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OVERNIGHT MAIL

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RESPONSE TO THE U.S. NUCLEAR REGULATORY COMMISSION (NRC) AUDIT
OBSERVER INQUIRIES (AOI) FROM THE BECHTEL SAIC COMPANY, LLC (BSC),
QUALITY ASSURANCE AUDIT BQAP-BSC-05-07

Reference: Ltr, Collins to Williams, dtd 1/9/06 (NRC Observation Audit Report
No. OAR-05-05, Observation Audit of Bechtel SAIC Company, LLC, Internal
Audit BQAP-BSC-05-07)

The purpose of this letter is to provide responses to the NRC AOIs and other issues raised by the NRC in its observation audit report OAR-05-05 (Reference). In those cases for which the resolution of issues is the subject of ongoing Condition Report (CR) actions, the current status of these efforts is provided. Completion of the ongoing CR actions will be tracked through the Corrective Action Program (CAP).

On January 9, 2006, NRC issued its Audit Observation Report OAR-05-05 (Reference) that described certain weaknesses and deficiencies observed during the course of an audit conducted by BSC at the Lawrence Livermore National Laboratory (LLNL) on August 23–25, 2005. The BSC audit focused on experiments intended to determine environmental conditions that may be encountered within the repository after permanent closure and the long-term performance of materials anticipated to make up components of the repository-engineered barriers.

The response to AOIs and issues raised in the NRC observation audit report includes a thorough evaluation of technical issues, performance of critical self-assessments, and utilization of the CAP. The Office of Civilian Radioactive Waste Management (OCRWM) responses in Enclosure 1 explain the results of its evaluations. Although NRC did not require a written response to other issues identified in the report, Enclosure 1 also contains responses to the deficiencies and weaknesses identified during the audit.

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A crosswalk to the various CRs initiated as a result of the audit is contained in Enclosure 2. As reflected in the responses (Enclosure 1), OCRWM recognizes shortcomings in the BQAP-BSC-05-07 audit, and is implementing improvements for future U.S. Department of Energy (DOE)/BSC audits.

In addition to the responses summarized in Enclosure 1 and the corrective actions identified in Enclosure 2, the OCRWM Acting Director requested that an independent review team evaluate the issues identified in the NRC Audit Observation Report No. OAR-05-05-05. Enclosure 3 is the report documenting the results of this independent review.

The following is a brief summary of the AOI responses in Enclosure 1.

- **AOI-OAR-05-05-01** - The issue relates to the adequacy of the justification for the use of the 100°C threshold for the onset of seepage in the seepage evaporation abstraction.

Response Summary: The response clarifies the technical basis for the seepage threshold. Additional discussion on thermal-hydrologic-chemical (THC) processes provides background information on THC modeling and explains that evaporative concentration causes a reduction in fluid volume. It also shows that the expected composition of potential seepage waters is dilute, and that at temperatures above the threshold, the salt accumulation and potential brine volume are limited.

- **AOI-OAR-05-05-02** - The issue relates to the appropriateness of using deliquescence relative humidity values below 40 percent in reports documenting the dust deliquescence model and the physical and chemical environment model.

Response Summary: The response clarifies the validation process used for the in-drift precipitates/salts model, and how that model serves as a tool for the dust deliquescence model and the physical and chemical environment model. The response shows that the two models do not rely on deliquescence relative humidity predictions outside the validation range.

- **AOI-OAR-05-05-03** - This AOI identified apparent inconsistencies between two reports, one of which states that localized corrosion initiates at exposure temperatures exceeding 160°C with a water film. The other report screens out initiation of localized corrosion for water film formed by deliquescence at elevated temperatures.

Response Summary: The first report, General Corrosion and Localized Corrosion of Waste Package Outer Barrier (BSC 2004), was issued prior to the Analysis of Dust Deliquescence for FEP Screening (BSC 2005a). The more recent report contains updated information on dust deliquescence and supports a conclusion that while dust deliquescence is expected to occur, the process should be excluded from the performance

assessment because the effects of such delinquency have been determined to be insignificant. OCRWM plans to revise the first report to remove any inconsistencies with the second report.

- **AOI-OAR-05-05-04** - This AOI identified the citation of cancelled documents in analysis model reports. The AOI described such references as contrary to Quality Assurance Requirements and Description (QARD), Section 6.2.5.C. The AOI requests clarification regarding any plans to use cancelled documents to support the license application (LA).

Response Summary: DOE does not intend to rely on cancelled documents as inputs to the LA. On May 30, 2006, procedure revisions became effective directing that a document may not cite previous versions of the same document as direct input. This change will reduce the number of future citations to “superseded” documents. However, these procedures recognize that a designation of “cancelled” or “superseded” with respect to a document does not necessarily mean that all of the information in the document is unsuitable for use. OCRWM is currently evaluating the use and control of information from older documents to provide assurance of adequacy for intended use.

- **AOI-OAR-05-05-05** –This AOI is a compilation of issues related to the use of the Vaisala humidity probes at LLNL. The issues involve calibration of the probes, the technical basis for calibration, and potential misrepresentation of the status of probe calibration in the associated scientific notebook. In addition, issues were raised about how past corrective actions related to this subject were implemented. Also, an issue was raised regarding LLNL’s implementation of QARD requirements related to probe calibration.

Response Summary: DOE believes that the humidity probes were adequately calibrated and recalibrated in accordance with the manufacturer’s instructions using a calibration methodology consistent with industry practice. This conclusion was based on a thorough evaluation of the technical, quality, and audit communication issues identified in this AOI. DOE conducted self-assessments, issued CRs, conducted root cause analyses, and evaluated previous CRs that might be related to the issues raised by the subject observation audit report. Some of the activities are not yet completed, but sufficient information is available to reach the conclusions summarized here. Once the remaining activities are complete, DOE expects that the data gathered from these probes can be used for their intended purposes. Although the content of scientific notebook entries could have been more complete, DOE believes that there was no “misrepresentation” of information in the scientific notebook. Corrective actions have been initiated to improve various aspects of the audit process.

With respect to the LLNL's implementation of QARD requirements related to probe calibration, the root cause evaluation and the corroborative OCRWM Independent Review (Enclosure 3, p. 16) both conclude that the humidity probes were calibrated in accordance with the QARD, but some of the probes were used beyond the calibration period. Use of measuring and test equipment beyond the calibration period is a violation of the QARD, and is documented in a CR. We are currently evaluating the generic implications of this issue with respect to Measurement & Test Equipment (M&TE) calibration at other program participants and will document the issues and any corrective actions required in the CAP.

There are no new regulatory commitments in this letter or its enclosures. Actions and dates described in Enclosure 1 are provided to status ongoing activities. If you have any questions, please feel free to contact J. Russell Dyer at (702) 794-1301 or e-mail russ_dyer@ymp.gov.



Mark H. Williams, Director
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RAO:AVG-1100

Enclosures:

1. Response to the NRC Audit Observer
Inquiries AOI-OAR-05-05-01 through
AOI-OAR-05-05-05, Areas of Weakness,
and Other Issues Associated with the NRC
Observation Audit Report
2. Crosswalk of AOIs, Weaknesses and
Deficiencies from the NRC Report
OAR-05-05, and Related CRs
3. OCRWM Independent Review Team Report of
the BSC Quality Assurance Audit
BQAP-BSC-05-07, which includes CD
version

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ENCLOSURE 1

**RESPONSE TO NRC AUDIT OBSERVER INQUIRIES
AOI-OAR-05-05-01 THROUGH AOI-OAR-05-05-05,
AREAS OF WEAKNESS, AND OTHER ISSUES ASSOCIATED WITH
NRC OBSERVATION AUDIT REPORT**

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CONTENTS

	Page
RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-01 (ORIGINALLY AOI-BQAP-BSC-05-07-01)	1
RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-02 (ORIGINALLY AOI-BQAP-BSC-05-07-02)	15
RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-03 (ORIGINALLY AOI-BQAP-BSC-05-07-5)	19
RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-04 (ORIGINALLY AOI-OAR-05-07-06)	21
RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-05 (ORIGINALLY AOI-OAR-05-07-07)	25
RESPONSE TO WEAKNESS (ORIGINALLY AOI-BQAP-BSC-05-07-3)	43
RESPONSE TO WEAKNESS (ORIGINALLY AOI-BQAP-BSC-05-07-4)	45
RESPONSE TO WEAKNESSES AND DEFICIENCIES FROM NRC AUDIT OBSERVER REPORT SECTIONS 4.2, 4.3, AND 4.4.9	49

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**RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-01
(ORIGINALLY AOI-BQAP-BSC-05-07-01)**

NRC Audit Observer Inquiry AOI-OAR-05-05-01 states:¹

The EBS Physical and Chemical Environment Model Report assumes a 100°C threshold for the onset of seepage. The statement, "Seepage waters do not enter the drifts until the host rock temperatures fall below 100°C," does not seem to be supported by sufficient justification.

The attachment to AOI-OAR-05-05-01 states:

The EBS Physical and Chemical Environment Report (Section 6.2.2.4, page 6-6) states that the Drift-Scale THC Seepage model shows that there can be no seepage at drift temperatures above about 100°C due to the presence of a vaporization barrier. It is not clear if the results provided in the Drift-Scale THC Seepage Model (Figures 6.5-4 to 6.5-7) take account of the effect of dissolved salts on the boiling point. Ground water containing dissolved salts may only be partially vaporized at certain temperatures above 100°C, leaving the salts in the heated zone in the form of concentrated brine. Depending on the type of salts, the brine may be stable at temperatures significantly higher than 100°C at ambient pressure (e.g., higher than 180°C for the brine containing NaNO₃-KNO₃-NaCl). The vaporized water may condense at a low temperature zone and mix with the surrounding new ground water. This mixed water with the salts from the new ground water or from the surrounding rock may re-enter the heated zone and partially vaporize, causing more salts to accumulate. In addition, new ground water may also enter the heated zone and cause the accumulation of salts.

The report also used the Drift Scale Test results (Figure 6.2-2) to support the above argument. However, Figure 6.2-2 was obtained during the heating phase of the test; there might not be enough time for the salt to accumulate in the heated zone.

Response:

The issue presented by AOI-OAR-05-05-01 is the adequacy of the justification for the use of the 100°C threshold for the onset of seepage in the seepage evaporation abstraction. This response considers the issue first in terms of thermal-hydrologic (TH) processes and then in terms of thermal-hydrologic-chemical (THC) processes. The TH discussion summarizes the basis for the threshold, which is approximately 4°C above the boiling point of pure water at the repository level. The THC discussion shows that the potential for concentrated brine development to contribute to seepage at temperatures higher than the threshold is not significant in terms of potential impacts to performance. The THC discussion is presented in four parts: (1) background on the THC seepage model, (2) the reduction of fluid volume at or above 100°C by evaporative

¹ Text from NRC input on the audit observer inquiry form completed during Audit BQAP-BSC-05-7.

concentration, (3) the dilute composition of seepage in THC modeling, and (4) the limited salt accumulation and potential brine volume.

For clarification purposes, note that the primary basis for the 100°C seepage threshold is not provided in *Engineered Barrier System: Physical and Chemical Environment* (BSC 2005a, Section 6.2.2.4). Rather, the 100°C threshold is developed in *Drift-Scale Coupled Processes (DST and TH Seepage) Models* (BSC 2005b). Development and validation of the THC seepage model is described in *Drift-Scale THC Seepage Model* (BSC 2005c). *Engineered Barrier System: Physical and Chemical Environment* (BSC 2005a) analyzes the in-drift environment based upon the THC seepage model results. These reports form the basis for this response. Additional discussion that acknowledges and supports the information presented in this response is planned for inclusion in the next revision of *Drift-Scale THC Seepage Model* (BSC 2005c).

TH Processes and the 100°C Seepage Threshold

The performance assessment accounts for thermal effects on seepage by setting seepage to zero when the drift crown temperature is greater than 100°C (BSC 2004a, Section 6.5.2.1). At temperatures of 100°C or lower, and at locations where seepage occurs, the seepage is set equal to the ambient seepage as calculated using the drift seepage abstraction (BSC 2004a).

The seepage threshold temperature criterion of 100°C is based on the validated TH seepage model (BSC 2005b), which simulates liquid and vapor flow through an unsaturated fracture-matrix system, seepage into the drift, heat transport, and thermal effects resulting from boiling and condensation. Importantly, for seepage to occur there must be sufficient downward liquid flux and sufficient saturation in the fractures above the drift opening to overcome the capillary diversion response, even under heated conditions. In theory, seepage occurs when the potential of water in the fractures of the host rock at the drift wall is zero or greater, corresponding to 100% liquid saturation. The TH seepage model allows seepage to occur at partial saturation. This practice accommodates model limitations such as spatial resolution near the drift wall and use of the continuum approach. The threshold fracture saturation for seepage is typically in the range of 10% to 50% (BSC 2005b, Section 6.2.2.2.2; BSC 2006, Section 6.2.3.2). In addition, the threshold local percolation flux required for seepage has been evaluated with the seepage model for performance assessment, a model constructed and calibrated to represent seepage from fractured rock under ambient conditions (BSC 2004b, Section 6.6.1). Values for the threshold local percolation flux vary up to hundreds of millimeters per year depending on rock permeability, capillary strength, and rock permeability heterogeneity.

Simulations with the TH seepage model demonstrate that, when TH processes are considered, no seepage occurs at or above 96°C because of a combination of capillary diversion and vaporization effects (BSC 2004a, Sections 6.5.2.1 and 6.5.2.2; BSC 2005b, Section 8.1). A threshold temperature value of 100°C is used to account for modeling uncertainty (e.g., grid size effects) and to ensure that the criterion accounts for the possibility of heat-pipe conditions that could produce elevated liquid flux in fractures close to the drift opening.

THC Processes and the 100°C Seepage Threshold

The discussion below provides background on the THC seepage model and then shows that, when THC processes are considered, the 100°C threshold remains a reasonable representation of seepage behavior. Neither the magnitude of seepage nor the onset temperature is likely to have been underestimated. Three lines of reasoning are presented to develop and corroborate this result: (1) the reduction of fluid volume by evaporative concentration, (2) the dilute composition of seepage when it is predicted to occur, and (3) the limited amounts of soluble salts that are predicted to form in fractures.

Background on the THC Seepage Model—With the exception of boiling point elevation due to dissolved salts, the coupled processes described in the U.S. Nuclear Regulatory Commission (NRC) attachment to AOI-OAR-05-05-01 are included in the THC seepage model (BSC 2005c). In addition to TH processes, the THC seepage model addresses the transport of aqueous and gaseous species, mineralogical characteristics and changes, and aqueous and gaseous chemistry. The model explicitly includes evaporative concentration and salt accumulation, and the resulting effects on solution composition and mobility in fractures. When the fracture liquid saturation drops below 10^{-5} or the ionic strength goes above 4 mol/kg, the aqueous phase is treated as unreactive and is not concentrated further; instead, dryout occurs (BSC 2005c, Sections 5 and 6.4.3.1). This limit ensures that the calculated ionic strength does not exceed the range of applicability of the activity coefficient model used within the THC seepage model. Note that the saturation limit is much lower than the 10% threshold fracture saturation required for seepage. Ignoring water-rock reactions for dissolved mass at very low saturations (approximately 10^{-5} or less) over the limited time period of occurrence does not significantly affect the computed trends in aqueous phase concentrations and precipitated mineral amounts over long periods of time and a wide range of liquid saturations. Moreover, it does not significantly affect the representation of seepage behavior, which is the subject of this audit observer inquiry response.

Boiling point elevation caused by dissolved salts is not included in the THC seepage model. This model simplification is justified because the evaporative concentration that causes boiling point elevation also greatly reduces the amount of liquid available for liquid-phase flow in fractures or seepage. As is shown below, at 100°C the extent of evaporative concentration is about 2,500-fold, relative to fracture and matrix waters present before heating. This estimate of evaporative concentration provides perspective on the amounts of soluble salts that would be required to cause seepage at 100°C. An aqueous phase cannot exist at a temperature of 100°C or greater in the repository environment unless it has high dissolved solids.

(1) Reduction of Fluid Volume at or above 100°C by Evaporative Concentration—The first of three points used to support the 100°C threshold is the reduction of fluid volume by evaporative concentration. To estimate the possible extent of fluid reduction, the characteristics of brine at 100°C or greater are evaluated. First, an upper-bound relative humidity at 100°C is estimated from the temperature and the total pressure at the repository elevation, assuming the gas-phase mole fraction of water is unity. The vapor pressure of pure water at 100°C is 1.01325 bar (Dean 1992, Tables 2.7 and 5.6). Total pressure at the repository is estimated to be 0.89112 bar (BSC 2004c, Appendix XIX). The ratio yields relative humidity of 87.9%. Using this relative humidity value, equilibrium compositional information can be determined for representative waters from the THC seepage model. For example, at 100°C and relative humidity

of 87.9%, the ionic strength is approximately 4.3 mol/kg for a water that is representative of the waters expected in the host rock near the drift opening during the time period of interest (i.e., bin 4) (BSC 2005a, Figure 6.13-1). The associated evaporative concentration factor for this water composition is about 2,500 (DTN: MO0304SPACSALT.000, file "04c3t1e.xls").

This evaluation tends to overestimate brine volume (i.e., underestimate the concentration factor) because the relative humidity may be less, or the temperature could be greater than 100°C, either of which tends to decrease the water activity and thus increase the brine strength. Note that boiling point elevation by dissolved salts is explicitly included in this evaluation.

As was discussed previously, the threshold fracture saturation for seepage is typically in the range of 10% to 50% (BSC 2005b, Section 6.2.2.2.2; BSC 2006, Section 6.2.3.2). The threshold local percolation flux required for seepage varies up to hundreds of millimeters per year depending on rock permeability, capillary strength, and rock permeability heterogeneity (BSC 2004b, Section 6.6.1). Given the potential for 2,500-fold evaporative concentration, the conditions represented by these two thresholds are unlikely to be met at temperatures of 100°C or greater.

It is noted that vapor-liquid reflux conditions may exist in the fracture network above a heated drift, increasing the local flux and liquid saturation. However, the water associated with such fluxes is dilute, and the temperature is always limited to that of boiling, dilute water (approximately 96°C). This small temperature difference (between 96°C and 100°C) corresponds to a large difference in the potential for evaporative concentration and increased brine strength.

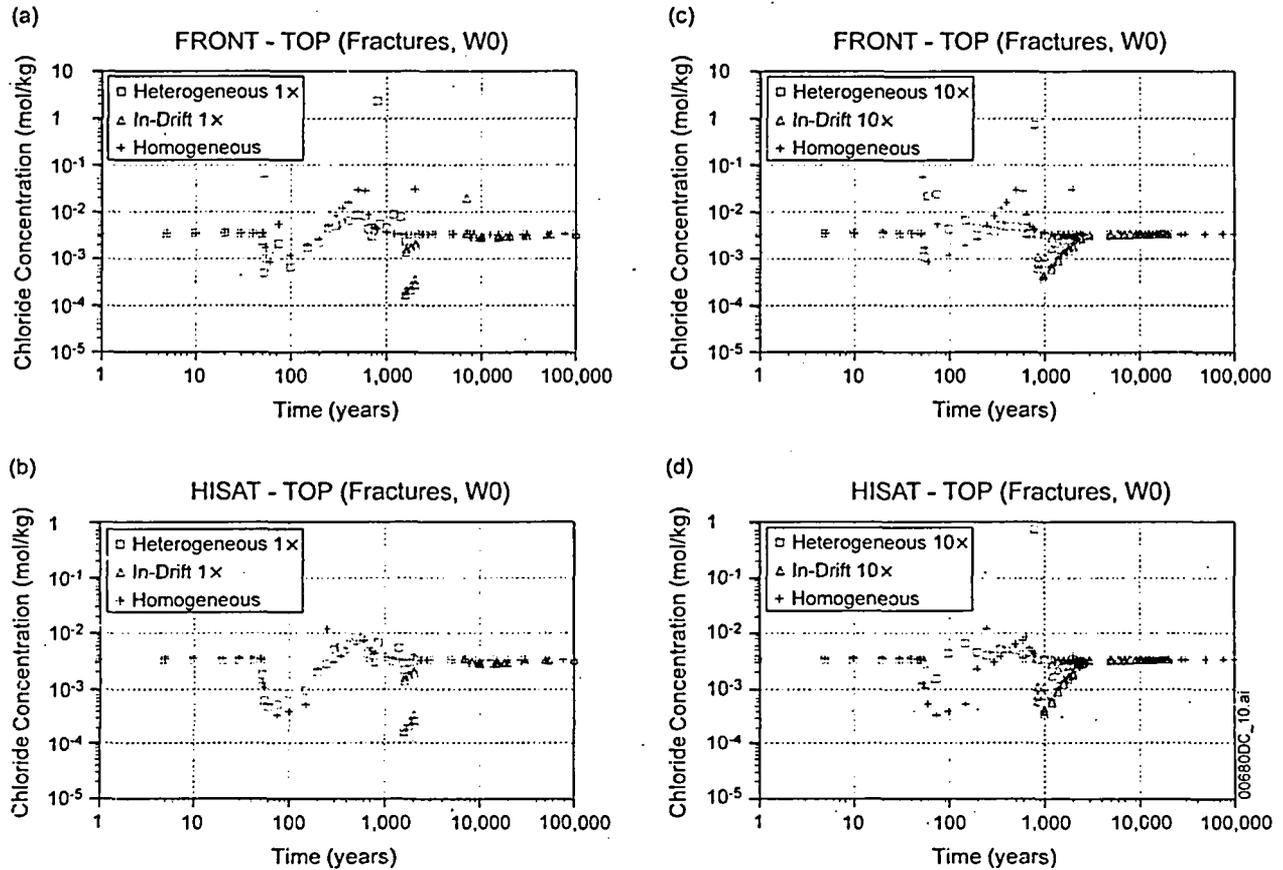
(2) Dilute Composition of Seepage in THC Modeling—The second approach to evaluating the potential for seepage at temperatures of 100°C or greater is to directly analyze the predicted composition of seepage for conditions when seepage does occur. This approach involves integrating aspects of the two ambient seepage models (i.e., the seepage calibration model and the seepage model for performance assessment) (BSC 2004d; BSC 2004b) with the THC seepage model (BSC 2005c). A sensitivity analysis (BSC 2006, Sections 6.2 and 6.3) was conducted combining the hydrologic parameters used in the ambient seepage models with the THC seepage model elements (BSC 2005c, Section 6.5). The combination of these models is referred to in this response as the integrated THC seepage model.

The integrated THC seepage model simulations (BSC 2006, Section 6.2) were done with a realization of the heterogeneous fracture permeability field using the statistics from the seepage model for performance assessment (BSC 2004b), and percolation flux of 6, 16, and 25 mm/yr corresponding to the present-day, monsoonal, and glacial-transition climate states, respectively. Simulations were also done in which these boundary fluxes were increased 10-fold. Water compositions from the model grid within the host rock were analyzed for pre-defined time steps (BSC 2006, Sections 6.2 and 6.3). In addition, when seepage was produced in the heterogeneous simulations, the composition of that seepage was evaluated directly. All heterogeneous simulations were based on the W0² pore water composition (BSC 2005c, Section 6.2.2.1) as the initial condition and compositional boundary condition for the fractures and rock matrix. The W0 composition is one of five initial pore water compositions used by the THC seepage model. The

² W0 through W4 are designations for the initial pore waters used in *Drift-Scale THC Seepage Model* (BSC 2005c).

sensitivity study also compared the heterogeneous simulations conducted with the integrated THC seepage model to the base case THC seepage model simulations (BSC 2005c, Section 6.5) using the same rock properties and percolation flux conditions as the heterogeneous simulation with 1× percolation flux, but with a larger value for the fracture capillary strength parameter (BSC 2006, Section 7.1.2).

Study results show that the predicted seepage waters are comparable to, or more dilute than, compositions retrieved from within the host rock for the heterogeneous and homogeneous permeability simulations. In addition, the predicted seepage waters are very dilute compared to the brine strength required for waters to exist at 100°C and relative humidity of 87.9% (BSC 2006, Section 6.2 and Figures 6.2-23 to 6.2-26, 6.2-29, and 6.2.30). Figure 1 provides example results of chloride concentration histories. More detailed information on predicted seepage compositions and temperatures for the 1× and 10× percolation flux cases is given in Tables 1 and 2. In all cases, seepage occurred only when drift-wall temperature was less than 100°C. Thus, within the temporal resolution of reported model results, the compositions corroborate discussions presented previously that seepage of concentrated brine, at temperatures of 100°C or greater, is unlikely.



Source: BSC 2006, Figures 6.2-23a and c and 6.2-24a and c.

NOTE: Attributes FRONT, TOP, and HISAT refer to waters in the host rock above the drift. They are described in *THC Sensitivity Study of Repository Edge and Heterogeneous Permeability Effects* (BSC 2006, Section 6.1.2.2; BSC 2004e, Sections 6.2.1.3 and 6.2.1.4). Except for in-drift waters (i.e., seepage), points shown represent data with attribute INDX=5 for HISAT waters and INDX=4 for FRONT waters (also with INDX=5 for FRONT-TOP waters only, at time greater than or equal to 3,000 years (BSC 2006, Section 6.1.2.2)). For in-drift water, points shown represent all in-drift gridblocks with liquid saturations greater than zero within 20 cm of the drift wall.

Figure 1. THC Simulations: Modeled Total Aqueous Chloride Concentrations as a Function of Time for Various Model Locations; Homogeneous and Heterogeneous Fracture Permeability Fields (1x and 10x Mean Infiltration Rates)

Table 1. Selected Major and Minor Aqueous Species Concentrations (mol/kg) for 1x Mean Infiltration Rate (In-Drift Heterogeneous Case)

Year	pH	T(°C)	Ca ²⁺	Mg ²⁺	Na ⁺	Cl ⁻	SiO ₂ (aq)	HCO ₃ ⁻	SO ₄ ²⁻	K ⁺	F ⁻	NO ₃ ⁻
1601	6.8	94.5	2.23 × 10 ⁻⁵	6.40 × 10 ⁻⁷	3.86 × 10 ⁻⁴	1.63 × 10 ⁻⁴	3.44 × 10 ⁻⁴	1.65 × 10 ⁻⁴	6.49 × 10 ⁻⁵	5.85 × 10 ⁻⁵	6.73 × 10 ⁻⁵	5.15 × 10 ⁻⁶
1801	6.8	93.1	2.37 × 10 ⁻⁵	7.39 × 10 ⁻⁷	4.93 × 10 ⁻⁴	2.07 × 10 ⁻⁴	3.85 × 10 ⁻⁴	2.10 × 10 ⁻⁴	7.56 × 10 ⁻⁵	7.23 × 10 ⁻⁵	8.80 × 10 ⁻⁵	6.53 × 10 ⁻⁶
2001	6.8	91.3	2.80 × 10 ⁻⁵	9.99 × 10 ⁻⁷	6.41 × 10 ⁻⁴	2.66 × 10 ⁻⁴	4.70 × 10 ⁻⁴	2.63 × 10 ⁻⁴	9.75 × 10 ⁻⁵	9.09 × 10 ⁻⁵	1.14 × 10 ⁻⁴	8.41 × 10 ⁻⁶
7005	7.7	65.1	3.90 × 10 ⁻⁴	3.97 × 10 ⁻⁵	7.92 × 10 ⁻³	3.50 × 10 ⁻³	2.53 × 10 ⁻³	2.77 × 10 ⁻³	1.10 × 10 ⁻³	5.78 × 10 ⁻⁴	7.44 × 10 ⁻⁴	1.03 × 10 ⁻⁴
8315	7.7	60.9	4.48 × 10 ⁻⁴	4.58 × 10 ⁻⁵	7.35 × 10 ⁻³	2.87 × 10 ⁻³	2.23 × 10 ⁻³	3.12 × 10 ⁻³	1.05 × 10 ⁻³	5.07 × 10 ⁻⁴	6.59 × 10 ⁻⁴	9.03 × 10 ⁻⁵
10007	7.7	56.2	5.26 × 10 ⁻⁴	5.34 × 10 ⁻⁵	7.26 × 10 ⁻³	2.75 × 10 ⁻³	1.95 × 10 ⁻³	3.45 × 10 ⁻³	1.00 × 10 ⁻³	4.41 × 10 ⁻⁴	5.73 × 10 ⁻⁴	8.65 × 10 ⁻⁵
15010	7.8	46.6	6.91 × 10 ⁻⁴	7.39 × 10 ⁻⁵	7.45 × 10 ⁻³	2.79 × 10 ⁻³	1.60 × 10 ⁻³	3.91 × 10 ⁻³	1.02 × 10 ⁻³	3.41 × 10 ⁻⁴	4.97 × 10 ⁻⁴	8.76 × 10 ⁻⁵

Source: DTN: LB0504DSTTHCR3.006; file "thc6_w0_smpa1_1x_indrift.xls."

