



## Department of Energy

Washington, DC 20585

QA: QA

APR 24 2003

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### ISSUANCE OF DEFICIENCY REPORT(S) (DR) BSC(O)-03-D-129, BSC(O)-03-D-130 AND BSC(O)-03-D-135 RELATED TO DATA INTEGRITY

Enclosed are DRs BSC(O)-03-D-129, BSC(O)-03-D-130, AND BSC(O)-03-D-135 generated as a result of OQA Audit QQAP-BSC-03-05.

Please provide responses that meet the applicable requirements of Administrative Procedure (AP)-16.1Q, *Management of Conditions Adverse to Quality*. Send the original of your responses to Deborah G. Opielowski, Navarro Quality Services, P.O. Box 364629, Mail Stop 455, North Las Vegas, Nevada 89036-8629. Initial response to the DRs are due ten working days from the date of this letter. Any extension to the due dates must be requested in accordance with AP-16.1Q.

If you have any questions, please contact either Kerry M. Grooms at (702) 794-1367 or Marilyn A. Kavchak at (702) 794-5423.

R. Dennis Brown, Director  
Office of Quality Assurance

OQA:KMG-1083

#### Enclosures:

1. DR BSC(O)-03-D-129
2. DR BSC(O)-03-D-130
3. DR BSC(O)-03-D-135



R. W. Andrews

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APR 24 2003

cc w/encls:

N. K. Stablein, NRC, Rockville, MD

Robert Latta, NRC, Las Vegas, NV (2 cys)

S. W. Lynch, State of Nevada, Carson City, NV

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F. H. Dove, NQS, Las Vegas, NV

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D. G. Opielowski, NQS, Las Vegas, NV

C. M. Palay, NQS, Las Vegas, NV

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8. ☒ DEFICIENCY REPORT  
☐ CORRECTIVE ACTION  
REPORT  
NO. BSC(O)-03-D-129  
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DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)  
AP-SIII.2Q, Revision 1, ICN 0, "Qualification of Unqualified Data ...."  
2. Related Report No.:  
OQAP-BSC-03-05

3. Responsible Organization:  
BSC Science and Analysis Project  
4. Discussed With:  
Terry Steinborn, Ed Cikanek, Robert Andrews, Michael Jaeger

5. Requirement:  
Section 5.1.2 b) states: "Prepare, revise, or expand a Technical Work Plan prepared in accordance with AP-2.27Q, Planning for Science Activities, or prepare a data Qualification Plan to include:

4) Data evaluation criteria, including specific information such as size of sample to be tested, statistical method to be used, and identification of computer codes to be used."

6. Description of Condition:  
Contrary to the stated requirement, the data evaluation criteria in at least three of five planning documents are vague and do not contain specific information to measure the successful/unsuccessful application of individual criteria. The three planning documents are (1) DQP-EBS-MD-000001, Revision 01, (2) TWP-WHS-GE-000001, Revision 00, and TWP-MGR-GE-000002, Revision 00. Specific examples from DQP-EBS-MD-000001 include:

1. "Are the data reasonable in terms of compatibility with other existing data (thermodynamic consistency)?"
2. "Does analysis of comparable qualified and unqualified data indicate a reasonable level of accuracy for the fundamental thermodynamic data?"

Specific examples from TWP-WHS-GE-000001 include:

(Continued on Condition Adverse to Quality Continuation Page 2)

Has work been stopped? ☐ Yes ☒ No

7. Initiator:  
Floyd H. Dove  
Printed Name  
Signature  
Date  
9. Does a stop work condition exist?  
☐ Yes ☒ No ☐ N/A  
If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:  
None

11. QA Review:  
Floyd H. Dove  
Printed Name  
Signature  
Date  
12. Response Due Date:  
10 Working Days after Issuance

13. QAM Issuance Approval:  
Printed Name R. Dennis Brown  
Signature  
Date

14. Corrective Actions Verified/Closure  
QAR Printed Name  
Signature  
Date  
15. QAM Closure Approval:  
Printed Name  
Signature  
Date

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**CONDITION ADVERSE TO QUALITY CONTINUATION PAGE**

Block 6 Description of Condition (Continued from Deficiency Report/Corrective Action Report Page 1)

1. "Are the data collection methods reasonable in view of standard measurement and instrumentation practice at the time the data were collected?"
2. "Does analysis of comparable qualified and unqualified data sets indicate a reasonable level of accuracy for the testing?"
3. "Is the documentation associated with the data sufficient to allow an assessment of the methods used and the results obtained?"

