

January 26, 2005

MEMORANDUM TO: Michael E. Mayfield, Director
Division of Engineering Technology
Office of Nuclear Regulatory Research

FROM: Michele G. Evans, Chief **/RA/**
Engineering Research Applications Branch
Division of Engineering Technology
Office of Nuclear Regulatory Research

SUBJECT: AUDIT TRIP REPORT REGARDING INTEGRATED CHEMICAL
EFFECTS TESTING AT THE UNIVERSITY OF NEW MEXICO

On December 7-8, 2004, Kevin Coyne and Robert Tregoning, of the Office of Nuclear Regulatory Research, and Richard McIntyre, of the Office of Nuclear Reactor Regulation, conducted a quality assurance implementation audit of the Integrated Chemical Effects Testing (ICET) facility located at the University of New Mexico in Albuquerque, New Mexico. The purpose of the audit was to determine if testing activities conducted at the ICET facility were performed in accordance with a quality assurance program that complied with the applicable requirements of 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The attached trip report describes the results of this audit. The audit identified several findings that need to be resolved so that the testing conforms with 10 CFR 50, Appendix B requirements. A plan has been developed to address these findings prior to initiating additional testing. Should you require additional information, please contact Kevin Coyne at 415-1399.

Attachment: As stated

January 26, 2005

MEMORANDUM TO: Michael E. Mayfield, Director
Division of Engineering Technology
Office of Nuclear Regulatory Research

FROM: Michele G. Evans, Chief **/RA/**
Engineering Research Applications Branch
Division of Engineering Technology
Office of Nuclear Regulatory Research

SUBJECT: AUDIT TRIP REPORT REGARDING INTEGRATED CHEMICAL
EFFECTS TESTING AT THE UNIVERSITY OF NEW MEXICO

On December 7-8, 2004, Kevin Coyne and Robert Tregoning, of the Office of Nuclear Regulatory Research, and Richard McIntyre, of the Office of Nuclear Reactor Regulation, conducted a quality assurance implementation audit of the Integrated Chemical Effects Testing (ICET) facility located at the University of New Mexico in Albuquerque, New Mexico. The purpose of the audit was to determine if testing activities conducted at the ICET facility were performed in accordance with a quality assurance program that complied with the applicable requirements of 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The attached trip report describes the results of this audit. The audit identified several findings that need to be resolved so that the testing conforms with 10 CFR 50, Appendix B requirements. A plan has been developed to address these findings prior to initiating additional testing. Should you require additional information, please contact Kevin Coyne at 415-1399.

Attachment: As stated

DISTRIBUTION:

DRAA R/F DET R/F BPJain, DET A. Hsia, DET TQuay, NRR
MJohnson, NRR DThatcher, NRR SBlack, NRR RBarrett, NRR/DE

DOCUMENT NAME: G:\DRAA\KCoyne\UNM ICET Trip Report.wpd

OAD in ADAMS? (Y or N) Y ADAMS ACCESSION NO. ML043520114 TEMPLATE NO. RES-006
Publicly Available? (Y or N) Y DATE OF RELEASE TO PUBLIC _____ SENSITIVE? N

To receive a copy of this document, indicate in the box: "C" = Copy w/o encl "E" = Copy w/encl "N" = No copy

OFFICE	DRAA/RES	E	DIPM/NRR	ERAB/DET	SUNSI Review	ERAB/DET	E
NAME	KCoyne		RMcIntyre	RTregoning	RTregoning	MEvans	
DATE	12/17/04		12/17/04	1/26/05	6/30/08	1/26/05	

OFFICIAL RECORD COPY

Quality Assurance Program Implementation Audit for
Integrated Chemical Effects Testing at the University of Mexico

I. Purpose

On December 7-8, 2004, an NRC audit team composed of Kevin Coyne and Robert Tregoning, of the Office of Nuclear Regulatory Research, and Richard McIntyre, of the Office of Nuclear Reactor Regulation, conducted a quality assurance (QA) implementation audit of the Integrated Chemical Effects Testing (ICET) facility located at the University of New Mexico in Albuquerque, New Mexico. The purpose of the audit was to determine if testing activities conducted at the ICET facility were performed in accordance with a quality assurance program that complied with the applicable requirements of 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