Table 2. Selected Major and Minor Aqueous Species Concentrations (mol/kg) for 10x Mean Infiltration Rate (In-Drift Heterogeneous Case)

Year	pH	T(°C)	Ca ²⁺	Mg ²⁺	Na ⁺	Cl ⁻	SiO ₂ (aq)	HCO ₃ ⁻	SO ₄ ²⁻	K ⁺	F ⁻	NO ₃ ⁻
860	7.1	90.1	2.10 × 10 ⁻⁴	8.79 × 10 ⁻⁶	2.14 × 10 ⁻³	1.08 × 10 ⁻³	1.68 × 10 ⁻³	7.95 × 10 ⁻⁴	3.95 × 10 ⁻⁴	2.78 × 10 ⁻⁴	2.22 × 10 ⁻⁴	3.40 × 10 ⁻⁵
1001	7.1	84.1	2.50 × 10 ⁻⁴	9.48 × 10 ⁻⁶	2.17 × 10 ⁻³	1.11 × 10 ⁻³	1.60 × 10 ⁻³	8.84 × 10 ⁻⁴	4.04 × 10 ⁻⁴	2.48 × 10 ⁻⁴	2.11 × 10 ⁻⁴	3.48 × 10 ⁻⁵
1201	7.2	76.9	4.58 × 10 ⁻⁴	1.40 × 10 ⁻⁵	3.32 × 10 ⁻³	1.70 × 10 ⁻³	2.18 × 10 ⁻³	1.39 × 10 ⁻³	6.19 × 10 ⁻⁴	3.22 × 10 ⁻⁴	2.94 × 10 ⁻⁴	5.34 × 10 ⁻⁵
1401	7.3	70.1	7.17 × 10 ⁻⁴	1.38 × 10 ⁻⁵	4.21 × 10 ⁻³	2.20 × 10 ⁻³	2.50 × 10 ⁻³	1.89 × 10 ⁻³	8.02 × 10 ⁻⁴	3.49 × 10 ⁻⁴	3.42 × 10 ⁻⁴	6.92 × 10 ⁻⁵
1601	7.4	64.1	9.66 × 10 ⁻⁴	1.05 × 10 ⁻⁵	4.67 × 10 ⁻³	2.50 × 10 ⁻³	2.52 × 10 ⁻³	2.26 × 10 ⁻³	9.12 × 10 ⁻⁴	3.34 × 10 ⁻⁴	3.53 × 10 ⁻⁴	7.88 × 10 ⁻⁵
1801	7.5	59.3	1.12 × 10 ⁻³	8.27 × 10 ⁻⁶	4.70 × 10 ⁻³	2.57 × 10 ⁻³	2.36 × 10 ⁻³	2.43 × 10 ⁻³	9.37 × 10 ⁻⁴	2.98 × 10 ⁻⁴	3.42 × 10 ⁻⁴	8.08 × 10 ⁻⁵
2001	7.6	54.9	1.28 × 10 ⁻³	9.70 × 10 ⁻⁶	4.86 × 10 ⁻³	2.71 × 10 ⁻³	2.30 × 10 ⁻³	2.63 × 10 ⁻³	9.86 × 10 ⁻⁴	2.75 × 10 ⁻⁴	3.43 × 10 ⁻⁴	8.50 × 10 ⁻⁵
2202	7.8	47.4	1.63 × 10 ⁻³	6.02 × 10 ⁻⁵	5.16 × 10 ⁻³	3.14 × 10 ⁻³	2.48 × 10 ⁻³	2.84 × 10 ⁻³	1.14 × 10 ⁻³	2.31 × 10 ⁻⁴	3.57 × 10 ⁻⁴	9.86 × 10 ⁻⁵
2402	7.9	42.0	1.78 × 10 ⁻³	9.98 × 10 ⁻⁵	4.97 × 10 ⁻³	3.19 × 10 ⁻³	2.28 × 10 ⁻³	2.87 × 10 ⁻³	1.16 × 10 ⁻³	1.90 × 10 ⁻⁴	3.42 × 10 ⁻⁴	1.00 × 10 ⁻⁴
2550	8.0	39.1	1.86 × 10 ⁻³	1.24 × 10 ⁻⁴	4.86 × 10 ⁻³	3.21 × 10 ⁻³	2.16 × 10 ⁻³	2.90 × 10 ⁻³	1.17 × 10 ⁻³	1.70 × 10 ⁻⁴	3.32 × 10 ⁻⁴	1.01 × 10 ⁻⁴
3002	8.1	33.8	2.01 × 10 ⁻³	1.62 × 10 ⁻⁴	4.68 × 10 ⁻³	3.25 × 10 ⁻³	1.97 × 10 ⁻³	2.99 × 10 ⁻³	1.18 × 10 ⁻³	1.37 × 10 ⁻⁴	3.13 × 10 ⁻⁴	1.02 × 10 ⁻⁴
5003	8.2	28.7	2.18 × 10 ⁻³	1.70 × 10 ⁻⁴	4.59 × 10 ⁻³	3.27 × 10 ⁻³	1.82 × 10 ⁻³	3.18 × 10 ⁻³	1.19 × 10 ⁻³	1.16 × 10 ⁻⁴	2.98 × 10 ⁻⁴	1.03 × 10 ⁻⁴
8005	8.3	26.4	2.31 × 10 ⁻³	1.56 × 10 ⁻⁴	4.65 × 10 ⁻³	3.28 × 10 ⁻³	1.77 × 10 ⁻³	3.43 × 10 ⁻³	1.19 × 10 ⁻³	1.11 × 10 ⁻⁴	2.91 × 10 ⁻⁴	1.03 × 10 ⁻⁴
10007	8.3	25.2	2.36 × 10 ⁻³	1.52 × 10 ⁻⁴	4.67 × 10 ⁻³	3.28 × 10 ⁻³	1.75 × 10 ⁻³	3.53 × 10 ⁻³	1.20 × 10 ⁻³	1.07 × 10 ⁻⁴	2.87 × 10 ⁻⁴	1.03 × 10 ⁻⁴
15010	8.3	23.1	2.36 × 10 ⁻³	1.43 × 10 ⁻⁴	4.76 × 10 ⁻³	3.29 × 10 ⁻³	1.70 × 10 ⁻³	3.57 × 10 ⁻³	1.20 × 10 ⁻³	1.03 × 10 ⁻⁴	2.81 × 10 ⁻⁴	1.03 × 10 ⁻⁴

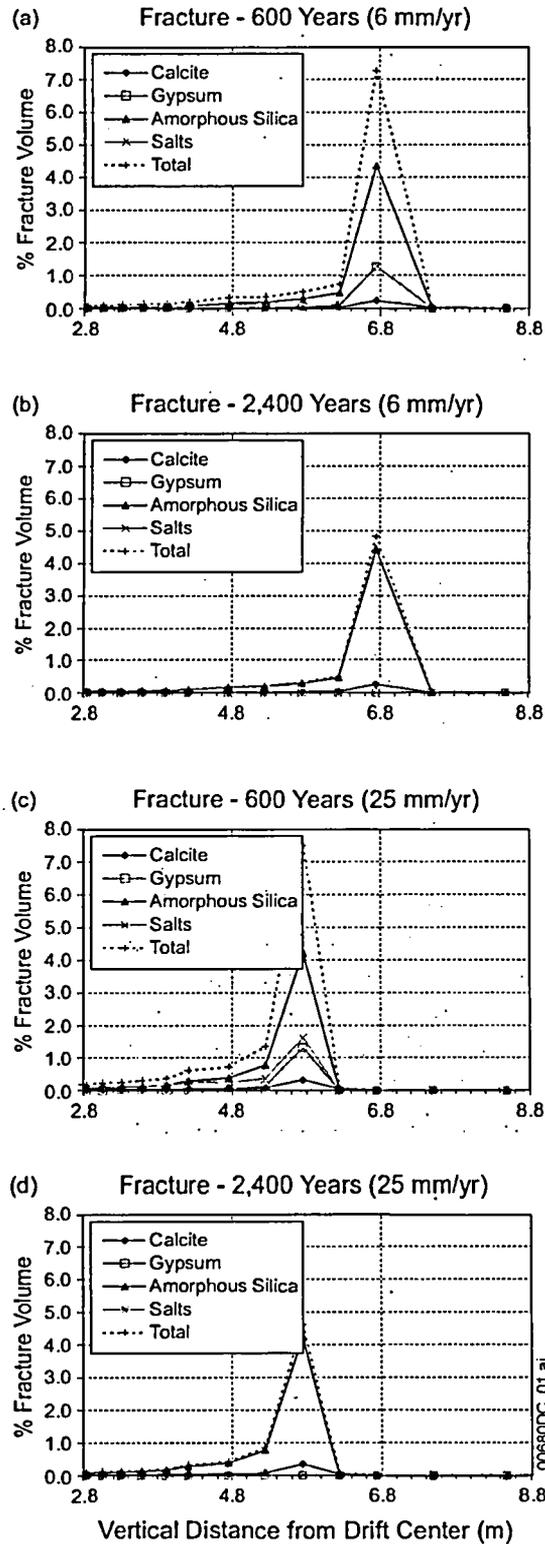
Source: DTN: LB0504DSTTHCR3.006; file "thc6_w0_smpa1_10x_indrift.xls."

(3) Limited Salt Accumulation and Potential Brine Volume—The third point supporting the use of the 100°C threshold is the limited salt accumulation and associated potential brine volume. Simulations using the validated THC seepage model (BSC 2005c, Section 6.5) show that soluble salts accumulate mostly where the boiling front persists for the longest time. Evaporation of incident percolation flux and condensate reflux in this zone builds up minerals and soluble salts in the fractures. Mass transfer between the fractures and matrix is limited, so that the precipitated salts form predominantly in the fractures.

Temporary stability of the boiling zone represents a balance between heat production and heat transfer, and the rate of percolation from above. Less heat production or greater percolation flux, leads to a smaller dryout zone, and earlier resaturation of the dryout zone. This behavior has been recognized for many years based on TH modeling and field testing (BSC 2005d). For THC processes, it means that minerals and salts may accumulate near the drift or further away, but the greatest accumulation occurs in a relatively narrow zone where most of the boiling occurs. This behavior is shown in Figures 2 and 3, which show the results from sensitivity studies of the imposed percolation flux and the composition of water used for initial and boundary conditions.

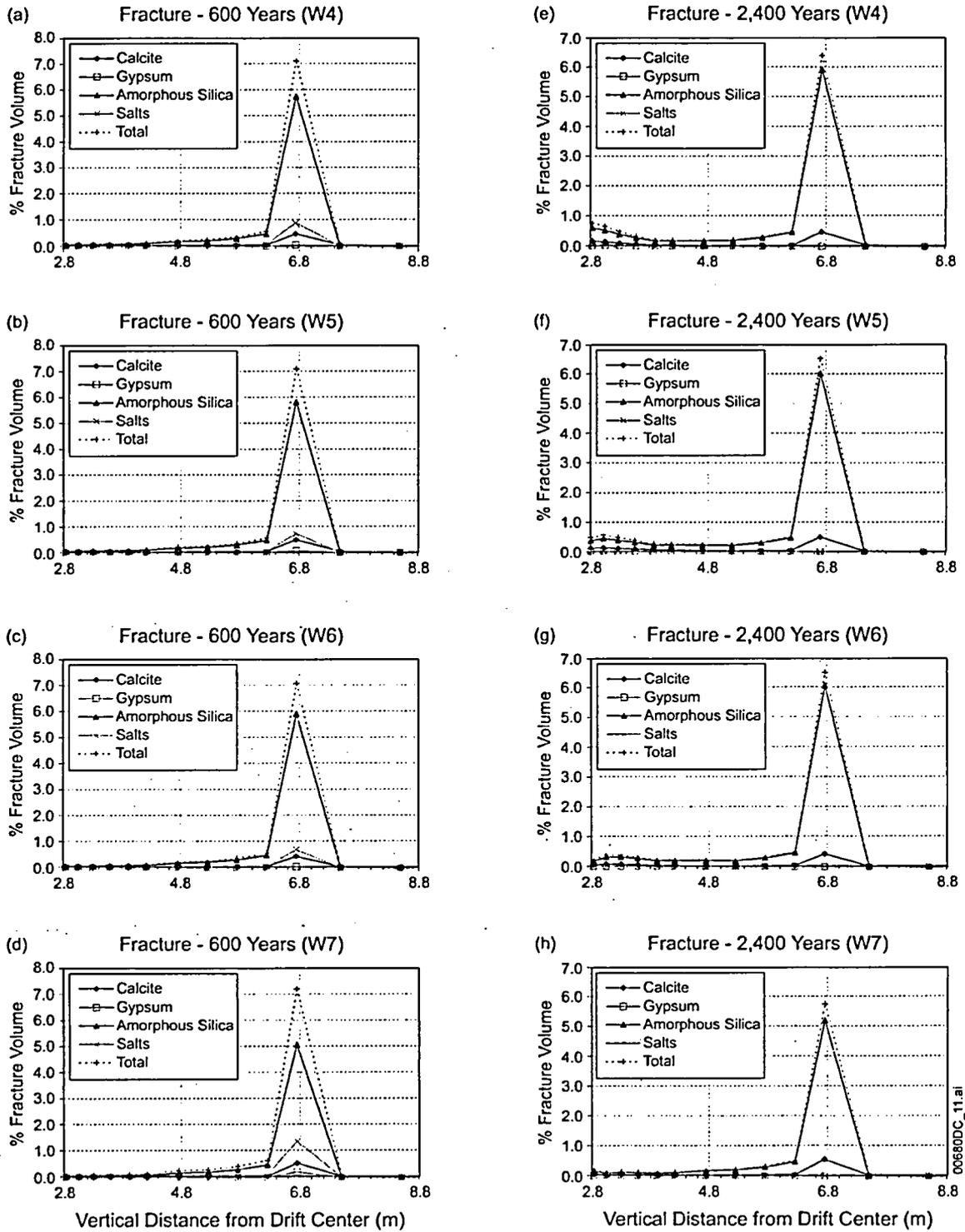
The very soluble salts precipitated in the THC seepage model are forms of NaNO₃, K₂SO₄, Na₂SO₄, MgSO₄, halite (NaCl), and sylvite (KCl), in addition to less soluble calcite (CaCO₃), gypsum (CaSO₄·H₂O), fluorite (CaF₂), and amorphous silica (SiO₂) (BSC 2005c, Section 4.1.3). Redissolution of calcite, amorphous silica, and gypsum occurs slowly and is limited by intrinsic solubility limits, common-ion effects, and retrograde solubility (calcite). Thus, these less soluble precipitates will not contribute significantly to brine strength at temperatures of 100°C or greater.

Modeling results (Figures 2 and 3) show that, over the approximately 1,500-year period of salt accumulation, amorphous silica is the major contributor to fracture mineralization, and that the accumulation of very soluble salts (typically halite) is on the order of 1% of fracture volume. This prediction is reasonable considering the total amount and the composition of formation water that is evaporated during the thermal period. It is not particularly sensitive to the compositional boundary and initial conditions (Figures 2 and 3) or to the implementation of dryout and redissolution of soluble salts in the THC seepage model.



Source: BSC 2005c, Figure 6.5-43.

Figure 2. THC Seepage Model (Tptpl1): Vertical Profile of Predicted Mineral Abundances above the Drift Crown at 600 and 2,400 Years Using Input Water Composition W0 and Fixed Infiltration Rates (6 and 25 mm/yr)



Source: BSC 2005c, Figures 6.5-44 and 6.5-45.

NOTE: Profiles from 2,400 years to the end of the simulated time period (100,000 years) remain essentially unchanged from the 2,400-year profiles.

Figure 3. THC Seepage Model (TptII): Vertical Profile of Predicted Mineral Abundances above the Drift Crown at 600 and 2,400 Years Using Input Water Compositions W4, W5, W6 and W7 and Stepped Infiltration Rates (6, 16, and 25 mm/yr)

This accumulation estimate is used to evaluate the fracture saturation, if the very soluble salts are redissolved at 100°C, as well as the potential volume of brine available for seepage. The approach is approximate but reasonable because fracture saturation is less at temperatures greater than 100°C or relative humidity less than 87.9%, and because fracture saturation alone does not account for other hydrologic factors that limit the potential for seepage. Assuming that the very soluble salt consists of NaCl, which has the smallest formula weight, and that 1% of the fracture volume contains 21.7 kg NaCl per cubic meter of fracture volume (calculated based on a density of approximately 2.17 g/cm³ for NaCl (Dean 1992, Table 3.2)), there are approximately 371 mol NaCl per cubic meter of fracture volume. A threshold saturation of 10% for the onset of seepage—the lowest value of the range discussed previously—gives approximately 100 kg H₂O per cubic meter of fracture volume. Dissolving the precipitated salt into the water gives a molality (or ionic strength, for NaCl) of approximately 4 mol/kg. This ionic strength is comparable to the brine strength (4.3 mol/kg) for formation water equilibrated to 100°C and relative humidity of 87.9% as previously described in the evaporative concentration evaluation, which explicitly accounts for boiling point elevation. Thus, seepage may be possible at these conditions, but not at higher temperature or lower relative humidity, which will decrease saturation. This outcome is consistent with the 100°C seepage threshold temperature from the TH seepage model (BSC 2005b, Section 8.1).

Considering the discussion above in terms of bounding the potential brine volume, there are approximately 3.71 mol NaCl precipitated in the fractures per cubic meter of rock given that the fracture volume is approximately 1% of rock volume. Because this mineral precipitation occurs in a zone about 1 m thick or less, this zone would contain roughly 120 mol in the area above a waste-package length of drift (i.e., about 5 m × 6 m), corresponding to a volume of about 30 liters of brine. Thus, over the period of salt accumulation (about 1,500 years), the maximum volume of available brine for seepage from a zone above a single waste package would be about 30 liters, an exceedingly small value.

The possibility of seepage above 100°C is further unlikely because less liquid may be formed and some or all of that liquid may never reach the drift wall. First, the distribution of soluble salts in fractures is more limited than evaluated above, such that the narrow zone of salt precipitation and subsequent brine formation will be well removed from the drift wall for most waste package locations. Next, the capillary response of the fracture network will divert some or all of the limited quantity of brine around the drift opening. In addition, brine formed upon initial redissolution of fracture salts will be imbibed into the adjacent matrix, which is dewatered, has strong capillary suction, and has ample capacity to hold the brine volume. In other words, for seepage to occur, there must be enough water for the local saturation at the drift wall to be greater than the threshold saturation despite the mechanisms described above that will limit water availability at the drift wall. It is unlikely that this condition will be met at or above 100°C.

Greater accumulation of halite and other soluble salts (more than 1% of fracture porosity) has been observed in simulations (e.g., BSC 2006, Figure 6.1-26) which show that as much as 5% of the fracture volume may be occupied by halite, accompanied by substantial reduction in calculated fracture permeability. Such results do not necessarily mean that seepage of brine will occur at drift-wall temperatures greater than 100°C; seepage will be impeded by increased capillary strength within the mineralized fractures and by imbibition of brine into the adjacent rock matrix.

As a final note on the results presented above, AOI-OAR-05-05-01 reveals a concern that the cited rock dewatering data from the Drift Scale Test (BSC 2005a, Figure 6.2-2) showing a sharp dewatering response at approximately 100°C were “obtained during the heating phase of the test; there might not be enough time for the salt to accumulate in the heated zone.” These data support the analysis presented above because they demonstrate that the rock matrix is substantially and consistently dried out in the temperature range for which redissolution of soluble salts in the fractures occurs. Thus, imbibition of liquid from the fractures into the rock matrix is likely, and drift seepage is not. The cited data were collected with neutron moisture probes, which register the bulk moisture content of the medium within the radius of investigation and are therefore sensitive to matrix saturation and not fracture saturation. Accordingly, the dewatering response observed is predominantly that of the matrix. While these data do not represent accumulation of brine formed in fractures from redissolved salts, that is not the intended use of these data when cited as support of a 100°C threshold for the occurrence of seepage. Rather, the Drift Scale Test matrix saturation data help to show that hydrologic conditions for seepage do not exist at higher temperatures.

Although not a direct analog of expected postclosure conditions, the Drift Scale Test was designed to produce the same types of coupled processes expected in the repository, subject to limitations on duration and spatial scale. Accordingly, the THC seepage model uses these and other data from the Drift Scale Test for predictive model validation purposes, not for direct, empirical representation of seepage likelihood or composition (BSC 2005c, Section 7.1).

Summary

This response has addressed the concern expressed in AOI-OAR-05-05-01 (formerly AOI-BQAP-BSC-05-07-1) that drift seepage may occur at temperatures of 100°C or greater because of boiling point elevation. It also addresses the concern that cited data from the Drift Scale Test may not support the model results.

When TH processes are considered, simulations with the TH seepage model (BSC 2005b) demonstrate that no seepage occurs at or above 100°C because of a combination of capillary diversion and vaporization effects (BSC 2004a, Sections 6.5.2.1 and 6.5.2.2; BSC 2005b, Section 8.1). These simulations provide the primary basis for the seepage threshold temperature criterion of 100°C.

Analysis presented in this response shows that, when THC processes are considered, the 100°C threshold remains a reasonable representation of seepage behavior and that neither the magnitude of seepage nor the onset temperature is likely to have been underestimated. The THC seepage model (BSC 2005c) explicitly includes evaporative concentration and salt accumulation, and the resulting effects on solution composition and mobility in fractures up to very small saturations or high ionic strengths. While boiling point elevation is not included in the model, seepage at or above 100°C is unlikely for the following three reasons:

1. The potential volume of mobile fluids in the near-field host rock is substantially decreased by evaporative concentration at temperatures of 100°C or greater (and relative humidity of 87.9% or less).

2. The composition of seepage is dilute, within the temporal resolution of the reported model results, when it is predicted to occur (always below 100°C) by an integrated simulation that combines hydrologic parameters from the ambient seepage models with chemical processes from the THC seepage model.
3. The limited amounts of soluble salts that are predicted to accumulate in fractures do not support the formation of sufficient brine volume to produce seepage.

This line of reasoning uses the condition of 100°C because it is the seepage cutoff temperature developed in the TH seepage model, and the relative humidity of 87.9% is the maximum value (maximizing brine volume) possible at 100°C for repository conditions.

References:

- BSC (Bechtel SAIC Company) 2004a. *Abstraction of Drift Seepage*. MDL-NBS-HS-000019 REV 01. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20041103.0003.
- BSC 2004b. *Seepage Model for PA Including Drift Collapse*. MDL-NBS-HS-000002 REV 03. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20040922.0008.
- BSC 2004c. *Ventilation Model and Analysis Report*. ANL-EBS-MD-000030 REV 04. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20041025.0002.
- BSC 2004d. *Seepage Calibration Model and Seepage Testing Data*. MDL-NBS-HS-000004 REV 03. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20040922.0003.
- BSC 2004e. *Post-Processing Analysis for THC Seepage*. ANL-NBS-HS-000045 REV 00. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20040929.0002.
- BSC 2005a. *Engineered Barrier System: Physical and Chemical Environment*. ANL-EBS-MD-000033 REV 05. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050829.0008.
- BSC 2005b. *Drift-Scale Coupled Processes (DST and TH Seepage) Models*. MDL-NBS-HS-000015 REV 02. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050114.0004.
- BSC 2005c. *Drift-Scale THC Seepage Model*. MDL-NBS-HS-000001 REV 04. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050218.0001.
- BSC 2005d. *Multiscale Thermohydrologic Model*. ANL-EBS-MD-000049 REV 03. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050711.0001.
- BSC 2006. *THC Sensitivity Study of Repository Edge and Heterogeneous Permeability Effects*. ANL-NBS-HS-000047 REV 00. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20060112.0001.
- Dean, J.A. 1992. *Lange's Handbook of Chemistry*. 14th Edition. New York, New York: McGraw-Hill. TIC: 240690.

LB0504DSTTHCR3.006. THC Seepage Model Sensitivity to Heterogeneity—Summary MS Excel Tables of Predicted Thermal, Hydrological, and Chemical Data. Submittal date: 04/27/2005.

MO0304SPACSALT.000. EBS Chemistry THC Seepage Model Abstraction Lookup Table for TSPA-LA. Submittal date: 04/14/2003.

**RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-02
(ORIGINALLY AOI-BQAP-BSC-05-07-02)**

NRC Audit Observer Inquiry AOI-OAR-05-05-02 states:¹

The EQ3/6 model for deliquescence relative humidity (RH_d) was validated for relative humidity (RH) range from 100% to 40% (see notes for Table 7-8 in the IDPS report (ANL-EBS-MD-000045 REV 02). It has also been shown that the calculated boiling points or deliquescence relative humidities at low values are significantly different from those obtained by experiments. However, the Dust Deliquescence model (ANL-EBS-MD-000074 REV 00) presented results (see Figures 6.2-5 and 6.2-5 (*sic*)) that have deliquescence relative humidity values much lower than 40%. Similarly the equilibrium RH data calculated by EQ3/6 model for solutions containing mixed salts well below 40% were also presented in the P&C Environment model (ANL-EBS-MD-000033 REV 04) (e.g., Figures 6.13-2 and 6.13-13).

Response:

This response to AOI-OAR-05-05-02 has three parts. The first part addresses the observation related to the dust deliquescence model (BSC 2005a), citing relevant changes in a newer version of that report (BSC 2005b). The second part summarizes the in-drift precipitates/salts model validation process and validation results. The final part addresses the observation related to the physical and chemical environment model.

Dust Deliquescence Model—The observation regarding the dust deliquescence model is now addressed in REV 01 of that report (BSC 2005b). The version cited (REV 00) (BSC 2005a) inadvertently omitted information regarding the in-drift precipitates/salts deliquescence relative humidity (RH_d) validation range. This omission was captured in CR 6366. In REV 01, the validation range is clearly delineated in the figures and discussion of uncertainty and validation ranges is clarified in the figure notes and in the text (BSC 2005b, p. 6-36). As stated in the dust deliquescence model report (BSC 2005b, p. 6-36), in-drift precipitates/salts RH_d predictions outside the validation range are not used to support the conclusions of the report.

In-Drift Precipitates/Salts Model Validation—The intended use of the in-drift precipitates/salts model (BSC 2004) is to predict the effects of evaporation and deliquescence on the composition of water and mineral assemblages in the repository during the postclosure period. Accordingly, the model was designed to predict pH, ionic strength, mineral precipitation and dissolution, and concentrations of dissolved components as a function of temperature, relative humidity (RH), carbon dioxide fugacity, and initial water composition.

RH_d is the minimum RH for which the most soluble salts in a solution deliquesce for a given set of environmental conditions. Because aqueous components are not infinitely soluble, aqueous solutions are only stable at RH values between 100% and the RH_d . Below the RH_d , all water either evaporates or becomes incorporated in the solid phase. Thus, an additional intended use of the in-drift precipitates/salts model is to estimate the RH_d .

