous 2 years of audits and surveillances of BSC activities were reviewed and evaluated for effectiveness of the actions taken. The NRC observers' (hereafter, observers') objective was to assess the effectiveness of the OQA audit team (hereafter, audit team), the audit process, and BSC implementation of QARD provisions. This report documents the observers' determination of the OQA team's audit effectiveness and BSC implementation of the QARD provisions.

2.0 MANAGEMENT SUMMARY

The observers determined that BSC audit was limited regarding the assessment of data inputs. Due to the small number of documents evaluated (less than 10 percent of AMRs identified for license application), a definitive determination of input data quality/integrity could not be made. The observers agreed with the audit team's conclusions, findings, and process improvement issues within the limited scope of the audit. The observers determined that the audit team members were qualified and independent of the areas being audited, however, the observers concluded that the audit team was limited in its expertise in the various technical disciplines. A few of the auditors were not familiar with the automated Technical Data Management System (TDMS) functions, which were a critical tool in accomplishing the objectives of this audit. The audit team leader concluded that the limited number of available documents critical to license application prevented conclusive determination of input data acceptability.

As noted above, the audit scope was limited to a small number of technical products and not all were critical to license application. This was the first audit of data integrity for data used in a technical products intended for licensing, and the approach, level of detail, and time necessary to access large numbers of data records could not be fully anticipated. The audit team recognized that evaluation of the first two of five process steps outlined in the checklist took a disproportionate amount of time to complete. The observations made indicated that overall transparency, traceability, adequacy, appropriateness, and suitability of data is indeterminate and further technical evaluation is required to fully judge the products being produced for license application.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Ted Carter	Team Leader	NRC
Tom Matula	Senior QA Engineer	NRC
David Esh	Technical Specialist	NRC
Beth Schlapper	Technical Specialist	NRC
Rodney M. Weber	QA Specialist	Center for Nuclear Waste Regulatory Analyses (CNWRA)

3.2 OQA Audit Team

Marilyn Kavchack,	Navarro Quality Services (NQS), Las Vegas, Audit Team Leader
Beth Bennington	OQA Las Vegas, Auditor
James Voigt	NQS Las Vegas, Auditor
Bruce Foster	NQS Las Vegas, Auditor
Christian Palay	NQS Las Vegas, Auditor
Harvey Dove	NQS Technical Specialist
Eric Zwahlen	Management and Technical Support (MTS)/Golder Associates, Technical Specialist
Ron Linden	MTS/Golder Associates, Technical Specialist

3.3 DOE Observer

Jon White DOE, Repository Engineering and Design Division

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The audit regarding the data inputs supporting the development of selected AMRs was conducted in accordance with Administrative Procedure AP–18.3Q, Internal Audit Program, and AP–16.1Q, Management of Conditions Adverse to Quality. The NRC staff's observation of this audit and development of this report was based on NRC Manual Chapter 2410, Conduct of Observation Audits, dated July 12, 2000.

4.1 Scope of the Audit

The audit team conducted this performance-based audit to determine the acceptability of data inputs used to support selected AMRs, implementation of procedures supporting the development of technical products, and follow-up of previously identified issues documented in corrective actions over the previous 2 years. The QARD, DOE/RW–0333P, Revision 12, Scientific Process Guidelines Manual, TDR–WIS–MD–000001 R–01, and applicable implementing procedures were used to generate the performance based audit checklist. This

audit focused on eight AMRs selected for their status as recently developed or nearing completion. The eight AMRs reviewed during the audit were:

- Geologic Framework Model 3.1, MDL–NBS–GS–000002 (I0035)
- Field Thermal Analysis, MDL–NBS–GS–000005 (I0060)
- 3D UZ S/S Model Grid, ANL–NBS–HS–000015 (I0000)
- Future Climate Analysis, ANL–NBS–GS–000008, (U0000)
- Calibrated Properties Model, MDL–NBS–HS–000003 (U0035)
- Characteristics of Receptor for Biosphere Model, ANL–MGR–MD–000005 (B0010)
- Agricultural and Environmental Input Parameters for Biosphere Model, ANL–MGR–MD–000006 (B0030)
- Hydrogen Induced Cracking of Drip Shield, ANL–EBS–MD–000006 (W0105)

Specifically, the audit concentrated on the critical process steps for determination of data adequacy and qualification status. These steps included the following process steps:

- Planning
- Data Input and Development
- Technical Product Input Selection
- Analysis and Documentation
- Data Control and Management of Data

