

**U. S. NUCLEAR REGULATORY COMMISSION COMMENTS
ON DOE'S RESPONSE TO OBSERVATION AUDIT
REPORT OAR-05-05**

1.0 AUDIT OBSERVATION INQUIRIES

The U.S. Nuclear Regulatory Commission (NRC) submitted five audit observation inquiries (AOI) to the U.S. Department of Energy (DOE) requesting additional information concerning issues identified during the audit at Lawrence Livermore National Laboratory (LLNL) on August 15-31, 2005. DOE provided a response to the five AOIs in a letter dated September 11, 2006. The NRC staff has reviewed DOE's response and has reached the following conclusions:

- AOI-05-05-01, concerning the Drift Scale THC Seepage Analysis Model Report, is closed. The issues related to this AOI will be reviewed as part of the key technical issues (KTI) process (Refer to Section 1.1);
- AOI-05-05-02, concerning data presented outside the model's validation range, is closed. Verification of the corrective actions will be performed by the On-Site Representatives to confirm the extent of condition related to this issue was adequately addressed (Refer to Section 1.2);
- AOI-05-05-03, concerning inconsistencies found in two reports related to localized corrosion at elevated temperatures, is closed. DOE committed to correct the inconsistencies in a future revision of the analysis model reports. Completion of the corrective actions will be verified by the On-Site Representatives (Refer to Section 1.3);
- AOI-05-05-04, concerning referencing cancelled documents, was not adequately addressed in the DOE response. As such, the NRC is unable to close this AOI pending clarification of the project controls related to the referencing of cancelled documents in technical products that support the potential license application (Refer to Section 1.4);
- AOI-05-05-05, concerning the adequacy of the calibration of the Vaisala temperature and humidity probes at elevated temperatures, remains unresolved. The information provided in the DOE response did not provide an adequate technical basis to address the NRC's concerns on this issue. This AOI will remain open (Refer to Section 1.5).

The following sections provide details of the staff's review of the responses to the AOIs. The staff will continue to monitor the actions taken regarding the issues in this enclosure.

Enclosure

1.1 (Closed) AOI-OAR-05-05-01 “Drift-Scale THC Seepage Analysis Model Report”

The staff has reviewed DOE’s response concerning water seepage into the drifts, as presented in the Drift-Scale Thermal-Hydrological-Chemical Seepage Model. The NRC audit team observers questioned whether sufficient technical justification had been documented to support the assumption that no dripping will take place if the temperature in the drift wall is above 100 degree Celsius (°C). The NRC audit team observers also questioned why DOE had not considered the salt affects on the boiling point. These issues were discussed in Section 4.5.1.1 of the NRC Observation Audit Report.

DOE’s response, as provided in the cover letter, and pages 1-13 of Enclosure 1 “Response to the NRC Audit Observer Inquiries AOI-05-05-01 through AOI-05-05-05, Areas of Weakness, and Other Issues Associated with the NRC Observation Audit Report,” stated that the potential for concentrated brine development to contribute to seepage at temperatures higher than the threshold was not significant in terms of the potential impacts. DOE indicated that: (1) evaporative concentration causes a reduction in fluid volume; (2) the expected composition of potential seepage waters is dilute; and (3) at temperatures above the threshold, the salt accumulation and potential brine volume are limited. Thus, at the temperatures above the threshold, DOE concluded that salt accumulation and potential brine volume would be limited. This basis was consistent with the technical information DOE has presented in past meetings and Project documents. However, the staff questions whether DOE has adequately reconciled related field test observations with the conclusions reached.

The staff notes that the issues concerning seepage above 100°C and the effect of salts on the boiling point are closely related to three technical agreements ((Toxicity Equivalence Factors)TEF 2.01, TEF 2.08, and (General) GEN 1.01, comment 15), which have been reviewed by the NRC. As such, the staff has determined that the issues related to this AOI, and the position concerning the adequacy of the assumptions, will be reviewed as part of the pre-licensing key technical issues process. This AOI is closed.

1.2 (Closed) AOI-OAR-05-05-02 “Analysis of Dust Deliquescence for Features, Events and Processes (FEP) Screening”

The staff has reviewed DOE’s response regarding the inclusion of model results in reports, when the model results present data that are outside the model’s range of validation. This issue was discussed in Section 4.5.1.2 of the NRC Observation Audit Report. As noted by the staff, during the licensing review process, the NRC can only rely on data that has been appropriately validated.

DOE’s response, as provided in the cover letter, and pages 15-18 of Enclosure 1, addressed NRC’s issue by referring to a change made in Revision 01 to ANL-EBS-MD-000074 “Analysis of Dust Deliquescence for FEP Screening.” This recent revision addressed the inadvertently omitted information regarding the in-drift precipitates/salts deliquescence relative humidity validation range. The validation range was clarified in the figures and discussion presented in the new revision, in the notes to the figures, and in the text. DOE stated that the predictions outside the validation range

were not used to support the conclusions of the report. The On-Site Representatives will review the associated corrective actions to confirm that the extent of condition related to this issue was adequately addressed. The results of these reviews will be documented in a future On-Site Representative's report. This AOI is closed.

1.3 (Closed) AOI-OAR-05-05-03 "Inconsistencies for Overall Localized Corrosion Modeling"

The staff has reviewed DOE's response to the issue of inconsistencies found in two reports reviewed during the NRC audit observation, which related to whether localized corrosion would occur at elevated temperatures. Specifically, ANL-EBS-MD-000003 "General Corrosion and Localized Corrosion of Waste Package and Outer Barrier" and ANL-EBS-MD-000074 "Analysis of Dust Deliquescence for Features, Events, and Process Screening" presented inconsistent information as to whether localized corrosion would initiate at elevated temperatures. This issue was discussed in Section 4.5.2.3 of the NRC Observation Audit Report.

DOE's response, as provided in the cover letter, and pages 19-20 of Enclosure 1, addressed NRC's issue by committing to revise ANL-EBS-MD-000003 to remove the inconsistencies. Confirmation of the implementation of the proposed corrective actions will be performed by the On-Site Representatives, subsequent to the next revision. The results will be documented in a future On-Site Representative's report. This AOI is closed.

1.4 (Open) AOI-OAR-05-05-04 "Referencing of Cancelled Documents"

The staff has reviewed DOE's response concerning the referencing of cancelled documents. The NRC audit team observers questioned whether the referencing of cancelled documents was consistent with Section 6.2.5.C. of the Quality Assurance Requirements Document (QARD), Revision 16, and why the cancelled report being referenced was not available in the current report database. These issues were discussed in Section 4.4.4 of the NRC Observation Audit Report. At the time of the audit observation, Revision 16 of the QARD was in effect. Section 6.2.5.C of Revision 16 is now Section 6.2.5.B of the current Revision 18.

DOE's response, as provided in the cover letter, and pages 21-23 of Enclosure 1, discussed the issue of referencing cancelled documents and summarized three issues related to this AOI. The first issue concerned the availability of cancelled documents in the current database. The second issue related to compliance with QARD Section 6.2.5.C concerning the referencing of cancelled documents. The third issue related to the use of cancelled documents to support the potential license application. DOE concluded by stating that they do not intend to rely on cancelled documents as input to the license application. References were provided to revisions made to the procedures, in response to this issue, that clarified DOE's position.