II. Background

Pressurized water reactors (PWR) containment buildings are designed to contain radioactive material releases and to facilitate core cooling in the event of a loss of coolant accident (LOCA). The cooling process requires water from the break and from containment spray to be collected in a sump and recirculated. Concerns have been raised about the potential for accumulation of corrosion products to significantly degrade the capability to circulate water through the containment sump. The purpose of the ICET facility is to investigate corrosion product release under representative post-LOCA conditions and to study the possible interaction between the corrosion products (e.g. formation of gelatinous material of agglomerates, etc.) and the effects of these products on sump performance. The ICET program is being conducted as a joint research program between NRC and the Electric Power Research Institute (EPRI) under a Memorandum of Understanding (MOU) on Cooperative Nuclear Safety Research. An addendum to the EPRI/NRC MOU defines the testing program and the relationship between the NRC and nuclear industry for the ICET program.

The NRC selected the Los Alamos National Laboratory (LANL) as the prime contractor to conduct the testing. LANL subcontracted with the University of New Mexico (UNM) to implement the ICET program. Because data and results derived from this testing are expected to be used for safety-related analyses and evaluations, the EPRI/NRC MOU specified that the testing facilities and contractors be selected based, in part, on their ability to comply with the appropriate quality assurance requirements of 10 CFR 50, Appendix B.

The team noted that the NRC statement of work (SOW) for the ICET program and the associated LANL proposal stated that the work should be conducted consistent with the intent of the appropriate sections of 10 CFR 50, Appendix B, or ISO-9000. The team noted that this QA guidance was ambiguous in that 10 CFR 50, Appendix B, and ISO-9000 do not define technically equivalent QA programs. As discussed in SECY 03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," the NRC staff has identified several areas where an ISO-9000 program, by

ATTACHMENT

itself, would not meet the intent of 10 CFR 50, Appendix B. Despite the ambiguity in the ICET project QA requirements contained in the initial SOW, the team determined that LANL personnel intended to establish a QA program consistent with the requirements of 10 CFR 50, Appendix B, rather than ISO-9000.

III. Scope of Review

Because the ICET program is expected to provide data that will be used to support regulatory and licensing decisions concerning the performance of the safety-related emergency core cooling containment sump, the NRC staff intended for the testing program to be performed under a QA program that complied with 10 CFR 50, Appendix B. With regard to the procurement of safety-related services, 10 CFR 50, Appendix B, Criterion IV, "Procurement Document Control," specifies that, to the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of 10 CFR 50, Appendix B. Therefore, the team reviewed the extent of testing activities and identified the Appendix B criteria that were pertinent to the ICET program. The scope of the QA audit was based on these pertinent criteria.

IV. Summary of Findings and Observations

The team walked down the test facility, interviewed the facility operations staff, reviewed the ICET QA program and supporting procedures, and discussed the implementation of the QA program with the LANL and UNM principal investigators. At the time of the QA audit, test instruction ICET-PI-004, "Test Operations, Test #1 (NaOH at pH = 10)," was in progress.

Findings

The UNM ICET facility appeared to be well constructed and was in good material condition. Although the team identified several areas where the ICET QA program failed to comply with the requirements of 10 CFR 50, Appendix B, the ICET QA program provided a reasonable foundation to develop an Appendix B compliant QA program. The team identified the following QA program deficiencies in the ICET facility QA program:

- Individuals responsible for ICET project QA functions lacked sufficient independence from cost and schedule considerations.
- The ICET project QA Program Manual (QAPM) included adequate programmatic design control measures, however, the team identified some calculation control issues that could have been reasonably identified during an independent review process. The team concluded that these specific issues would not adversely affect ICET test program performance.
- The ICET QA program did not include a formalized process for selecting, reviewing, approving, and auditing suppliers. Furthermore, appropriate quality assurance requirements for procured activities were not passed on to suppliers

in procurement documents.