In addition to the above process evaluation steps, corrective actions identified through previous audit and surveillance activities were evaluated for effectiveness. The corrective actions selected for review were:

- BSC–02–D–074, Use of Data Not Obtained From TDMS (two occurrences)
- BSC–01–D–063, Incorrect Data Labeling (eight sets)
- BSC(B)–03–D–054, No Road Maps for Data Sets (seven sets)
- BSC(B)–02–D–191, Use of Data from Uncontrolled Source (two occurrences)
- BSC(O)–02–D–123, No Road Map for Data Set (three sets)
- BSC–02–D–009, No Technical Data Review Record for Qualified Data (three sets)
- BSC–01–D–055, Impact Review Not Initiated for Superceded Data Set (one set)

4.2 Conduct and Timing of the Audit

The audit scope was limited to a small number of technical products and not all were critical to license application. This was the first audit of technical products intended for licensing, and the approach, level of detail, and time necessary to access large numbers of data records could not be fully anticipated. The audit team recognized that evaluation of the first two of five process steps outlined in the checklist took a disproportionate amount of time to complete. The observations made indicated that overall transparency, traceability, adequacy, appropriateness, and suitability of data is indeterminate and further technical evaluation is required to fully judge the products being produced for license application. The audit team leader indicated that further audits are to be conducted to evaluate overall data integrity. Since this was the first activity specifically intended to assess data integrity, lessons learned will provide valuable input to the planning of additional audits.

The audit team and observers caucused at the end of each day to discuss the audit status and any new and developing issues. The observers were encouraged to participate in the discussions with any comments, concerns, or questions. The audit team met with BSC management, as appropriate, each morning, with observers present, to discuss the current audit status and potential discrepancies. The observers determined that the timing of the audit was not appropriate for the team to evaluate the BSC quality program and that fewer technical documents were available than expected and not sufficient to determine data integrity.

4.3 Audit Team Qualification and Independence

This audit team consisted of one audit team leader who is a qualified lead auditor, four auditors, three technical specialists, and one DOE observer. The observers reviewed the qualifications for the Audit Team Leader and all the auditors and determined that the qualifications of these audit members met the requirements of AP–18.1Q, Audit Personnel Qualification. The observers concluded that the audit team was limited in its expertise to perform the necessary tasks to adequately determine if data was appropriate for its intended use. Some of the auditors were not familiar with the automated TDMS which was a critical tool in accomplishing the objectives of this audit.

4.4 Examination of Data, Critical Process Steps

4.4.1 Planning

Four procedures formed the basis of this area's review. The auditors reviewed procedure adequacy to the QARD including: (i) planning, preparation, review and approval; (ii) data qualification and use of accepted data; and (iii) scientific notebook references.

One potential deficiency was noted. Three planning documents reviewed did not contain specific documentation to measure the application of cited criteria.

The observers agreed with the audit team findings in this area.

4.4.2 Data Input and Development

The implementation of three procedures and their adequacy to the QARD was reviewed. These procedural areas included: (i)Management of Technical Product Inputs; (ii) Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data; and (iii) Submittal and Incorporation of Data to the TDMS.

One potential deficiency was noted in this area. The auditors review of one Qualification Data Report found 24 technical publication inputs that were not documented using sufficient evaluation criteria. The summary evaluation provided in the report was determined by the auditors to be insufficient.

The observers agreed with the audit team findings in this area.

4.4.3 Analysis and Documentation

For this critical process step, the auditors evaluated the management of technical product inputs as defined in AP–3.15Q, Managing Technical Product Inputs. Included in the review were adequacy with respect to the QARD, data identification and control, appropriate data status, reference agreement/traceability with the various document information systems and technical data bases, and the appropriate and consistent use of data.

No potential deficiencies were noted in this area.

The observers agreed with the audit team findings in this area.

4.4.4 Technical Product Input Selection

Implementation of procedures for Scientific Analyses and Models were evaluated for this step. The auditors reviewed documents for QARD implementation, input/output transparency and traceability, overall technical adequacy, checking and review adequacy related to data inputs.

One potential deficiency was noted in this area. Errors were found in the traceability of data to the TDMS and in references cited for three of the models reviewed.

The observers agreed with the audit team findings in this area.