¹ Text from NRC input on the audit observer inquiry form completed during Audit BQAP-BSC-05-7.

The model validation criteria are discussed in *In-Drift Precipitates/Salts Model* (BSC 2004, Section 7). The in-drift precipitates/salts model was needed to evaluate changes in the composition of natural waters resulting from high degrees of evaporation and concentration. Some species concentrations (e.g., NO_3^- and Cl^- , the predominant forms of nitrogen and chlorine) can change by 6 orders of magnitude or more due to evaporation; thus, the validation criterion for rapidly equilibrating constituents was set at 1 order of magnitude (factor of 10). For pH, a logtransformed parameter that can vary by ± 4 pH units or more, the validation criterion was set at one pH unit. The RH_d validation criterion originally was set at $\pm 15\%$ (RH units). However, this criterion was lowered to $\pm 10\%$ (RH units), which is equivalent to ± 0.1 in units of activity of water.

The model validation was performed by comparing independent in-drift precipitates/salts model predictions to a variety of data and to one alternative model. Specifically, it involved comparisons of independent in-drift precipitates/salts model predictions to the following:

- Four sets of evaporation data (synthetic average J-13 well water, synthetic average 100× J-13 well water, synthetic Topopah Spring Tuff pore water, and seawater) (BSC 2004, Section 7.1)
- Solubilities of 24 salts in binary systems at temperatures ranging from 25°C to 140°C (BSC 2004, Sections 7.2.1.1.1 and 7.2.1.2.1)
- Solubilities of numerous salts in ternary salt systems at various temperatures (BSC 2004, Section 7.2.2)
- RH_d of numerous binary salt solutions at various temperatures covering a RH_d range from 97% (K_2SO_4 at 25°C) to 12% (MgCl_2 at 140°C) (BSC 2004, Sections 7.2.1.1.2 and 7.2.1.2.2)
- Evaporation predictions using an alternative model up to an ionic strength of 1 mol/kg (BSC 2004, Section 7.3).

The results of the comparisons include the following:

- pH was always predicted within 0.78 pH units or less of reported measurements (BSC 2004, Section 7.5.1).
- Ionic strength was always predicted within 67% or less (BSC 2004, Section 7.5.2).
- Br^- , CO_3^{2-} , Cl^- , F^- , Na^+ , K^+ , NO_3^- , and SO_4^{2-} concentrations were nearly always predicted within a factor of 3 or less (BSC 2004, Section 7.5.4). The primary exception, K^+ , was predicted within a factor of 3 or less in all cases except the later stages of seawater evaporation, for which predictions were within a factor of 5. In addition, one of the predicted Na^+ concentrations was not within a factor of 3 of a measured value, which was determined to be an outlier.

- RH_d of single salt solutions (except for $\text{Ca}(\text{NO}_3)_2$) was always predicted within 10% of reported measurements (in RH units) when the predicted RH_d exceeded 40% (BSC 2004, Section 7.5.3).

These comparisons of independent data to model predictions build confidence in the model for predicting the primary in-drift precipitates/salts outputs to the performance assessment: pH, ionic strength, concentrations of Cl^- and NO_3^- , and $\text{Cl}^-:\text{NO}_3^-$. They also build confidence in model prediction of RH_d above 40% when $\text{Ca}(\text{NO}_3)_2$ is not present. When $\text{Ca}(\text{NO}_3)_2$ is present, the validation limit for RH_d is 60%..

Physical and Chemical Environment Model—The observation regarding the physical and chemical environment model (BSC 2005c) is the prediction and presentation of water chemistries in the RH range below 40% (e.g., BSC 2005c, Figures 6.13-2 and 6.13-13) where the model is not valid for predicting RH_d . The figures cited in the concern show predicted pH, ionic strength, concentrations of various aqueous components, and the $\text{Cl}^-/\text{NO}_3^-$ ratio as a function of RH. Although the end points of these plots at low RH indicate the model predictions of RH_d , predicted RH_d is not identified in these figures for comparison purposes. The figures were prepared for the comparison of the parameters listed in the legend over the entire model ranges, not to compare the predicted RH_d values. It should be noted that a newer version of the physical and chemical environment model report is the currently controlled version (BSC 2005d). However, no changes relevant to AOI-OAR-05-05-02 occurred in the revision. The controlled version will be cited from here on.

In the cited figures, the model outputs are all plotted within their validation ranges. The in-drift precipitates/salts report (BSC 2004, Section 7.5) explains that the validation criteria for these outputs are met over the entire range of RH. While it is true that the RH_d validation criterion is not met for RH_d below 40% and for RH_d below 60% when $\text{Ca}(\text{NO}_3)_2$ is a major dissolved salt, the validation criteria for pH, ionic strength, Cl^- , NO_3^- , and $\text{Cl}^-:\text{NO}_3^-$ do not depend on the performance of the model with respect to RH_d . In-drift precipitates/salts RH_d predictions outside the validation range are not used to support the conclusions of the physical and chemical environment model report (BSC 2005d) nor are they used in the performance assessment for prediction of RH_d . Because model prediction of RH_d is not validated below 40% nor below 60% when $\text{Ca}(\text{NO}_3)_2$ is a major dissolved salt, the physical and chemical environment model conservatively sets the RH_d at 0 to ensure wet conditions in all such circumstances (BSC 2005d, p. 6-215).

References:

BSC (Bechtel SAIC Company) 2004. *In-Drift Precipitates/Salts Model*. ANL-EBS-MD-000045 REV 02. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20041111.0002.

BSC 2005a. *Analysis of Dust Deliquescence for FEP Screening*. ANL-EBS-MD-000074 REV 00. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050629.0004.

BSC 2005b. *Analysis of Dust Deliquescence for FEP Screening*. ANL-EBS-MD-000074 REV 01. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050829.0002.

BSC 2005c. *Engineered Barrier System: Physical and Chemical Environment*. ANL-EBS-MD-000033 REV 04. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.200500718.0003.

BSC 2005d. *Engineered Barrier System: Physical and Chemical Environment*. ANL-EBS-MD-000033 REV 05. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050829.0008.

**RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-03
(ORIGINALLY AOI-BQAP-BSC-05-07-5)**

NRC Audit Observer Inquiry AOI-OAR-05-05-03 states:¹

Apparent inconsistencies have been found between the localized corrosion model criteria found on page 8-6 in the General and Localized Corrosion of the Waste Package Outer Barrier report (ANL-EBS-MD-000003, Rev. 2) as compared to the model criteria found in the Analysis of Dust Deliquescence for FEP Screening AMR (ANL-EBS-MD-000074, Rev. 00). For example, the ANL-EBS-MD-000003, Rev. 2 states on pages 1-3, 6-97, and 8-6 "If the exposure temperature exceeds 160°C and a water film is present on the waste package surface, then localized corrosion initiates", however, the ANL-EBS-MD-000074, Rev.00 AMR considers that localized corrosion will not initiate when a water film is formed by deliquescence at elevated temperatures (page 7-1), even though it has been shown experimentally that some salt assemblage may deliquesce at temperatures over 190°C (page 7-2).

Response:

Analysis of Dust Deliquescence for FEP Screening (BSC 2005a) contains updated, current information on dust deliquescence and was approved subsequent to *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004). The analyses presented in *Analysis of Dust Deliquescence for FEP Screening* (BSC 2005a) address the experiments that show that some salt assemblages may deliquesce at temperatures over 190°C. Based on these analyses, the physiochemical characteristics of brines produced through deliquescence of minerals in deposited dusts are not expected to generate an environment favorable for the initiation and propagation of localized corrosion for Alloy 22 (UNS N06022) waste packages. In addition, only very small quantities of brine will form at elevated temperatures, and the chemistry of the brine will be benign. Both of these factors hinder the initiation of localized corrosion and the extent of propagation. Thus, while dust deliquescence is expected to occur, this process has been excluded from the performance assessment because the effects of such deliquescence have been determined to be insignificant. It is planned that *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004) will be revised to remove any inconsistencies with *Analysis of Dust Deliquescence for FEP Screening* (BSC 2005a).

Screening (inclusion or exclusion) of features, events, and processes (FEPs) is documented in the Project's FEP reports. FEP 2.1.09.28.0A, Localized corrosion on waste package outer surface due to deliquescence, is screened out in *Screening of Features, Events, and Processes in Drip Shield and Waste Package Degradation* (BSC 2005b) based on the analyses presented in *Analysis of Dust Deliquescence for FEP Screening* (BSC 2005a). Therefore, the disposition of this FEP is documented in a manner consistent with *Analysis of Dust Deliquescence for FEP Screening* (BSC 2005a).

¹ Text from NRC input on the audit observer inquiry form completed during Audit BQAP-BSC-05-7.

References:

BSC (Bechtel SAIC Company) 2004. *General Corrosion and Localized Corrosion of Waste Package Outer Barrier*. ANL-EBS-MD-000003 REV 02. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20041004.0001.

BSC 2005a. *Analysis of Dust Deliquescence for FEP Screening*. ANL-EBS-MD-000074 REV 01. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050829.0002.

BSC 2005b. *Screening of Features, Events, and Processes in Drip Shield and Waste Package Degradation*. ANL-EBS-PA-000002 REV 05. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20050817.0003.

**RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-04
(ORIGINALLY AOI-OAR-05-07-06)**

NRC Audit Observer Inquiry AOI-OAR-05-05-04 states:¹

The NRC observers noted the term “cancelled” associated with a document being cited in the reviewed analysis model reports. Specifically, the drip shield and waste package outer barrier report (ANL-EBS-MD-000001, Revision 1), which was a cancelled document, was referenced numerous times in the two analysis model reports reviewed. This cancelled report was not in the current report database. Because the referencing of canceled (sic) documents is contrary to QARD Section 6.2.5.C, and could be problematic during the potential license (LA) application review, the NRC is requesting clarification by DOE related to the Project's plans to use cancelled documents to support the LA.

Response:

AOI-OAR-05-05-04 raises three issues. First, a cancelled report, *Environment on the Surfaces of the Drip Shield and Waste Package Outer Barrier* (BSC 2004), was not located in the current report database during the audit. Second, the position was expressed that “the referencing of canceled (sic) documents is contrary to QARD Section 6.2.5.C and could be problematic.” Third, clarification was requested on the plans regarding the potential use of cancelled documents to support the license application. These issues were entered into the Corrective Action Program on December 21, 2005, as Condition Report (CR) 7267. CR 7267 acknowledges that the term cancelled carries with it a perception of “null and void” that can create misunderstanding. Accordingly, the CR includes an activity to identify a different term for older reports that still appropriately serve some support functions. The resolution of CR 7267 is ongoing, with multiple actions in various stages of completion. This response reflects the status of these actions as of July 31, 2006.

Investigation and resolution of the first issue regarding document access is complete. During the investigation, the problem of access to the cancelled document could not be duplicated. The investigation validated that both cancelled and superseded documents are available through the Controlled Document Information System (CDIS), the web-based Record Information System (RISweb), or both. These findings were discussed with the U.S. Nuclear Regulatory Commission (NRC) on-site representative on March 24, 2006.

The second issue is that referencing cancelled documents is contrary to *Quality Assurance Requirements and Description* (QARD) (DOE 2006), Section 6.2.5.C. Initial CR planning focused on the Postclosure Activities Group, the group that produced the reports cited in AOI-OAR-05-05-04. The implementing procedures—LP-SIII.9Q-BSC, *Scientific Analyses*, and LP-SIII.10Q-BSC, *Models*—explicitly allow the use of information from cancelled or superseded documents for direct input, provided the justification for use is documented in the report using the information; this was the case for the reports cited in AOI-OAR-05-05-04. The following is

¹ Text from NRC input on the audit observer inquiry form completed during Audit BQAP-BSC-05-7.

excerpted text from LP-SIII.10Q-BSC, Section 5.2.1(l) (Rev. 0, ICN 2), which was in force when AOI-OAR-05-05-04 was written:

Input obtained from the product output of a document under AP-6.1Q control that has been cancelled/superseded must be demonstrated to be suitable for intended use and justified within the technical product. When appropriately justified, these inputs are considered qualified for intended use within the product. If the document and the product output have been superseded, the reason for supersession must be considered. One or more of the following factors shall be used when presenting the case that inputs are suitable for intended use:

- Reliability of input source
- Qualifications of personnel or organizations generating the input
- Extent to which the input demonstrate the properties of interest
- Prior uses of the input
- Availability of corroborating input.

On May 30, 2006, new revisions (Revision 1 for both) of LP-SIII.9Q-BSC (Rev. 0, ICN 2) and LP-SIII.10Q-BSC (Rev. 0, ICN 2) became effective. Statements have been added to the relevant sections of both procedures directing that a document may not cite previous versions of the same document as direct input. Besides improving traceability and transparency, this change will result in additional information being carried forward into the most recent versions of a document. It is noted that a new revision of the QARD (DOE 2006) has been issued since AOI-OAR-05-05-04 was written, but the language of interest in Section 6.2.5 remains the same:

The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work.

An evaluation of LP-SIII.9Q-BSC and LP-SIII.10Q-BSC against QARD requirements regarding the use of obsolete or superseded documents has been conducted. The results indicate that the procedural controls established in LP-SIII.9Q-BSC and LP-SIII.10Q-BSC meet the requirements of QARD Section 6.2.5.C. These procedural controls ensure that information is suitable for its intended use (e.g., that the information is not obsolete or superseded). In the procedure for document control (LP-6.3Q-BSC, *Document Control*), the classification of a document as "cancelled" simply indicates that a document has been removed from a current status (decontrolled). These "cancelled" documents are still available in the records system. Revisions are planned for LP-6.3Q-BSC and the controlled document information system database to create a classification of documents (other than "cancelled" or "superseded") for older documents with information that is still appropriate to use. Some documents that will not be referenced in the LA and are no longer appropriate for their intended use (e.g., a drawing that is no longer consistent with the technical baseline) will still be classified as "cancelled."

The third issue raised by AOI-OAR-05-05-04 is the request for clarification regarding the potential use of "cancelled" documents to support the license application. Before submittal, DOE will review the license application to ensure the appropriateness of documents referenced in the license application. In addition, CR 7267 includes actions to evaluate and revise work processes and procedures concerning the use of cancelled or superseded documents across the project.

In summary, cancelled documents will not be relied on as inputs to the LA. On May 30, 2006, procedure revisions became effective directing that a document may not cite previous versions of the same document as direct input. This change will reduce the number of future citations to superseded documents. However, these procedures recognize that a designation of "cancelled" or "superseded" with respect to a document does not necessarily mean that all of the information in the document is unsuitable for use.

References:

BSC (Bechtel SAIC Company) 2004. *Environment on the Surfaces of the Drip Shield and Waste Package Outer Barrier*. ANL-EBS-MD-000001 REV 01. Las Vegas, Nevada: Bechtel SAIC Company. ACC: DOC.20041116.0005.

DOE (U.S. Department of Energy) 2006. *Quality Assurance Requirements and Description*. DOE/RW-0333P, Rev. 17. Washington, D.C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management. ACC: DOC.20060504.0008.

LP-6.3Q-BSC, Rev. 0, ICN 1. *Document Control*. Washington D.C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management. ACC: DOC.20060209.0007.

LP-SIII.9Q-BSC, Rev. 0, ICN 2. *Scientific Analyses*. Washington, D.C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management. ACC: DOC.20050912.0006.

LP-SIII.9Q-BSC, Rev. 1. *Scientific Analyses*. Washington, D.C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management. ACC: DOC.20060518.0006.

LP-SIII.10Q-BSC, Rev. 0, ICN 2. *Models*. Washington, D. C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management. ACC: DOC.20050912.0003.

LP-SIII.10Q-BSC, Rev. 1. *Models*. Washington, D. C.: U.S. Department of Energy, Office of Civilian Radioactive Waste Management. ACC: DOC.20060518.0004.

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**RESPONSE TO NRC AUDIT OBSERVER INQUIRY AOI-OAR-05-05-05
(ORIGINALLY AOI-OAR-05-07-07)**

NRC Audit Observer Inquiry AOI-OAR-05-05-05 states:¹

During the observation of Audit BQAP-BSC-05-07, the NRC determined that LLNL had not complied with the requirements of Section 12.0 of the QARD and BSC Procedure LP-12.1Q-BSC, related to initiating corrosion rate experiments. Specifically, it was concluded that LLNL initiated these quality affecting activities (i) without calibrated instruments, (ii) had not established an adequate basis for calibration when nationally recognized standards were not available, and (iii) misrepresented the correct status of the calibration of the humidity probes in the associated scientific notebook.

The NRC Observers also identified concerns related to the implementation of the Corrective Action Program (CAP) associated with Condition Reports (CRs) 2247 and 5430. Specifically, the NRC observers determined that LLNL had not complied with the requirements of Procedure AP-16.1Q concerning (i) documentation of deficiencies, (ii) preventing recurrence, and (iii) the failure to adequately addressing [sic] deficient conditions in subsequent experiments using uncalibrated probes. At the conclusion of the audit, no CR had been initiated related to the use of un-calibrated probes associated with the Scientific Notebook SCI-484 experiments. The failure to recognize this repetitive condition related to instrument calibration and initiate a CR is identified as an example of ineffective implementation of QARD requirements at LLNL related to the CAP.

Based on the review of these issues, the NRC concluded that LLNL had not satisfactorily and effectively implemented the QARD requirements related to the control of measuring and test equipment or the CAP. This conclusion was in disagreement with the conclusions reached by the BSC audit team. Therefore the NRC is requesting a documented basis and justification as to why these issues did not constitute an unsatisfactory implementation of the QARD at LLNL.

Response:

To address the above issues, the U.S. Department of Energy (DOE) and Bechtel SAIC Company, LLC (BSC) initiated a detailed assessment of the technical and quality issues raised by the U.S. Nuclear Regulatory Commission (NRC). Described below are the status of the various actions taken and the conclusions reached to date. This response is divided into two parts; the first dealing with the technical issues related to the calibration of Vaisala temperature-humidity probes, and the second dealing with issues related to compliance with applicable quality assurance procedures.

The discussion in this response regarding *Quality Assurance Requirements and Description* (QARD) refers to revision 16 (DOE 2004), which was in force at the time of the audit and AOI-OAR-05-05-05.

¹Text from NRC input on the audit observer inquiry form completed during Audit BQAP-BSC-05-7.

1. Technical Aspects of Vaisala Temperature-Humidity Probes

1.1 Introduction

Section 5.1 of Collins (2006) contained several issues related to the handling, calibration, and use of measuring and test equipment in LLNL experiments and the use of resulting data. Collins (2006) identified a number of potential technical product weaknesses (Section 5.2) or deficiencies and identified or alluded to other issues. These matters have been documented in several Condition Reports (CRs).

This response describes the Level A Root Cause Analyses for CRs 7395 and 7418. Many corrective action activities are ongoing; this response documents the status of these activities as of July 31, 2006. The root cause analysis for CR 7418 was approved on July 20, 2006. Section 2 provides an update on CR 7395.

1.2 Description of Identified Issues of NRC Interest

This response addresses three issues identified by NRC (Collins 2006) that relate to LLNL's use and calibration of temperature-humidity probes manufactured by Vaisala Corporation of Woburn, MA, as well as the use of data produced by these instruments. Specifically, Sections 4.4.6 and 5.1 of Collins (2006) identify these three probe-related issues:

1. LLNL initiated experiments to study the deliquescence effect on the corrosion of the outer surface of the waste package using Vaisala humidity probes that were not vendor-qualified nor calibrated for the upper temperature limits of the experiment. This is in non-compliance with the QARD, which requires that test instruments be calibrated before use. (Section 4.4.6)
2. The information identified by the NRC observers during the review of the two CRs 2247 and 5430 brought into question the validity of the data collected, when the subject humidity probes were used, during the corrosion experiments conducted between the years 2002 and 2005 at LLNL. ... [T]he NRC observers questioned whether the corrosion data could be considered technically sound and defensible. (Section 4.4.6)
3. Scientific Notebook SCI-484 identified the Vaisala probes as calibrated and documented the calibration date for the probes. However, appropriate documentation was not included, in the scientific notebook, identifying the limitation on the use of the humidity probes at high temperatures. Failure to identify this *potential misrepresentation* [emphasis added] of the information in the scientific notebook to management for further investigation is identified as a deficiency. (Section 4.4.6)

The following sections present the results of the investigations into these issues (identified as Issues 1, 2, and 3) and preliminary conclusions. Two additional issues related to calibration processes are documented in the CRs listed below and are in the process of being evaluated.

- CR 7499, Potential Emerging Trend—Inconsistent Application of Measuring and Test Equipment Requirements
- CR 8063, Measuring and Test Equipment Calibration and Use of the Out of Calibration Report/Process.

1.3 DOE Response to NRC Issues

As required for a Level A CR, BSC chartered a Root Cause Team to perform the preliminary investigation of the conditions. Given the potential importance of the issues, DOE also commissioned an Independent Review Team to evaluate the issues.

The Root Cause Team charter for CR 7418 required the team to investigate conditions related to the NRC's use of the term "misrepresentation" in its audit observation report. As noted in Enclosure 3 (Office of Civilian Radioactive Waste Management Independent Review Team Report, 2006, p. 20), the issue of "misrepresentation" was discussed with the NRC signatory of the NRC Audit Observation Report (Collins, 2006), and it was determined that the NRC did not intend to suggest willful misrepresentation in its Observation Audit Report. In light of that discussion, the Independent Review found no intent to misrepresent or falsify scientific notebook entries or the calibration of relative humidity/temperature probes.

The scope of the root cause investigation spanned approximately eight years, from 1998 to present. The Root Cause Team relied in part on the memories of personnel involved and Yucca Mountain Project records.

1.3.1 Issue Number 1—Use of Uncalibrated Probes—Investigation Results

1.3.1.1 Introduction

As indicated above, the first issue addressed by this response involves the NRC's position that deliquescence experiments undertaken at LLNL involved the use of temperature–humidity probes that had not been appropriately vendor-qualified or calibrated for the temperatures encountered in the course of the experiments. The NRC report described this issue as a violation of the QARD (DOE 2004) (i.e., the temperature–humidity probes were not appropriately calibrated for the range in which they were used). The results of the investigations into these concerns and the conclusions reached are addressed below.

1.3.1.1.1 Use of Vaisala Temperature–Humidity Probes in LLNL Studies

LLNL uses various temperature–humidity probes from Vaisala Group. The initial temperature–humidity probes, specifically the Vaisala HMP240 Series Dewpoint and Temperature Transmitters Model HMP243, were purchased in 1998. At the time the probes were initially purchased and calibrated, and for the period during which Vaisala provided recalibration services, Vaisala was on the YMP Qualified Supplier List for the performance of such services. During this period, Vaisala was also accredited by the American Association for Laboratory Accreditation (A2LA), and the Vaisala calibration laboratory met the requirements of ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, and

ANSI/NCSL Z540-1-1994, American National Standard for Calibration Laboratories and Measuring and Test Equipment—General Requirements.

Although the probes are commercial grade components, the calibration activities were performed and documented in a manner appropriate for YMP quality-affecting activities. LLNL used the probes in question in dust deliquescence studies as a component of overall work related to waste package performance.

A timeline showing the involvement of Vaisala in YMP activities and events associated with the use of the Vaisala probes is provided in Table 1.3-1.

Table 1.3-1. Summary Timeline of Project Activities Related to Use of Temperature–Humidity Probes by LLNL

Date	Event
1998	Vaisala placed on Qualified Supplier List as supplier and calibrator of temperature–humidity probes. Original qualification process used multipoint check and accepted standards to establish performance curves. Subsequent recalibration activities entailed use of “single-point” approach to determine whether performance was still consistent with the initially established linear performance curve. Instruments are specified by the manufacturer to perform over a range from -40°C to +180°C (see Section 1.3.1.1.3)
March 2002	Vaisala no longer provided calibration services to YMP; however, certain instruments calibrated before this date remained valid through their re-calibration due date
July 2002	LLNL attempted to use National Institute for Standards and Technology (NIST) as calibration supplier; however, NIST did not perform instrument adjustments
December 2002	LLNL established a three-temperature at three-humidity (nine-point) calibration statement of work for Thunder Scientific to increase confidence in the linearity (both temperature and humidity) of the instrument. This calibration approach used the initial performance curves established by Vaisala in establishing and adjusting the instrument response spectra
December 2002	Thunder Scientific placed on Qualified Supplier List as calibration supplier
September 2002 (to August 2005)	Probes, calibrated by Thunder Scientific, and previously calibrated Vaisala probes were used in mixed salt deliquescence experiments
November 2003	LLNL staff questioned the use of instruments at temperatures beyond the range at which the probes have been calibrated (i.e., using instruments calibrated at 20°C, 40°C, and 60°C at temperatures above 60°C)
November 2003	LLNL requested additional data from manufacturer supporting instrument use at full temperature range of instrument (i.e., -40°C through +180°C); manufacturer-published literature assures performance over the full range of the instrument
February 2004	LLNL conducted confirmatory testing of probes at 90°C to 110°C
March 2004	CR 2247 issued. CR 2247 addressed use of instruments at temperatures beyond the range (60°C) at which the instrument was calibrated (see October 2004 below)
October 2004	Additional confirmatory mixed salt experiments conducted at LLNL at temperatures between 110°C and 180°C as a result of CR 2247
April 2005	CR 5430 issued. CR 5430 raised questions regarding the possible impacts to Project data if it was determined that use of the instruments at temperatures beyond the range at which they have been calibrated was inappropriate. This CR confirmed caveats for use of data included in DTNs. CR closed in January 2006.
August 2005	Audit BQAP-BSC-05-07 was conducted
August 2005	CR 6479 issued. CR 6479 identifies deficient conditions in LLNL scientific notebook used in humidity measurements. CR remains open, pending additional management review.
December 2005	NRC documented temperature-humidity probe issues identified in August 2005
December 2005	CR 7185 issued. CR 7185 documented NRC observer inquiry AOI-OAR-05-05-05
January 2006	NRC audit observer report issued
January 2006	CR 7418 issued. CR 7418 documented NRC perceptions that the temperature-humidity probes have been improperly used because they were used “outside of their calibrated range”
February 2006	CR 7418 root cause analysis chartered

1.3.1.1.2 Instrument Description

The HMP243 probe measures temperature and humidity and converts humidity values to relative humidity through a microprocessor. The basic version of HMP240 series transmitters has one sensor head; the output variables are dewpoint temperature and mixing ratio. Optionally, the

transmitter can be equipped with an additional temperature sensor head that measures the ambient temperature used in the calculation of relative humidity, absolute humidity, wet-bulb temperature, and dewpoint difference to ambient temperature.

According to the manufacturer's user's guide (Vaisala 2002), HMP243 probes are designed and specified to operate in a temperature range from -40°C to $+180^{\circ}\text{C}$, and a relative humidity range from 0% to 100%. Both of these ranges are consistent with the requirements of the experiments conducted at LLNL. The accuracies of the relative humidity and temperature established by Vaisala, the manufacturer, are given as $(\pm 0.5 + 2.5\%$ of the reading) percent relative humidity for humidity and $\pm 0.1^{\circ}\text{C}$ for temperature.

1.3.1.1.3 Initial Temperature Calibration of New HMP243 Probes

The temperature sensor uses a resistance temperature detector (RTD). The RTD establishes an accurately duplicated temperature coefficient of resistance-versus-temperature curve. The initial temperature response is established using a two-point temperature calibration (to a NIST-traceable standard) and is recalibrated by comparing a single NIST-traceable temperature standard on the response spectra. In other words, the temperature calibration is established along a defined temperature slope, using a linear instrument. The temperature recalibration determines whether the calibration temperature point falls on the "as calibrated" curve. If so, the temperature component of the instrument is in calibration.