- The ICET QA program lacked sufficient controls for the preparation, review, and approval of QA Procedures (QAPs), project instructions, and design drawings. The ICET project team was unable to provide objective evidence that certain quality documents had been prepared and independently reviewed under the QA program. Furthermore, no controlled design drawings were produced to document critical features of the facility design.
- Test instruction ICET-PI-004, "Test Operations, Test #1 (NaOH at pH = 10)," lacked sufficient provisions for assuring that all pertinent test prerequisites were met. In particular, the procedure did not include verification steps for important initial test conditions such as coupon loading or the initial loading of concrete dust and latent debris.
- With the exception of instrumentation associated with the data acquisition system, the QAPM did not address the calibration of test instruments needed to assure test data validity. In particular, the team identified that instrumentation such as the flow totalizer and chemical analysis bench equipment were not programmatically addressed by the ICET QAPM.
- The ICET QAPM did not include requirements for quality audits of ICET activities. Although one QA surveillance of ICET activities had been documented, the team concluded that the surveillance report lacked sufficient objective evidence to substantiate the surveillance conclusions.

Observations/Recommendations

- Although the ICET QA program did not comply with 10 CFR 50, Appendix B, in all pertinent areas, it provided a good programmatic foundation for future improvements. The team concluded that the ICET QA program could be brought into 10 CFR 50, Appendix B, compliance provided that the findings described in this report were satisfactorily addressed.
- The staff should ensure that future NRC contracts for research intended to support safety-related regulatory applications unambiguously specify QA requirements consistent with 10 CFR 50, Appendix B. Reference to the QA requirements of ISO-9000 may lead to confusion if the intent of the project is to establish a QA program capable of providing safety-related data or analyses under 10 CFR 50, Appendix B, QA program.
- The ICET project team should evaluate the need to establish a long term deficiency reporting process similar to that required of a safety-related vendor under 10 CFR Part 21. This evaluation should consider if there is a reasonable potential to identify defects following ICET project closeout and, if so, identify a process to report these defects to the appropriate organization.

V. Detailed Observations

The results of the team's review of the ICET QA program is summarized in the following sections.

1. Organization

Scope

The audit team reviewed the organizational relationships established to support the ICET program to verify that quality assurance functions were performed with sufficient independence from cost and schedule considerations. 10 CFR 50, Appendix B, Criterion I, "Organization," states in part that the persons and organizations performing the quality assurance function shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. In particular, such persons and organizations performing quality assurance functions shall report to a management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

Observations

The ICET project organization was described in ICET QA Program Manual (QAPM), Section 1.0, "Organization." Although the ICET QA Program Manual described the relationships between the NRC, EPRI, LANL, and the University of New Mexico, QA functions were distributed among the program participants, with no single individual or organization identified as having overall responsibility for the quality assurance program. In discussions with program participants, the team determined that the LANL principal investigator was the main individual responsible for creation and implementation of the QA program. However, Section V, "Management and Personnel," of LANL Proposal R-2986-04-0 for the ICET program identified the LANL PI as being responsible for the technical integrity, schedule, and financial performance of the work. Therefore, the team concluded that QA functions were being performed without sufficient independence from cost and schedule.

The team noted that LANL procured the services of a consultant to provide independent QA support for the ICET project. However, LANL was unable to demonstrate through objective and documented evidence that the QA consultant provided a level of independent QA oversight consistent with the intent of 10 CFR 50, Appendix B, Criterion I.

Conclusions

The team concluded that the individuals responsible for ICET project QA functions lacked sufficient independence from cost and schedule considerations.

2. Quality Assurance Program

Scope

Criterion II, "Quality Assurance Program," states, in part, that quality assurance program shall be established that complies with the requirements of 10 CFR 50, Appendix B. Additionally, this program shall be documented by written policies, procedures, or instructions. Additionally, the program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained. The team reviewed the ICET QA program to determine if a QA program addressing the pertinent requirements of 10 CFR 50, Appendix B, had been established.

Observations

The ICET QA program was defined in the ICET project QA Program Manual (QAPM). The QAPM specified that quality control for the ICET project was to be consistent with the intent of the appropriate sections of 10 CFR 50, Appendix B. The team determined that the QAPM addressed each of the criteria that were pertinent to the project with the exception of auditing requirements contained in Criterion XVIII of 10 CFR 50, Appendix B. The teams' findings in this area are discussed in Section V.11, "Audits," below. Specific requirements contained in the QAPM applicable to the ICET project were implemented through more detailed Quality Assurance Procedures (QAPs). As described in the remainder of this report, the team determined that the ICET QAPM and associated QAPs did not comply with 10 CFR 50, Appendix B, requirements in all pertinent areas. However, the QAPM provided a good programmatic foundation for future improvements.