Specific examples from TWP-MGR-GE-000002 include:

1. "Are the data collection methods reasonable in view of standard measurement and instrumentation practice at the time the data were collected?"
2. "Are these data, or similarly collected data, generally accepted by the technical community for use in non-YMP applications?"
3. "Does analysis of comparable qualified and unqualified data sets indicate a reasonable level of accuracy for the testing?"

It should be noted that the evaluation criteria in each planning document are almost identical even when the data being qualified are different.

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8. ☒ DEFICIENCY REPORT  
☐ CORRECTIVE ACTION  
REPORT  
NO. BSC(O)-03-D-130  
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QA: QA

DEFICIENCY REPORT/CORRECTIVE ACTION REPORT

1. Controlling Document: (Document ID and Revision or Date)  
AP-SIII.2Q, Revision 1, ICN 0, "Qualification of Unqualified Data...."

2. Related Report No.:  
OQAP-BSC-03-05

3. Responsible Organization:  
BSC Science and Analysis project

4. Discussed With:  
Terry Steinborn, Robert Andrews, Michael Jaeger

5. Requirement:

1. Section 5.3.1 a) requires the results of data qualification tasks be documented. The Data Qualification report, analysis, or model report shall include, as applicable, a discussion of the evaluation criteria, evaluation results, and abandoned methodology.
2. Attachment 2 requires the Technical Assessment to be performed by subject matter experts who will evaluate the appropriateness of the methodology and the appropriateness of the resulting data.

6. Description of Condition:

1. The data qualification report, TDR-EBS-MD-000022, Revision 00b, "Data Qualification Update and Revision of the Geochemical Thermodynamic Database, Data0.ymp," includes 24 technical publications that were not evaluated individually in accordance with each of the four evaluation criteria.

Also, one evaluation criterion was discarded from the technical assessment. The criterion was : "Are the qualifications of the personnel or organizations generating the data comparable to qualification requirements of personnel generating similar data under the approved 10 CFR 63, Subpart G quality assurance program?" The decision to abandon this criterion was not addressed within the data qualification report.

2. Subject matter experts were not identified for each of the 24 Technical Assessments included in the data qualification report.

Has work been stopped? ☐ Yes ☒ No

7. Initiator:

Floyd H. Dove  
Printed Name

Signature

04/17/03  
Date

9. Does a stop work condition exist?

☐ Yes ☒ No ☐ N/A

If Yes, Check One: ☐ A ☐ B ☐ C ☐ D

10. Recommended Actions:  
None

11. QA Review.

Floyd H. Dove  
Printed Name

Signature

04/17/03  
Date

12. Response Due Date:

10 Working Days after Issuance

13. QAM Issuance Approval:

Printed Name R. Dennis Brown

Signature

Date

4/23/03

14. Corrective Actions Verified/Closure

QAR Printed Name

Signature

Date

15. QAM Closure Approval

Printed Name

Signature

Date

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**DEFICIENCY REPORT/CORRECTIVE ACTION REPORT**

<p>1. Controlling Document: (Document ID and Revision or Date)</p> <p>AP-SIII.9Q, Revision 0, ICN 1, <i>Scientific Analyses</i>          AP-SIII.10Q, Revision 1, <i>Models</i></p>	<p>2. Related Report No.:</p> <p>OQAP-BSC-03-05</p>
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<p>3. Responsible Organization:</p> <p>BSC Performance Assessment</p>	<p>4. Discussed With:</p> <p>G. De, P. Pasupathi, A. Smith, K. Rautenstrauch, K. Rasmussen, V. Fissekido, P. Persoff, and H.H. Liu</p>
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5. Requirement:

(I) AP-SIII.9Q, Attachment 3 – Scientific Analysis Outline

“...Information presented in the scientific analysis documentation shall be transparent and traceable.”

...(Sections 1,2,3 not stated)

4. Inputs- “...Inputs shall be correctly selected, identified in the scientific analysis documentation, correctly cited, and incorporated.”