1.3.1.1.4 Initial Humidity Calibration of New HMP243 Probes

The calibration process for humidity uses a relative humidity relationship for well-characterized mixed salts and back-calculates within the processor to an *absolute* humidity at the humidity sensor. The initial humidity response spectra of the HMP243 probe was established by Vaisala using a multipoint calibration process based on NIST-traceable dry nitrogen and salts (NaCl, LiCl, and K_2SO_4). Initial relative humidity response was set at 0.0% for dry nitrogen and 75.5% for NaCl solutions. Intermediate relative humidity values were established at 11.3% and 97.6% for LiCl and K_2SO_4 solutions, respectively. Correlation of the instrument response with the appropriate standard was established through adjustment of the processor output.

Mixed salt values are established in ANSI/ASTM E104-02, *Standard Practice for Maintaining Constant Relative Humidity by Means of Aqueous Solutions*. The ASTM values are from "Humidity Fixed Points of Binary Saturated Aqueous Solutions" (Greenspan 1977, pp. 89-96).

Reference comparisons (calibration) using NIST-traceable instruments, rather than the primary salts and nitrogen, may also be used. Probe response is established through adjustment of the processor output. As such, the manufacturer's initial calibration process for the probes entailed the use of traceable standards and multiple points to establish linear performance characteristics that later serve as the basis for required recalibration activities.

1.3.1.1.5 Initial Calibration of Repaired HMP243 Probes

For those instances in which there is a need for repairs (e.g., sensor replacement) to a probe that has been in service, LLNL returns the instruments to Vaisala for replacement/repair. The humidity response was recalibrated by Vaisala in the same manner as the initial calibration

following any sensor replacement. Following the completion of the repairs, the probe was sent to the qualified calibration supplier Thunder Scientific to perform a calibration check in accordance with Yucca Mountain Project requirements.

3.1.1.6 HMP243 Probe Recalibration (Verification)

Probe measurements of temperature and humidity are converted within the processor to *relative* humidity. Because the humidity component is more susceptible to change through temperature or humidity degradation, Vaisala recommends calibrating the temperature-humidity probes at a defined interval using NIST-traceable standards at two humidity points and a single temperature on the linear response. The two recalibration humidities confirm whether the instrument has remained within calibration. The two humidity points must be at least 50% relative humidity apart. Demonstration that performance remains consistent with the originally established performance curve is considered an acceptable method of recalibration.

To augment its confidence in Vaisala's calibration method, in 2002 LLNL specified that Thunder Scientific employ an expanded recalibration approach using three humidity measurements at three temperatures (20°C, 40°C, and 60°C). This approach provided additional data points along the linear response curve to demonstrate acceptable performance and confirm instrument linearity. During 2003 and 2004, LLNL also requested BSC to help address questions regarding the use of a recalibration process that does not encompass the temperatures at which the probes are used. These requests culminated in the issuance of CR 2247. In each instance, the clarifications indicated the calibration process was acceptable, thereby resolving earlier concerns about calibration.

3.1.1.7 Additional LLNL Calibration Confirmation Measurements

In addition to expanding the number of data points used during recalibration, LLNL conducted additional confirmatory measurements to develop an experimentally derived uncertainty range. The LLNL measurements established an uncertainty of 1.6% RH at one standard deviation (1 σ), at temperatures from 90°C to 110°C. This uncertainty was based on an LLNL-developed statistical analysis of uncertainty. As LLNL has not quantified the uncertainty above 120°C, any data obtained by the probes at temperatures above 120°C were identified and used in a qualitative (or corroborative) manner only.

During the root cause investigation resulting from CR 7418, test results to establish the probe response at higher temperatures were obtained from Vaisala for the HMP233 probe. This probe has the same characteristics as the HMP243 probe, as it uses the same sensor (Vaisala 2002). Results from a series of three tests, for temperatures up to 180°C, were obtained. These test results closely correlated with the LLNL results documented in CR 2247 (issued on March 30, 2004). The test results supported the instrument use range and also served to validate the conservative uncertainty applied to RH values from 90°C to 120°C.

It is significant to note that during the audit exit discussions, some confusion regarding the recalibration of the probes was introduced via mention of a "bi-thermal" calibration chamber under development at the time at LLNL and the explanation of how that chamber might be used

in the future. In actuality, the “bi-thermal” chamber played no role in the formal calibrations or recalibration of the Vaisala probes in use at LLNL at the time of the audit.

1.3.1.1.8 Calibration

In the scientific community, there are two fundamental philosophies regarding the appropriate method to be used to calibrate and recalibrate measuring and test equipment.

1. An instrument is calibrated or recalibrated at points that span the instrument use range. In other words, an instrument used from 0 to 100 units must be calibrated (or recalibrated) from at least 0 to 100 units and preferably beyond this range (e.g., at -5 and 105 units).
2. An instrument is calibrated or recalibrated at one or more points within its range of use, as long as the instrument response is well understood (i.e., clearly established during initial calibration). For example, an instrument with a use range from 0 to 100 units and a well-understood response, such as linearity, may be calibrated or recalibrated at a point within that range (e.g., at 48 units). Demonstration of compliance at the single point is considered to be demonstration of compliance at any point in the specified operating range (recommended by Vaisala (Vaisala 2002)).

Both philosophies are considered acceptable and either may be used to provide an appropriate measurement confidence for the instrument user. LLNL chose Vaisala’s recommendation in establishing the primary recalibration method for the HMP243 probes.

1.3.1.1.9 Quality Assurance Requirements and Description Requirements

YMP requirements for measuring and test equipment at the time of the audit were established in Section 12, “Control of Measuring and Test Equipment,” of the QARD. The QARD also establishes requirements for accuracy of calibration standards. “Accuracy” as defined in LP-12.1Q-BSC, *Control of Measuring and Test Equipment*, is “[t]he degree of agreement of the measurement with the true value of the quantity measured.”

The QARD, Section 12.2.2, establishes requirements for measuring and test equipment use:

The use of measuring and test equipment shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected, or items inspected or tested since the last calibration.

1.3.1.1.10 LP-12.1Q-BSC

YMP procedure LP-12.1Q-BSC defines the terms “calibration” and “accuracy” as they are to be used for experiments related to the YMP. Similar to the QARD, LP-12.1Q-BSC does not define or establish quantitative calibration measures. Instrument calibration suppliers, under controlled laboratory conditions, strive to operate within a two standard deviation (2σ) expanded uncertainty. This expanded uncertainty or coverage factor defines that approximately 95.4% (the

calculated 2σ value) of instrument measurements fall within the established tolerance (NIST 1994).

1.3.1.1.11 Industry Perspectives

The recognized industry definition for “calibration” is established through the International Organization for Standardization (ISO) *International Vocabulary of Basic and General Terms in Metrology (VIM)* (ISO/VIM 1993, Section 6.11). The American National Standards Institute directly references the ISO definition and establishes a similar definition, used nationally (ANSI/NCSL Z540-1-1994, p. 1).

ISO and the National Institute of Standards and Technology (NIST) also provide perspectives on instrument use and the circumstances in which they expect the user to be responsible for establishing measurement needs. NIST also states, related to traceability, that the validity of any claim related to the use of the result or value is the responsibility of the instrument user (NIST 2005). As a result, it is appropriate that LLNL, as the user of the instrument, establish the test and calibration methods to be used for the Vaisala probes once they are in service.

1.3.1.1.12 NRC and NIST Approaches to Instrument Calibration and Recalibration

Vaisala’s calibration and recalibration have been referred to as a “single-point” calibration. In actuality, multiple temperature and multiple humidity responses are used in the initial calibration of the instrument and the development of the initial performance curve. Initial calibration for the measurement of interest—humidity—spans essentially the entire humidity range of interest, from 0% to 97.6%. Until 2002, Vaisala performed recalibration humidity checks at a single temperature but using two humidity values, separated by at least 50% relative humidity. The recalibration check determined if the instrument was still performing in the same manner as established at the time of initial calibration and within established tolerances. Recalibration activities performed by Thunder Scientific since 2002 have involved determinations at three separate humidities, each at three temperatures.

Although not exactly the same situation as the calibration of the Vaisala probes regarding the calibration of effluent radiation monitors, NRC states, “Single point calibrations using secondary sources are acceptable where detectors are inherently linear.” NRC also states, “[T]herefore, “single-point” calibrations using secondary sources (e.g., solid sources), should be considered adequate to meet the requirements of standard Technical Specifications where detectors are inherently linear” (NRC 1995). This text supports the underlying philosophy of LLNL’s (and Vaisala’s) use of a limited number of data points to demonstrate appropriate recalibration of an instrument, as long as this use is consistent with the manufacturer’s recommendations and demonstrates the necessary linearity. In this instance, the approach used by both Vaisala and Thunder Scientific met (and in the latter instance, exceeded) the manufacturer’s recommendations.

In addition, NIST supports the practice of single-point calibration when the equipment responds in an inherently linear manner as described in *NIST/SEMATECH e-Handbook of Statistical Methods* (NIST 2006). In this handbook, NIST describes the calibration designs for “appropriate” calibrations where the reference standard for units to be measured already exists

(e.g., humidity, temperature). Among those “appropriate” calibration designs are procedures for “single-point” calibration. The practice of single-point calibration is also widespread in the environmental, medical, and manufacturing industries, including facilities subject to NRC regulation (e.g., Conax Buffalo Technologies—thermocouples for temperature measurements for semiconductors; Turner BioSystems—fluorometers; YSI Temperature—precision thermometers).

Finally, *NIST Quality Manual for Measurement Services: QM-1* (NIST 2005) states “NIST policy on traceability asserts that providing support for a claim of traceability of the results of a measurement or value of a standard is the responsibility of the provider—whether NIST or another organization—of that result or value, that assessing the validity of such a claim is the responsibility of the user of that result or value.” In addition, ISO/IEC 17025, Section 5.4.2, states, “The laboratory shall use test and/or calibration methods, including methods for sampling, which meets the needs of the client and which are appropriate for the tests and/or calibration data.”

Because of industry positions such as these, the requirements are sufficiently flexible for identifying the number of points at which operating ranges must be checked across an instrument’s range. These attributes depend on the needs of the user and the degree of confidence required in their measurements. Therefore, a single- or two-point calibration performed by the manufacturer at one temperature is not necessarily insufficient.

To enhance their level of confidence in the Vaisala probe measurements at high temperatures, LLNL scientists had the device calibrated at 3 points across the range and at 3 operating temperatures using Thunder Scientific as the qualified supplier. They also performed confirmatory tests of these probes (Table 1.3-1 and Section 1.3.1.1.6) at high temperatures. These results confirmed the validity of the instrument performance, thus establishing a higher degree of confidence in the device’s measurement uncertainty.

In summary, LLNL activities were within established industry metrology practices for acceptance of the calibrations as valid for the entire measurement range based on the specifications published by the manufacturer, calibrations received from Vaisala/Thunder Scientific, and their own independent verification efforts.

1.3.1.1.13 Review of Procurement Documents

While investigating whether the calibration and recalibration methods used and/or recommended by Vaisala were appropriate, documents were reviewed associated with the procurement of calibration services and any audits and surveillances of the calibration suppliers conducted by YMP from 1996 to 2005. An extensive review of procurement packages, bid requests, correspondence, Statements of Work, Scopes of Work, and Supplier Deviation Disposition Requests that describe purchases and calibration services was performed.

The Statement of Work for Thunder Scientific calibration service documents that the nine-point recalibration performed by Thunder was intended to calibrate the instruments used for the full temperature range (−40°C to +180°C) and full relative humidity range (0% to 100%) during the period 2002 to present, as established by the manufacturer. Similarly, the previous Vaisala

calibration Statement of Work, although not directly relevant for the data of interest that were used in technical products (because Thunder Scientific provided the recalibrations), indicated that the calibration was intended to demonstrate compliance for the same full temperature and relative humidity ranges.

1.3.1.1.14 Audits, Surveillances, and Supplier Evaluations

The Root Cause Team evaluated 13 other BSC Quality Assurance and DOE Office of Quality Assurance audits, surveillances, supplier surveys and supplier audits performed on probe and calibration suppliers. These evaluations, dated from 2001 to January 2006, included procurement, measuring and test equipment, and scientific notebooks. Nine of the 13 audits were identified as compliance audits, which concentrated on procedural implementation and did not directly address product technical adequacy. Review of the audit reports showed that although four audits were described as performance based, they also focused heavily on compliance, rather than the adequacy of the technical basis for the calibration.

The Root Cause Team also evaluated 15 vendor surveillances performed by BSC QA; however, the surveillances focused primarily on procedure compliance and did not address the technical adequacy of work. A review of supplier evaluations performed of Vaisala and Thunder Scientific was also conducted. As a result, the Root Cause Team concluded the activities conducted at the calibration services suppliers were performed in a manner consistent with Yucca Mountain Project requirements and procedures. No significant anomalies were identified in the course of these surveillances and supplier evaluations.

1.3.1.2 Issue Number 1—Qualification and Calibration of the Probes—Conclusions

Issue Number 1, as identified in Section 5.1 of OAR-05-05, is as follows:

LLNL initiated experiments to study the deliquescence effect on the corrosion of the outer surface of the waste package using Vaisala humidity probes that were not vendor-qualified nor calibrated for the upper temperature limits of the experiment. This is in non-compliance with the QARD, which requires that test instruments be calibrated before use.

As a result of the above analysis, DOE concludes:

- At the time of the initial use of the probes at LLNL, the Vaisala temperature–humidity probes used in the experiments had been appropriately calibrated by the probe manufacturer. Until 2002, Vaisala was a qualified (i.e., on the YMP Qualified Suppliers List) calibration services supplier.
- The calibration method used by Vaisala to perform the initial pre-service calibration was a multipoint method that used appropriate standards to develop a linear performance curve for the probes.
- Vaisala, the original manufacturer, specified the operational range of the probes as extending from -40°C to $+180^{\circ}\text{C}$; as such, the probes were considered to be calibrated for the entire operating range of interest within a defined range of uncertainty.

- During subsequent recalibration activities performed by Vaisala and other YMP calibration vendors before early 2002, a *single-point* calibration method was used to demonstrate that the performance of the probes remained consistent with the original performance curve. This methodology is considered by Vaisala and NIST to be an acceptable method for recalibration of the probes and is consistent with industry practice. In addition, the following NRC statement regarding the calibration of effluent radiation monitors at commercial power plants supported an analogous position: “Single point calibrations using secondary sources are acceptable where detectors are inherently linear” (NRC 1995).
- After Vaisala ceased the performance of calibration activities for the YMP, the probes were subsequently recalibrated by a qualified calibration services supplier, Thunder Scientific, using a calibration method that meets or exceeds the requirements of the original probe manufacturer.
- As a result, the probes were appropriately qualified before the initiation of the experiments and there was no violation of a DOE QARD requirement that test instruments be calibrated before use.

1.3.2 Issue Number 2—Data Validity

1.3.2.1 Introduction

The second issue addressed by this response is the NRC’s concern that activities implemented by LLNL as a result of CRs 2247 and 5430 brought into question the validity of the data collected using the probes during corrosion experiments conducted between 2002 and 2005. As a result, the NRC questioned “whether the corrosion data could be considered technically sound and defensible” (Collins 2006, Section 4.4.6).

The following sections briefly address the investigation results.

1.3.2.1.1 Use of HMP243 Data in Technical Products

The investigation resulting from CR 7418 involved review of documentation related to data produced by the temperature-humidity probes used in technical documents and the calibration status of each instrument while in use. Through interviews and review of YMP documentation, results of the investigation show data collected with Vaisala HMP243 probes were subsequently used in three analyses in a qualitative (indirect and/or corroborated) manner: *Analysis of Dust Deliquescence for FEP Screening* (BSC 2005), *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004a), and *Environment on the Surfaces of the Drip Shield and Waste Package Outer Barrier* (BSC 2004b).

The investigation also included review of the calibration status of HMP243 and related humidity probes maintained by LLNL, regardless of use in YMP-related technical products. Unrelated to the initial calibration, the concern regarding the status of ongoing calibrations and suitability of the data as further discussed below are addressed in CRs 7499 and 8063.

1.3.2.1.2 Data Use Summary

A number of concerns regarding the use of out-of-calibration reports (OCRs) and potential impact on data obtained with the probes were identified during the course of the root cause and other investigations associated with this response. CR 8063 documents conditions related to the out-of-calibration process and implementation, and, in some cases, not completing a final assessment of the data quality prior to using the data in a technical product. The results of the post-calibration check are required to assess the measurement results and any potential impacts to data from using an instrument beyond its calibration due date or found out of tolerance. In addition, measurement uncertainty, as documented in the respective data files, is not carried forward or discussed in the final technical product. Appropriate documentation of measurement uncertainty is a necessary component in assessing the validity of any measurement result. This issue is being addressed in CR 7499.

1.3.2.2 Issue Number 2—Conclusion

This section addresses the issues raised by the NRC regarding data obtained from the temperature–humidity probes identified in the NRC report:

The information identified by the NRC observers during the review of the two CRs 2247 and 5430 brought into question the validity of the data collected, when the subject humidity probes were used, during the corrosion experiments conducted between the years 2002 and 2005 at LLNL. ... [T]he NRC observers questioned whether the corrosion data could be considered technically sound and defensible. (Collins 2006, Section 4.4.6)

The investigation determined that the data were properly obtained and used in an appropriate manner. However, during the investigation, a number of issues potentially adverse to quality were identified and documented in CRs, which are listed in Enclosure 2. The impact of these conditions adverse to quality on the data is under evaluation, and the data will be requalified, if necessary.

1.3.3 Issue Number 3—Reference to Misrepresentation—Investigation Results

1.3.3.1 Introduction

In its report, the NRC used the term “misrepresentation” in connection with statements made in LLNL scientific notebook SN-LLNL-SCI-484-V1 (Staggs 2005) regarding the calibration of the Vaisala temperature–humidity probes. As noted in Section 1.3 and Enclosure 3, NRC did not intend to suggest willful misrepresentation in its Observation Audit Report. The DOE expects complete and accurate documentation of technical and licensing-related activities and appreciates the seriousness of the NRC’s concern regarding the calibration status of the subject probes.

1.3.3.2 Issue Number 3—Conclusions

This response to Issue Number 3 addresses the NRC’s concern that LLNL’s statements within SN-LLNL-SCI-484-V1 (Staggs 2005) “misrepresented” the facts. In addition, the NRC

questioned why an issue of such importance was not raised to management in a timely manner. As stated in OAR-05-05:

Scientific Notebook SCI-484 identified the Vaisala probes as calibrated and documented the calibration date for the probes. However, appropriate documentation was not included in the scientific notebook, identifying the limitation on the use of the humidity probes at high temperatures. Failure to identify this potential misrepresentation of the information in the scientific notebook to management for further investigation is identified as a deficiency. (Collins 2006, Section 5.1)

The LLNL and BSC personnel present at the audit believed (and continue to believe), as documented in Section 1.3.1 of this report, that the probes were properly calibrated given that (1) they had been originally calibrated and recalibrated in a manner consistent with the manufacturer's recommendations, and (2) the specified operational range of the probes extended from -40°C to $+180^{\circ}\text{C}$. It was only at the re-exit meeting held in December 2005 that Yucca Mountain Project personnel better understood the importance of this issue to the NRC.

1.3.4 Summary and Conclusions

This response addresses three issues raised by the NRC Audit Observation Team following an audit conducted by BSC personnel at LLNL in August 2005. The NRC in OAR-05-05 formally documented the issues. These issues were also documented in the YMP Corrective Action Program in the form of several CRs, which initiated a number of in-depth investigations of the circumstances surrounding the subject audit and issues identified by the NRC. This response specifically addresses the issues identified in CR 7418.

The issues raised by the NRC primarily involved the calibration of temperature-humidity probes used by LLNL personnel conducting experiments for YMP, the adequacy of the data that was gathered using these probes, and a perception that LLNL personnel had misrepresented the calibration status of the probes during the experiments of interest.

The conclusions of this investigation are presented below:

- The temperature-humidity probes were adequately calibrated and recalibrated in accordance with the manufacturer's instructions with an acceptable calibration methodology consistent with industry practice.
- The data gathered from these probes were not suspect and could be used by Project personnel involved in the preparation of technical documents that may serve as the basis for the License Application.
- During the August 2005 audit and subsequent exit meetings, LLNL and BSC personnel did not misrepresent information, and the Scientific Notebook accurately reflected the status of the subject probes.

2. Quality Assurance Aspects

In preparation for the audit activities at LLNL, the BSC audit team reviewed scientific notebooks and identified ongoing LLNL testing activities to identify the measuring and testing equipment, samples, scientific notebooks, condition reports, and quality assurance (QA) records that would be evaluated at LLNL. The audit team members had not chosen the Vaisala temperature–humidity probes or CRs 2247 and 5430 to evaluate. During the course of the audit at LLNL, and based on discussion with the NRC observers, the auditors became aware that the NRC observers were concerned with the calibration of the Vaisala temperature–humidity probes and the associated corrective actions of CRs 2247 and 5430. Several discussions between the auditors, NRC observers, and LLNL personnel (without the Audit Team Leader) were held to get a better understanding of the calibration of the temperature–humidity probes and the relationship with CRs 2247 and 5430. After the observers departed LLNL, an auditor further discussed the ongoing testing (validation) activities at LLNL with LLNL personnel in support of the corrective actions of CR 2247 (closed) and CR 5430 (still open at that time) and decided that the corrective actions were reasonable and appropriate. The calibration status of the probes beyond 120°C was identified in CR 5430 and corrective measures were in process to eventually produce a LLNL calibration process for the temperature–humidity probes. Additionally, prior to the audit, CR 2247 (Level B) was thoroughly evaluated by a quality assurance representative during the processing of the CR, and BSC surveillance (BQA-SI-05-035, Hartstern 2005) of the effectiveness of CR 2247 found the corrective actions to be effective. However, none of these additional discussions were communicated with the NRC observers.

Based on the fact that the audit of the measuring and test equipment previously identified for evaluation during the audit was satisfactory and that an open CR questioned the calibration of the temperature–humidity probes beyond 120°C, the audit team concluded that LLNL had effectively implemented QARD Section 12, “Control of Measuring and Test Equipment.” Based on the evaluation of the CRs, the overall implementation of QARD Section 16, “Corrective Action,” by LLNL was determined to be effective. The audit team did not perform an in-depth review of CRs 2247 and 5430 during the audit or use these CRs for their determination of the effectiveness of LLNL’s corrective action implementation. The final decisions by the auditors regarding the effectiveness of the LLNL implementation of the QARD were made in the last auditor meeting held on August 30, 2005 after most of the NRC observers had departed.

The failure to thoroughly discuss the audit results and any NRC observer concerns with the audit observers prior to the audit exit contributed to the NRC’s disagreement with the conclusions reached by the BSC audit team. Based on the fact that different conclusions were reached, OCRWM staff initiated self-assessments and corrective actions to improve the audit process as follows.

A BSC self-assessment completed on January 20, 2006 identified ten opportunities for improvement and one adverse condition. Nine of the opportunities for improvement and the one adverse condition were forwarded to the BSC QA organization for response. Most of these improvement items are associated with the auditing process and the interface with outside observers during the audit. In addition, a self-assessment conducted by DOE addressed the effectiveness of communications during NRC observed audits. As a result, Level D CR 8011 was

issued to identify recommendations to improve the efficiency of audit activities and ensure that improvements are integrated across DOE and BSC organizations.

Level D CR 7375 was written to document weaknesses and deficiencies identified by the NRC concerning the revision of the audit scope prior to the start of the audit and the failure to include a technical specialist in the audit activities at LLNL. Both of these issues are discussed further in Response to Weaknesses and Deficiencies from the NRC Audit Observation Report Sections 4.2, 4.3, and 4.4.9. Enhancements were made to the BSC QA Internal Audit Guidelines to address the issues and the guidelines were issued on February 28, 2006. CR 7375 was closed on March 7, 2006.

Level B CR 7395, issued January 17, 2006, was written to document the failure of the Audit Team Members to notify the Audit Team Leader of any potential condition or circumstance that could require a change of the audit scope. Several issues concerning the control of the Vaisala temperature-humidity probes, LLNL corrective action program implementation and submittal of records to the Records Processing Center (RPC) were identified by the NRC observers in the NRC Observation Report issued January 9, 2006. The conclusions by the observers were in disagreement with those results identified by the audit team in the audit report. On February 1, 2006, the Level B CR 7395 was re-issued as a Level A CR stating that the audit team had not written CRs for the issues identified by the NRC (i.e., NRC concluded that the audit team should have found that LLNL was not effectively implementing its QA program and the audit team did not examine the objective evidence necessary to evaluate the conditions identified by the NRC).

With respect to the status of CR 7395, the Root Cause Analysis Report for Condition Report 7395 was completed on May 18, 2006, and CR action planning was completed on June 26, 2006. The corrective actions include revision of BSC audit procedures and audit guidelines, creation of a BSC desktop information for interfacing with observers, modification of a training module, and generation of a training instruction. Completion of all corrective actions is projected for August 31, 2006.

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**RESPONSE TO WEAKNESS
(ORIGINALLY AOI-BQAP-BSC-05-07-3)**

NRC Audit Observer Report Section 4.5.2.1 states:

[T]he following information is needed to make a determination of the adequacy of the information related to the corrosion rates:

- A technical basis for modeling the general corrosion rates of the dual-phase (α/β) Titanium Grade 24 alloy in a representative repository environment using the general corrosion rates from the single phase (α) Titanium Grade 7.
- A technical basis for the general corrosion rates for Titanium Grade 24 base material and Titanium Grade 7 / 24 weldments in the as-welded and stress-relieved conditions, as would be expected on an as-fabricated drip shield in a representative repository environment.

Response:

Justification for the estimation of the general corrosion rate of the dual phase (α/β) Titanium Grade 24 (UNS R56405) from the known general corrosion rate of Titanium Grade 7 (UNS R52400), a single phase (α) titanium alloy, has been provided in *Screening of Features, Events, and Processes in Drip Shield and Waste Package Degradation* (BSC 2005, Section 6.2.3). Although experimentally determined general corrosion rates of the Titanium Grade 24 under repository conditions are not available at this time, a conservative estimate of these rates was made by comparison of the general corrosion rates of Titanium Grade 5 (UNS R56400) (i.e., Titanium Grade 24 without palladium) and Titanium Grade 7 in oxidizing acidic environments. This environment is considered repository-relevant because the aqueous environment in the repository is oxic. Handbook data (Schutz and Thomas 1987, Table 7, p. 679) obtained in boiling 25% HNO₃ show the general corrosion rate of Titanium Grade 5 is approximately 4 times that of Titanium Grade 7. Since the purpose of palladium alloying additions is to help maintain the passivity of a titanium alloy (see FEP 2.1.03.03.0B in BSC 2005, Section 6.2.7), the general corrosion rate of Titanium Grade 24 (i.e., the palladium-containing analogue of Titanium Grade 5) is expected to be lower than that of Titanium Grade 5. On this basis, the general corrosion rate of Titanium Grade 24 is conservatively taken to be 5 times that of Titanium Grade 7. This value is consistent with and corroborated by other Project documents. For example, in *Aqueous Corrosion Rates for Waste Package Materials* (BSC 2004, Section 6.5.2), the general corrosion rate of the Titanium Grade 24 drip shield support material was conservatively estimated (based on a comparison of corrosion rate data obtained in boiling 3% HCl solutions) to be about 5 times greater than that for the Titanium Grade 7 drip shield plate material.

To confirm this estimated value for the general corrosion rate of Titanium Grade 24, a series of experiments is currently being conducted. These experiments will include determination of the general corrosion rates of similar materials (i.e., Titanium Grade 29 (UNS R56404) and/or Titanium Grade 23 (UNS R56407) with palladium) to Titanium Grade 24 under repository-

relevant environments using polarization resistance and cyclic potentiodynamic polarization. The results of these experiments are expected to be available before the end of fiscal year 2006. It should be noted that the general corrosion rate of Titanium Grade 7 was estimated from weight loss measurements of both as-welded and nonwelded materials. No difference was observed between the corrosion rates of base metal and welds. Because welded regions are under a state of stress, and there was no difference observed between the corrosion rates of base metal and welds, it is expected that stress relieving will not adversely affect the general corrosion resistance of this material. On this basis, the effect of welding is included indirectly in the general corrosion rates estimated for the Titanium Grade 24 alloy.