The QA program included specific requirements for indoctrination and training of personnel performing activities affecting quality for the ICET project. The team reviewed ICET project training records and determined that the training program met the requirements of 10 CFR 50, Appendix B, Criterion II.

Conclusions

Although the ICET QA program did not comply with 10 CFR 50, Appendix B, in all pertinent areas, it provided a good programmatic foundation for future improvements. The team concluded that the ICET QA program could be brought into 10 CFR 50, Appendix B compliance if the findings described in this report were satisfactorily addressed.

3. Design Control

Scope

10 CFR 50, Appendix B, Criterion III, "Design Control," states that measures shall be established to assure that applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures, and instructions. The team reviewed the design control measures used to ensure that technical requirements

contained in the ICET project test plan were appropriately translated into procedures, instructions, and drawings.

Observations

Section 3 of the ICET Project QAPM contained a description of the design control measures applied to the project. These measures included documentation, review, approval, and control of design inputs, technical reports, and supporting calculations that define or verify test loop design and test parameters. The QAPM design control measures were implemented by QAP 3.1, "Design Control," QAP 3.2, "Technical Documents," and QAP 3.3, "Design Calculations and Analysis." The team reviewed these QAPs and found them to be consistent with the ICET project QAPM. The team also reviewed a sample of calculations associated with the test tank design and operation, including Calculation ICET-CALC-002, "Coupon Location in Racks Calculation," ICET-CALC-003, "CPVC Pipe Leachability Test Calculation," ICET-CALC-005, "Gasket Leaching Test Calculation," and ICET-CALC-006, "Submerged Coupon Water Velocities." Although these calculations were reviewed and approved, the team noted several issues associated with the technical quality of the calculation documentation, including:

- the use of engineering judgement in calculation ICET-CALC-003 and ICET-CALC-005 was inconsistently documented and justified;
- minor math errors in the coupon rack loading calculation; and,
- the calculation method used to determine submerged coupon water velocities was not well documented and could not be independently verified without extensive discussions with the LANL PI.

The team determined that these calculation issues could have been reasonably identified during an independent calculation review. Although these issues highlight weaknesses in the independent review process for calculations, the team concluded that the calculations were adequate to support the ICET test program. In particular, the UNM PI provided additional information during the audit to justify the inconsistently documented engineering judgement used in calculation ICET-CALC-003 and ICET-CALC-005. Further, UNM performed dye testing to verify submerged coupon water velocities which mitigated the importance of the ICET-CALC-006 results. The team also concluded that the minor math errors in the test coupon loading calculation should not adversely impact the test results provided the as-tested coupon loading configuration was adequately documented.

Conclusions

The ICET project QAPM included adequate programmatic design control measures, however, the team identified some calculation control issues that could have been reasonably identified during an independent review process. The team concluded that these specific issues would not adversely affect ICET test program performance.

4. Procurement Document Control and Control of Purchased Material, Equipment, and Services

Scope

The team reviewed the procurement controls used for the ICET test program. In particular, the team reviewed the procurement controls implemented for LANL contracts with the University of New Mexico, Assaigai Analytical Labs, and Secor, Inc. 10 CFR 50, Appendix B, Criterion IV, "Procurement Document Control," states, in part, that measures shall be established to assure that requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services. Furthermore, 10 CFR 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services," states that measures shall be established to assure that purchased material, equipment, and services conform to procurement documents. These measures shall include provisions for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of or products upon delivery.

Observations

The team reviewed the ICET project quality requirements for procuring materials, components, and services for use at the ICET test facility at UNM. QAPM Section 7.0, "Control of Test Material, Equipment and Services," and QAP 7.1, "Control of Test Material, Equipment and Services," establish the technical and quality requirements for the procurement of material, equipment and technical services for subcontractors that support the ICET project. In reviewing these documents, the team concluded that the QAPM and QAP did not include processes for supplier source evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; and QA program implementation inspections at the supplier source.