After reviewing DOE's response, the staff is unable to confirm the basis for the position that DOE is in compliance with QARD Section 6.2.5.C. Specifically, DOE's response

was unclear related to: (1) the use of the term “do not intend”; (2) the statement that the changes to the program will reduce future citations to cancelled documents; and (3) the statement that the designation of “cancelled” or “superseded” does not necessarily mean all the information in the document is unsuitable for use. These statements, along with the revisions made to the respective procedures, do not provide an adequate explanation as to how compliance with the QARD is achieved. The following information provides additional discussion concerning the issues associated with this AOI.

1.4.1 Retrievability of Cancelled Documents

The first issue related to the retrievability of the referenced cancelled document. DOE’s discussion with the NRC On-Site Representatives on March 24, 2006, sufficiently resolved this issue where DOE demonstrated that the cancelled analysis model report that had been referenced, was retrievable in the current system and was available in the report database as a controlled document at the time of the audit. This issue, related to the AOI, is closed.

1.4.2 QARD Requirements Related to Cancelled Documents

The second issue concerned compliance with QARD Section 6.2.5.C and related to at least two procedures used at the Yucca Mountain Project which allowed the referencing of cancelled documents as an acceptable practice. During the audit observation, the NRC questioned whether this practice was consistent with QARD Section 6.2.5.C which stated *“The disposition of obsolete or superseded documents shall be controlled to ensure that they are not used to perform work.”* The staff noted that cancelled documents, as well as superseded documents, should be considered a type of obsolete document.

DOE’s response stated on pages 21-22 of Enclosure 1, that Procedure LP-SIII.9Q-BSC “Scientific Analysis” and Procedure LP-SIII.10Q-BSC “Models,” at the time of the audit, allowed the use of information from cancelled or superseded documents for direct input, provided the justification for use was documented in the report using the information. DOE stated that, subsequent to the audit, these two procedures were revised and statements added directing that a document may not cite previous versions of the same document as direct input. DOE also stated that the procedural controls established in Procedure LP-SIII.9Q-BSC and Procedure LP-SIII.10Q-BSC meet the requirements of QARD Section 6.2.5.C.

Based on the staff’s review of the current versions (Revision 1/ICN 1) of the two procedures referenced in DOE’s response, it was determined that the change to the procedures does not adequately address the NRC’s concerns. Specifically, the revised version of the procedures was not sufficiently modified to ensure compliance with the QARD concerning referencing cancelled documents. Section 5.2.1 (n) of Procedure LP-SIII.9Q-BSC is stated below. The bolded portion of the statement is the addition in Revision 01 that was intended to bring the procedure into compliance with QARD Section 6.2.5.C. This same revision was also found in Section 5.2.1(l) of Procedure LP-SIII.10Q-BSC. Section 5.2.1(n) stated:

*“Input obtained from product output of a document under document control (e.g., RM-PRO-2001) that has been cancelled or superseded must be demonstrated to be suitable for intended use and justified within the technical product.” **The scientific analysis may obtain inputs from other cancelled or superseded documents but may not cite an input from a previous version of itself.** When appropriately justified, these inputs are considered qualified for intended use within the document. If the document and the product output have been cancelled or superseded, the reason for cancellation or supersession must be included in the justification for use of the input.”*

Based on the revised wording in Section 5.2.1 of the two procedures, referencing of cancelled and superseded documents is still permitted, when the data is suitable for use and justified, which is contrary to the provisions of QARD Section 6.2.5.C.

In contrast to the revised text in Procedure LP-SIII.9Q-BSC and Procedure LP-SIII.10Q-BSC, the staff does find that the statement in Procedure RM-PRO-2001 “Document Control” Revision 0 (formally LP-6.3Q-BSC) adequately addresses the issue and conforms to the requirement in QARD Section 6.2.5.C. Procedure RM-PRO-2001, Section 4.6.3 stated *“Ensure that a cancelled, superseded or revision/change of a controlled document is not used in performance of work.”*

However, a note was included with Section 4.6.3 of Procedure RM-PRO-2001 which challenges the intent of how this step is applied and brings into question whether compliance with QARD 6.2.5.C is fully achieved through the use of this procedure. The note states; *“If a current revision/change of a document includes a transition statement that the previous revision/change can be used in special circumstances, the previous revision/change will have a status of Limited Use and may be used for a defined period of time.”* It is not clear to the staff how this note would be applied to the statement in Step 4.6.3 and compliance with the QARD maintained.

The statements in the procedures referenced above are not consistent with the requirement in the QARD concerning the use of cancelled or superceded documents. Therefore, the staff is unable to close this AOI concerning the issue of compliance with QARD Section 6.2.5.C without further interaction. The staff recommends that DOE re-evaluate the adequacy of the procedural guidance discussed above to ensure compliance with the QARD can be achieved.

1.4.3 Previous Quality Assurance Findings Concerning the Use of Cancelled Documents

The problem concerning the use of obsolete and cancelled documents was previously identified in 2004, in Condition Report 3579 “Use of Obsolete and Superseded Documents in Quality Affecting Work.” Resolution for this condition report included an interpretation of QARD Section 5.2.6.C, which determined that this section of the QARD did not apply to technical work products, even when these products were direct inputs used to perform quality-affecting work that would subsequently support the Total

System Performance Assessment License Application. The staff disagrees with this interpretation and considers analysis model reports and technical reports as documents used to perform quality affecting work, and therefore, must comply with QARD Section 6.2.5.C. Additionally, the staff considers analysis model reports and technical reports as controlled documents, as described in QARD Section 6.2.1, in that, they specify technical requirements and/or quality requirements. Based on this inappropriate interpretation of the QARD, Condition Report 3579 was closed without any corrective action. The staff recommends that DOE re-evaluate the conclusion reached in Condition Report 3579.

1.4.4 Referencing Cancelled Documents to Support the Potential License Application

The third issue concerned DOE's plans to reference cancelled documents to support the potential license application. The staff has determined that the response in the cover letter and pages 21-23 of Enclosure 1 does not provide a clear explanation of DOE's plans concerning referencing cancelled documents to support the potential license application. Specifically, the cover letter states that: "*DOE does not intend [emphasis added] to rely on cancelled documents as inputs to the license application,*" and notes that revisions have been made to DOE procedures that direct that; "*. . . a document may not cite a previous revision of the same document as direct input.*" DOE further stated on page 23 of Enclosure 1 that the procedure revisions: "*. . . will reduce the number of future citations to superseded documents,*" and that: "*However, these procedures recognize that a designation of "cancelled" or "superseded" with respect to a document does not necessarily mean that all the information in the document is unsuitable for use.*" The staff finds that DOE's response does not adequately address the issue of whether cancelled documents will be used to support the potential license application. In particular, the use of the phrase "*do not intend*" in the cover letter supplemented by the additional information provided in Enclosure 1, does not provide a clear basis to demonstrate compliance with the requirements in the QARD. The staff is unable to close this AOI concerning the issue of referencing cancelled documents without further information. The staff recommends that DOE establish a clear position concerning referencing cancelled documents, without the use of words such as "intend," to ensure consistent procedural controls and effective implementation of the QARD requirements.