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**RESPONSE TO WEAKNESS
(ORIGINALLY AOI-BQAP-BSC-05-07-4)**

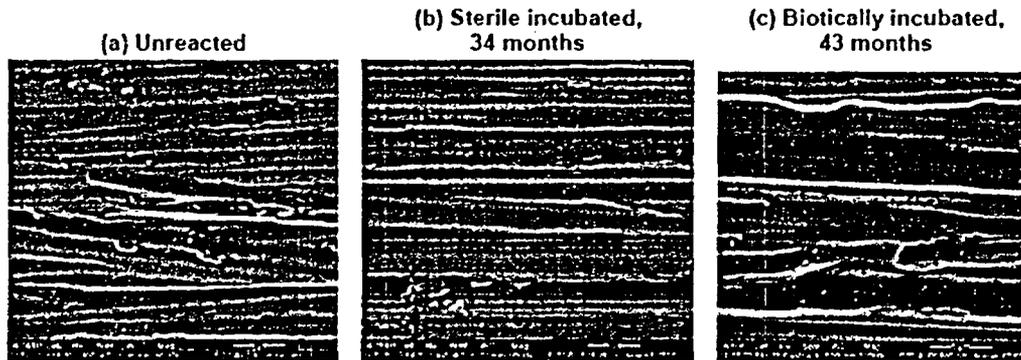
NRC Audit Observer Report Section 4.5.2.2 states:

[T]he NRC observers identified the need for additional justification for modeling microbiologically induced corrosion, using a scaling factor to the generalized corrosion model. The scanning electron micrographs of the corrosion under biotic conditions in Figure 6-67 of ANL-EBS-MD-000003, appear significantly different from typical general corrosion. Specifically, the NRC observer noted that micropores were found on the specimens that were tested under the biotic condition. This may be an indication of localized corrosion, as opposed to general corrosion.

Response:

This response provides the basis and justification beyond what is provided in *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004) for modeling microbially influenced corrosion with a scaling factor for general (not localized) corrosion in light of the fact that scanning electron micrographs (BSC 2004, Figure 6-67, p. 6-106) indicate that the corrosion morphology under biotic conditions appears different from general corrosion.

In the study that produced these scanning electron micrographs (BSC 2004, Figure 6-67, p. 6-106), Alloy 22 (UNS N06022) coupons were incubated with sterile or nonsterilized Yucca Mountain rock in simulated concentrated (10×) groundwater supplemented with 0.1% glucose for almost 5 years (Martin et al. 2004). Coupons were incubated with Yucca Mountain tuff that was either left unsterilized or was pre-sterilized prior to being placed in the experimental vessels held either at room temperature or 30°C. Alloy 22 coupons from microcosms held at 30°C were withdrawn, cleaned, and imaged using scanning electron microscopy. An unreacted Alloy 22 coupon was also cleaned in the same manner and imaged in parallel for comparison. These scanning electron microscopy results are shown in Figure 1. Coupons incubated in the nonsterile microcosm reactors showed the development of micropores, primarily along the ridges formed by polishing, while coupons incubated in sterile microcosms and those that were not reacted in microcosms showed no evidence of pinhole formation after one cleaning cycle (although repeated cleaning cycles resulted in formation of micropores). The micropores appeared uniform in shape except where they had grown together and ranged in size from 0.2 to 0.7 μm in diameter.

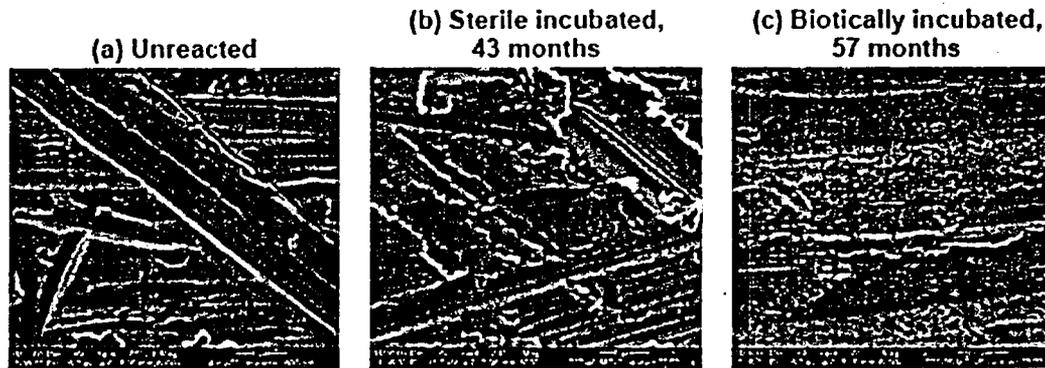


Source: Horn et al. 2005, Figure 5.

Figure 1. Comparison of Scanning Electron Microscopy–Imaged Alloy 22 Coupons Exposed at 30°C (a) Untested (8,000×), (b) Sterile Incubated at 30°C for 34 Months (8,000×), and (c) Biotically Incubated at 30°C for 43 Months (10,000×)

Analyses of the cleaning process used on these samples, which involved the use of ultrasonication in HCl (150 mL hydrochloric acid (HCl, specific gravity 1.19) in 1 L of water), brushing, rinsing, and immersion in a NaOH/KMnO₄ solution, indicate that the micropores may have formed during the cleaning process, which used solutions outside the range of possible repository exposure environments and were not directly caused by microbial activity (Martin et al. 2004). Martin et al. (2004) hypothesized that microbial activity could alter the surface in such a way that it was more susceptible to corrosion during the cleaning process. It is conceivable, therefore, that micropore formation did not result from the microbial activity by itself, even after 5 years of exposure to a glucose-supplemented environment at 30°C but instead from a combination of microbial activity and exposure to an acidic cleaning process using solutions outside the range of those possible in repository exposure environments.

Scanning electron microscopy images of unexposed, sterile control, and nonsterile coupons exposed at room temperature are shown in Figure 2. Alloy 22 coupons exposed to microbial environments showed the presence of micropores (before and after cleaning) after almost 5 years of exposure. Similar degradation was not seen in sterile controls after 43 months of exposure. The observed micropores were of similar size to those seen at 30°C; however, they were more numerous and not restricted to polishing ridges. Atomic force microscopy and scanning electron microscopy analyses indicate that the overall surface roughness of the nonsterile coupons decreased as a function of exposure time, even as microscale roughness increased due to the micropores.



Source: BSC 2004, Figure 6-67.

Figure 2. Comparison of Scanning Electron Microscopy–Imaged Alloy 22 Coupons Exposed at Room Temperature (8,000 \times) for (a) an Untested Coupon, (b) a Coupon Sterile Incubated for 43 Months, and (c) a Coupon Biotically Incubated for 57 Months

The micropores do not have the macroscopic appearance of pitting corrosion, which typically results in pit diameters on the order of several microns (Priyantha et al. 2005, Figures 11, 13, and 17). Priyantha et al. (2005, Figure 11) reported pit diameters on Alloy 22 between 1.6 and 17.3 μm , with the largest fraction with pit diameters between 4 and 5 μm , after a 10-day exposure to a pH = 3, saturated NaCl solution at 80°C under potentiostatic conditions. The micropores on the nonsterile coupons are between 0.2 and 0.7 μm (Martin et al. 2004). If these micropores formed due to microbial activity, then it is possible that they are metastable pits that never transitioned to stable pitting even after almost 5 years of exposure to a glucose-supplemented microbe-containing solution. This strongly suggests that microbial activity is not sufficient to cause stable pit formation (i.e., localized corrosion) on Alloy 22. In addition, the presence of grinding marks on both sterile and nonsterile coupon surfaces indicates that the total amount of dissolution in the presence of microbes was low compared to active dissolution. Also, as noted above, the overall surface roughness of the nonsterile coupons decreased as a function of exposure time. This is consistent with a general corrosion-like dissolution process enhanced by micropore formation.

The weight-loss from the above experiment was not estimated; however, it is clear from the discussion above that microbial activity did have some effect on the Alloy 22 surface morphology, particularly for exposures at room temperature. The enhancement in dissolution rate due to microbial activity was estimated in a study by Lian et al. (1999), using 12 strains of Yucca Mountain bacteria, including acid, slime, and sulfide producers, as well as iron-oxidizing bacteria. This study showed that microbial activity can enhance corrosion rates of Alloy 22 by a factor of 2. The growth medium was supplemented with 0.5% glucose and 0.75% protease peptone in 100 \times concentrated simulated J-13 well water (Lian et al. 1999). On the basis of these experiments and the discussion above, application of an enhancement factor to the Alloy 22 general corrosion rate is sufficient to represent the effects of microbial activity on Alloy 22 degradation rates in repository environments.

Given the information presented above, additional discussion regarding the modeling of microbially influenced corrosion with a scaling factor for general corrosion is planned for inclusion in the next revision (i.e., Revision 03) of *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004).

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RESPONSE TO WEAKNESSES AND DEFICIENCIES FROM NRC AUDIT OBSERVER REPORT SECTIONS 4.2, 4.3, AND 4.4.9

NRC Audit Observer Report Section 4.2 states:

BSC provided its original audit plan to NRC on July 25, 2005. However, on August 3, 2005, less than two weeks before initiation of the audit, BSC issued a revised audit scope that reduced the areas to be reviewed during the audit. This reduction in audit scope brought into question whether the audit objectives, stated as a broad assessment of data input and technical products, could be fulfilled. As a minimum, the change in scope weakened the audit and reduced the number of products that would be reviewed. Overall, NRC finds that the reduced audit scope also limited the opportunities to identify issues with the data input and technical products.

NRC also observed that preparations for the audit were delayed, in that audit checklists were not complete and available until the start of the audit. This was inconsistent with past experiences related to audits, conducted by DOE and BSC, in which the audit scope and audit checklists were generally completed well in advance of the audit activity, allowing project personnel and NRC staff to adequately prepare for the audit.

NRC finds that reducing the scope of the audit at the last minute and not having the audit checklist available until the beginning of the audit represented an audit weakness.

Response:

As stated by the NRC, the original audit plan was issued on July 25, 2005, three weeks before the scheduled start date of the audit. The original plan included a reference to the total system performance assessment (TSPA) for the license application (LA) in an effort to describe how Bechtel SAIC Company, LLC (BSC) selected the work to be audited. Some recipients of the plan interpreted this reference to mean that the performance assessment for the LA would be included in the audit. In order to clarify this point, a revised plan was issued on August 3, 2005, removing the reference to the performance assessment for the LA. However, there was no reduction in audit scope as a result of the revised plan because the audit objectives, data, and technical products evaluated remained the same. BSC quality assurance (QA) management and the Audit Team Leader had several conversations with other BSC personnel, DOE personnel, and NRC representatives to discuss the scope of the audit in order to ensure a common understanding of the scope of the audit. The Audit Team Leader had the impression that everyone involved understood that the purpose of the revision to the original audit plan was simply to remove the reference to the TSPA.

To minimize the possibility of future misunderstandings, Level D CR 7417 was initiated on January 24, 2006 regarding the need for additional management review of audit plans, and CR 7388 was initiated on January 27, 2006 regarding the need for informing NRC and other observers of changes to audit plans. These CRs were the results of a self-assessment initiated to

address management concerns associated with communications with the observers during the conduct of the audit.

In addition, Level D CR 7375 was initiated on January 13, 2006 to document weaknesses identified by the NRC concerning the revision of the audit plan prior to the start of the audit and not having the audit checklist available until the start of the audit. The corrective actions for CR 7388, CR 7375 and CR 7417 included revisions to the BSC QA Internal Audit Guidelines, providing additional instruction for audit planning and review.

It is acknowledged that the final audit checklist was not available until the start of the audit. In the future, BSC will strive to prepare for audit activities far enough in advance to allow technical specialists and NRC observers to have time to prepare for the audits.

Level D CR 7384 initiated on January 27, 2006 and CR 7375 pertain to the timely transmittal of checklists to observers. The corrective actions for CR 7375 and CR 7384 included revisions to the BSC QA Internal Audit Guidelines providing additional instruction for checklist control and timeliness of completion of checklists. These corrective actions were completed on February 28, 2006.

NRC Audit Observer Report Section 4.3 states:

The NRC observers reviewed the qualification for the audit team members, including the technical specialists assigned to the team, and determined they were qualified and independent of areas reviewed. Several senior-level QA personnel were included on the BSC audit team. These individuals were cognizant of the DOE and BSC QA requirements and the various procedural requirements related to the type of work being reviewed during the audit. The technical specialists assigned to the audit were knowledgeable in the areas reviewed and asked in depth questions during interviews. However, BSC did not include either of the two technical specialists in the LLNL portion of the audit, thereby reducing the effectiveness of the audit to identify technical issues with the experiments being conducted at LLNL. This concern was expressed to the BSC audit team during the audit. Not including the technical specialists in the LLNL portion of the audit is identified as an audit weakness.

Response:

The NRC's concern regarding lack of participation of the technical specialists at LLNL is acknowledged; however, the decision not to send the technical specialists to LLNL was made in consultation with the technical specialists. After reviewing the report, *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004), and formulating checklist and interview questions, the specialists concluded that a visit to LLNL was not warranted. The technical specialists were evaluating completed work and completed records (e.g., approved analysis model reports and scientific notebooks), all of which were sufficiently available from the Records Processing Center. If clarification on a technical issue was needed, the technical specialists decided that participation by telephone would be sufficient. Based on this, the LLNL portion of the audit was considered to be primarily compliance-based; therefore, it was not

anticipated that the presence of technical specialists would be needed to fulfill the objectives of this phase of the audit. (Note: only the LLNL portion of the audit was compliance-based; the rest of the audit was performance-based, which may have caused confusion.) In the future, BSC will continue to evaluate the technical specialists' role and their level of involvement in audits and make appropriate decisions based on the audit scope.

Level D CR 7375 was initiated in part to document concerns identified by the NRC regarding the physical presence of the technical specialists in the audit activities at LLNL. No corrective actions were necessary for this part of CR 7375. However, CR 7375 indicates that if the root cause analysis for CR 7395 initiated on January 17, 2006, determines that not including technical specialists in the audit activities at LLNL was the root cause or a contributing cause of the concern, corrective actions would be planned and completed under CR 7395. CR 7375 was closed on March 7, 2006. Root Cause 1 for CR 7395 found that the lack of adequate work organization and audit planning contributed to the deficiency related to the use of technical specialists during audit activities at LLNL. CR 7395 corrective actions will address these issues.

NRC Audit Observer Report Section 4.4.9 states in summary form:

The NRC describes concerns in part regarding (i) the incomplete submittal of all the documents to the Records Processing Center, (ii) the lack of an accurate statement in the associated AMR concerning the cleanliness of the samples, and (iii) the potential impact of the samples not being clean on the conclusions reached on the corrosion rate values. The NRC identifies these concerns as deficiencies in Section 5.1, which summarizes the NRC observations.

Response:

Subsequent to the audit, it was determined that all relevant documents were appropriately submitted to the Records Processing Center as mentioned below in relation to CR 7382. *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004, Section 6.4.3.1.4) refers to the cleaning procedure but does not mention directly the presence of spots or stains. The cleanliness of the specimens has negligible impact on the calculated corrosion rates. Minor stains or spots are mostly an optical artifact and do not contribute to the calculated weight loss and, therefore, corrosion rates.

Supporting Information

CR 7382 was initiated to address the NRC concern that the scanning electron microscope (SEM) images collected as part of the general corrosion testing were not submitted to the technical data management system. Investigation for this CR revealed that the SEM images were available through the Records Processing Center. To close the CR, copies of SEM images were placed in the technical data management system (TDMS). The Long Term Corrosion Test Facility 5+ year data for Alloy 22 are documented in the volumes of scientific notebook SN-LLNL-SCI-241 (Estill 2003; Fix and Wong 2004a; Fix and Wong 2004b). The calculated corrosion rates for the two types of Alloy 22 coupons exposed to electrolytes in six vessels (Vessels 25 to 30) are in Supplement #11 (or Binder 11) of SN-LLNL-SCI-241-V1 (Estill 2003). This information is in the Records Processing Center.

The TDMS database also contains the information on corrosion rates (DTN: LL030412512251.057) from Binder 11 (Estill 2003). Optical images of the coupons (weight loss or 2×1 in. and crevice or 2×2 in.) before and after cleaning are in Supplement #8 or Binder 8 (Estill 2003). This information is in the Records Processing Center. The procedure for cleaning the coupons before weighing them and calculating the corrosion rates is in TIP-CM-51, *Long Term Corrosion Test Facility Specimen De-Scaling Procedure for Alloy 22, Alloy C4, Titanium Alloys, TiGr 7, TiGr 12, and TiGr 16 Specimens*. As detailed in TIP-CM-51 (see also *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004, Section 6.4.3.1.4)), cleaning was performed by immersing the coupons mainly in acidic electrolytes. Cleaning was relatively simple for coupons immersed in the simulated concentrated water (SCW) and simulated dilute water (SDW) electrolytes (vessels 27 to 30). The solutions in vessels 27 to 30 were alkaline in nature, and cleaning in the acidic electrolyte quickly removed all the surface deposits. This was documented using optical and scanning electron microscopy images as a supplement (Binder 8) to SN-LLNL-SCI-241-V1 (Estill 2003). The scanning electron microscopy images for Alloy 22 coupons before and after cleaning are available from the Records Processing Center (Binder 10 or Supplement #10) (Estill 2003).

The appearance of the deposits before cleaning is described in a conference paper (Wong et al. 2004). For coupons exposed to the acidic simulated acidified water (SAW) electrolytes during testing (Vessels 25 and 26), cleaning was more challenging than for the specimens exposed to SDW and SCW solutions. The cleaning procedure for SAW coupons was more complex, and more steps were required to reach the final result (see TIP-CM-51). At the end of the cleaning sequence, some specimens immersed in SAW electrolyte still showed what could be called stains or spots; however, further cleaning steps did not change the weight of the specimen. Therefore, the cleaning was complete even though some stains remained.

In a previous version of *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (CRWMS M&O 2000, Section 6.5.5), when actual deposits still remained on the specimen surface after descaling, a conservative correction factor was applied. This factor was based on the thickest observed deposit, which corresponded to a corrosion rate of 63 $\mu\text{m}/\text{yr}$. A series of scanning electron microscopy photos of actual descaled specimens were included in the analysis model report (CRWMS M&O 2000, Attachment I). However, as stated in this response, as well as in the current revision of *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004, Section 6.4.3.1), the more recent descaling procedure (TIP-CM-51) involved multiple cleanings until scanning electron microscopy photomicrographs indicated no remaining deposits. The current version of *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004, Section 6.4.3.1.4) also mentions that the ASTM G 1-90, *Standard Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens*, chemical cleaning process was performed a sufficient number of times so that no remaining deposits were indicated by scanning electron microscopy. Furthermore, a postcleaning process drying oven and desiccators were used to minimize air exposure (decreasing the amount of postcleaning film formation and increasing the measured weight loss, resulting in higher determined corrosion rates). Thus, *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004) does indicate that, at least for some specimens, there was postcleaning film formation present. However, the cleaning stains were sufficiently thin that their contribution to the measured weight loss was below the weight loss balance resolution (BSC 2004, Section 6.4.3.3).

In spite of several steps in the cleaning (mostly documented in detail in SN-LLNL-SCI-241-V2 (Fix and Wong 2004a) for the titanium coupons, which were cleaned after the Alloy 22 coupons), some coupons still exhibited what was documented as discoloration or spots. This can be found in SN-LLNL-SCI-241-V2; for example, after all the cleaning steps, the titanium coupons exposed to vapor phase of SAW at 90°C appeared “golden and spotted” (Fix and Wong 2004a, p. 102). The presence of a postcleaning film formation is also indicated in *General Corrosion and Localized Corrosion of Waste Package Outer Barrier* (BSC 2004, Section 6.4.3.1.4). Photographs of the cleaned Alloy 22 coupons can be found in Supplement #8 (Binder 8) (Estill 2003). In the RISweb (Estill 2003, MOL.20030707.0241) there is a listing of the images, but the images are not available from the web. The images can be requested from the Records Processing Center where they are contained on compact discs. For example, images #5 of cleaned coupons DCA019 and DCA021 (exposed to Vessel 25 SAW vapor at 60°C) show a stain following the border of where the crevice former attached to the coupon. Similarly, the Leica 100× images #5 of coupons DCA022, DCA023, and DCA024 (exposed to Vessel 25 SAW liquid at 60°C) shows a surface of different color inside and outside the annulus of the crevice former. Similar statements can be made for the DCB, DWA, and DWB specimens (See Supplement 8 or Binder 8) (Estill 2003). Similarly, the low magnification images (of the entire coupon) also may show stains in other areas of the coupons exposed to SAW solutions (Binder 8) (Estill 2003). Similar stains or spots can also be seen in cleaned coupons exposed to SAW at 90°C (Vessel 26) (e.g., DCA049). An explanation of the aspect of specimens before and after cleaning and corresponding images can be found in DTN: LL060102012251.159.

Even though stains, spots, or discoloration may be visible in optical images, the specimens are not compromised for the purpose of measuring corrosion rates. A stain may be produced by a thin adherent oxide that is protective and therefore not dissolved or completely removed during the cleaning process. A stain can also be produced by uneven ambient temperature drying of the surface of the coupon after the final rinsing. These thin protective oxides (of maybe different thickness in different areas of the coupons) would show as stains, but they do not contribute measurably to the weight of the specimen. In many cases, a stain is visible in an optical image as an artifact of light interference, but when the stain is examined under scanning electron microscopy, it is not visible or detectable (i.e., a deposit cannot be discerned on the surface).

The following discussion supports a conclusion that these sporadic stains do not influence the corrosion rate of Alloy 22.

- The balance used for measuring of weight (a measure of corrosion rate) has a resolution of 0.5 mg (BSC 2004, Section 6.4.3.3) and was used to measure weight changes for samples with an average weight of about 58 g. Weight differences of less than approximately 0.5 mg will not be captured by the balance. That is, if a uniform 10-nm-thick Cr_2O_3 layer would cover continuously a 57-cm² area coupon, its weight would be 0.3 mg; that is, less than the detection limit of the scale. The density of Cr_2O_3 is 5.21 g/cm³ (Weast and Lide 1989, p. B-85). Therefore, a stain on the entire surface of the sample would not impact the weight loss measurement.
- Calculations show that there is little difference in the corrosion rate values between coupons exposed to the three electrolytes (SDW, SCW, and SAW) (DTN: LL030412512251.057). The average corrosion rates for each vessel (electrolyte)

are in the vicinity of 10 nm/yr. For the most-stained cleaned coupons (SAW solutions), the corrosion rates are not lower than for the less-stained cleaned coupons (SCW and SDW solutions) (Binder 11 (Estill 2003)). That is, since the coupons exposed to the SAW solutions are the coupons showing stains and these coupons do not show lower corrosion rates than the coupons exposed to SCW or SDW solutions, the conclusion is that stains do not contribute to the weight difference used for the calculation of the corrosion rates.

As supportive evidence for the previous discussion, short-term electrochemical tests have also shown that the dissolution rates of Alloy 22 in SAW and SCW solutions were similar. Constant potential tests at +0.1V (Ag/AgCl) performed on Alloy 22 immersed in SAW and SCW solutions at 90°C have shown the same order of current densities after 1 day immersion (the current density was slightly higher in the SCW solution) (Lian et al. 2002, Figures 4 and 6).

Supplement #10 (Binder 10) (Estill 2003) contains scanning electron microscopy images of the weight loss coupons before and after cleaning at 30×, 100×, and 1,000× magnification. The existence of these images is stated in MOL.20030707.0243 (Estill 2003), but they are not directly available from RISweb or TDMS. The images are available upon request from the Records Processing Center. These and other images clearly show that the cleaning of the coupons was in-depth. A few particles may be discernable in certain scanning electron microscopy images, but this would not contribute to the measured weight (less than detection limit of the balance). DTN: LL060102012251.159 contains additional information. As an added protective measure, a descriptive and collected selection of images were assembled and submitted to TDMS under DTN: LL060102012251.159.

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ENCLOSURE 2

**CROSSWALK OF AOIs, WEAKNESSES AND DEFICIENCIES FROM THE
NRC REPORT OAR-05-05, AND RELATED CRs**

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**CROSSWALK OF AOIs, WEAKNESSES AND DEFICIENCIES FROM THE NRC
REPORT OAR-05-05, AND RELATED CRs**

The crosswalk contained in this enclosure (Table 1) describes issues raised in the NRC Observation Audit Report No. OAR-05-05 dated January 9, 2006 (Collins 2006), along with the specific report section in which the issue is discussed. Each issue is categorized by one of the following designations: weakness, deficiency, Audit Observer Inquiry (AOI), and AOI-related. "AOI-related" refers to those issues that are related to a particular AOI, but are not discussed directly in the AOI text. The final two columns contain information regarding the related enclosure response and condition reports (CRs), respectively. Note that while many CRs of different levels have been initiated as a result of the AOIs and OAR-05-05, the crosswalk provides a selected listing of the more important and/or closely related CRs. Also, not all CRs listed in the crosswalk are individually discussed in Enclosure 1. For some issues, no CR was created because there were no indications of conditions adverse to quality during the response development process. Nevertheless, CR 7432 (closed to CR 7395) indicates that once an issue is identified, a CR should be initiated in a timely manner before the associated evaluation is completed. All issues in the crosswalk are addressed through CRs, enclosure responses, or both.