Three subcontractors were used by LANL to support the ICET test program: (1) Assaigai Analytical Labs, Incorporated (AALI) provided chemical analysis support; (2) the University of New Mexico implemented the ICET program; and (3) Secor, Incorporated provided independent QA review support. The team determined that a formalized process was not used to select, review, and assess the quality performance of these contractors. This was evidenced by the fact that Assaigai was performing chemical analyses for UNM without the benefit of a formal audit of their technical capabilities. Also, appropriate quality assurance requirements were not passed down to contractors in the procurement documents. For example, the LANL Task Order contract with UNM specified that testing performed by UNM at the ICET facility will be conducted under an "informal quality assurance program" rather than under the formal ICET QA program. Additionally, LANL Task Order contract with AALI did not invoke any quality assurance requirements for water chemistry analysis activities.

The team reviewed the capabilities of UNM and AALI and did not identify any issues that indicated that these suppliers were unable to perform the required activities. Although SECOR provided QA support services, these services did not directly impact the conduct of the test program.

Conclusions

The ICET QA program did not include a formalized process for selecting, reviewing, approving, and inspecting suppliers. Furthermore, appropriate quality assurance requirements for procured activities were not passed on to suppliers in procurement documents. However, the team reviewed the capabilities of UNM and AALI and did not identify any issues that indicated that these suppliers were unable to perform the required activities.

5. Instructions, Procedures and Drawings and Document Control

Scope

The team reviewed the programmatic controls established for QA program documents. In particular, the team reviewed the scope of written procedures prepared to support the ICET test program and the preparation, review and approval process for documents. The basis for this review is described under 10 CFR 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings," which states that activities affecting quality shall be prescribed by documented instructions, procedures, and drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, and drawings. Additionally, Criterion VI, "Document Control," states that measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality.

Observations

Several types of quality-related procedures were written by the ICET project team to support testing, including the ICET Project QAPM, QAPs, and project instructions. The project instructions were used to provide detailed instructions for the operation of the test loop.

The scope of QAPs and project instructions were adequate to cover testing activities. However, the team noted that there were programmatic weaknesses in the control of quality-related documents. For example, QAP 3.2, "Technical Documents," provided some guidance on the preparation, review and approval of the Project Basis Document and a final NUREG/CR report, but this guidance was not applied to the control of QAPs and project instructions. Additionally, the team noted several issues associated with the control of QAPs and project instructions:

- The official laboratory copy of project instruction ICET-PI-004, "Test Operations, Test #1 (NaOH at pH = 10)," had numerous pen-and-ink revisions to test parameters such as the simulated spray and chemical injection rates and water sampling requirements. In several cases, there was no objective evidence that the revisions had been independently reviewed. Although ICET-PI-004 had an informal "approved for use" signoff from NRC and EPRI project team members, the pen-and-ink changes were dated the day after these approval signoffs.
- The review and approval process for project instructions and QAPs was done

without the benefit of a formal QA process. The ICET project did not have a documented process for preparing, reviewing, approving, and revising QAPs and PIs.

- The ICET QAPM lacked programmatic controls for the preparation, review, and approval of controlled drawings. The team determined that controlled drawings should have been used to document the test facility configuration in a manner capable of supporting interpretation and independent verification test results. In reviewing the scope of testing activities, the team determined that a controlled drawing of the internal test tank configuration showing the orientation of the test coupon racks in relation to the test tank inlet headers, the outlet, and spray nozzles should have been prepared. Additionally, a controlled simplified flow diagram to document the recirculation and spray flow paths should have been issued to document the test loop configuration.

Based on the above observations, the team determined that the ICET project lacked adequate measures to control the preparation, review, and approval of QAPs, project instructions, and design drawings. However, the team determined that this issue would not invalidate the results of the ICET testing in progress at the time of the review, provided that the ICET project team adequately documents the as-tested configuration and updates project procedures and instructions in a manner consistent with 10 CFR 50, Appendix B, requirements.