4.4.5 Data Control and Management of Data

The requirements of two procedures and one plan were reviewed for this step. Review of Technical Products and Data, and Control of the Electronic Management of Information, formed the basis of this review. Review elements included: (i) adequacy with respect to the QARD; (ii) adequacy of Technical Product Review packages; (iii) information protection; control of backup media; (iv) data integrity, security, and retrievability; and (v) the adequacy of the Technical Data Management Plan.

No potential deficiencies were noted in this area.

The observers agreed with the audit team findings in this area.

4.4.6 Examination of Corrective Actions

Corrective actions related to data for the previous 2 years were noted in the audit checklist and tied to specific checklist questions. Each auditor was made aware of these previous findings and reviewed the effectiveness of the actions as the auditor progressed through the checklist. These previous corrective actions were discussed during daily caucuses as they related to specific checklist questions. However, as indicated under the steps above, deficiencies continue to be noted.

The observers attended several discussions with the Performance Assessment Technical Input manager and learned of the current efforts by BSC to review, identify, and correct data inconsistencies with technical products. The process currently in place is supported by

personnel who appear capable and knowledgeable of data requirements and previous issues. This process has been effective in screening out many errors similar to those previously identified by the BSC and OQA audits. However, the BSC organization indicated that it is taking further action in this area. It has reviewed deficiency reports for the last 4 years, grouped similar deficiencies, and found trends it intends to report in a forthcoming corrective action. The observers prepared an audit inquiry for the purposes of acknowledging BSC's intent related to data discrepancies and to provide for timely follow-up (Section 5.3).

4.5 Examination of Technical Activities

Three different audit teams were used by DOE to more efficiently cover the information. As a result, only a subset of the technical activities evaluated in this audit were able to be observed directly by NRC technical specialists.

DOE's electronic data management system was observed to be a potentially powerful tool to enable evaluation of data traceability and data verification. However, approximately 9000 data tracking numbers (DTNs) reside in the system, and some of the DTNs represent enormous amounts of information. The total number of DTNs set for evaluation in the course of the audit was on the order of 100 or approximately 1 percent of the total in the system. As an example, a DTN associated with the calibrated properties model (MO0012MWDGFM02.002) contained 3,081 files and over a gigabyte of information. Evaluation of the transparency and traceability by NRC technical specialists of the DTNs themselves was rather straightforward using the electronic information management system (i.e., the correct information source was referenced). However, verification of the technical information used from or contained within some of the larger DTNs was very difficult to determine in anything more than a superficial manner during the course of the audit.

A more extensive audit directed at verifying the technical adequacy and transparency of the data extracted from both simple and more difficult DTNs (and a larger sample of DTNs over a larger range of documents) is needed in order to make conclusions pertaining to the adequacy of data for a license application.

An audit checklist item was to evaluate the consistency between information/references cited in the audited AMR and other Project documents. This type of evaluation is much more time-consuming and requires that documents which may have used consistent types of information be evaluated during the course of the audit. Because of the state of development of many of the project documents, the NRC observers agree with the DOE audit team that consistent use of common sets of information could not be conclusively evaluated during the course of this audit.

4.5.1 Calibrated Properties Model MDL–NBS–HS–000003

The purpose of this report is to document the model that provides calibrated property sets for unsaturated zone (UZ) flow and transport process models. The calibrated property sets contain matrix and fracture parameters for use in various natural system models. The calibration process includes inversions utilizing iTOUGH V5.0.

The technical specialists evaluation focused on 17 DTNs. The DTNs contained information on saturations, water potentials, pneumatic pressure, infiltration maps, numerical grids, uncalibrated fracture data, and various other types of information. In general, it was apparent that the correct DTNs were referenced as sources of information. However, many of the natural system DTNs contained large amounts of information which made evaluation of the accurate selection/transfer of information (from the DTNs to the report or into calculations) infeasible during the course of the audit. Table 4 (Uncalibrated Fracture Property Data) and Table 15 (Calibrated Mountain-Scale Fracture Permeabilities) were observed to have errors compared to the information contained in the referenced DTNs.

The audit team determined that scientific notebook LBNL–SC–SCI–229 was incorrectly referenced as LBNL–SC–SCI–299 and that the incorrect reference was carried forward from the notebook review into the report. This has been classified as a potential quality observation.

The observers agreed with the audit teams findings in this area.

4.5.2 Development and Qualification of the Thermodynamic Database Geochemical Modeling Calculations and Analyses TDR–EBS–MD–000022

The purpose of the document was to incorporate unqualified data sets into the database, perform an extension of the information in the database from 25 °C to higher temperatures where possible, and to develop a qualified database for use in geochemical modeling calculations.