1.5 **(Open) AOI-OAR-05-05-05 "Use of the Vaisala Temperature/Humidity Probes at Temperatures Outside their Calibrated Range"**

The staff has reviewed DOE's response related to the calibration status of the Vaisala temperature probes used in experiments described in Scientific Notebooks SN-LLNL-SCI-474-V2 "Mixed Salts" and SN-LLNL-SCI-484-V1 "Deliquescence of Mixed Salts, Measurements of Deliquescence Relative Humidity and Determination of Boiling Point from Deliquescence Relative Humidity." This issue was discussed in Sections 4.4.6 and 4.4.8 of the NRC Observation Audit Report. The staff has reviewed additional information available in Condition Report 2247 "Measuring and Test Equipment Used Outside the Range of Calibration" and Condition Report 5430 "Data Acquired by Vaisala Temperature/Humidity Probes Above 90 Degree Celsius is Indeterminate," including the causal analysis and the August 16, 2004, LLNL memorandum related to the status of

calibration of the Vaisala probes at the time the experiments were being conducted.

DOE's response was provided in the cover letter; on pages 25-38 of Enclosure 1; and in Enclosure 3 "Office of Civilian Radioactive Waste Management (OCRWM) Independent Review Team Report of the BSC Quality Assurance Audit BQAP-BSC-05-07." DOE concluded that the Vaisala probes were adequately calibrated in accordance with manufacturers' instructions with an acceptable calibration methodology consistent with industry practices.

After reviewing DOE's response, the staff does not agree with the conclusion that the Vaisala probes were adequately calibrated for use through the full range of temperatures and humidity in the LLNL SCI-474 and SCI-484 experiments. As such, the qualification of the data collected at the elevated temperatures should be considered indeterminate until additional technical justification is provided to support the qualification of the data. Within this area, the staff has identified a number of concerns related to DOE's response and has reached the following conclusions:

- The information documented in Condition Reports 2247 and 5430 accurately recognized the problem with the use of the Vaisala probes at high temperatures. However, the corresponding corrective actions were ineffective in preventing further non-compliance with QARD Section 12.2.1 (Refer to Section 1.5.1);
- An adequate basis for the calibration of the Vaisala probes was not documented, as required by QARD Section 12.2.1.A, at the time of their use in the elevated temperature experiments conducted at LLNL (Refer to Section 1.5.2);
- The Vaisala probes were accepted as calibrated, based on the manufacturer's literature, but were not adequately tested to ensure conformance with the manufacturer's published requirements, as required by QARD Section 7.2.12 (Refer to Section 1.5.3);
- The test data collected by the Vaisala probes to demonstrate linearity at elevated temperatures, where a national standard did not exist, does not meet the Yucca Mountain project requirements for an acceptable uncertainty level at elevated temperatures (Refer to Section 1.5.4);
- A basis for calibration of the Vaisala probes, when no nationally recognized standard was available, was not established and implemented prior to use of the probes in accordance with the requirements of QARD Section 12.2.1.A (Refer to Section 1.5.5);
- The Vaisala probes were not appropriately labeled with "Limited Calibration" stickers as an action related to Condition Report 2247, when the elevated temperature calibration issue remained unresolved (Refer to Section 1.5.6);
- Other technical and performance issues related to the use of the Vaisala probes at elevated temperatures have not been adequately addressed, such as probe drift, failure of the probes at high temperatures, and the recommendation by the probe manufacturer to increase the frequency of calibration when using the

probes at high temperatures (Refer to Section 1.5.7);

- An explanation was not provided in DOE's response as to why corrective actions identified in Condition Report 2247 were not adequately implemented for Scientific Notebook 484 documenting the limitations for use of the Vaisala probes (Refer to Section 1.5.8).

The staff finds that the issues identified in Condition Reports 2247 and 5430 concerning the need to calibrate the Vaisala probes "*through the entire range of use*" were not adequately addressed before closing the two condition reports, nor were they adequately addressed in the response letter to the NRC. Therefore, the qualification status of the data collected outside the calibrated range of the Vaisala probes is indeterminate. The following sections provide details of the staff's review of the response to AOI-05-05-05. The staff is unable to close this AOI concerning the use of the Vaisala probes at elevated temperatures, without further information.

1.5.1 Condition Reports 2247 and 5430 Identified the Problem with the Vaisala Probes But Were Ineffective in Preventing Further Non-Compliance

The staff's review of Condition Reports 2247, issued March 2004, and Condition Report 5430, issued April 2005, found that LLNL correctly identified the problem concerning the use of the Vaisala probes outside their range of calibration. Specifically, LLNL identified that no nationally recognized standard existed for calibrating the probes at the elevated temperature used in the SCI-474 experiments. This issue was appropriately identified by the LLNL Engineering Assurance organization while performing an annual compliance review of Scientific Notebook SCI-474 and documented in the DOE corrective action program. The staff finds that LLNL took appropriate action to initiate development of a process to calibrate the probes at the higher temperatures and included a qualified calibration vendor and the National Institute of Standards and Technology (NIST) in the efforts to develop the bi-thermal calibration process. The staff finds that LLNL took proper action to document the proposed calibration process, as required by QARD Section 12.2.1, in a Test Implementing Procedure and in Scientific Notebook SN-LLNL-SCI-487, V-1 "Research Supporting Environmental Chemistry Experiments."

In documenting the calibration issue, LLNL provided numerous statements in Condition Reports 2247 and 5430 concerning the problem with the calibration status of the Vaisala probes. For example, LLNL stated:

- *"The industry current standards do not support traceable calibrations above 70 °C. There has been some indication by NIST that it may be possible to conduct calibrations up to 90 °C, but that is not typically performed by any recognized standards testing lab. The NIST two-pressure humidity generator is the primary standard used for relative humidity calibrations. This is the type of standard used by Vaisala to perform all in-house standardized calibrations. Currently, Thunder Scientific manufactures most of the two-pressure calibrators utilized by various calibration labs, including Vaisala, to perform relative humidity calibrations against a primary standard. However, it has an upper limit*

operating temperature range of 70 °C and should be operated below this range to provide for some control.” (Page 17 of Condition Report 2247)

- *“Exhaustive research was done to locate a calibration supplier capable of calibrating the probe over a full range of use [emphasis added] of the equipment but none, including NIST, had the equipment to perform the calibration at temperatures above 90 °C. NIST and other calibration service providers stated that there was no NIST traceable standard for the higher temperatures.” (Page 5 of Condition Report 2247)*
- *“The temperature/humidity sensor problem is isolated to work being performed by LLNL-YMP personnel. LLNL Scientists/Investigators are already aware of this particular issue and are working to resolve it. LLNL is not aware of any other instruments used on the project that cannot be calibrated throughout the entire range of use.” [emphasis added] (Page 6 of Condition Report 5430)*
- *“In short, there is no current standard that can be used to properly calibrate humidity probes at temperatures above 70 °C. In addition, Vaisala has not provided sufficient evidence to support the accuracy of their humidity probes at elevated temperatures.” (Page 17 of the Cause Analysis Report for Condition Report 2247)*

LLNL also identified a potential solution to the problem. On page 10 of Condition Report 2247, the following statement was provided:

“One potential solution is to fund one of the calibration service vendors to build a High-Temperature Two Pressure Humidity Generator that would be developed based on the scientific principles of current NIST standards. NIST and Thunder Scientific have indicated that these principles should be applicable to the range of temperatures required for proper calibration. It should be noted that initially this would not be a NIST traceable standard, but that it could be defended as equivalent to this standard.” (Page 10 of Condition Report 2247)

Despite the recognition by LLNL, as documented in the condition reports, that the calibration of the Vaisala probes was limited, experiments were continued using the Vaisala probes at temperatures as high as 180°C.