Conclusions

The team concluded that the ICET QA program lacked sufficient controls for the preparation, review, and approval of QAPs, PIs, and drawings. The ICET project team was unable to provide objective evidence that QAPs and PIs had been prepared and independently reviewed under QA program controls. Furthermore, no controlled design drawings were produced to document critical features of the facility design. However, the team determined that this issue would not invalidate the results of the ICET testing in progress at the time of the review, provided that the ICET project team adequately documents the as-tested configuration and updates project procedures and instructions in a manner consistent with 10 CFR 50, Appendix B, requirements.

6. Test Control

Scope

The team reviewed the measures implemented to control testing activities. This included review of test instructions, a walk down of the test facility, interviews with test facility operators, and control of test parameters.

This review was based on the requirements of 10 CFR 50, Appendix B, Criterion XI, "Test Control," which states that a test program shall be established to assure that testing is performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. Test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the

test is performed under suitable environmental conditions.

Observations

The team walked down the test facility and determined that the facility material condition was good. In particular, the test equipment appeared to be in working order, test conditions such as temperature and flow were consistent with test plan requirements, and no leaks or obvious degraded conditions were identified. The team observed a daily chemistry sample and determined that the operating staff was knowledgeable about the test facility operation and followed appropriate test instructions.

In reviewing the project instruction ICET-PI-004, the team concluded that the procedure lacked sufficient documentation of test initial conditions. Although calculation ICET-CALC-002 specified test coupon loading based on test plan requirements, the test tank coupon loading configuration was not verified and documented in the test instruction. Additionally, the initial loading of concrete dust and latent debris samples for test 1 was not documented in ICET-PI-004. Based on the above observations, the team concluded that ICET-PI-004 lacked sufficient provisions for assuring that all pertinent test prerequisites were met. However, the team concluded that this weakness would not invalidate the testing results provided the ICET project team identified all pertinent test initial conditions and provided objective evidence that these conditions were met.

Conclusions

The team concluded that the project instruction ICET-PI-004 lacked sufficient provisions for assuring that all pertinent test prerequisites were met. In particular, the procedure did not include verification steps for important test initial conditions such as coupon loading or specify the initial loading of concrete dust and latent debris. However, the team concluded that this weakness would not invalidate the testing results provided the ICET project team identified all pertinent test initial conditions and provided objective evidence that these conditions were met.

7. Control of Measuring and Test Equipment

Scope

The team reviewed the measures implemented by the ICET project team to ensure that test instrumentation was properly controlled and calibrated. The team assessed the instrumentation used to support testing, associated calibration records, and programmatic controls for the instrument calibration program. The review was based on the requirements of 10 CFR 50, Appendix B, Criterion XII, "Measuring and Test Equipment," which states that measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

Observations

The team reviewed the quality requirements for calibration of critical equipment and

instrumentation at the ICET facility. The ICET QAPM, Section 12.0, "Control of Measuring and Test Equipment," and ICET-PI-001, "Data Acquisition Setup and Inspection," described calibration activities for the ICET project. However, the team determined that these calibration controls applied only to equipment and instruments that supported the Data Acquisition System (e.g., thermal couples, Ph electrode, pump variable frequency drive loading, and test loop flow). Other critical test loop and bench equipment and instruments were not included in a formal calibration program. The team determined that several critical instruments, which did not support the digital acquisition system, should have been included in a formal calibration program, including the kinematic viscometer, turbidity measuring instrumentation, flow totalizer (used to measure test tank water volume), and tank water level indicator. Additionally, the ICET QA program did not specify any post-test calibration requirements.

In discussions with the LANL and UNM PI, the team determined that ICET project personnel had not performed a comprehensive review of calibration requirements for the instrumentation necessary to support test data collection. Therefore, the ICET team had not formally identified the complete scope of critical measuring and test equipment, and associated calibration requirements, needed to support the ICET project.

Although the ICET QAPM did not include calibration requirements for all pertinent test instrumentation, the team reviewed available calibration records for a sampling of instruments such as the kinematic viscometer and turbidity measurement equipment and did not identify any immediate concerns with equipment function. However, the team concluded that the ICET project personnel should conduct a comprehensive review of instrumentation and measurement equipment needed to support the ICET project in order to identify critical instrumentation and associated calibration requirements.