The technical specialists evaluated the criteria for which qualification was determined and the backgrounds of the members of the qualification team. The qualification team members had extensive backgrounds in geochemical modeling and appeared to be highly qualified for the task. The primary data qualification method was technical assessment. Many of the data values to populate or use in creation of the database were brought in from handbooks as accepted data. The qualification lead stated that geochemical data can be difficult. The primary method of technical assessment was to look at variability in a data set and qualitative judgement was used to select a particular data value for the qualified database. The qualification lead stated that uncertainties in geochemical modeling mainly come from modeling approaches and not necessarily from the thermodynamic data itself.

All of the extractions of data and manipulations were thoroughly checked. Checking was done following the AP–SIII.9Q, Scientific Analyses, checking process even though the report was not written to AP–SIII.9Q. Aside from a list of the persons who checked what parts of the database, no objective evidence was available to support the assertion of thorough checking. In addition, the list did not identify a checker for some of the Microsoft® Excel files (approximately 79 files of moderate to high complexity).

The audit team determined that the 24 technical assessments were not robust enough to support data qualification. This issue has been documented by the audit team as a potential deficiency.

The observers agreed with the audit teams findings in this area.

4.5.3 Hydrogen-Induced Cracking of the Drip Shield ANL–EBS–MD–000006

The purpose of this report was to evaluate the potential for hydrogen-induced cracking of the drip shield. The drip shield is designed to prevent or minimize water contact with the waste and may also limit the potential for mechanical damage of the engineered system.

The technical specialists focused on the treatment and adequacy of the data in the report. Three primary sources of information were used in the model for evaluation of hydrogen induced cracking of the drip shield: (i) the general corrosion rate of the material, (ii) a hydrogen absorption factor, and (iii) a critical threshold. Two of the three data sources were assumptions. The critical hydrogen concentration during the regulatory time period was calculated as 750 mg/g whereas the assumed threshold was 1,000 mg/g. Therefore, hydrogen-induced cracking was not included in the performance assessment calculations. Galvanic coupling from carbon steel drift support materials contacting the titanium was also evaluated. Galvanic coupling was evaluated to create approximately 100 to 400 mg/g hydrogen. The NRC observers asked whether combined effects of hydrogen-induced cracking from both general corrosion and galvanic coupling were considered. The author stated they had not been but that they felt when galvanic processes were occurring, general corrosion would be negligible.

The auditors evaluated the AP–2.14Q, Review of Technical Products and Data, materials produced during the document review process and concluded that a thorough technical review had been performed on the product.

The data from the DTN for general corrosion was corrected for the effect of silica precipitation during the weight-loss measurements. The correction factor was not identified in the report and therefore there was not transparency and traceability of the information used in the report without recourse to the originator. The audit team identified this issue as a potential deficiency.

The observers agreed with the audit teams findings in this area.

4.5.4 Rock Properties Qualification Report, TDR–MGR–GE–000003, Revision 00

The purpose of the qualification report was to document the process and rationale through which unqualified mechanical rock property data were consolidated into a single qualified data set.

The audit team technical specialists focused on the criteria through which qualification was achieved. The data being evaluated represented empirical measurements from up to six different institutions. Some qualified data was available, therefore a combination of the corroboration method and the technical assessment method was used to determine whether the unqualified data could be qualified. The auditors questioned why criteria for qualification, as specified in AP–SIII.2Q, Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data, were not clearly presented in the report. The author said it was especially difficult to specify qualification criteria at the planning stage when dealing with natural system rock property data. Overall, because the technical assessment determined there was agreement of a "substantially positive fashion," the data was determined to be qualified. None of the data was rejected in the qualification effort. Some subsets of the data had small sample

sizes and large variability in the data, therefore qualification was primarily subjective in nature. The issue of data qualification criteria resulted in a potential deficiency report.

The NRC observers questioned what the use of the information was going to be. The author said most of the information would be used within the repository design group but that some may be used in mechanical processes models. During the interview of a number of technical staff members, the NRC observers were pleased to see a positive attitude with respect to being audited.

The observers agreed with the audit team findings in this area. In addition, the NRC observation documented in Section 5.2 of this report is related to data qualification and technical assessment.

4.5.5 Development of Numerical Grids for UZ Flow and Transport Modeling, ANL–NBS–HS–000015, Revision 01G

The purpose of the grid report was to describe the methods used to develop numerical grids of the unsaturated hydrogeologic system beneath Yucca Mountain.