DOE’s response, as provided on pages 35-36 of Enclosure 1, stated *“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,”* is not consistent with the LLNL documentation in the two condition reports. The staff’s review of the available documentation concludes that LLNL was aware of the calibration problem during the time period the SCI-474 and SCI-484 experiments were underway. LLNL was in the process of developing a calibration process using the bi-thermal calibration method with the apparent plans to calibrate the probes after completing the experiments. This post-calibration concept is not consistent with the requirements of QARD Section 12.2.1, which require calibration prior to use.

1.5.2 The Basis for Calibration of the Vaisala Probes was Not Adequately Documented for the Elevated Temperatures Used in the LLNL Experiments

The requirements in the QARD concerning the calibration of instruments do not define the term “calibrate” and do not establish the details of what constitutes an acceptable calibration process. As such, it is left to the user of the equipment to ensure an adequate calibration has been performed for the intended use of the equipment. The basis for this calibration is to be documented in accordance with the requirements of QARD Section 12.2.1.A. An adequate basis for establishing and performing calibrations to meet quality assurance program requirements is to rely on applicable industry standards.

According to DOE’s September 11, 2006, response letter to the NRC and information documented in Condition Report 2247, the Vaisala probes had been calibrated by the manufacturer at a single temperature of 23°C. In December 2002, the calibration vendor was changed from Vaisala to Thunder Scientific, Inc. Thunder Scientific, Inc. is an accredited humidity calibration services that, according to their website, performs calibration services for relative humidity measuring equipment for use at temperatures from 0°C to 70°C. The Thunder Scientific, Inc. calibration is performed at three temperatures of 20, 40, and 60°C. However, in the Scientific Notebook SCI-484 experiments, the Vaisala probes were used by LLNL at temperatures up to 180°C. At issue is whether LLNL obtained adequate justification from Vaisala or Thunder Scientific, Inc. to support the conclusion that the Vaisala probes were calibrated for use at the elevated temperatures.

There are numerous industry standards that provide instructions and acceptance criteria for the calibration of instruments and equipment. One of these, which DOE referenced on page 36 of Enclosure 1 (referenced as NRC 1995) is the NRC’s NUREG/CR-5569 “Health Physics Database.” DOE quoted from the NUREG/CR that: *“Single point calibrations using secondary sources are acceptable where detectors are inherently linear.”*

NUREG/CR-5569 provides guidance related to single point calibrations and discusses how single point calibrations can be applied to effluent monitors in a way that would be acceptable to the NRC. The NUREG provides additional information beyond the portion quoted in DOE’s response. On page 93-94, NUREG/CR-5569 states:

“Single point calibrations using secondary sources are acceptable where detectors are inherently linear.”“Assuming a licensee calibrates at a single point, the licensee should consider selecting that point at or near an alarm or action level. Routinely calibrating near an alarm point, coupled with the ongoing comparison of real time monitor readings against laboratory analysis of periodic grab samples containing normal levels of radioactive effluents seems to provide adequate assurance of proper monitoring operability.”

As discussed in NUREG/CR-5569, single point calibrations are viewed as acceptable for limited situations where the calibration point is near the point of interest. This differs from the experiments at LLNL where the single temperature calibration point, and later

the three temperature calibration points, were being considered adequate for a very wide range of temperatures.

Vaisala provides information concerning one-point calibration on their website. They state *“If the process is operated within narrow boundaries, a one-point calibration is practical.”* As can be seen from the NRC position in the NUREG/CR and Vaisala’s statement, the use of single point calibrations should be applied to a very limited situation which was not applicable to the actual range of use of the probes by LLNL. Therefore, the staff has determined that the use of a single point calibration at 25°C, as the basis for considering the Vaisala probes calibrated from -40°C to +180°C (i.e., a range of 220°C), would not be appropriate to support the qualification of data derived from these measurements.

There are numerous industry standards concerning the calibration of instruments. Many of these standards provide information related to the issue of calibrating Measurement and Test Equipment (M&TE) over the range of use. Table 1 provides examples of some of these standards.

TABLE 1: EXAMPLES OF CALIBRATION STANDARDS

STANDARD	STATEMENT
American National Standard ANSI-N323-1978 “Radiation Protection Instrumentation Test and Calibration”	Calibration is defined as <i>“To determine the response or reading of an instrument relative to a series of known radiation values <u>over the range of the instrument.</u>”</i> [emphasis added]
International Atomic Energy Agency Safety Series Report #16 “Calibration of Radiation Protection Monitoring Instruments”	Section 1.3 states: <i>“The primary objectives of calibration are . . . (2) To determine, under a controlled set of standard conditions, the indication of an instrument as a function of the value of the quantity intended to be measured. This should be done over the <u>complete range of indication</u> [emphasis added] of the instrument.”</i>
American National Standard ANSI-N42.13-1978 “Calibration and Usage of Dose Calibrator Ionization Chambers for Assay of Radionuclides”	Section 4.2.2 states: <i>“Calibration of the equipment should cover as completely as practicable the activity ranges for which it will be used.”</i> Section 4.2.3 also states: <i>“Calibration shall be performed <u>over the range of proposed application.</u>”</i> [emphasis added]
Handbook of Statistical Methods (see NIST website link)	Section 2.3.6 states: <i>“Instrument calibration is intended to eliminate or reduce bias in an instrument’s readings over a range for all continuous values. For this purpose, reference standards with <u>known values for selected points</u></i>

	<i>covering the range of interest [emphasis added] are measured with the instrument in question. Then a functional relationship is established between the values of the standards and the corresponding measurements.”</i>
Handbook of Statistical Methods (see NIST website link)	Section 2.3.7 states: <i>“For linear calibrations, it is sufficient to control the end-points and the middle of the calibration interval to ensure that the instrument does not drift out of calibration. Therefore, check standards are required at three points, namely, at the lower-end of the regime, at the midrange of the regime, and at the upper-end of the regime.”</i>

As evident by the various industry standards, a proper calibration of the Vaisala probes should be performed over the full range of use of the instruments. For the important to waste isolation work being performed at Yucca Mountain Project, the staff expects DOE to establish a calibration standard that is technically defensible over the full range of use. The staff recommends that DOE adopt a position related to calibration requirements for quality affecting activities that would be consistent with industry standards.