Conclusions

With the exception of instrumentation associated with the data acquisition system, the QAPM did not address the calibration of test instruments needed to assure test data validity. In particular, the team identified that instrumentation such as the flow totalizer and chemical analysis bench equipment were not programmatically addressed by the ICET QAPM. However, based on a sampling review of equipment calibration records, the team did not identify any immediate concerns with ICET instrumentation function.

8. Handling, Storage, and Shipping

Scope

The team reviewed the programmatic controls for handling and storage of test coupons, performed a walkdown of the test coupon storage area, and discussed test coupon control with the LANL PI. This review was based on 10 CFR 50, Appendix B, Criterion XIII, "Handling, Storage, and Shipping," which states that measures shall be established to control the handling, storage, shipping, cleaning and preservation of materials in accordance with work and inspection instructions to prevent damage or deterioration. Because the test coupons were supplied by EPRI, the handling, storage, and shipping controls prior to the receipt of coupons at the UNM facility were outside the scope of this

audit.

Observations

Project instruction ICET-PI-002, "Coupon, Receipt, Preparation, and Storage," provided instructions for pre-test and post-test handling of test coupons. The team determined that ICET-PI-002 provided sufficient guidance for the initial receipt inspection, pre-test, and post-test handling of test coupons. However, neither the project instruction nor the ICET QAPM provided guidance for the storage of test coupons. During a walkdown of the test coupon storage area, the team determined that the coupons were satisfactorily stored in a limited-access environmentally controlled area.

Conclusions

With the exception of a lack of programmatic controls for test coupon storage, the team concluded that controls for test coupon handling were adequate. The team determined that the lack of programmatic controls for test coupon storage had a minimal impact because test coupons were being stored in a limited-access, environmentally controlled area.

9. Corrective Action

Scope

The team reviewed the measures used by the ICET project team to identify, evaluate, and resolve conditions adverse to quality. This review was based on the requirements of 10 CFR 50, Appendix B, Criterion XVI, "Corrective Action," which states that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

Observations

Programmatic guidance for the ICET corrective action program were described in procedure QAP 16.1, "Corrective action Reports." The team reviewed this procedure and concluded that the programmatic controls for corrective action reporting, evaluation, resolution were adequate. The team also determined that the three corrective action reports written by project personnel at the time of the audit were processed in a manner consistent with project QA requirements.

The team questioned if the ICET project team had considered the potential for reporting conditions adverse to quality after project closeout. The team was concerned that adverse conditions, such as calculation errors, test loop design deficiencies, or equipment calibration issues discovered after project closeout, could impact the ICET test data. Although the ICET QAPM did not include a process for long term reporting of defects, the team recommended that the ICET project team evaluate the need for a long term deficiency reporting program. This evaluation should include a determination if adverse conditions identified after project closeout could reasonably affect the validity of test data.

Conclusions

The team concluded that a corrective action program appropriate for the scope of testing activities and consistent with the requirements of 10 CFR 50, Appendix B, had been implemented for the ICET test program. The team recommended that the ICET project team evaluate the need to implement a long term deficiency reporting program following project closeout.

10. Quality Assurance Records

Scope

The team reviewed the measures established for the control of quality records associated with the ICET project. This review was based on the requirements of 10 CFR 50, Appendix B, Criterion XVII, "Quality Assurance Records," which states, in part, that sufficient records shall be maintained to furnish evidence of activities affecting quality and that these records shall be identifiable and retrievable.

Observations

Because the quality record storage location for ICET project was located at the Los Alamos National Laboratory, the team was unable to observe actual record storage practices. However, based on a review of the ICET QAPM and QAP 17.1, "Records Management," the team determined that an adequate quality record management program had been established for the ICET project. In particular, QAP 17.1 specified sufficient controls to ensure that QA records could be identified and retrieved. Additionally, the LANL PI stated that a QA record custodian had recently been assigned to the project.

Conclusions

The team concluded that adequate programmatic controls had been established for QA records management. However, because the official records storage location was at LANL, the team was unable to observe the implementation of these controls.

11. Audits

Scope

The team reviewed the programmatic controls established for QA auditing and surveillance activities. This review was based on the requirements contained in 10 CFR 50, Appendix B, Criterion XVIII, "Audits," which state, in part, that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

Observations

The ICET QAPM did not include any requirements for quality audits of ICET activities.