Table 1. Crosswalk of AOIs, Weaknesses and Deficiencies from NRC Report OAR-05-05, and Related CRs

NRC Report Section	Description	Category	Related Enclosure 1 Response	Related CR
4.2 5.1	Planning and preparation: The change in scope limited the number of documents that would have been looked at during the audit. It weakened the audit and limited opportunities to identify issues with data and technical inputs.	Weakness	Response to Weaknesses and Deficiencies, Section 4.2	7375(D) 7388(D) 7417(D)
4.3 5.1	Planning and preparation: Technical Specialists not being included on the LLNL audit team reduced the effectiveness of the audit to identify technical issues with experiments being conducted at LLNL.	Weakness	Response to Weaknesses and Deficiencies, Section 4.3	7375(D) 7395(A)
4.3	This concern (i.e. about the lack of Technical Specialists) was expressed to the BSC audit team during the audit by NRC. Not including the Technical Specialists in the LLNL portion of the audit is identified as an audit weakness.	Weakness	Response to Weaknesses and Deficiencies, Section 4.3	7375(D) 7395(A)
4.2	Planning and preparation: Checklist not ready until start of audit.	Weakness	Response to Weaknesses and Deficiencies, Section 4.2	7375(D) 7384(D)
4.5.2.1 5.1	Lack of adequate justification in products: The NRC identified the lack of justification for using the general corrosion rates for the single phase (α) Titanium Grade 7 (UNS R52400) alloy in the modeling of the dual phase (α/β) Titanium Grade 24 (UNS R56405) alloy in representative repository environments.	Weakness	Response to Weakness (Originally AOI-BQAP-BSC-05-07-3)	None*
4.5.2.2 5.1	Additional justification needed for modeling micro-biologically influenced corrosion using scaling factor to the generalized corrosion model.	Weakness	Response to Weakness (Originally AOI-BQAP-BSC-05-07-4)	None*
4.4.9 5.1	Samples (impact of inadequate cleaning): The NRC made a determination that incomplete cleaning would impact determination of corrosion rate values.	Deficiency	Response to Weaknesses and Deficiencies, Section 4.4.9	None*
4.4.9 5.1	Inadequate statements in analysis report: The NRC finding of scale still remaining on sample is inconsistent with a statement in the AMR which indicated <u>all</u> scale had been removed.	Deficiency	Response to Weaknesses and Deficiencies, Section 4.4.9	None*
4.4.9 5.1	Records: Scanning electron microscope images not submitted to Records Processing Center.	Deficiency	Response to Weaknesses and Deficiencies, Section 4.4.9	7382(C)

Table 1. Crosswalk of AOIs, Weaknesses and Deficiencies from NRC Report OAR-05-05, and Related CRs (Continued)

NRC Report Section	Description	Category	Related Enclosure 1 Response	Related CR
4.4.9 5.1	...[T]he failure to submit Binder #11 as part of the project records, the incorrect statement in the associated analysis model report related to the final condition of the corrosion samples, and the concern related to the impact of inadequate cleaning of the samples on the conclusions reached on the corrosion rate values is identified as a deficiency. The NRC observers identified these issues to the BSC audit team; however, no CR was issued. The failure to issue a CR to document these conditions is identified as a deficiency.	Deficiency	Response to Weaknesses and Deficiencies, Section 4.4.9	7395(A)
4.5.1.1	AOI-OAR-05-05-01: Drift Scale Seepage Analysis Model Report. Basis not provided for not considering salt effect on boiling point. The statement "seepage waters do not enter the drifts until the host rock temperature falls below 100°C (212°F)" is not supported by sufficient justification.	AOI	Response to AOI-OAR-05-05-01	None*
4.5.1.2 4.5.1.5	AOI-OAR-05-05-02: Analysis of Dust Deliquescence for Features, Events, and Processes (FEP) Screening and Engineered Barrier System: Physical and Chemical Environment. Use of model results outside of model validation range. ANL-EBS-MD-000045 notes the validated relative humidity range for the EQ3/6 model as being from 100 to 40 percent. However, documents ANL-EBS-MD-000074 and ANL-EBS-MD-000033, Rev. 4, include relative humidity data calculation by the EQ3/6 model below the validated range. Relative humidity data below 40%, which was lower than the validation limit of the Pitzer model, was presented in the report (AMR ANL-EBS-MD-000033).	AOI	Response to AOI-OAR-05-05-02	None*
4.5.2.3	AOI-OAR-05-05-03: Inconsistencies for Overall Localized Corrosion Modeling. Inconsistencies identified between products ANL-EBS-MD-000003 and ANL-EBS-MD-000074. ANL-EBS-MD-000003 states on pages 1-3, 6-97, and 8-6, "If the exposure temperature exceeds 160°C (320°F) and water film is present on the waste package surface, then localized corrosion initiates;" however, ANL-EBS-MD-000074 considers that localized corrosion will not initiate when a water film is formed by deliquescence at elevated temperatures (page 7-1), even though it has been shown experimentally that some salt assemblage may deliquesce at temperatures over 190°C (374°F) (page 7-2).	AOI	Response to AOI-OAR-05-05-03	None*
4.4.4	AOI-OAR-05-05-04: Referencing Cancelled Documents. Potential for problems during license application. The NRC noted that some of the products contain references to "cancelled" documents. Specifically, <i>[Environment on the Surfaces of the] Drip Shield and Waste Package Outer Barrier</i> (ANL-EBS-MD-000001, Rev. 1).	AOI	Response to AOI-OAR-05-05-04	7267(C)

Table 1. Crosswalk of AOIs, Weaknesses and Deficiencies from NRC Report OAR-05-05, and Related CRs (Continued)

NRC Report Section	Description	Category	Related Enclosure 1 Response	Related CR
4.4.6 5.1	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 12.0, "Control of Measuring and Test Equipment" LLNL's starting experiments and the conduct of several years of data collection using Vaisala temperature probes not calibrated for the upper temperature limits of the experiment.	Deficiency AOI	Response to AOI-OAR-05-05-05,, Section 1	7185(B) 7418(A) 7499(B) 8138(C) 8129(D)
4.4.6 5.1	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 12.0, "Control of Measuring and Test Equipment." LLNL did not provide documented basis for use of M&TE outside the range of calibration where NIST standards do not exist.	Deficiency AOI	Response to AOI-OAR-05-05-05, Section 1	7185(B) 7418(A) 7499(B)
4.4.6 5.1	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 12.0, "Control of Measuring and Test Equipment." LLNL misrepresented the calibration status by documenting in the scientific notebook that the Vaisala probes had been calibrated.	Deficiency AOI	Response to AOI-OAR-05-05-05, Section 1	7185(B) 7418(A) 7499(B) 8128(D)
4.4.6 5.1	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Although this information (i.e., calibration status not identified by scientific notebook) was provided to the BSC audit team, it did not elevate this misrepresentation of the calibration status of the probes in the scientific notebook to DOE and BSC managements for further investigation.	Deficiency AOI-Related	Response to AOI-OAR-05-05-05, Section 2	7395(A)
4.4.6	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 12.0, "Control of Measuring and Test Equipment." There are no provisions in the QARD for starting an experiment with an instrument not calibrated at the temperatures in which it will be used, and then calibrating it after completion of the experiment and considering the experimental data as qualified.	AOI-Related	Response to AOI-OAR-05-05-05, Section 1	7418(A) 7499(B)
4.4.8 5.1	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective Implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). LLNL staff is allowed to determine when to document adverse conditions rather than being required to document all adverse conditions.	Deficiency AOI-Related	Not Directly Addressed in Enclosure 1	7424(B)
4.4.8	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). CR 5430 identified some but not all ranges of temperature being used in experiments. CR 5430 did not identify that experiments related to Scientific Notebook SCI-484 were currently underway and had been underway for 8 months, also using the Vaisala probes outside their calibrated range.	AOI-Related	Not Directly Addressed in Enclosure 1	7424(B)

Table 1. Crosswalk of AOIs, Weaknesses and Deficiencies from NRC Report OAR-05-05, and Related CRs (Continued)

NRC Report Section	Description	Category	Related Enclosure 1 Response	Related CR
4.4.8	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). The NRC noted that CR 2247 was issued as a Significance Level B. However, the subsequent problems documented in CR 5430, repetitive to the deficiencies identified in CR 2247, were characterized as a Level C. No explanation for the disparity in CR significance levels was provided during the audit.	AOI-Related	Not Directly Addressed in Enclosure 1	7424(B)
4.4.8	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Quality Assurance). The BSC audit team did not identify this issue (i.e., difference in significance levels assigned to CR 2247 and CR 5430) as an item requiring follow-up.	AOI-Related	Response to AOI-OAR-05-05-05, Section 2	7395(A)
4.4.8	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). Corrective actions in CR 2247 were not implemented as described. No provisions were established to ensure that future scientific notebooks that use Vaisala probes would refer to CR 2247.	AOI-Related	Response to AOI-OAR-05-05-05, Section 1	7424(B) 8201(D)
4.4.8	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). There was an action in the CR to reference CR 2247 in notebooks for future experiments. A scientific notebook, opened after the CR was issued but before it was closed, did not include a reference to the CR in the notebook.	AOI-Related	Response to AOI-OAR-05-05-05, Section 1	6479(B) 8128(D) 8201(D)
4.4.8	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). There were no tags placed on temperature probes nor were the temperature probes segregated to prevent use. Tagging with limited calibration stickers could have been a valuable part of the CAP to prevent future use in high temperature experiments.	AOI	Not Directly Addressed in Enclosure 1	7185(B) 7424(B) 7499(B) 8063(B)

Table 1. Crosswalk of AOIs, Weaknesses and Deficiencies from NRC Report OAR-05-05, and Related CRs (Continued)

NRC Report Section	Description	Category	Related Enclosure 1 Response	Related CR
4.4.8 5.1	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (Responsible Organization). LLNL had not issued a CR for the second set of experiments using the uncalibrated probes. The experiments related to Scientific Notebook SCI-484 had been initiated in August 2004. As of the date of this audit in August 2005, no CR had been issued related to the use of the uncalibrated humidity probes in the Scientific Notebook SCI-484 experiments. LLNL failure to recognize this repetitive non-conformance with the QARD requirements related to instrument calibration and issue a CR is an example of the ineffectiveness of the implementation of the QARD at LLNL related to the CAP.	Deficiency AOI	Not Directly Addressed in Enclosure 1	7185(B) 7424(B)
NRC Cover Letter	General Comment for QARD Sections 12.0 and 16.0: The NRC brought this matter (i.e., initial use of uncalibrated probes as well as continued use after problem was identified in CRs) to the attention of the BSC audit team; however, it did not document the condition of its audit reports or effectively reflect it in its assessment of LLNL's compliance with the QARD requirements.	AOI	Response to AOI-OAR-05-05-05, Section 2	7185(B) 7395(A)
4.4.6	AOI-OAR-05-05-05: Use of Vaisala Humidity Probes at Temperatures Outside their Calibrated Range. Ineffective implementation of QARD Section 16.0, "Corrective Action" (BSC Quality Assurance). The BSC audit team failed to initiate CRs for issues (AOIs) identified during audit.	AOI-Related	Response to AOI-OAR-05-05-05, Section 2	7273(D) 7395(A) 7432(C)
5.1	LLNL had issued two CRs (2247 and 5430) identifying problems with the use of the Vaisala humidity probes. However, the corrective actions associated with these CRs were ineffective in establishing adequate controls on the humidity probes to prevent their use in a second set of experiments.	Deficiency AOI	Not Directly Addressed in Enclosure 1	7185(B) 7424(B)

Source: Collins 2006 for columns 1 and 2.

NOTE: * No CR was created for some issues because there was no indication of a condition adverse to quality during the response development process. Nevertheless, CR 7432 (closed to CR 7395) indicates that once an issue is identified, a CR should be initiated in a timely manner before the associated evaluation is completed. CR 8011 is not included in the crosswalk because it does not address the specific NRC issues listed in column 2.

CAP = Corrective Action Program; CR = condition report; LLNL = Lawrence Livermore National Laboratory; M&TE = measuring and test equipment; NIST = National Institute of Standards and Technology; QARD = *Quality Assurance Requirements and Description*.

References

Collins, E.E. 2006. "U.S. Nuclear Regulatory Commission Observation Audit Report No. OAR-05-05, Observation Audit of Bechtel SAIC Company, LLC Internal Audit BQAP-BSC-05-07." Letter from E.E. Collins (NRC) to M.H. Williams (DOE/ORD), January 9, 2006, 0118067529, with enclosure "U.S. Nuclear Regulatory Commission Observation Audit Report No. OAR-05-05, 'Observation Audit of Bechtel SAIC Company, LLC, Audit of Scientific Investigation, Waste Package, and Drip Shield Degradation,' BQAP-BSC-05-07."

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United States Department of Energy

Office of Civilian Radioactive Waste Management

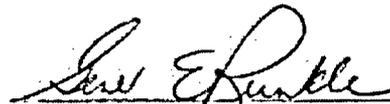
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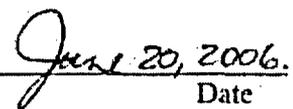
June 2006



Independent Review Team Report
of the BSC Audit BQAP-BSC-05-07

APPROVED BY:


Gene E. Runkle
Program Manager for Independent Evaluations
Office of Civilian Radioactive Waste Management


Date

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TABLE OF CONTENTS

EXECUTIVE SUMMARY	v
1.0 INTRODUCTION.....	1
1.1 Purpose.....	1
1.2 Audit Background.....	1
1.3 Summary of NRC Concerns	2
2.0 INDEPENDENT REVIEW TEAM METHODOLOGY.....	5
3.0 SUMMARY OF INFORMATION GATHERED DURING INDEPENDENT REVIEW	6
3.1 <i>Were the Vaisala humidity probes calibrated?.....</i>	<i>6</i>
3.2 <i>If the probes were properly calibrated, was the calibration performed in accordance with Yucca Mountain procedures and appropriately documented?.....</i>	<i>15</i>
3.3 <i>Why was the calibration issue not recognized as a quality issue by BSC management and included in the BSC audit findings?</i>	<i>18</i>
3.4 <i>Why was line management not included in audit activities at LLNL?.....</i>	<i>19</i>
3.5 <i>With regard to overall organizational culture, what is the ability of the organizations to work to standards and requirements, to stop work as required, and to understand quality assurance requirements and take appropriate actions?.....</i>	<i>19</i>
4.0 OTHER FINDINGS.....	20
A. <i>LLNL staff did not misrepresent calibration status in scientific notebooks.....</i>	<i>20</i>
B. <i>No quantifiable requirements are in place before work is performed.....</i>	<i>21</i>
C. <i>Response to AOIs is not timely.....</i>	<i>22</i>

TABLES AND FIGURES

Figure 1: Timeline for Use of Vaisala Probes	8
Table 1: Calibration History of Vaisala Probes	9

APPENDICES

A. National Institute of Standards and Technology Report.....	23
B. Personnel Contacted by the Independent Review Team at Yucca Mountain Project Offices and LLNL	31
C. Audit Timeline.....	33
C. History of Changes to the Procedure on Control of Measuring and Test Equipment	35

EXECUTIVE SUMMARY

Bechtel SAIC Company, LLC (BSC) conducted an audit August 15-31, 2005, to evaluate whether the quality of data input into models used to assess the repository waste package and drip shield provided technically sound and defensible results. The Nuclear Regulatory Commission (NRC) conducted an audit observation of the BSC audit team activities.

On January 9, 2006, NRC provided the Office of Civilian Radioactive Waste Management (OCRWM) an Observation Audit Report that expressed concerns about the conduct of the BSC audit and technical issues related to the calibration and use of Vaisala relative humidity/temperature probes by Lawrence Livermore National Laboratory (LLNL) to measure humidity and temperature in experiments. NRC's report observed LLNL's approach to calibration of the probe was not in compliance with the *Quality Assurance and Requirements Description* (QARD) document. NRC "concluded that the BSC audit was not effective in identifying, documenting, and alerting BSC and DOE management" to quality issues.

In February 2006, the OCRWM Acting Director requested that an independent review team investigate the issues identified in the NRC report. The Independent Review Team performed an investigation, including document review and interviews, in an effort to evaluate these issues.

The Independent Review Team found that a number of actions have been undertaken by OCRWM and BSC to address the issues raised by NRC. These actions included two self-assessments, a stop-work order covering LLNL experiments using the relative humidity/temperature probes, two Level A Condition Reports (CRs) with root cause analyses and extent of condition evaluations, and several Level B CRs. These activities are still underway.

The major findings of this review are:

- There is no evidence of intent on the part of LLNL scientists to misrepresent the calibration status of their relative humidity/temperature probes.
- The BSC procedure (LP-12.1Q-BSC) for control of measuring and test equipment does not properly implement the QARD because it allows for use of equipment past its recalibration due date.
- The LLNL technical approach to calibration of Vaisala relative humidity/temperature probes was valid. No national standards exist for calibrating the probes for the high temperatures involved in some experiments. LLNL used the manufacturer's recommended calibration process, and then developed several methods to further confirm probe response at high temperatures.
- The BSC audit team and BSC management did not respond effectively to the concerns expressed by NRC observation team, and did not take timely action to elevate NRC's concerns.

Independent Review Team Report
of the BSC Audit BQAP-BSC-05-07

- There were communication failures within OCRWM and BSC which impeded the ability to address the concerns that NRC raised during the audit.
- BSC and LLNL have not defined the requirements for accuracy, at a specified level of confidence, for data inputs to the corrosion models. A more quantitative assessment of the data requirements needed to support modeling efforts is required to determine if the LLNL results on deliquescence testing have appropriately addressed uncertainty.

1.0 INTRODUCTION

1.1 Purpose

This report documents the findings and observations of an Independent Review Team formed in February 2006 to provide information regarding issues raised by the Nuclear Regulatory Commission (NRC) concerning an audit conducted by Bechtel SAIC Company LLC (BSC) and calibration activities performed by scientists at Lawrence Livermore National Laboratory (LLNL). Deficiencies and weaknesses identified by NRC, and Audit Observation Inquiries (AOIs) submitted to DOE by NRC, involved:

- BSC's conduct of the audit
- Calibration work performed by LLNL and related documentation
- The technical content of the Analysis and Model Reports (AMRs) reviewed during the audit.

This report focuses on the concerns related to the LLNL's calibration of probes used in Yucca Mountain Project experiments, and on BSC's audit activities in relation to these concerns. The AOIs and technical matters not related to the calibration issue are being addressed by other ongoing actions.

1.2 Audit Background

On August 15-31, 2005, Bechtel SAIC Company, LLC (BSC) conducted a routine audit¹ to evaluate whether scientific investigations that provide input data into the repository waste package and drip shield models provided technically sound and defensible results. The audit (BQAP-BSC-05-07) was titled *Performance-Based Audit of BSC Licensing and Nuclear Safety: Scientific Investigation, Waste Package and Drip Shield Degradation*. Two AMRs were selected for review: *General and Localized Corrosion of the Waste Package Outer Barrier* (ANL-MD-EBS-000003), and *Engineered Barrier System: Physical and Chemical Environment* (ANL-MD-EBS-000033). In tracing model inputs back to original source data the BSC audit team looked at the scientific approaches and methods used for data collection, including:

- The use and control of measuring and test equipment (M&TE)

¹ The audit was designated as BQAP-BSC-05-07, *Performance-Based Audit of BSC Licensing and Nuclear Safety: Scientific Investigation, Waste Package and Drip Shield Degradation*; the BSC audit report was approved by the BSC Quality Assurance Manager on October 7, 2005.

- Implementation of quality assurance (QA) requirements as defined in the OCRWM *Quality Assurance Requirements and Description (QARD)*².
- Collection, documentation, control, and use of data.

BSC quality assurance auditors conducted the audit in accordance with Line Procedure LP-18.6Q-BSC, *QA Internal Audit Program* and Administrative Procedure AP-16.1Q, *Condition Reporting and Resolution*. They also assessed the waste package and drip shield technical work against the NRC's *Yucca Mountain Review Plan* (NUREG-1804). Technical specialists were involved in audit activities in Nevada but not at LLNL.

Since the late 1990s, LLNL has performed experiments to measure the degradation of waste package materials under various conditions in order to provide input to computer models used to predict the performance of waste packages in a geologic repository. Probes to measure humidity and temperature are used during some of this work. In 1998, LLNL purchased relative humidity/temperature probes from Vaisala, a Finnish company that has offices in the United States.

These probes and other experimental measurement equipment must be calibrated in order for the results of experiments in which they are used to be acceptable for use in Yucca Mountain models and analyses. The QARD defines the overarching requirements for calibration, and a procedure, LP-12.1Q-BSC³, directs implementation of those requirements. Documentation of calibration and testing activities must be included in scientific notebooks or on a form included in LP-12.1Q-BSC. Section 3.1 below provides specific information on the calibration and use of the Vaisala probes.

1.3 Summary of NRC Concerns

NRC observers conducted an audit observation of the BSC audit team activities in accordance with NRC Manual Chapter 2410, "Conduct of Observation Audits." To assess the effectiveness of the audit and to evaluate the implementation of the QA program by BSC and LLNL, NRC observers attended meetings and reviewed documents related to the BSC audit. NRC personnel provided feedback to the BSC audit team during the audit and communicated with BSC and OCRWM after conclusion of the audit. The principal NRC interactions are listed in Table 2 in Section 3.6.

On January 9, 2006, NRC provided its Observation Audit Report OAR-05-05⁴ to the OCRWM Director of the Office of License Application and Strategy. NRC concluded that, "Although most of the audit observation results were found to be acceptable, several areas were identified as

² OCRWM, *Quality Assurance and Requirements Description*, DOE/RW-0333P, Rev. 16, August 23, 2004.

³ BSC, LP-12.1Q-BSC, *Control of Measuring and Test Equipment*, Rev. 0, ICN 1, October 31, 2005. At the time of the audit, Rev. 0, ICN 0 was in effect.

⁴ NRC, *Observation Audit Report OAR-05-05, Observation Audit of Bechtel SAIC Company, LLC, Audit of Scientific Investigation, Waste Package, and Drip Shield Degradation, BQAP-BSC-05-07*, January 9, 2006.

deficiencies or weaknesses.” The following is a summary of the deficiencies and weaknesses related to the audit process and calibration that were identified in Section 5.1 of the NRC report:

NRC Audit-Related Issues

- BSC reduced the audit scope less than two weeks prior to the beginning of audit activities, and there was a delay in availability of the audit checklists. (*weakness*)
- Technical specialists were not included in audit activities at LLNL. (*weakness*)
- Documents were found to be missing from the records package for corrosion experiments. These were located at LLNL, and upon reviewing them NRC raised several technical issues to the BSC audit team; however, a Condition Report (CR) was not issued. (*deficiency*)

NRC Calibration-Related Issues

- LLNL used Vaisala humidity probes that were not vendor-qualified or calibrated for the required temperature ranges. NRC characterized this matter as an ineffective implementation of the QARD, which requires that test instruments be calibrated before use. (*deficiency*)
- LLNL conducted experiments to calibrate the Vaisala humidity probes at the high temperatures used during experiments. No nationally recognized standard existed, nor was the manufacturer able to provide a standard process for calibration at high temperatures, and LLNL had not adopted a nationally recognized protocol for conducting calibrations. LLNL did not identify these concerns to BSC and OCRWM management as potentially significant issues related to the defensibility of the experiments. (*deficiency*)
- NRC characterized as “potential misrepresentation” LLNL scientists’ recording of information regarding calibration in scientific notebooks. (*deficiency*)
- LLNL researchers failed to issue a Condition Report under the Corrective Action Program for issues that could be easily rectified or were minor in nature, which is inconsistent with OCRWM’s procedures concerning corrective action reporting. (*deficiency*)
- LLNL had issued two CRs with regard to calibration of the relative humidity/temperature probes, but the corrective actions were ineffective with regard to controls placed on use of the probes in subsequent experiments. This was characterized as an example of ineffective implementation of the QARD as related to the Corrective Action Program. (*deficiency*)
- LLNL did not issue a CR on repetitive non-conformance with the QARD requirements related to instrument calibration, and has not established adequate provisions to prevent recurrence of the problem. This was characterized as an example of ineffective implementation of the QARD as related to the Corrective Action Program. (*deficiency*)

Independent Review Team Report
of the BSC Audit BQAP-BSC-05-07

NRC identified five Audit Observation Inquiries (AOI), characterized as “additional areas of technical product weakness,” in Section 5.2 of the Observation Audit Report. These AOIs were submitted to BSC in December 2005 for response. One AOI is specifically discussed in this report: AOI-OAR-05-05-05, “Use of the Vaisala Humidity Probes at Temperatures Outside their Calibrated Range.”

2.0 INDEPENDENT REVIEW TEAM METHODOLOGY

At the direction of the OCRWM Acting Director the OCRWM Program Manager for Independent Evaluations, Gene Runkle, initiated an independent investigation of the calibration-related issues raised in NRC's report to determine what had occurred and to assess weaknesses that had allowed this situation to develop. This investigation and report provides information to the Acting Director to support management analysis and decision-making.

The Independent Review Team included the following individuals, external to OCRWM, to support the evaluation:

- Dr. Peter Huang, an expert from the National Institutes of Standards and Technology (NIST) with extensive knowledge of humidity monitoring equipment and calibration, including familiarity with the Vaisala brand of probes used at LLNL. Dr. Huang's full report is included as Appendix A.
- Dr. Robert Uhrig, a retired professor of nuclear engineering with executive management experience at a nuclear utility, including responsibility for quality assurance for four nuclear power plants.

The OCRWM Office of the Director developed a number of areas of inquiry, which provided the structure for the independent review.⁵ The Independent Review Team conducted interviews of BSC, OCRWM, LLNL, and NRC staff to determine facts and ascertain timelines. The Independent Review Team identified individuals that had direct knowledge of or participated in the audit, as well as key individuals at LLNL that were involved in experiments and calibration activities associated with the relative humidity/temperature probes (see Appendix B). The interviews were conducted over a three-week period in February 2006. Based on these interviews, the team constructed a timeline of audit activities (Appendix C), and a history of changes to the procedure on control of measuring and test equipment (Appendix D). Procedures, technical reports, Condition Reports, and other documents were collected and reviewed as part of this process.⁶

The Independent Review Team's findings in the areas of inquiry appear in Section 3.0.

⁵ OCRWM Working Document, "Headquarters Independent Review Research and Evaluation of BSC/LLNL Audit," February 2, 2006.

⁶ A list of reviewed documents and a list of relevant Condition Reports are provided on the References disk that accompanies this report.

3.0 SUMMARY OF INDEPENDENT REVIEW TEAM RESULTS AND CONCLUSIONS

The following subsections provide the Independent Review Team's results and conclusions on each of the areas of inquiry identified by OCRWM.

3.1: Were the Vaisala humidity probes calibrated?

The calibration of instruments and equipment against nationally and/or internationally recognized standards applicable to the specific conditions of the experiments is required by the QARD, and is essential to the traceability and defensibility of the technical work related to licensing of the Yucca Mountain repository. When a nationally recognized standard is not available, the QARD requires that the basis for calibration be documented. LP-12.1Q-BSC provides additional requirements concerning implementation of the QARD requirements.

The NRC audit observers were particularly concerned about the calibration of LLNL's Vaisala relative humidity/temperature probes at a low temperature and the use of those probes during experiments at high temperatures (over 100 °C). The calibration processes changed with time, as did the calibration methodology used. The timeline for the use of the Vaisala relative humidity/temperature probes at LLNL is shown in Figure 1.⁷ The calibration history of these probes is separated into three time periods on the basis of the calibration methodology used, and is summarized in Table 1.

The Independent Review Team's discussions with LLNL personnel indicated that LLNL's focus was on the scientific adequacy of the guidance given by Vaisala and on continuous improvements of the calibration approach by further defining uncertainty and extending the temperature range.

Definition of Calibration

For the purposes of this report, the Independent Review Team found that the primary calibration of the temperature and humidity probes used in the development of quantitative models was performed by the manufacturer, Vaisala (1998 – 2002), and the qualified vendor, Thunder Scientific Corp (2002). In addition, LLNL developed a salt test (2004) and bi-thermal method (2005) to further confirm experimental results at the higher temperature regions. LLNL used both of these methods to provide a better estimate of the uncertainty of the primary calibration when extrapolated to higher temperatures.

Data for temperatures greater than 120 °C have been labeled "conditional" by LLNL and are not to be used for quantitative model development. To account for probe drift⁸, LLNL made some minor adjustments to its data based on the bi-thermal method results and these are recorded in

⁷ LLNL, Susan Carroll, "RH Probe and Experimental Timeline," UCRL-AR-218422, March 1, 2006.

⁸ Drift is a progressive (continuously upward or continuously downward) change in the number displayed on the readout of a piece of test equipment.

the Data Tracking Number “read me” files that include the adjusted and non-adjusted results. The adjusted probe readings may still be considered to be provisional calibration results, and the resulting data files are marked that they can only be used for qualitative purposes above 120 °C.

Because LLNL and BSC have not formally defined the uncertainty budgets⁹ associated with these methods, the confirmatory results have not yet been included in the formal calibration associated with the temperature and humidity probes for data used for quantitative purposes. The ISO Standard 17025:2005 - *General Requirements for the Competence of Calibration and Testing Laboratories* may be useful in defining the uncertainty budget associated with this activity.

Until the uncertainty budgets are fully established, the Independent Review Team recommends that the Vaisala and Thunder Scientific Corp. calibrations be considered the formal calibrations, with the bi-thermal and salt tests providing further confirmation of the high-temperature probe response and uncertainty. Removal of the provisional status for results from the LLNL bi-thermal system should await completion of the uncertainty budget.

⁹ An uncertainty budget is a list of components contributing to the uncertainty of a measurement, with a numerical value given for each component. An uncertainty budget may be organized according to the methods used to characterize the components (e.g., statistical analysis of repeat measurements), or it may be organized according to the possible causes of error (e.g., uncertainty of temperature measurement). In either case, the components listed in the budget should cover all significant sources of possible error in the budget.