As part of the data checklist, the audit team performed a review of the various data sets, notebooks, correspondence, and plans via the TDMS for the associated Record Roadmap—DTN GS960808312231.004. The audit team used the various records to assess the data qualification level used to prepare the grid report. The observers again noted that the electronic data management system was a powerful tool for use in data tracking from source data to supersede information.

The observers agreed with the audit team's findings in this area.

4.6 Evaluation of QA Program Procedural Sufficiency

The audit team assessed BSC procedure adequacy against the requirements of the QARD. With the exception of one quality observation, the procedures were found to adequately reflect the requirements of the QARD.

The observers agreed with the audit team findings in this area.

4.7 Potential Audit Findings

4.7.1 Potential Deficiency Reports

The audit team identified three conditions adverse to quality during its review. The audit team identified these conditions adverse to quality as deficiency reports (DRs) or referenced them as Document Input Reference System (DIRS) which are then attached to existing DRs.

4.7.1.1 Potential Audit Finding No. 1

During the audit, the audit team found that three of the model reports reviewed contained DTNs not traceable to the TDMS. In addition, errors in data references were also found. These models were:

- ANL–MGR–MD–000006, Agricultural and Environmental Input Parameters for Biosphere Model
- MDL–NBS–HS–000003, Calibrated Properties Model
- ANL–EBS–MD–000006, Hydrogen Induced Cracking of Drip Shield

4.7.1.2 Potential Audit Finding No. 2

During the review of three planning documents, data evaluation did not contain specific documentation to measure the application of cited criteria. These documents were:

- DQP–EBS–MD–000001
- TWP–WHS–GE–000001
- TWP–MGR–GE–000002

4.7.1.3 Potential Audit Finding No.3

The audit team determined that one Qualification Data Report contained 24 technical publications used as direct inputs but were not adequately documented using sufficient evaluation criteria. The team considered the summary evaluation contained in the report to be insufficient.

- TDR–EBS–MD–00022

4.8 Potential Quality Observations

4.8.1 Quality Observations

The audit team identified five minor deficiencies not considered significant to document quality or were representative of single occurrences. The following outline these observations:

- Procedure inconsistency between AP–2.27Q, Planning for Science Activities; and AP–SIII.2Q, Qualification of Unqualified Data and the Documentation of Rationale for Accepted Data
- Scientific notebook incorrectly identified in a Calibrated Properties Model Report
- Electronic data from a scientific notebook used in the Geologic Framework Model but not properly controlled
- Subject matter expert in one data qualification report not identified

- No rationale for not addressing qualifications of personnel/organizations generating data from those under a 10 CFR Part 63 program

5.0 NRC STAFF FINDINGS

The NRC observers determined that the audit team for Audit OQAP–BSC–03–05 was not effective in determining the level of compliance of BSC activities. Requirements associated within the development of AMRs relative to those contained in the QARD were acceptable with the exceptions identified as the potential deficiencies and the potential quality observations.

5.1 NRC Audit Exit Summary

During the audit exit meeting, the observer team leader expressed appreciation for the cooperation and responsiveness given the observation team during their observation activities. In addition, the observer team leader stated that the observers agreed with the audit team's findings and recommendations, as presented at the audit exit meeting. The following comments were made by the observer team leader.

NRC Closing Comments Presented by Ted Carter During the Data Verification Exit Meeting on March 27, 2003.

Let me start off by saying that the observation team agrees with the findings of the audit team. <pause>

The overall assessment of the observation audit team is that the audit was indeterminate. <pause>

- The audit scope was limited due to the small number of technical products evaluated.
- It is noted that this was the first audit regarding data verification in technical products intended for licensing. As a result, the approach, level of detail, and time necessary to access the data records may not have been fully anticipated.
- The audit team recognized that it took a disproportionate amount of time to complete the first two critical process steps, planning and data input and development.
- Tracking the many DTNs in the data management system was also time consuming.
- The audit was limited in its determination of the overall adequacy, appropriateness, and suitability of the supporting data.
- Based on the audit findings, potential issues remain concerning input, both programmatic and technical. But because of the limited scope of the audit, the extent of these issues remain indeterminate and additional evaluation activities to be performed by BSC and OQA are necessary.