Based on the information provided in DOE’s response letter, the information reviewed in Condition Reports 2247 and 5430, and a review of selected industry standards related to the calibration of M&TE, the staff has determined that the conclusion that *“At the time of the initial use of the probes at LLNL, that the probes had been appropriately calibrated”* is not supported by the information provided to the NRC nor the information included in the condition reports that were issued at the time the SCI-474 and SCI-484 experiments were being performed. As such, the staff does not agree with the conclusion that the Vaisala probes had been properly calibrated in accordance with QARD Section 12.2.1, in that, an adequate basis for the calibration of the probes, consistent with industry standards, had not been established prior to use of the probes in the SCI-474 and SCI-484 experiments.

1.5.3 Use of Manufacturer’s Literature to Establish Compliance with Calibration Requirements for Commercial Grade Items

LLNL originally selected the Vaisala temperature/humidity probes for use in their experiments, according to Condition Report 2247, because Vaisala was a recognized leader in the industry in the area of capacitive thin-film polymer humidity sensors. This type of sensor was used extensively in the industry to monitor real time relative humidity across a broad range of temperatures and was considered ideal for many of the tests conducted for the Yucca Mountain Project at LLNL. The configuration and specifications for the HMP-240 and HMP-230 series were a good match for the types of tests conducted at LLNL, and, as stated on page 30 of Enclosure 1 to DOE’s response letter, *“According to the manufacturer’s user guide, HMP-243 probes are designed and specified to operate in a temperature range from -40 °C to +180 °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 NRC's Audit Observation Report, Section 4.4.6, concluded that the Vaisala probes were being used outside the manufacturer's documented range of acceptable use. After reviewing the response to this issue, the staff agrees that Vaisala had provided information stating the probes could be used at a very wide range of temperatures and humidity that met the needs for the LLNL experiments. However, accepting a manufacturer's claim at face value as a basis for considering the probes calibrated is not adequate for use of their product in quality affecting work. The Vaisala probes were purchased as commercial grade items. As such, the manufacturer's literature represented a manufacturer's general statement that their equipment can be used under certain conditions.

LLNL took the appropriate action to question the basis of the statements made in the literature by Vaisala for use of their probes. As noted on page 5 of Condition Report 2247, LLNL stated

"Based on the manufacturer's literature and numerous communications with the manufacturer, calibration of the Vaisala temperature/humidity probes at the points recommended by the manufacturer (25 °C for temperature) will satisfy the use of the instrument throughout the entire range of the instrument (0 to 200 °C). Vaisala would not provide the documentation (proprietary) used to make this statement therefore, the accuracy of the values acquired at elevated temperatures could not be verified."

This conclusion was a correct assessment by LLNL, since the probes were commercial grade items and the basis for Vaisala's statement of the probes' operating range in their literature could not be verified. The probes should not have been considered as adequately calibrated for use in quality affecting work. LLNL's concern regarding the lack of documentation to support Vaisala's assertions was also consistent with DOE guidance concerning calibration laboratories. DOE issued a memorandum on November 9, 2000, (MOL 20001204.0313) concerning use of consensus standards and had endorsed ANSI/NCSL Z540-1-1994 "Calibration Laboratories and Measuring and Test Equipment General Requirements," as satisfying the QARD. Section 10.4 of this standard states "*Where it is necessary to employ methods that have not been well established, these shall be subject to agreement with the customer, be fully documented and validated, and be available [emphasis added] to the customer or other recipients of the relevant reports.*" LLNL, by not obtaining the proprietary information from Vaisala that was the basis for the calibration claim, did not satisfy this DOE endorsed standard.

Requirements for commercial grade items are described in Section 7.2.12 of the QARD, Revision 16. Section 7.2.12.D.3 states: "*After receipt of a commercial grade item, the purchaser shall ensure that . . . (3) Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.*" In the case of the Vaisala probes, testing would be required to confirm the probes calibration status at the full range of temperature advertised by the manufacturer.

As can be seen from statements in Condition Report 2247, LLNL understood and documented that no nationally recognized standard was available for the calibration of temperature and humidity sensors above 70°C. LLNL also understood that without

reviewing the proprietary information that was withheld by Vaisala, that a determination could not be made concerning the uncertainties associated with the probes at elevated temperatures to ensure the accuracy of the data collected was consistent with the needs of the project. At this point, LLNL should have recognized that the provisions of QARD Section 7.2.12.D.3 could not be met and the probes could not be considered calibrated for use at temperatures beyond the calibrated range of the instruments.

The staff agrees with LLNL's actions to question Vaisala's technical basis for the claims made in their literature, to document this concern in the corrective action program and to pursue alternatives to establish a defensible calibration status for the probes. However, the staff does not agree with the conclusion that "*At the time of the initial use of the probes at LLNL, that the probes had been appropriately calibrated.*" The staff has concluded that LLNL had not satisfactorily and effectively implemented QARD Section 12.2.1 in that the issue related to the adequacy of the calibration of the Vaisala probes was not resolved prior to the initiation of quality affecting experiments using those probes.

1.5.4 Linearity of the Vaisala Probes

The calibration of an instrument involves the selection of reference standards with known values to cover the range of interest; measurements taken against these reference standards at selected points with the instrument to be calibrated; and the development of a calibration curve. The calibration curve may or may not be linear, but it is developed with sufficient calibration points such that the characteristics of the instrument are known throughout the entire range of use with uncertainties sufficiently defined to understand the limitations on the data collected.

In DOE's response letter, the position was taken that the calibration performed by Vaisala was sufficient for the use of the probes in the experiments at LLNL. The basis for this conclusion was provided by DOE on page 35 of Enclosure 1, which stated: "*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.*" Since Vaisala only performed their calibration at a single temperature (23°C), the staff assumes the reference made to a multipoint method was the Vaisala test report results provided on the CD included with Enclosure 3 of DOE's response letter. The staff notes that this test report, which was referenced as proprietary in Condition Report 2247, was not available to the LLNL staff at the time the SCI-474 and SCI-484 experiments were being conducted using the Vaisala probes.

After reviewing the Vaisala test report, the staff finds that the report documented readings at temperatures well beyond any available calibration standard. The test report, at best, represented a benchmark test of how the Vaisala probes respond to various humidity levels at various temperatures. Since the temperatures the probes were exposed to above 70°C cannot be related back to a qualified referenced standard, the test report data does not meet the criterion of being a calibration performed under a qualified quality assurance program. Therefore, DOE's assertion that "appropriate standards" were used to establish linearity of the probes cannot be substantiated for the entire range of -40°C to +180°C, since there are no nationally recognized calibration standards above 70°C, according to Condition Report 2247 and the calibration vendor,

to compare the test readings to. Therefore, the readings taken beyond the calibrated points during the Vaisala tests are simply reference readings on the probe with no basis to support their accuracy.