Figure 1. Timeline for Use of Vaisala Probes

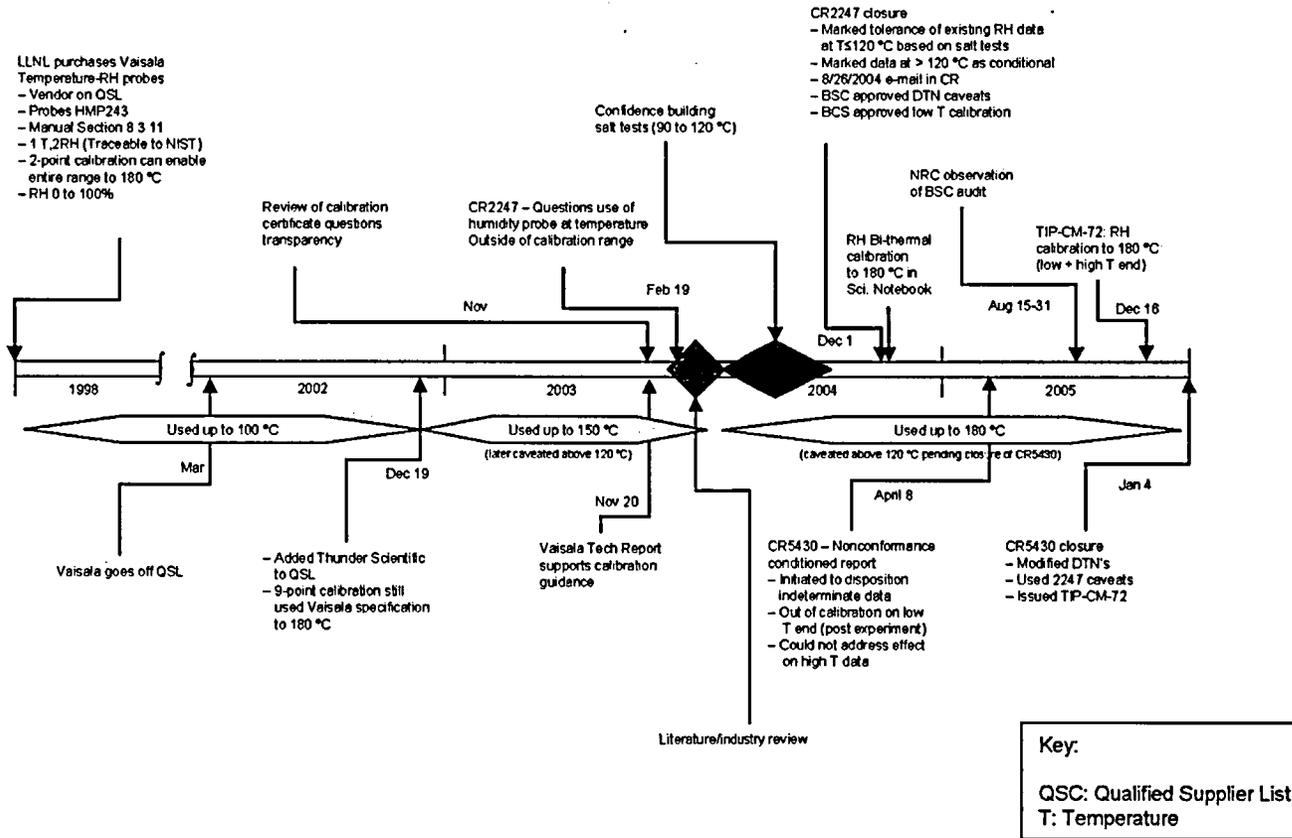


Table 1. Calibration History for Vaisala Probes

Dates	Calibration Approach
Period 1. 1998 to March 2002	
November 1998 – February 2002	<ul style="list-style-type: none"> • BSC Qualified Supplier’s List included Vaisala as manufacturer of relative humidity/temperature probes and provider of associated calibration services. • LLNL purchase order (November 5, 1998) for 3 Vaisala models specified the following: “Transmitter, Digital Display, 0-1 volt outputs (temp & hum), Temp. in degrees C / Humidity in %RH [relative humidity], Temp. Range -40 °C to 180 °C, NIST Certificate. The above equipment shall comply with the attached Buyer’s Q.A. Requirements”. • Vaisala used NIST-traceable 2-point methodology for calibration (2 relative humidities at least 50% apart at room temperature). • Operating manual for Vaisala’s HMP243 probe¹⁰ specified a range of temperatures from -40 °C to 180 °C. Vaisala’s guidance was that with annual calibration, probes could be used for experiments up to 180°C and be within a tolerance of 0.025 x % RH + 0.5% RH.¹¹ • Experiments during this period did not exceed 100°C. LLNL relied on information provided by Vaisala for the calibration process.
February 2002 – March 2002	<ul style="list-style-type: none"> • BSC’s routine supplier audit confirmed Vaisala’s effective implementation of quality assurance requirements in prior Yucca Mountain work. • Vaisala changed its quality assurance program to conform to International Standards Organization (ISO) 9000 standard rather than NQA-1 standards specified in QARD. • BSC removed Vaisala from Qualified Supplier List for future work.

¹⁰ Vaisala Oyi, U145en-2.1, HMP243 Transmitter Operating Manual, May 1998.

¹¹ The tolerance is the manufacturer’s assurance that the instrument will read the true value to within the stated limits. From their literature, it is not clear what level of confidence the stated accuracy refers to.

Table 1. Calibration History for Vaisala Probes, continued

Dates	Calibration Approach
Period 2. Late 2002 to Late 2004	
December 2002	<ul style="list-style-type: none"> • BSC included Thunder Scientific Corp. on Qualified Supplier List for calibration services for relative humidity/temperature probes. • LLNL replaced Vaisala's 2-point (2 humidities at 1 temperature) calibration at room temperature with 9-point (3 humidities at 3 temperatures) NIST-traceable calibration using 3 temperatures (25 °C, 40 °C, and 60 °C) and 3 relative humidities (15%, 50% and 85%). • Thunder Scientific Corp. used 9-point method for calibrating LLNL's probes. • LLNL continued to use the calibrated probes in 2003 to perform experiments at temperatures up to 150 °C, following Vaisala's specification and guidance that its probes calibrated at low temperature accurately measured relative humidity within a specified tolerance up to 180 °C.
November 2003 – February 2004	<ul style="list-style-type: none"> • LLNL and Thunder Scientific Corp. expressed concerns regarding use of low-temperature calibration techniques at higher temperatures (i.e. >60 °C). • LLNL obtained a Technical Notice, "Product Performance Validation," from Vaisala (November 20) that supported Vaisala's specifications and indicated that probes calibrated at low temperature could be used up to 180 °C. Vaisala would not provide additional, proprietary information.¹² • Both NIST¹³ and Thunder Scientific Corp. expressed reservations to LLNL about the Vaisala Technical Notice.

¹² In response to an inquiry from BSC in early 2006, Vaisala released without restrictions three Test Reports dated 11/14/2001, 2/19/2003, and 6/6/2003 on the model HMP233 Humidity & Temperature Transmitter, the pilot model for Vaisala's Model HMP243 probe. The report dated 2/19/2003 indicated that the HMP233 probe was tested over the temperature range from 120 °C to 180 °C.

¹³ Dr. Peter Huang provided short consultations by telephone to LLNL staff during development of their calibration process.

Table 1. Calibration History for Vaisala Probes, continued

Dates	Calibration Approach
November 2003 – February 2004, continued	<ul style="list-style-type: none"> • Without additional information to verify Vaisala specifications and guidance, LLNL initiated CR 2247 (February 19),¹⁴ to identify other calibration options above the 60 °C range. • CR 2247 included recommendations that: <ol style="list-style-type: none"> 1. LLNL write a report on probe performance at higher temperatures based on simple equilibrium salt tests. 2. BSC review LLNL’s report and provide guidance on documenting data collected at higher temperatures.
March 2004 – July 2004	<ul style="list-style-type: none"> • LLNL conducted equilibrium salt tests in response to CR 2247, which calculated that the probes calibrated to 60 °C were accurate to ±1.6% relative humidity (1σ) from 90 °C to 120 °C. • As part of the corrective action plan for CR 2247, LLNL proposed to: <ol style="list-style-type: none"> 1. Fabricate a 2-pressure system for confirming probe calibration at higher temperatures 2. Extend calibration confirmation by measuring sensor response at elevated temperatures using the known water vapor pressure of saturated salt solutions.
August 24, 2004 – September 2004	<ul style="list-style-type: none"> • Corrective actions proposed by LLNL would have required funding beyond what was allocated to LLNL for that Fiscal Year, so BSC notified LLNL that additional funding would need to be requested in the next fiscal year. BSC considered values above 120 °C to be “conditional” because they could not confirm the accuracy of relative humidity measurements at temperatures above 120 °C. • Caveats were required to be added in relevant data tracking number (DTN) “read me” files for any test above 120 °C in the Technical Data Management System (TDMS) where experimental data are recorded. • LLNL conducted a series of deliquescence experiments using resistivity techniques on equilibrium mixed salts to show that brines form from 120 °C to 180 °C.

¹⁴ OCRWM, CR 2247, “M&TE Used Outside the Range of Calibration,” February 19, 2004.

Table 1. Calibration History for Vaisala Probes, continued

Dates	Calibration Approach
October 2004 – December 2004	<ul style="list-style-type: none"> • Based on the equilibrium mixed salt test results, CR 2247 was closed (December 1), with the requirement that relative humidity data at temperatures greater than 120 °C, be recorded as “conditional” with appropriate caveats in Data Tracking Number (DTN) “read-me” files. • The primary method for calibrating the probes was the 9-point method by Thunder Scientific Corp. and application of tolerance limits established in CR 2247. LLNL’s results independently supported Vaisala’s calibration process and guidance as noted in December 2002 (with some additional small corrections needed because of drift). • LLNL and Thunder Scientific Corp. began development of a bi-thermal method for confirmation of probe response from 115 °C to 180 °C.¹⁵
Period 3. 2005 to Present	
April – December 2005	<ul style="list-style-type: none"> • LLNL initiated CR 5430 (April 8) to examine the potential impact of the probe calibration processes on earlier data collected with the probes. • LLNL completed development of the bi-thermal method for confirming response of relative humidity/temperature probes from 115 °C. to 180 °C, pending establishment of formal uncertainty budgets associated with this method. • Both pre- and post-test confirmation measurements were made on relative humidity/temperature probes used in deliquescence and corrosion experiments at elevated temperatures (and documented in scientific notebook LLNL-SCI-487-V.3, as well as in the TDMS). • LLNL reported that uncertainty associated with virtually all earlier relative humidity measurements, up to 120 °C, was ±1.6% relative humidity (one standard deviation).

¹⁵ This activity became part of the work performed under action number 5430-004 in the corrective action plan for CR 5430, “Data Acquired by Vaisala Temperature/Humidity Probes Above 90 Degrees Celsius Is Indeterminate.

Table 1. Calibration History for Vaisala Probes, continued

Dates	Calibration Approach
April – December 2005, continued	<ul style="list-style-type: none"> • LLNL decided that the combined bi-thermal confirmation and low-temperature 9-point calibration methods yielded relative humidity measurements from 25 °C to 180 °C that could be used without caveats. • However, BSC required that measurements above 120 °C be treated as conditional. LLNL added caveats to the DTNs for measurements above 120 °C, pending closure of CR 5430. • Technical Implementation Procedure (TIP) CM-72¹⁶ for routine use of bi-thermal calibration method for 115 °C to 180 °C was approved by LLNL (December 16).¹⁷
January 2006	<ul style="list-style-type: none"> • CR 5430 was closed (January 4) based on documentation that: <ol style="list-style-type: none"> 1. Measurements up to 180 °C that included pre- and post-test calibrations no longer needed caveats. 2. Calibration of probes used in earlier tests was within the tolerance established at 120 °C. 3. Values obtained with probes above 120 °C prior to development of bi-thermal calibration method were designated as “conditional” values by caveats in the DTN “read me” files. • LLNL informed BSC (January 20) that it voluntarily suspended use of Vaisala relative humidity/temperature probes pending resolution of issues raised by NRC.
February 2006	<ul style="list-style-type: none"> • BSC QA Manager issued a stop-work order to BSC on the use of the Vaisala probes (February 7). LLNL acknowledged the stop-work order the same day it was formally issued by BSC to LLNL (February 10).

¹⁶ LLNL, TIP-CM-72, “Calibration of RH Meters Using the Bi-Thermal RH Calibration System.”

¹⁷ Dr. Susan Carroll of LLNL indicated that all bi-thermal tests at LLNL were conducted at temperatures up to 180 °C. This TIP refers to an upper temperature of 160°C at one point but refers to 180 °C in all other locations.

NIST Evaluation of the LLNL Relative Humidity and Temperature Probe Calibration Program

As part of this independent review, Dr. Peter Huang of NIST evaluated the approach and technical adequacy of the LLNL calibration processes used since 1998. The evaluation was conducted in accordance with the general guidelines of Sections 5.2 to 5.10 of ISO Standard 17025:2005 - *General Requirements for the Competence of Calibration and Testing Laboratories*. Although LLNL was not required to conform with ISO 17025, for the present evaluation ISO 17025 provides a broadly accepted guide to good practices for calibration laboratories.

Observations from Dr. Huang's evaluation of the calibration methodology currently used by LLNL include:

1. The basic physical principles of LLNL's bi-thermal method are well established, and the choice of methodology was reasonable.
2. The design and operation of the equipment used for the bi-thermal calibration are adequate to the task.
3. Out of the twenty requirements of ISO 17025:2005, sixteen requirements were met (i.e., "In Conformance"), two were not met (i.e., "Out of Conformance"), and with respect to two requirements, NIST had comments noting that minimum standards were met, but recommended improvements to provide a better evaluation of variance or uncertainty.
4. The two "Not in Conformance" requirements were:
 - The determination of the uncertainty budget was not conducted with sufficient rigor, such as described in the *ISO Guide to the Expression of Uncertainty in Measurement*.
 - Quality control procedures for monitoring the validity of tests and calibrations undertaken have not been established.

The amount of additional work needed by LLNL on relative humidity/temperature probe calibration depends on the uncertainty that is acceptable to LLNL and BSC for use in quantitative model development. During February 2006, when the Independent Review Team asked for the allowable uncertainty for use in scientific work, it was reported that LLNL and BSC do not have defined requirements in this area for the quantitative model inputs and analyses. Rather, LLNL had been satisfied when the results fell within the range of $\pm 1.6\%$ relative humidity (one standard deviation). NIST has conservatively estimated the uncertainty of relative humidity measurements using the Vaisala probes under the manufacturer's calibration specifications as $\pm 7\%$ at a level of confidence of 95% (equivalent to approximately $\pm 3.5\%$ at the one standard deviation level of confidence); implementation of the bi-thermal approach brought

this conservative estimate of uncertainty down to 6% (equivalent to approximately $\pm 3\%$ at the one standard deviation level).

On April 4, 2006 the BSC Manager of Post Closure Activities provided a memo identifying the acceptable uncertainty for the LLNL humidity probes. The acceptable uncertainty was based on an analysis of how the data is used in the relevant AMRs. The memo stated that the uncertainty of relative humidity/temperature probes needs to be demonstrated to $\pm 5\%$ RH at 180 °C to be sufficient for their modeling processes. The confidence level used by BSC to define the $\pm 5\%$ was not specified.

Conclusion

Based on discussions with LLNL personnel and Dr. Huang's evaluation, it is the Independent Review Team's conclusion that LLNL's technical approach to calibration of the relative humidity/temperature probes was sound. LLNL's concern about the scientific adequacy of the guidance given by Vaisala motivated them to implement improvements in their calibration approach.

3.2: Was the calibration performed in accordance with Yucca Mountain procedures and appropriately documented?

The QARD establishes requirements for the control, calibration, and maintenance of measuring and test equipment (M&TE) used on the Yucca Mountain Project. With regard to calibration, section 12.2.1A of the QARD requires that M&TE "shall be calibrated, adjusted, and maintained as a unit at prescribed intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards." The QARD also requires that in cases where no recognized standards exist, "the basis for calibration shall be documented." Additionally, the QARD requires tagging, segregation, and documentation of out-of-calibration M&TE (including equipment where the due date for recalibration has passed), and does not allow M&TE to be used pending recalibration. The QARD does not have provisions for allowance of deviations or exceptions to the requirements for out-of-calibration M&TE. The QARD provides specific requirements for the content of documentation related to calibration. The QARD requirements related to calibration of M&TE are implemented through a BSC procedure, LP-12.1Q-BSC, *Control of Measuring and Test Equipment*.

The Independent Review Team identified several issues related to adherence to procedures and proper documentation. Each of these is discussed below.

Use of Probes Beyond Calibration Effective Date

The Independent Review Team found that prior to 2004, the M&TE control procedure required: (1) an "Out of Service" tag to be placed on M&TE that was out of calibration, (2) the equipment to be segregated, and (3) an Out-of-Calibration Report to be completed. However, BSC revised

the procedure in 2004¹⁸ based on input from LLNL, to allow for use of “other similar tags” as alternatives to the tag specified in the procedure (the other two requirements were unchanged).

Based on interviews with LLNL staff, LLNL followed the revised procedure and placed a limited-use tag on the probes that had exceeded their calibration date, but it is not clear whether this was in place during the time of the BSC audit. The Independent Review Team verified that Out-of-Calibration Reports are routinely issued at LLNL for M&TE that has gone beyond its calibration time limits. Because the wording of the procedure had been changed to allow the use of “other similar tags,” and because the rationale for the revision had included an indication that LLNL used M&TE after its recalibration due date in certain circumstances, LLNL staff believed that their practices with regard to M&TE were in compliance with LP-12.1Q-BSC.

The change made in 2004 to LP-12.1Q-BSC does not properly implement requirements in Section 12.2.3 of the QARD. The QARD does not allow for use of M&TE that has exceeded recalibration due dates. BSC, the owner of the procedure, did not recognize during the procedure revision process that the use of M&TE past its recalibration due date is not allowed under the QARD. LP-12.1Q-BSC was again revised in October 2005, but retained the reference to “other similar tags,”¹⁹ and therefore still does not properly implement the QARD. (See Appendix D for the history of changes to LP-12.1Q-BSC.)

NRC’s Audit Observation Report also identified a procedural compliance issue involving the use of calibrated probes beyond their calibration effective date:

“Out of calibration measuring and test equipment were not controlled. The Vaisala humidity probes identified in CR 2247 were not tagged, segregated, nor otherwise controlled to prevent use until they had been calibrated. This is a requirement of section 12.2.3B of the QARD.”

The NRC concern is substantiated because LLNL continued to use calibrated probes after their calibration effective date for ongoing experiments that exceeded the annual calibration cycle. There is no provision in the QARD for continued use of M&TE after the calibration due date.

Documentation in Scientific Notebook

In the Observation Audit Report, NRC stated that, “no explanation or notation was included in the scientific notebook identifying the humidity probes as not being calibrated at the high range of temperatures being used in the experiments.” NRC specifically referred to Scientific Notebook SCI-484, Volume 3 in making this comment.

In researching this issue, the Independent Review Team discovered that NRC had examined Scientific Notebook SCI-484, Volume 3²⁰ during the audit, but the information NRC was

¹⁸ BSC, AP-12.1Q, Control of Measuring and Test Equipment, Revision 0, ICN 3, effective date April 30, 2004, approved by the Repository Development Manager.

¹⁹ BSC, LP-12.1Q-BSC, Control of Measuring and Test Equipment, Revision 0, ICN 1, effective date October 25, 2005, approved by the Deputy Manager, Post-Closure Activities.

²⁰ LLNL, SN-LLNL-SCI Number 484, Volume 3, “Deliquescence of Mixed Salts; Measurements of Deliquescence of Relative Humidity (DRH) and Determination of Boiling Point from DRH Values,” notebook initiated August 3, 2004.

seeking was actually in Scientific Notebook SCI-487, Volume 1.²¹ However, Scientific Notebook SCI-487, Volume 1 was not provided to NRC at the time of the audit.

Approval of Documentation of the Bi-Thermal Calibration Method

The Independent Review Team reviewed Scientific Notebook SCI-487, Volume 1, and found that it contained full documentation of the bi-thermal process, including pictures of the equipment set-up. LP-12.1Q-BSC provides the requirement for documenting and approving the development of methods to calibrate M&TE where no nationally recognized standards are available. Documentation can be provided either in a scientific notebook, or on an M&TE Justification form that is provided as Attachment 3 to the procedure. If a scientific notebook is used, LP-12.1Q-BSC requires that the documentation provide, at a minimum, the information called for on the M&TE Justification form, including review and approval of the calibration method by a Principal Investigator, Responsible Manager, or Engineering Test Lead. While the requirement for approval is not explicitly stated in the text of LP-12.1Q-BSC Section 5.2, it can be inferred from the information requirements of the M&TE Justification form.

LLNL documented the development of the bi-thermal calibration method in Scientific Notebook SCI-487, Volume 1. However, there is no indication in the notebook of the required approval prior to the process being used. Therefore, this documentation did not meet the requirements of LP-12.1Q-BSC.

When the TIP for the bi-thermal method was approved on December 16, 2005, by the Responsible Manager of the pertinent technical area at LLNL, it met the approval requirement for an alternative calibration process under LP-12.1Q-BSC.

Conclusion

On the basis of discussion with LLNL personnel, the Independent Review Team determined that the LLNL scientific notebooks, along with the data in the TDMS, provide a satisfactory level of documentation of the bi-thermal calibration method. In examining the notebooks, the Independent Review Team found a procedural violation with regard to documenting the required approval for the development of the bi-thermal approach to calibrate the probes. The TIP issued in December 2005, however, was approved by the Responsible Manager.

²¹ LLNL, SN-LLNL-SCI Number 487, Volume 1, "Research Supporting Environmental Chemistry Experiments," notebook initiated December 20, 2004.

3.3: Why was the calibration issue not recognized as a quality issue by BSC management and included in the BSC audit findings?

The relative humidity/temperature probe calibration issue was not recognized as a quality assurance issue by BSC management due to multiple technical considerations as well as attitudinal and interpersonal issues.

The technical considerations which led to the lack of recognition of the calibration issue as a quality assurance issue by BSC management include:

- Differences in expectations regarding the scope of the audit and in the definition of terms between NRC representatives and BSC QA personnel began before the audit was initiated. NRC had expected the entire audit to be “performance-based” (i.e., determining the technical adequacy of processes and products), while BSC focused mainly on the compliance issues within the scope of the audit.
- Based on interviews, the Independent Review Team determined that the BSC audit team did not consider the NRC’s concern about the use of the relative humidity/temperature probes outside of the designated temperature range to be a problem.
- The BSC audit team thought that they had adequately and successfully evaluated the M&TE area based on questions identified on the audit checklist.
- The BSC audit team did not have expert consultants or other BSC technical staff present at LLNL during the audit to recognize and review issues in greater detail.
- As part of the audit planning process, the BSC QA management and the audit team did not review past CRs for trend information concerning M&TE problems. The Independent Review Team’s review of the Quarterly Trend Reports found that they do not provide useful information regarding specific technical areas associated with the CRs.

Conclusion

BSC management clearly missed opportunities to address NRC concerns, which were repeatedly articulated by NRC staff that observed the audit. The relative humidity/temperature probe concerns identified by NRC were not adequately addressed by BSC during the audit period and afterwards. The lack of BSC technical personnel participating in the portion of the audit conducted at LLNL contributed to the lack of recognition of the gravity of the NRC’s concerns. The BSC QA audit team assumed that the LLNL technical issues brought to their attention by NRC during the audit were adequately addressed in CRs and did not require further action. Also, BSC’s focus on the audit checklist contributed to NRC’s concerns not being escalated and addressed.

Both DOE and BSC need to continue to reinforce a nuclear culture that respects the regulatory status of the NRC and improve communications in its audit functions and other interactions with the regulator.

3.4: Why was line management not included in audit activities at LLNL?

BSC line management was not included in audit activities at LLNL due in part to changing practices with regard to participation of line management in QA audits. During previous BSC QA audits, a licensing representative participated in all audits. This changed over time, to where QA would request support from the BSC line organizations only when deemed necessary.

Conclusion

The lack of involvement of line management contributed to the BSC QA staff not recognizing the significance and impact of NRC's concerns during the audit.

The Independent Review Team was informed that, as a result of the issues arising from the August 2005 audit, a representative of the BSC licensing organization will participate in future audits conducted by BSC QA staff.

3.5: With regard to the overall organizational culture, what is the ability of the organizations to work to standards and requirements, to stop work as required, and to understand quality assurance requirements and take appropriate actions?

Based on interviews and a review of documents, it appears that OCRWM and BSC generally work to the implementing procedures and stop work if needed. During the review, it was noted that BSC issued a stop-work order for the LLNL experiments using the suspect humidity probes, and prior to that stop-work order LLNL had voluntarily stopped this work.

From the interviews, it is apparent that staff in OCRWM, BSC, and LLNL believe they have adequate quality assurance training and understand the requirements of quality implementing procedures. However, the issue with allowing "similar" tagging of M&TE past recalibration due dates and the revision of LP-12.1Q-BSC indicates that BSC does not consistently review procedure revisions against the QARD requirements.

Conclusion

OCRWM and BSC have the responsibility to work to standards and the ability to stop work as necessary. LLNL and BSC both took stop-work actions in connection with subjects of the audit addressed in this report.

4.0 OTHER FINDINGS

A. LLNL staff did not misrepresent calibration status in scientific notebooks.

In the NRC Observation Audit report, dated January 9, 2006, the “NRC determined that LLNL had not complied with the requirements of Section 12.0 of the QARD related to the performance of corrosion rate experiments. Specifically, it was concluded that LLNL had initiated these experiments: (i) without properly calibrated instruments; (ii) had not established an adequate basis for calibration when nationally recognized standards were unavailable; and (iii) misrepresented the correct status of the calibration of the humidity probes in the associated scientific notebook.”

The Independent Review Team focused closely on the allegation of “misrepresentation,” since that term is defined as the intent to mislead or deceive, as distinguished from inaccuracy. The Independent Review Team asked the NRC audit observation team to provide them with the pages in the LLNL Scientific Notebook that indicated LLNL misrepresented the correct status of calibration. NRC indicated that pages 19 and 42 of LLNL-SCI-484-V.1 were used in making that determination. They also indicated that additional entries on pages 58, 59, and 60 were entered after the on-site audit and were of a similar nature. The initial entries are reproduced below.

LLNL-SCI-484-V.1

Page 19 Entry Dated and Signed 8/13/04-

“RH & Temp was measured using a HMP243 S/N Y4750012 Cal due 1/28/05 Probes above cell were from an HMP243 S/N A135733 (US110014 signed 8/16/04) Cal due 6/03/05”

Page 42 Entry Dated and Signed 2/16/05-

“Installed Vaisala HMP243 probe (RH) S/N T4610030 Cal due 4/21/05. Connected output of RH probe to Gamry PSTAT cards”

As part of the independent review, the OCRWM Program Manager for Independent Evaluations discussed the issue of misrepresentation with the NRC signatory of the report. This NRC manager stated that the NRC was concerned about the fact that the probes had been calibrated at lower temperatures than the ranges expected in experiments, and that the absence of disclosure of this fact in the scientific notebook meant that the true state of calibration had not been accurately represented. He stated that he recognized the difference between inaccuracy and willful misrepresentation, and that the Observation Audit Report had not intended to suggest willful misrepresentation.

The Independent Review Team has also conducted interviews with managers and staff at LLNL and found no intent to misrepresent or falsify scientific notebook entries and in particular, the calibration of relative humidity/temperature probes. As evidenced in this report, it is clear that

the LLNL staff had performed their calibrations from 1998 to 2002 in accordance with manufacturer's specifications and that thereafter they continued to modify and improve the calibration process through 2006. These modifications included the implementation of a 9-point NIST-traceable calibration performed by Thunder Scientific Corp. from 2002 through 2004 and the addition of the bi-thermal calibration method for calibrating the probes from 115 °C to 180 °C after 2004.