The following was also stated after the summary and recognized as being outside the scope of this audit:

- An Audit Observer Inquiry was written by the observation audit team requesting additional information on Corrective Action Report (CAR), BSC (B)–03–107. BSC indicated during the audit that they will document this CAR as a result of a review of approximately 46 data-related deficiency reports issued from 1998 to the present. Because of the importance of the matter, the NRC requests a response to this audit inquiry within 45 days of the date March 27, 2003 of this Audit Observer Inquiry.

>>This is the closing statement of the observation audit team and will be included in the NRC Observation Audit Report.<<

5.2 NRC Observations Outside the Scope of the Audit

5.2.1 Technical Assessment and Data Qualification

Of the data qualification reports evaluated in this audit, technical assessment was strongly relied upon as the method for qualification of unqualified data. NUREG–1298 Qualification of Existing Data for High-Level Nuclear Waste Repositories is a Generic Technical Position which identifies four alternative methods that are acceptable for qualifying existing data. One of these methods is peer review in accordance with NRC's generic technical position elucidated in NUREG–1297, Peer Review for High-Level Nuclear Waste Repositories. A peer review is defined as "... an in-depth critique of assumptions, calculations, extrapolations, alternative interpretations, methodology, and acceptance criteria employed, and of conclusions drawn in the original work. Peer reviews confirm the adequacy of work." Peer review is appropriate in many circumstances including when "Data adequacy is questionable—such as, data may not have been collected in conformance with an established QA program." In some cases it appears that DOE's technical assessment process is directed at trying to assess the adequacy of highly uncertain data with much less emphasis on evaluating the adequacy of the work which generated the unqualified data.

5.2.2 Use of Different Types Information to Support a License Application

In some instances, data that was originally assigned a to-be-verified designation was converted to an assumption and then inserted directly into an analysis. In addition, many data sets for use in the performance assessment or supporting models are classified as accepted data. Accepted data can be established fact (e.g., handbooks) or not-established-fact data. For not-established-fact data, a documented rationale for accepted data may include (per AP–SIII.2Q) various options such as: (i) best available or only data source, (ii) historical precedence, and (iii) inclusion in a refereed or peer-reviewed journal or publication. From an NRC technical specialist perspective, adequate confidence is needed in data used to support a license application regardless of the type of information (e.g., qualified, assumption, accepted). Use of not-established-fact accepted data and data-oriented assumptions would appear to be an area that should be the focus of an audit to see if these data classes are being appropriately handled. If only one unqualified data source is available, this would appear to be a reason to be cautious of directly incorporating the data into the analysis as an accepted-data-source. This type of audit would need to be heavily biased towards technical specialists familiar with the data being evaluated.

5.2.3 Technical Checking

In some cases there was good evidence of technical review of the audited materials. However, in other cases there was sparse evidence of technical checking of calculations and data. For example, DTN MO0302SPATHDYN.001 associated with Data Qualification: Update and Revision of the Geochemical Thermodynamic Database, the file name Data0.ymp, contains 79 Excel spreadsheets as well as many other files. Some of the spreadsheets contain fairly complicated calculations and many unit conversions. It is unlikely that a technical checker would be able to effectively evaluate the accuracy of the information contained in the spreadsheets during the document review. This is not an isolated example as there are many difficult DTNs contained in the data tracking system. The NRC technical specialists believe it is important to have a robust technical checking process, but it was unclear during the course of this audit that robust technical checking would be feasible given the current management of information in sometimes large sets of files.

5.3 NRC Audit Observer Inquiry

The NRC generated the following inquiry as a result of observing audit OQAP–BSC–03–05.

BSC management has reviewed data related deficiency reports occurring over the last 4 years, grouped the results, and identified areas of concern (potential trends). This information was not an identified item within the audit plan, but the observation team became aware of this activity through the on-site representative's contacts with BSC management. BSC indicated their intent to issue a CAR in this area and indicated that descriptive wording was being drafted subsequent to formal issuance of the CAR. Therefore, the following inquiry was written:

> The Audit Observation Team determined that BSC performed a review of approximately 46 data-related Deficiency Reports issued from 1998 to the present. BSC has indicated their intent to document the results of this review in a CAR, BSC (B)–03–107. The initial entries are being developed by BSC. The NRC requests that DOE provide the outcome of this CAR evaluation, the results of the root cause analysis, and the associated corrective action plan. If BSC does not issue the CAR, NRC requests the justification for this decision.
>
> Because of the importance of this matter, the NRC requests a response to their audit inquiry within 45 days of the date of this Audit Observer Inquiry. If these actions are not completed by this date, please respond verbally or in writing.