4.1 Data and Parameters- “Provide a list or tables of data and parameters and their sources. The values in the data cited shall be verified to be the same as those in the TDMS.”

[Continued On Condition Adverse To Quality Continuation Page 2]

6. Description of Condition:

Contrary to the above requirements, three out of eight Analysis Model Reports (AMRs) audited during OQAP-BSC-03-05 had the following conditions identified as follows:

Inconsistent with Requirement I, the AMR titled “Identification of Ingestion Exposure Parameters,” ANL-MGR-MD-000006, Revision 1D, has the following conditions:

1. An additional column of data, “Max Average Monthly Relative Humidity,” is not contained within MO0210SEPCLIMA.001, the cited input DTN residing in the TDMS. Consequently, the table is not traceable back to the TDMS.
2. The DTN referenced in the AMR Table 4.1-3 as a note was incorrect and the listed values had been modified to accommodate different units of measurement without explanation. Hence, the table is not transparent.

[Continued On Condition Adverse To Quality Continuation Page 2]

Has work been stopped? ☐ Yes ☒ No

<p>7. Initiator:</p> <p>Christian Palay <i>Christian Palay</i> 4/16/2003</p> <p>Printed Name Signature Date</p>	<p>9. Does a stop work condition exist?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D</p>
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10. Recommended Actions:

None.

<p>11. QA Review:</p> <p>Christian Palay <i>Christian Palay</i> 4/16/2003</p> <p>Printed Name Signature Date</p>	<p>12. Response Due Date:</p> <p>10 Working Days after Issuance</p>
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13. QAM Issuance Approval:

Printed Name *R. Dennis Brown* Signature *R. Dennis Brown* Date *4/22/03*

<p>14. Corrective Actions Verified/Closure:</p> <p>QAR Printed Name Signature Date</p>	<p>15. QAM Closure Approval:</p> <p>Printed Name Signature Date</p>
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☐ SWO

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**CONDITION ADVERSE TO QUALITY CONTINUATION PAGE**

**Block 5 Requirement [continued from Deficiency Report/Corrective Action Report 1]**

**II) AP-SIII.10Q, Attachment 2 – Model Documentation Outline**

"...Information presented in the model documentation shall be transparent and traceable."

...(Sections 1,2,3 not stated)

**4. Inputs-** "...Technical product inputs shall be correctly selected, identified in the model documentation, correctly cited and incorporated..."

**4.1 Data and Parameters**

- "Provide lists or tables of technical product inputs that were used directly in the development of the model."

**Block 6 Description of Condition [continued from Deficiency Report/Corrective Action Report page 1]**

Inconsistent with Requirement II, the AMR titled "Hydrogen Induced Cracking of Drip Shield," ANL-EBS-MD-000006, Revision 1, cites two input DTNs, MO0003SPASUP02.003 and LL990610605924.079. The results of the development of a correction factor for the effects of silica deposition were documented in table 1 of section 4.1 of the AMR. However, the process for developing the correction factor was not documented within the AMR, and the correction factor is not reflected within the DTNs in the TDMS. Consequently, data that is reported in table 1 of section 4.1 of the subject AMR does not match the cited DTNs, MO0003SPASUP02.003 and LL990610605924.079. Additionally, the development of the correction factor is not apparent within the AMR and the AMR originator had to explain the source of the correction factor for the effects of silica disposition. Therefore, the table 1 of section 4.1 is not transparent with regards to its development, and the table is not traceable back to the cited DTNs residing in the TDMS.

The AMR MDL-NBS-HS-000002, Revision 1, has the following conditions inconsistent to Requirement II:

Table 4 identifies two model layers with the same label of tcwf. The referenced source, DTN LB0207REVUZPRP.001, shows this second model layer as tswf. Table 4 of MDL-NBS-HS-000002 also records a tcwf (instead of tswf) model layer van Genuchten parameter value as  $3.2 \times 10^{-4}$ . The referenced source DTN LB0207REVUZPRP.001 shows this value as  $3.2 \times 10^{-3}$ .

Table 15 (calibrated Mountain-Scale Fracture Permeabilities) records a Basecase permeability for Model Layer ptn21 as  $2.11 \times 10^{-11}$ . The output DTN LB02091DSSCP31.002 shows a permeability value for the corresponding layer as  $2.11 \times 10^{-12}$ .