Since LLNL did not have access to the Vaisala test report, they could not make a determination of whether the Vaisala probes were adequate to meet the uncertainty requirements established for the experiments. According to the statement on page 15 of Enclosure 3, the BSC Manager of Post Closure Activities had provided a memo identifying 5% as the acceptable uncertainty for the probes at 180°C. As part of the evaluation of the LLNL data performed by DOE, in response to the NRC's Audit Observation Report, NIST was asked to calculate an estimated uncertainty for the LLNL data that had been collected. This estimate was provided by letter from NIST, dated May 26, 2006, and was included as Appendix A to Enclosure 3. As stated on page 29 of Enclosure 3, the estimated uncertainty determined by NIST was 7% for the data collected between 1998 and 2004, a value in excess of the stated 5% acceptable uncertainty.

The staff also reviewed the data collected in the Vaisala test report. Although a plot of the data does show a linear response for portions of the range from of -40°C to +180°C, it does not demonstrate a linear response at the lower and upper ends of this range. For example, on page 3 of the February 19, 2003 test report, a table was provided showing percent error for the relative humidity measurements at various temperatures. At 177.9°C, the humidity reading of 8.3% relative humidity was recorded when the expected value was 6.2%, resulting in a 2.1% relative humidity error. This equates to a 33% error between the expected reading versus the reading taken using the probe. Therefore, based on the review of the information provided to the NRC, the staff does not find the basis for establishing the linearity of the probes at elevated temperatures to be supported by the objective evidence nor does the data collected meet the uncertainty criteria established by the BSC Manager for Post Closure Activities.

1.5.5 Requirement to Establish a Basis for Calibration when a Nationally Recognized Standard Is Not Available

During the period from 2004 to 2005, LLNL recognized the need to establish a defensible basis for the use of the Vaisala probes at temperatures above the calibrated range of the Thunder Scientific, Inc. calibration service. LLNL had issued Condition Report 2247 and Condition Report 5430, which included numerous references to the calibration issues and references to the bi-thermal calibration process as a potential solution. For example, Action Number 5430-005, on page 21 of Condition Report 5430, stated:

"If the two-temperature system can be used to adequately calibrate relative humidity probes at elevated temperatures, a LLNL-YMP Technical Implementation Procedure (TIP) will be written and followed to ensure consistency. The TIP will include justification for using a calibration process that is not traceable to NIST, (i.e., there is no NIST traceable standard for the calibration of temperature and humidity sensors above 60 °C.)" [emphasis added]

During the NRC observation of the audit activities at LLNL during the week of August 22, 2005, LLNL provided a tour and description of the bi-thermal experiment to the audit team and NRC observers and provided a draft of Technical Implementing Procedure (TIP)-CM-72 "Calibration of Relative Humidity (RH) Meters Using the Bi-thermal RH Calibration System." Procedure TIP-CM-72 correctly stated the intent of the procedure to perform calibrations on the Vaisala probes for use at the elevated temperatures in both the purpose and scope as stated below:

Section 1.0 Purpose: *"This technical implementing procedure describes the process to calibrate [emphasis added] relative humidity probes used in high temperature applications using a bi-thermal system."*

Section 2.0 Scope: *"This procedure is applicable to LLNL personnel assigned to the Yucca Mountain Project. It addresses the calibration of Vaisala Temperature/Relative Humidity probes used in scientific experiments at temperatures from 115 to 160 °C." (Note that Section 4.1 and following sections of the TIP reference the upper temperature range as 180 °C as opposed to the 160 °C value).*

It was NRC's audit observers understanding during the LLNL site visit that Procedure TIP-CM-72 had been written to satisfy the QARD 12.2.1 requirement related to the lack of a national standard for calibrating the Vaisala probes at the high temperatures. LLNL was correct in their decision to develop and document a basis for calibrating the Vaisala probes at the higher temperatures. However, it is noted that QARD Section 12.2.1.A, not only requires the basis for the calibration to be documented, but also requires that the measuring and test equipment be calibrated, adjusted and maintained as a unit at prescribed intervals or prior to use. This means that "post calibration" of the Vaisala probes would not meet the requirements of the QARD.

DOE's response to the NRC issue described in the NRC Observation Audit Report, Section 4.4.6, discussed LLNL's plans to perform a bi-thermal experiment described in Scientific Notebook SCI-487-V1. DOE stated on page 17 of the Independent Review Team Report, provided as Enclosure 3 to the response letter, that:

"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 requirements for documenting and approving the development of methods to calibrate M&TE where no nationally recognized standards are available." DOE continued by stating on the following paragraph: "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 alternate calibration [emphasis added] process under LP-12.1Q-BSC."

Although the bi-thermal calibration process described in Scientific Notebook SCI-487 and Procedure TIP-CM-72 may provide a basis for an acceptable calibration of the Vaisala probes at temperatures above which a nationally recognized standard is currently available, the adequacy of this calibration process has not been determined by DOE. Irrespective of the acceptability of this process, the bi-thermal experiment to calibrate the Vaisala probes was planned for implementation after the SCI-474 and SCI-484 experiments had been completed and data collected. In fact, it is the staff's understanding that the bi-thermal experiments have yet to be completed. The staff's concern expressed in the NRC Observation Audit Report was that QARD Section 12.2.1.A, required establishing the basis for calibrating the humidity probes and performing the calibrations prior to conducting the experiments to collect data at elevated temperatures. Conducting the bi-thermal calibration of the Vaisala probes after using the probes to collect data (i.e., post-calibration) is not consistent with the provisions of the QARD, nor NRC's expectations for collecting data that would be used to support a potential license application, and does not provide a scientific basis that the humidity probes were responding accurately at the beginning of the experiments. Post-calibration only confirms that the probes are responding accurately at the end of the experiments. Probe performance during the experiments is indeterminate.

The staff is concerned that DOE has not demonstrated that the bi-thermal process provides an adequate basis for calibration of the Vaisala probes at temperatures above which a nationally recognized standard is currently available. The staff also notes the comment made in the May 26, 2006, NIST letter, included in Appendix A to Enclosure 3, on page 27 which states "*Until the uncertainty of the bi-thermal calibration system is firmly established, it is recommended that the results of the bi-thermal calibration system be treated as provisional [emphasis added].*" The NIST letter also provided an assessment of the LLNL bi-thermal calibration process in regard to ISO 17025:2005 Standard "General Requirements for the Competence of Calibration and Testing Laboratories." ISO 17025 provides a broadly accepted guide of good practices for calibration laboratories. Starting on page 27, the NIST letter identified that for most of the specific conformance sections of ISO 17025, LLNL was in compliance. However, for compliance with Section 5.9.1, quality control procedures for monitoring the validity of tests and calibrations undertaken have not been established and were out of conformance with ISO 17025 guidance.

After reviewing the response concerning the calibration of the probes, the staff finds that DOE had documented a basis for a calibration method where a nationally recognized standard did not exist. However, the information provided indicated that the technical basis to support the use of the bi-thermal process, as a calibration method, has not been established. Therefore, the staff does not agree with the conclusion that LLNL had satisfactorily and effectively implemented QARD Section 12.2.1.A related to the SCI-474 and SCI-484 experiments, in that this calibration method had not been performed prior to use of the probes to collect quality affecting data above 70°C.