Despite this programmatic weakness, LANL subcontracted with Secor, Inc., to provide QA review support. This support included the performance of a quality assurance surveillance. The team reviewed the QA surveillance report dated December 7, 2004, and determined that report lacked sufficient objective evidence to substantiate the audit conclusions. The lack of well documented, independent, QA surveillance and audit activities was more significant in light of the absence of an independent QA function for the ICET program (as discussed in Section V.1, above).

Conclusions

The ICET QAPM did not include any requirements for quality audits of ICET activities. Although one QA surveillance of ICET activities had been documented, the team concluded that the surveillance report lacked sufficient objective evidence to substantiate the surveillance conclusions.

VI. Personnel Contacted

J. Dallman	LANL
J. Kindinger	LANL
P. McClure	LANL
K. Howe	UNM
B. Letellier	LANL
J. Gisclon	EPRI
W. Seier	Secor, Inc.

VII. Documents Reviewed

<u>Document Number</u>	<u>Description</u>	<u>Revision</u>
Test Plan	Characterization of Chemical and Corrosion Effects Potentially Occurring Inside a PWR Containment Following a LOCA	Revision 12.a
LANL Task Order No. 0409J-120-04 3C	Subcontract with University of New Mexico to support debris head-loss and chemical-effects testing	
LANL Task Order No. 12296-001-05 39	Subcontract with Assaigai Analytical Labs, Inc., for water chemistry analysis support	
LANL Task Order No. 07678-001-04 89	Subcontract with SECOR, Incorporated, for quality assurance program support	
	Integrated Chemical Effects Test Project Quality Assurance Program Manual	Revision 0
QAP 2.1	Quality Assurance Training	Revision 0
QAP 3.1	Design Control	Revision 0
QAP 3.2	Technical Documents	Revision 0
QAP 3.3	Design Calculations and Analysis	Revision 0
QAP 5.1	Preparation and Control of QA Manuals and Procedures	Revision 0
QAP 6.1	Document Control	Revision 0
QAP 7.1	Control of Test Material, Equipment, and Services	Revision 0
QAP 16.1	Corrective Action Reports	Revision 0
QAP 17.1	Records Management	Revision 0

<u>Document Number</u>	<u>Description</u>	<u>Revision</u>
ICET-PI-001	Data Acquisition System Setup and Calibration	Revision 0
ICET-PI-002	Coupon Receipt, Preparation, Inspection, and Storage	Revision 0
ICET-PI-003	Pre-Test Operations	Revision 0
ICET-PI-004	Test Operations	Revision 0
ICET-PI-005	Sampling and Chemical Analysis	Revision 0
ICET-PI-006	Fiberglass Inspection	Not Issued
ICET-PI-007	Gel Characterization	Not Issued
ICET-PI-008	Post-Test Operations	Revision 0
ICET-PI-009	DAS Alarm Response	Revision 0
	Memo from W. Seier to J. Dallman re. "Quality Surveillance Activities for the ICET Project"	December 7, 2004
CAR-001	During initial shakedown testing with the tank and piping full of water, 7 welds were identified as leaking water	October 18, 2004
CAR-002	During pre-test operations on November 14, 2004, the tank and loop were flushed with ammonia that was purchased over the counter. Upon inspection of the tank interior on November 15, spots on the tank walls and streaks looking like rust were observed in several places	November 16, 2004
CAR-003	Approximately 22 hours of data were not recorded by the DAS due to Excel file error	November 26, 2004
	Certificate of calibration for Viscometer No. 50 Z809	July 6, 2004
Certificate of Calibration Report No. 64045-1	Thermocouple input module serial calibration report	November 15, 2004
Calculation ICET-CALC-002	Coupon Location in Racks	
Calculation ICET-CALC-003	CPVC Pipe Leachability Test	

<u>Document Number</u>	<u>Description</u>	<u>Revision</u>
Calculation ICET-CALC-005	Gasket Leaching Test	
Calculation ICET-CALC-006	Submerged Coupon Water Velocities	
	ICET Test No. 1, Progress Report No. 1	December 1, 2004