The entries identified by the NRC observers in LLNL-SCI-484-V.1 reference the calibrations by Thunder Scientific Corp. that were performed in 2004 and 2005. As discussed in this report the Independent Review Team and NIST have found the calibration processes performed by LLNL to be sound, since there are no national standards for comparison at high temperature and high relative humidity.

LLNL-SCI-484-V.1 references the calibration processes for Thunder Scientific Corp. and indicates when the calibration was to be performed. The Independent Review Team found no evidence of any intent to mislead a reader.

B. No quantifiable requirements are in place before work is performed.

The Independent Review Team noted in documents and discussions with LLNL staff that statements were made such as "The probes could be used for experiments at temperatures up to 180 °C and be within a tolerance of $[0.025 \times \%RH + 0.5\% RH]$ " and "With some additional small correction for drift, the values of RH were accurate to $\pm 1.6\%$ RH unit at 1-sigma (one standard deviation.)" These tolerances resulted from statistical analyses of experimental results, rather than as design requirements for the experiment.

It appears that experiments were not designed with the specific tolerances in mind. The values for tolerance are dependent upon such factors as the equipment or technology used in the measurement; the variability of the properties of the materials involved in testing; and the care with which the experiment was carried out. Such an analysis may dictate the use of different or more precise measuring equipment. An analysis of the impact of precision (smallest measurable quantity) and accuracy (difference between measured value and true value) on the model results should guide the choice of instrumentation and methodology used.

On April 4, 2006, in response to the Independent Review Team's inquiry, the BSC Manager of Post-Closure Activities provided a memo stating the acceptable variance for the LLNL relative humidity/temperature probes. The acceptable variance was based on an analysis of how the data is used in AMRs. The memo stated that the accuracy of the probes needs to be demonstrated to $\pm 5\%$ relative humidity at 180 °C to be sufficient for the models.

The NIST report indicated that since the end of 2004, the calibrations obtained from Thunder Scientific Corp. and LLNL were internally consistent, and that a conservative estimate of the uncertainty of sensor measurements in the environment used is $\pm 6\%$ relative humidity at 180 °C (95% confidence limit). In addition, NIST defined a $\pm 7\%$ uncertainty estimate for the earlier time period. These values need to be compared on a common basis so LLNL can take steps to

provide the quality of data that is needed as inputs to quantitative models to predict corrosion rates. Work is needed to clarify the level of confidence of the BSC requirement, so that the acceptability of the LLNL results can be determined.

There is a lack of specific requirements defining data needs for the LLNL deliquescence tests. Not having specific data uncertainty requirements may necessitate re-running experiments to appropriately address uncertainty. Without defining acceptable levels of uncertainty in advance, OCRWM and BSC cannot make informed commitments of resources to focus on the most important data needs.

C. Response to AOIs is not timely.

To date, DOE has not provided a response to NRC on the AOIs they issued in August 2005 and revised in December 2005. The State of Nevada and Clark County each submitted an AOI in August 2005. The Department responded to the State of Nevada AOI on June 6, 2006, and has not yet responded to the Clark County AOI.

The BSC audit report does not discuss the AOIs from either NRC or the state and county observers. BSC has begun preparing a response for DOE. The Communications group at OCRWM is now responding to the State and county AOIs, but did not receive them until OLAS-RIS provided them the first week of February. Consideration should be given to reevaluating this process to allow for more expeditious responses to these inquiries and ensure that technical staff are involved in the process.

Appendix A:
NIST REPORT



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

May 26, 2006

Mr. Gene E. Runkle
Office of Civilian Radioactive Waste Management
U.S. Department of Energy, RW-1
1000 Independence Ave., SW
Washington, D.C. 20585

Dear Mr. Runkle:

Dr. Peter Huang has completed a technical evaluation of humidity probe tests and calibrations at LLNL, conducted at your request. Enclosed is the final version of the report, which I have reviewed and discussed with Dr. Huang.

Sincerely,

A handwritten signature in cursive script that reads "Dean Ripple".

Dr. Dean Ripple
Leader, Thermometry Group
Process Measurements Division
phone: 301-975-4801
fax: 301-548-0206
e-mail: dean.ripple@nist.gov

NIST

Summary of Quality Evaluation of Humidity Probe Tests and/or Calibrations at LLNL

Date of Evaluation: February 15 and 16, 2006

Technical Evaluator: Dr. Peter Huang, NIST

Introduction

I met with the staff members of LLNL and visited their laboratories to assess the technical requirements of the humidity probe calibration activities. Evaluations were made according to the general guidelines of Sections 5.2 to 5.10 (Technical Requirements) of the ISO 17025:2005 Standard "General Requirements for the Competence of Calibration and Testing Laboratories." The LLNL laboratories being evaluated are expected to meet internal LLNL requirements and adhere to LLNL procedures. LLNL has not declared or claimed conformance with ISO 17025. For the present evaluation, 17025 provides a broadly accepted guide of good practices for calibration laboratories.

As a brief technical background, the experiments conducted by LLNL require humidity measurements at temperatures that are not well supported by national measurement standards. I know of no national or commercial laboratories that are presently calibrating humidity probes or providing physical reference standards at temperatures above 100 °C—well below the maximum usage temperature of 180 °C. Additionally, there are no available standardized procedures for producing known moisture concentrations at high temperatures. For example, the ASTM standard E104-02: "Standard Practice for Maintaining Constant Relative Humidity by Means of Aqueous Solutions" for calibrating humidity sensors has an upper temperature limit of 80 °C. This situation has placed a significant burden on the LLNL staff of calibrating the humidity probes using LLNL-developed equipment and methods. For LLNL to demonstrate calibration of their probes was, and continues to be, a difficult challenge due to the absence of metrological standards and resources relevant for their usage temperature.

During my interview, I assessed the calibration process against Sections 5.2 to 5.10 of the Standard. The results of the evaluation according to the designated number in the ISO 17025:2005 Standard are given below. For an actual 17025 assessment, only the items listed as "Out of Conformance" require mandatory corrective action. If a "Comment" is given in lieu of "In Conformance" or "Out of Conformance," the comment may discuss issues or weaknesses identified by the assessor, but the assessor has judged that the minimum requirements of 17025 have been met.

Understanding that the validity of the humidity sensor calibrations may affect a large body of data that would be expensive to replicate, the section Estimate of Confidence Limits includes additional assessments that exceed the scope of ISO 17025. In particular, I have estimated confidence limits on the calibrated humidity sensors. These estimates are based only on my appraisal of the LLNL experiments and on my best technical judgment. Additional measurements on the sensors in question and additional work on establishing the uncertainty of the LLNL Bi-thermal Calibration System could refine these limits substantially.

Summary

The staff of LLNL working on this project display a good working knowledge of the principles of humidity measurements. The environment and facilities are appropriate for the work they were performing, and documentation of the procedures and equipment was available.

There are two key technical issues:

1. Were the humidity probes appropriate for an operating temperature of 180 °C?
2. Were the humidity probes properly calibrated at these temperatures, given the inability of secondary calibration laboratories or NIST to supply this calibration?

For the first question the LLNL staff produced documentation from the sensor manufacturer, Vaisala, which clearly stated that the sensors were designed for operation up to 180 °C. Overall I found the Vaisala HMP243 humidity/temperature probes were used properly. According to Vaisala's specifications, the probes could be used to 180 °C within a tolerance of 2.5 % of the reading + 0.5 %RH. LLNL therefore used probes in a manner consistent with the manufacturer's recommendations and specifications. Using an HMP233 sensor (serial number 623074), which is identical to the HMP243 sensors used by LLNL except for communications and software features, Vaisala conducted internal tests in 2003 (report dated 2/19/2003) that demonstrated reliable operation of the HMP233/243 series at temperatures up to 180 °C with 6 %RH, but with deviations from the expected values as high as 2.1 %RH.

Regarding the second question, a variety of calibration sources were used. In the period of 1998 to March of 2002 the Vaisala probes were calibrated annually by Vaisala Testing Laboratory located in the United States, along with its in-house reference probes traceable to NIST, for the range from 18 % to 90 % relative humidity values at 23 °C. Corrections were applied for observed drifts in accordance with the manufacturer's recommendations. This calibration protocol was in accordance with the manufacturer's recommendations for calibration of these units.

Beyond the end of 2002, the probes were calibrated by Thunder Scientific at nine points in the range of relative humidity from 15 % to 85 % in the temperature range from 25 °C to 60 °C. Thunder Scientific is a National Voluntary Laboratory Accreditation Program (NVLAP) accredited laboratory. NVLAP adheres to all relevant international standards for accrediting bodies and is one of several U.S. signatories to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation (ILAC). This calibration protocol, covering a larger range in temperature and a nearly equivalent range in relative humidity values, is also consistent with manufacturer's recommendations for calibration of these units.

Since national humidity standards are not available at high temperatures, LLNL decided to develop a bi-thermal method for calibrating humidity probes for 115 °C to 180 °C at the end of the year 2004. The method is based on the diffusion of water vapor produced by boiling water at 100 °C in a glass vessel to another vessel maintained at a higher temperature. In this bi-thermal equilibrium system, the water vapor pressure in the lower temperature vessel is assumed to be equal to that in the higher temperature one. The basic physical principles of their method are well established, and their choice of this method is very reasonable. The construction and operation

of the apparatus are adequate to the task as well. LLNL made required corrections for the drifts over time when the probes were used at high temperature conditions.

Improvements are needed in two areas specifically addressed in ISO 17025. First, the validation of the bi-thermal method is found to be in conformance with the minimum standards of ISO 17025, but establishment of the validity of the method to a high degree of confidence requires some additional work. Second, the calculation of the uncertainty for sensor measurements was found to be out of conformance with ISO 17025, and mandatory corrective action is needed. Ideally, the performance of the LLNL Bi-thermal Calibration System would be evaluated by an interlaboratory comparison of humidity probe calibrations at a full range of temperatures. The absence of other laboratories capable of reaching 180 °C excluded this path to demonstrate validity of the LLNL methods and apparatus. But a number of confirming measurements are possible, even in the absence of other laboratories performing similar work at 180 °C, including:

- a. tests of the Vaisala sensors over multiple runs and over an extended time, to assess the repeatability of the test and any possible drift of the sensors;
- b. comparison of the sensor probe calibration in the range 25 °C to 60 °C by Thunder Scientific with calibrations conducted using the LLNL Bi-thermal Calibration System;
- c. study of the dependence of the sensor probe calibrations on such systematic properties of the Bi-thermal Calibration System as water level, heating power, and rate of gas injection; and
- d. determination of the uniformity of temperature in the apparatus.

LLNL staff did implement tests b. and d. above. Mandatory corrective action is needed to establish a rigorously derived uncertainty budget, such as described in the *ISO Guide to Expression of Uncertainty in Measurements*. Relative humidity values measured with probes calibrated by Thunder Scientific were reported to be in agreement with those obtained from the Bi-thermal Calibration System. The thermal uniformity of the apparatus was checked using a NIST-traceable thermometer. To a lesser extent, test a. has been implemented, although the number of runs should have been higher, and the repeatability of multiple runs confirmed. Data already acquired with the Bi-thermal Calibration System could very well be useful in establishing the repeatability of the system without further measurements. Probe drift over several calibration cycles with the Bi-thermal Calibration System ranged from -4 % to 1 % relative humidity at 115 °C and -2 % to 0 % at 180 °C.

To complement the measurements that LLNL has already done, a more rigorous set of repeatability measurements should be made, along with a more rigorous determination of the uncertainty of calibrations with the Bi-thermal Calibration System. Relative humidity values were reported to be accurate to 1 % (one standard deviation) once the required corrections were made. An allowance for probe drift, which is comparable to the 1 % claimed uncertainty, should be added as a component of the uncertainty budget.

I note that ISO 17025 states that sensor drift is not normally included by the calibration laboratory in the uncertainty budget; the calibration uncertainty is only a record of the uncertainty at the time of calibration. If that methodology is adopted, the end user would need to add in the drift component separately. From a technical point of view, it only matters that probe drift be accounted for, by either the calibration laboratory or the end user, and that the users of

the probe have a clear understanding of the uncertainty attainable. We recommend that LLNL procedures identify which party (commercial calibration laboratory, LLNL calibration laboratory, or end user) should be responsible for incorporation of sensor drift allowances into the overall uncertainty of measurement.

Until the uncertainty of the Bi-thermal Calibration System is firmly established, it is recommended that the results from the Bi-thermal Calibration System be treated as provisional.

As an aside, information on the extrapolation of calibration results may prove useful in considering the calibration status of the LLNL probes. In some areas of thermophysical measurements, extrapolation is the norm. Examples are the scaling of viscosity by many orders of magnitude from absolute determinations of the viscosity of water, or the scaling of piston gage response from manometer measurements of a few atmospheres pressure. In other areas, the device being calibrated is never extrapolated, either because extrapolation is not needed or because extrapolation is known to fail. In short, there is no consensus on whether extrapolation is a valid method, and the validity of extrapolation must be considered on a case by case basis. When extrapolation is used, there needs to be firm evidence that the extrapolation process is reproducible from sensor to sensor. In the LLNL case, the situation is not black and white, but gray. On the one hand, extrapolation was favored because a) the manufacturer had proprietary knowledge that their sensor would work with extrapolation, b) the sensor itself is very simple and would be expected to be generally repeatable, and c) the lack of high-temperature standards meant that avoiding extrapolation was technically challenging. On the other hand, extrapolation was discouraged because there was no body of knowledge in the open literature justifying extrapolation.

Conformance to Specific Points of ISO 17025

5.2.1a. Personnel. Staff members are competent in performing humidity tests and/or calibrations, evaluating results. *In conformance.*

5.3.1a. Laboratory facilities. Laboratory facilities are set up to accommodate humidity probe tests and/or calibrations. *In conformance.*

5.4.1a. Appropriate methods and procedures for tests and/or calibrations within its scope are used. Calibration procedures are documented in TIP-CM-72 for the LLNL Bi-thermal Calibration System. Handling, transport, storage and preparation of RH probes to be tested and/or calibrated are documented in Measuring and Test Equipment (M&TE) program requirements and implementation. *In conformance.*

5.4.1b. Instructions on operation of humidity probes are available. *In conformance.*

5.4.1c. Manuals and reference data relevant to the work of the laboratory are readily available. *In conformance.*

5.4.3. The introduction of test and calibration method of Bi-thermal Calibration System developed by the LLNL for its own use is a planned activity. *In conformance.*

5.4.5 Validation of methods. *Comment:* validation has been performed by comparing calibration results between the Bi-thermal Calibration System and Thunder Scientific; however, additional

measurements and analysis are recommended to place the validation on a firmer footing. See discussion in the Summary above.

5.4.6. Estimation of uncertainty of measurement. Uncertainty analysis based on the guidelines of *ISO Guide to the Expression of Uncertainty in Measurement* has not been followed. *Out of conformance.* See discussion in the Summary above.

5.4.7.2c. Computers and automated equipment are maintained properly. *In conformance.*

5.5.1a. Proper sampling, measurement, and test equipment used for calibrations. *In conformance.*

5.5.2a. Humidity probes were used within the accuracy specified by the manufacturers. *In conformance.*

5.5.5. Calibration certificates provided by the manufacture and/or accredited laboratory are maintained. *In conformance.*

5.5.6. Humidity probes were periodically calibrated by the manufacture and/or accredited laboratory based on M&TE program. *In conformance.*

5.5.8. Humidity probes were labeled for calibration status. *In conformance.*

5.6.1a. Thermometers are traceable to NIST standards. *In conformance.*

5.6.2.1.1b. External calibration services were used from the manufacture and/or accredited laboratory that provide traceability to NIST. *In conformance.*

5.6.2.1.1c. Calibration certificates issued by these laboratories contained the results with uncertainty. *In conformance.*

5.6.3.1. A reference standard is not provided for tests and/or calibration of humidity probes. *Comment:* there are no available reference standards. LLNL staff are using the documented vapor pressure and thermodynamic properties of pure water as an intrinsic standard.

5.8. Handling of test and calibration items. Procedures for the transportation, receipt, handling, storage of test and/or calibration items are available from M&TE program requirements. *In conformance.*

5.9.1. Quality control procedures for monitoring the validity of tests and calibrations undertaken have not been established. *Out of conformance.* The basis for a quality control procedure exists in that probes are calibrated by both Thunder Scientific and provisionally calibrated by the LLNL Bi-thermal Calibration System, but a systematic procedure for monitoring the calibrations does not exist.

5.10.1.b. The results of tests and/or calibrations have been reported and documented in scientific notebooks. *In conformance.*

Estimate of Confidence Limits

ISO 17025 mandates corrective action for non-conformances that are identified. The standard does not identify any particular corrective actions, but the corrective action should be designed to prevent recurrence and should be of a “degree appropriate to the magnitude and risk of the problem.” In this particular case, where the use of the humidity sensors is well known, the “magnitude and risk of the problem” is best expressed as a question:

If the claimed uncertainties of the LLNL humidity sensors were in error, would the conclusions of the experiments relying on those sensors be altered appreciably after correction of the sensor uncertainties?

To help address this question, this section, which is outside the scope of a ISO 17025 assessment, has been added.

A simplified definition states that the uncertainty of a measurement is an estimate characterizing the range of values within which the true value lies, at a stated level of confidence. In this section, the goal is not to calculate the uncertainty itself, but to estimate a likely upper limit for the uncertainty. These estimates are the result of our best technical judgment. Determination of the uncertainties would require a careful evaluation of the uncertainty, complete with necessary control experiments and statistical analysis. These estimates are provided as a guide to the likely impact of the sensor calibrations on the body of data obtained with these sensors.

There are three relevant time spans:

Period 1 (1998 to March 2002): single-temperature calibration at 23 °C, extrapolated to 180 °C.

Period 2 (late 2002 to late 2004): calibration over the range 25 °C to 60 °C by Thunder Scientific.

Period 3 (end of 2004 to the present): calibration by Thunder Scientific and provisional calibration by the LLNL Bi-thermal Calibration System.

Data obtained during Period 3 showed that calibrations obtained from Thunder and LLNL were self-consistent. As noted above, the largest contributor to the uncertainty is the sensor drift observed. A conservative estimate of the uncertainty of sensor measurements in the environment of use is 6 %RH (95 % confidence limit) in Period 3, based on combining in quadrature the probable uncertainty of the LLNL Bi-thermal Calibration System (estimated as 3 %RH at 95 % confidence) and the observed sensor drift (estimated at not more than 5 % RH at 95 % confidence).

For Periods 1 and 2, a limit on uncertainty is based on the observation that the sensor drift is significantly larger than the discrepancy between the LLNL Bi-thermal Calibration System and the calibrations performed at much lower temperatures. Thus, the 95 % confidence limit will not be greatly higher than the 6 %RH limit of Period 3. A conservative estimate for this period can be made by combining in quadrature the 6 %RH for Period 3 with an estimate of the uncertainty for the extrapolation process. Using the so-called rectangular probability distribution model, the extrapolation standard uncertainty (at a confidence level of 95%) may be estimated as $(2/\sqrt{3}) \Delta$, where Δ is the maximum observed discrepancy between the LLNL calibration results and an extrapolated calibration. From Fig. 3 of "RH Probe and Experimental Timeline" by S. Carroll (UCRL-AR-218422, dated 3/1/2006), the extrapolation uncertainty can be calculated to be 3.7 %RH (95 % confidence). Adding this result in quadrature with 6 %RH, one obtains 7 %RH as a conservative 95 % confidence limit for the measurement results using the Vaisala probes during Periods 1 and 2.

In the approximate calculations above, there is some likely over counting of uncertainty components. For example, the observed discrepancy and drift may be partly due to limitations in the repeatability of the LLNL Bi-thermal Calibration System. Since the intent of this section is to provide conservative upper confidence limits on the probe performance, rather than uncertainty estimates, no attempt has been made to avoid over counting.

Appendix B:
Personnel Contacted by the Independent Review Team at
Yucca Mountain Project Offices and LLNL

The Independent Review Team interviewed the following staff in Las Vegas, NV and Livermore, CA:

NRC:

Robert Latta	On-Site Representative and Observation Audit Lead for the August 2005 audit, Las Vegas
Fred Brown	NRC Nuclear Material Safeguards and Security Headquarters
D. Blair Spitzberg	Region 4
Vincent Everett	Region 4 Technical Specialist

BSC:

Paul Dixon	Manager – Post Closure Activities
Mike Mason	QA Manager
Robert Hartstern	Quality Verification Manager
Robert Habbe	Audit Section Manager
Michael Carmichael	CAP Manager
Nancy Williams	Licensing
Ted Feigenbaum	General Manager
Charles Warren	QA (former BSC QA LLNL onsite rep)
Donald Beckman	Licensing and Nuclear Safety Manager
Pam Dahl	Licensing and Nuclear Safety

LLNL:

James Blink	LLNL Liaison
Cynthia Atkins-Duffin	Deputy Associate Director
Susan Carroll	Principal Investigator
David McCallen	Nuclear Systems Program Leader
Joe Rard	Investigator
Victor Barish	Engineering Assurance Manager
Leigh Gouveia	VP – PAC (subcontractor to BSC/QA)
Greg Gdouski	Technical area lead
Kirk Staggs	Principal Investigator
Steve Harris	BSC resident QA support
Tanya Reshel	M&TE custodian

Independent Review Team Report
of the BSC Audit BQAP-BSC-05-07

OCRWM:

James Blaylock	OQA
Mike Uhlshafer	Acting Manager – OQA
Ram Murthy	OQA
Kerry Grooms	OQA – Quality Assessments Team Lead
Mark Williams (via phone)	OLAS Director
April Gil	OLAS – Regulatory Interactions & Strategy Division (RISD) Director
John Arthur	Deputy Director ORD
Ken Powers	Associate Deputy Director – ORD
Neal Hunemuller	OLAS – RISD
David Haught	OLAS – RISD
Allen Benson	Communications Supervisor

Appendix C:
Audit Timeline

<i>Date</i>	<i>Event</i>
June - July 2005	Bechtel SAIC Company, LLC (BSC) began scoping and planning of internal audit BQAP-BSC-05-07, "BSC Waste Package Degradation Investigations and Analyses."
July 25, 2005	BSC submitted the original audit plan to the U.S. Nuclear Regulatory Commission (NRC).
August 3, 2005	BSC submitted a revised audit scope, removing reference to the Total System Performance Assessment.
August 15 - 31, 2005	BSC performed internal audit BQAP-BSC-05-07 and conducted initial meeting with NRC Observation Audit Lead and the Office of Civilian Radioactive Waste Management's (OCRWM) Office of Quality Assurance (OQA).
August 15-19	- Audit activities in Las Vegas
August 22-25	- Audit activities in Las Vegas and at Lawrence Livermore National Laboratory (LLNL)
August 29-31	- Audit team returns to Las Vegas to complete audit report.
August 24, 2005	NRC's Observation Audit Lead tried to provide comments to BSC QA Audit staff on deficiencies noted in the audit.
August 31, 2005	Initial debrief in morning, and exit meeting in afternoon between NRC Observation Audit Lead, BSC, and OCRWM OQA and Office of License Application and Strategy's (OLAS) Regulatory Interactions and Strategy Division (RISD). NRC expressed concerns and provided AOIs and weaknesses. The NRC Observation Audit Lead made eight additional attempts to communicate concerns to the BSC Audit Team Lead.
September 28, 2005	NRC's Observation Audit Lead provided clarifications on NRC findings to BSC Licensing and Nuclear Safety (LNS).
October 7, 2005	BSC issued audit report on BQAP-BSC-05-07 to NRC, OCRWM, BSC management and a wide outside distribution.
November 1, 2005	NRC communicated to the OCRWM's OQA and OLAS - RISD that BSC staff were not responsive to NRC concerns (after the issuance of the BSC audit report).
November 11, 2005	LLNL initiated self-assessment MSA-LNS-2006-008, "Management Self-Assessment of LLNL Scientific Notebooks;" final report approved November 30, 2005.
November 16, 2005 (and again on November 25, 2005)	The Office of Repository Development (ORD) Deputy Director was provided with a written description of the issues as part of a set of bulleted potential discussion items for a weekly teleconference with NRC.

Independent Review Team Report
of the BSC Audit BQAP-BSC-05-07

Date	Event
December 5, 2005	BSC LNS initiated self-assessment MSA-LNS-2006-013, "Effectiveness of BSC Interactions with NRC During Observed Audits" to identify improvements needed in interfaces with NRC during audits. Report approved January 25, 2006. One Level C and 10 Level D CRs were initiated.
December 7, 2005	NRC, BSC, and OCRWM OLAS - RISD and LLNL participated in a second debrief and re-exit of the audit. Five AOIs were identified, including the concern that Scientific Notebook – 484 misrepresented that the Vaisala humidity probes were calibrated.
January 9, 2006	NRC issued Observation Audit Report (OAR-05-05) " <i>Observation Audit of Bechtel SAIC Company, LLC, Audit of Scientific Investigation, Waste Package, and Drip Shield Degradation.</i> "
January 30, 2006	BSC initiated a Level A CR (7418) to establish a root cause analysis to address issues related to the use of the Vaisala humidity probes outside their range of calibration.
February 2, 2006	The OCRWM Acting Director initiated an Independent Review of the calibration of the Vaisala probes and BSC interactions.

Appendix D:
History of Changes to the Procedure on
Control of Measuring and Test Equipment

The Source of the Measuring and Test procedure is OCRWM/RW-0333P, *Quality Assurance Requirements and Description* (the QARD). Specifically, Section 12 of the QARD, entitled "Control of Measuring and Test Equipment," requires M&TE to be properly controlled, calibrated, and maintained.

Although there have been changes to the procedure (see below), the changes have been considered minor, as evidenced by the fact that the changes have been Interim Change Notices (ICNs) rather than Revisions.

The original issuance of the procedure AP-12.1Q (i.e. – Rev 0 ICN 0) *Control of Measuring and Test Equipment* was on 9/15/2000.

AP-12.1Q Rev 0 ICN 1 was effective 03/27/2001.

AP- 12.1Q – Rev 0 ICN 2 has an effective date of 02/06/2002.

AP- 12.1Q – Rev 0 ICN 3 (effective date 04/30/2004). Added the "or similar" tag to the requirement to tag Out-of-Service equipment. LLNL submitted the following comment²² during the procedure revision process:

"Section 5.7.2b) –

Change 1), first sentence to read: " Apply an M&TE Out of Service tag or other similar tag to indicate out of calibration conditions." As stated in the NOTE in comment 1, some M&TE used in ongoing corrosion experiments at LLNL cannot be recalled for calibration at the required intervals because it would disrupt data taking for these experiments. In these instances an OCR is issued to identify that M&TE is in use past its recalibration due date and a tag indicating this condition is affixed to the M&TE . Although tagging is appropriate in these conditions, an out of service tag is not for the following reasons:

- a. The equipment is not out of service... it is in use past its calibration due date.*
- b. Allowing personnel to observe equipment in use with an out of service tag attached might cause them to think that using other equipment with an out of service tag is acceptable.*

Change 2) to read: "as soon as possible segregate the out-of-calibration M&TE ..."

The BSC procedure owner accepted change 1 and incorporated the suggested wording into the procedure. LLNL change 2 was not accepted by the procedure owner.

²² LLNL, Comment Sheet for AP-12.1Q, Rev. 0, ICN 3, dated January 6, 2004.

Independent Review Team Report
of the BSC Audit BQAP-BSC-05-07

LP-12.1Q-BSC Rev 0 ICN 0 *Control of Measuring and Test Equipment* (effective date 02/04/2005) – The procedure was approved by the Repository Development Manager and superseded AP-12.1Q. This was the procedure in effect at the time of the August 2005 audit.

LP-12.1Q-BSC Rev 0 ICN 1 has an effective date of 10/31/2005. This clarifies labeling requirements and makes a number of miscellaneous administrative and editorial changes.