1.5.6 Use of "Limited Calibration" Stickers to Control the Use of the Vaisala Probes

The staff has reviewed DOE's response related to the issue of tagging, segregating and controlling the Vaisala probes identified in Condition Report 2247 to prevent their use. The NRC audit team observers had identified that the Vaisala probes at LLNL had not

been tagged with a "Limited Calibration" sticker in accordance with Procedure LP-12.1Q-BSC "Control of Measuring and Test Equipment." This issue is discussed in Section 4.4.8 of the NRC Observation Audit Report.

DOE's response, as provided on pages 15 and 16 of Enclosure 3 "Independent Review Team Report," discussed placing tags on probes that had exceeded their calibration due date. In the conclusion, DOE stated that *"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."*

Although the finding does support a non-compliance with the procedure and the QARD where M&TE was used after their calibration due date, DOE did not address the original issue identified by the NRC concerning why the Vaisala probes identified in Condition Report 2247, whether within their calibration due date or not, were not tagged to prevent their use outside the calibrated range of the instrument until the calibration issue was resolved. Procedure AP-12.1Q "Control of Measuring and Test Equipment," Revision 0 was in effect at the time Condition Report 2247 was issued. This procedure was replaced with Procedure LP-12.1Q "Control of Measuring and Test Equipment," Revision 0 on February 4, 2005, and was the procedure in effect when Condition Report 5430 was issued. Both procedures provide similar guidance related to handling M&TE which should be labeled as "Limited Calibration." Limited calibration is defined as *"M&TE that is calibrated to less than the full range, function, or accuracy specification."* If this condition occurs, both procedures direct the responsible individual to label the instrument with a "limited calibration" sticker and to determine the appropriate limits prior to use. Since Condition Report 2247 brought into question the adequacy of the calibration of the Vaisala probes at high temperatures, the probes should have been labeled with limited calibration stickers until the issue was resolved.

The staff finds that DOE's response to the issue related to the requirements of Procedure LP-12.1Q (formally AP-12.1Q) did not address why LLNL had not properly labeled the Vaisala probes with limited calibration stickers, in response to the elevated temperature calibration issue identified in Condition Report 2247. The staff recommends that DOE resolve this issue by determining why the probes were not tagged to prevent use outside the calibrated range of the instrument until the calibration issue was resolved and take appropriate action to resolve this issue. The staff also recommends that DOE confirm that the requirements for tagging and controlling all M&TE until their calibration status is resolved is clearly specified in the QARD and implementing procedures and controls are established to assure that those requirements are followed.

1.5.7 Technical and Performance Issues Related to the Use of the Vaisala Probes

During the review of DOE's response, several other issues were identified related to the operability of the Vaisala HMP-243 temperature/humidity probes. These issues concerned: 1) probe drift and whether drift may vary at different temperatures; 2) the high number of out-of-calibration and out-of-service conditions found with the Vaisala probes after they were sent back to the calibration vendor for an annual calibration; 3) the manufacturer's recommendation for a 2-month calibration cycle when using the probes at high temperatures as opposed to an annual calibration cycle as used by

LLNL; 4) the use of the probes to measure humidity values up to 15% at 180°C as shown in the graph in Section 6.1.2.2 of ANL-EBS-MD-000074 "Analysis of Dust Deliquescence for FEP Screening," Revision 1 when the manufacturer recommended limiting the use of the probes to a maximum of 10% humidity at that temperature level; and 5) LLNL's use of the probes at temperatures of up to 180°C when the manufacturer identified that the probes may be adversely affected (degraded) by exposures from 150°C to 220°C, which at the latter temperature the probes would fail. The staff also notes that, the unusually high failure rate encountered during recalibration (Item #2 above) strongly indicates that probe performance was adversely affected by exposure to temperatures greater than 150°C, which further complicates any attempt to provide a post-experiment calibration. The staff recommends that DOE ensure that all technical issues related to limitations on the use of the Vaisala probes be well understood and compensated for as they relate to any data supporting the potential license application.

1.5.8 Documentation of the Calibration Status of the Vaisala Probes in Scientific Notebook SCI-484

The staff has reviewed DOE's response related to the NRC's concern that information provided in Scientific Notebook SCI-484 misrepresented the calibration status of the Vaisala probes. This issue was discussed in Section 4.4.6 of the NRC Observation Audit Report. DOE's response, as provided on pages 37-38 of Enclosure 1, stated: *"During the August 2005 audit and subsequent exit meeting, LLNL and BSC personnel did not misrepresent information, and the scientific notebook accurately reflected the status of the subject probes."* Pages 20-21 of Enclosure 3 provided additional information related to this issue.

The NRC audit team observer's comments during the site visit at LLNL concerned several entries in Scientific Notebook SCI-484 that documented the serial numbers for the Vaisala probes used in the SCI-484 experiments followed by a calibration due date establishing that the probes were currently calibrated. No notation was made in SCI-484 concerning the limitations on the probes at high temperatures as identified in Condition Report 2247 which had been issued prior to the start of the SCI-484 experiments. The researchers and the Engineering Assurance Representative who approved the Scientific Notebook Compliance Review Worksheet for the SCI-484 experiments on August 6, 2004, were all involved with the calibration issue discussed in Condition Report 2247 and would have been aware of the instructions on page 20 of Condition Report 2247 that stated *"Investigators will document (make reference to) CR 2247 in open scientific notebooks identified as having used the Vaisala Temperature Humidity probes outside of their range of calibration."* SCI-484 was clear in identifying that the Vaisala probes would be used at the high temperatures identified as a concern in Condition Report 2247. On page 5 of SCI-484, under the heading of Environmental Conditions, the following statement is made *"The testing will be performed in an environmental chamber in which the temperature and relative humidity are controlled and measured. Test conditions are nominally 80 to 180 °C and 80% to 5% relative humidity."* The requirement to document that a nationally recognized standard or physical constant is not available as a calibration standard is included in Procedure AP-12.1Q (later replaced with Procedure LP-12.1Q). Step 5.2 of the procedure requires a justification for the basis of the calibration of the M&TE to be included on an attachment provided in the procedure or in the scientific notebook when no nationally

recognized standard or physical constant exists for use in performing the calibration. This procedurally required action was not completed by LLNL at the beginning of the experiments and no notation was included in Scientific Notebook SCI-484.

DOE's response letter does not explain why the researchers did not comply with the instructions in Condition Report 2247 or the requirements in Procedure AP-12.1Q by making the appropriate entry in Scientific Notebook SCI-484. Instead, as indicated in the root cause analysis associated with Condition Report 7418, the evaluation of this issue focused on what the NRC meant in its use of the term "misrepresentation." On page 38 of the root cause analysis, DOE determined that misrepresentation was synonymous with willful misrepresentation. Based on this determination, DOE management contacted the NRC manager who had signed the NRC's Observation Audit Report to ask if he had meant to portray the issue as willful misrepresentation. Upon learning that he had not, DOE then closed this issue. Page 27 of Enclosure 1 to the response letter stated: "*...the issue of misrepresentation was discussed with the NRC signatory of the Observation Audit Report 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 NRC had not made a determination of willfulness related to the LLNL scientific notebook. The NRC has an established process to determine willfulness of issues through an allegation review board. However, DOE used the NRC manager's statement as a basis for closing the misrepresentation issue without examining and providing an explanation of the real issue; why the scientific notebook entry incorrectly indicated the probes were calibrated, contrary to the statements in Condition Report 2247. As such, the staff does not agree with the conclusion that the "*scientific notebook accurately reflected the status of the probes.*" The staff recommends that DOE re-evaluate this issue, focusing on the actions that should have been taken in response to Condition Report 2247, and in compliance with Procedure AP-12.1Q, as opposed to focusing on the use of the term misrepresentation.

2.0 Other Technical Issues and Quality Assurance Issues Identified in the NRC Observation Audit Report

In addition to the five AOIs listed above, several issues were identified in the NRC Observation Audit Report related to technical issues and compliance issues with the QARD. The response concerning these issues was reviewed and comments are provided in the following sections.

2.1 Cleanliness of Specimens Used in Corrosion Rate Experiments

The staff has reviewed DOE's response concerning the availability of records pertaining to certain corrosion-rate experiments and the associated scanning electron microscope images. This issue was discussed in Section 4.4.9 of NRC's Observation Audit Report. DOE's response, as provided on pages 51-55 of Enclosure 1 and as discussed in Condition Report 7382 "All Data Images on Corrosion Testing Not Submitted to

Records,” adequately addressed the issue related to the availability of the records in the Records Processing Center and provided the MOL numbers demonstrating that this information had been entered into the system in the July 2003 time-frame.

The NRC audit team observers identified an issue concerning sample cleanliness and whether all scale had been removed from the sample specimens. DOE’s response stated on page 51, that further review identified only minor spots or stains present on the samples and that these optical artifacts do not contribute to the calculated weight loss and, therefore, corrosion rates.

However, the NRC audit team observers noted during the conduct of the audit that there appeared to be more than spots or stains present on the samples. The staff considers the technical aspects of this issue as very important because the results have a direct bearing on DOE’s determination of corrosion rates. As such, the staff recommends that DOE perform further evaluation of the images and document the basis for the conclusions.

2.2 Corrosion of Titanium Grade 24 Based on Titanium Grade 7 Data

The staff has reviewed DOE’s response concerning the adequacy of the technical justification in ANL-DSD-MD-000001 “Aqueous Corrosion Rates for Waste Package Material” to support the extrapolation of measured corrosion rates for Titanium Grade 7 to the modeling of Titanium Grade 24 corrosion rates and the Titanium Grade 7/24 weldments. This issue was discussed in Section 4.5.2.1 of NRC’s Observation Audit Report. DOE’s response, as provided on pages 43-44 of Enclosure 1, stated that DOE believes the general corrosion rate for Titanium Grade 24 is conservative compared to Titanium Grade 7. The NRC staff understands that a series of experiments to confirm these estimated values for the general corrosion rate for Titanium Grade 24 are currently underway. These experiments apparently include a determination of the general corrosion rates of similar materials (Titanium Grade 29 and/or Titanium Grade 23 with palladium) to Titanium Grade 24 under repository relevant environments. The staff will review the results of these activities as they become available.

2.3 Corrosion Scaling Factor for the Microbiological Induced Corrosion Model

The staff has reviewed DOE’s response to NRC’s observation that localized microbiological corrosion had been excluded from the waste package models without an adequately documented justification. This issue was discussed in Section 4.5.2.2 of the NRC Observation Audit Report. DOE’s response, as provided on pages 45-48 of Enclosure 1, described the basis for the assumption that providing a scaling factor for general corrosion is sufficient to represent the effects of microbial activity on Alloy 22 degradation rates in the repository environment.

The NRC Observation Audit Report stated that *“Although a general corrosion scaling factor was intended to represent a conservative approach, the exclusion of localized microbiologically influenced corrosion effects without a documented justification is identified as a weakness in the modeling used in the analysis model report.”* The NRC audit team observers had reviewed Analysis Model Report ANL-EBS-MD-000003

“General Corrosion and Localized Corrosion of Waste Package Outer Barrier,” during the audit and determined that DOE’s response letter continues to take the same position that was already presented in the analysis model report. The staff notes that DOE plans to incorporate additional discussions regarding the modeling of microbiological influenced corrosion, using a scaling factor for general corrosion, in the next revision of the analysis model report. Currently, the staff lacks sufficient information to conclude that microbiological induced corrosion is adequately bounded by the current assumptions applied to general corrosion. The staff recommends that future technical interactions be held to resolve this issue.

2.4 Use of the Corrective Action Program to Capture and Resolve Issues Related to the LLNL Experiments and NRC’s Audit Observations

Several issues were identified in the NRC Observation Audit Report concerning the use of the corrective action program related to the LLNL experiments and the conduct of the audit conducted by BSC. As a result of these issues, DOE entered a number of condition reports into the corrective action program as listed in Enclosure 2 “Crosswalk of AOIs, Weaknesses and Deficiencies from the NRC Report OAR-05-05, and Related Condition Reports” to the response letter. As part of our ongoing assessment of DOE’s corrective action program, the NRC staff will, as appropriate, review the related condition reports, the conclusions reached to resolve the issues and the effectiveness of the actions taken to close the condition reports. At the conclusion of our evaluation, the staff will issue a report of our findings.

3.0 Audit Planning and Implementation

Several concerns were identified by the NRC staff related to audit preparation and the conduct of the audit. These issues were discussed in Sections 4.2 and 4.3 of the NRC Observation Audit Report. DOE’s response, as provided on pages 49-51 of Enclosure 1, provided DOE’s views on the NRC observations.

Related to the preparation for the audit and the issue expressed by the NRC audit observation team of the change in the audit scope prior to the start of the audit and the delay in providing the audit checklist to the NRC, the staff notes that this issue has not occurred often, but has occurred on several previous occasions. For the NRC to effectively implement Manual Chapter 2410 responsibilities, changing of the audit scope on short notice or not making the audit scope clear to the NRC affects our planning and preparation which then affects our ability to have the correct personnel assigned and available to participate in the audit. To preclude this problem, the staff is requesting that DOE provide a briefing to the NRC of each audit that the NRC has identified to DOE that we plan to observe, at least three weeks before the audit. This briefing should cover the audit scope, *final* audit checklist, participants, and any travel arrangements that would be needed, related to audit activities at locations outside the Las Vegas area.

Regarding the issue of not including technical specialists in the site visit to LLNL, the NRC audit team observers found the opportunity to interface with the LLNL researchers on technical issues was very helpful in understanding the technical basis for several

conclusions reached in the analysis model report and for recognizing several issues that brought into question the adequate implementation of the QARD at LLNL. This site visit provided the NRC audit team observers with an enhanced technical perspective of the issues. The staff recommends that DOE include technical specialists in site visits where technical issues are included in the audit scope.