

## **SUMMARY OF NRC/DOE QUARTERLY QUALITY ASSURANCE MEETING APRIL 18, 2002**

This NRC/DOE Quarterly Quality Assurance Meeting was held on April 18, 2002 in Las Vegas, NV with video and audio connections to the NRC office in Rockville, MD, the DOE offices in the Forrestal Building, the Center for Nuclear Waste Regulatory Analyses (CNWRA or the Center) in San Antonio, TX and the Region IV NRC offices. A copy of the agenda is attached (Enclosure 1). A list of attendees is on Enclosure 2. The meeting convened with opening remarks from J. Russell Dyer (DOE). Dr. Dyer's opening remarks are included immediately following the summary of Dr. Chu's remarks.

### **Summary of Dr. Margaret Chu's Remarks**

In her opening remarks, Dr. Margaret S. Y. Chu, Director of DOE's Office of Civilian Radioactive Waste Management (OCRWM), stated her belief that the program is very important to the nation and its security. She believes that quality assurance (QA) is critical to assuring the scientific integrity of the program, and she intends to assure that the QA program is implemented in a manner that will support a successful license application. She emphasized her belief that OCRWM's QA program should:

- Strike the right balance between process and objective;
- Not only identify problems but properly focus on effective corrective actions; and
- Be proactive, not just a reaction to audits or CARs.

She has assigned Gene Runkle of her staff to assist the Yucca Mountain Site Characterization Office in achieving timely and continuous improvements in the QA process.

With regard to selecting a new Director of the Office of Quality Assurance, Dr. Chu indicated that she understands the urgency associated with filling this position and will do so deliberately to assure the right selection. She further indicated that she expects to interact with the NRC frequently and actively encourages feedback from the NRC.

The NRC indicated that they were gratified and encouraged by Dr. Chu's understanding of the importance of management involvement in solving the problems in DOE's QA program.

### **Dr. Russell Dyer's Opening Remarks**

Dr. Dyer stated that the Yucca Mountain Site Characterization Office (YMSCO) is completely on board with Dr. Chu's approach; her involvement and support is key to the project's success.

Both the BSC General Manager (Mr. Ken Hess) and the YMSCO Project Manager (Dr. Dyer) have substantially increased their personal involvement in the development of the OCRWM

Management Improvement Initiatives (OMII) and will continue personal oversight of the implementation of the CAR and OMII actions.

- YMSCO and BSC management has taken a far more aggressive approach to the problems than in the past;
- OMII is the DOE plan for bringing the Project's culture to a level needed to support licensed activities;
- OMII has been given new leadership and a substantial infusion of resources by DOE, BSC, the National Laboratories and USGS;
- DOE and BSC are re-evaluating the actions in the OMII and are significantly increasing the detail and, in some cases, the comprehensiveness of the planned actions;
- The Project is focusing the actions for the Software and Modeling CARs' root causes to significantly improve DOE's ability to prevent recurrence;
- The OMII will be a prepared, issued and administered under the DOE QA program procedures;
- The CAR corrective actions will be addressed via Procedure AP 16.1Q "Management of Conditions Adverse to Quality" and also tracked in OMII;
- OMII will contain all action plans;
- Performance metrics will be established and individuals assigned actions will be held accountable. DOE will provide the NRC with their plans for self assessments and QA oversight of the OMII by both DOE and BSC;
- The results of the performance measures, self assessments and results of QA oversight will be used to identify necessary course changes in our program.

DOE has also chartered a joint DOE and BSC senior management team to conduct a lessons learned evaluation of the past problems in approaching CAR root causes and OMII development.

- Their objective is to identify and implement lessons learned in the DOE QA Program.
- To date, they have identified a need to conduct a CAR/Root Cause conflict resolution meeting and the necessity to amend the CAR 001 Response.

Dr. Dyer stated that he would keep the NRC informed as that effort progresses.

Dr. Dyer indicated that DOE has an extensive set of performance metrics which will be provided to the NRC staff monthly. In many cases, the metrics appear to show positive performance; for example, the number of open quality deficiencies and their average age is declining, indicating that successful implementation of corrective actions.

However, he indicated that the statistic cannot be taken by itself, i.e. it does not tell it all:

- the total number of newly identified deficiencies has decreased over several months as has the percentage of new deficiencies issued by the BSC and DOE line organizations
- the number of deficiencies open for more than 100 days is increasing

Dr. Dyer indicated that he, Mr. Hess and the leadership team are more directly focusing on these and the other quality metrics than previously.

The OMII addresses improving YMP's self critical attitudes and the need to improve the ability for the line to identify and address conditions adverse to quality. The OMII Leadership Team (including the YMSCO Director, the BSC General Manager, and their senior staff) is meeting regularly to review progress and drive action. To improve management of the program, the YMP Deputy Project Manager has been designated as the "Project Corrective Action Coordinator." Further:

- BSC, the National Laboratories, USGS, and the DOE Office of Environmental Management are being directed to identify a responsible Point of Contact to interface with Dr. Dyer's organization and assist in the oversight and resolution of corrective action issues in their areas under the cognizance of the Corrective Action Coordinator;
- This responsibility includes evaluating performance metrics and ensuring that appropriate actions are taken in response to that data;
- This function will also assure that follow up actions such as self assessments to ensure that DOE corrective actions are effective.

Dr. Dyer noted that his opening remarks were more extensive than they have been in the past, reflecting the personal involvement and conviction of YMP senior management in improving performance. DOE intends to regularly update the NRC on status and results.

Quality Assurance Program Status (by Mr. Ram Murthy, Acting Director, OQA) – included as Enclosure 3

Primary topics discussed were the status of the QA organization, Corrective Action Report status, trending results/emerging issues and the Quality Assurance Requirements Document (QARD) revision.

The acceptance of the modeling CAR referred to in the presentation is, in fact, a modified response. Both CARs are being revisited to assure that there are appropriate and effective corrective actions. The NRC asked questions regarding the timing of issuing the Lessons Learned on these (and previous) CARs. The response is that completion of the Lessons Learned is fairly close, but that it is more important to get it done correctly than to issue it immediately.

Revision 12 to QARD is planned to incorporate the increased BSC QA responsibility. The NRC asked if the revision will be in place prior to giving BSC audit responsibility. DOE responded that this was the plan, but it was possible that the transition could take place prior to issuing Rev. 12 (although this would not reflect any reduction in QA commitments). Current timing for issuing Rev. 12 of the QARD is approximately six to eight weeks from the date of the meeting.

There was discussion of the planned revision to the QARD<sup>1</sup> to appropriately address the YMRP. NRC cautioned that the YMRP is a draft document and will not be finalized until after NRC obtains and evaluates public comments on it. Mr. Murthy acknowledged and stated

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<sup>1</sup> It is currently anticipated that this will be Revision 13 to the QARD.

that the QARD revision addressing the YMRP will be issued only after the final YMRP is issued and will take account of the changes as a result of the public comments. There was some discussion of what review criteria and/or comparison documents were being used for comparison with the YMRP. Ms. April Gil (DOE) indicated that licensing precedence from the commercial industry should be considered as a principal criteria. Mr. Stephen Cereghino (BSC) indicated that, to some extent, the Standard Review Plan (NUREG-0800) for power reactors was being used to support their review of the YMRP. Mr. Robert Latta (Onsite Representative, NRC) indicated that NUREG-0800 was not specifically applicable to YMP. Mr. Cereghino responded that comparable portions of NUREG-0800, particularly as they applied to similar types of systems (especially fuel handling, for example) were being used for review.

OCRWM Management Improvement Initiatives (presented by Mr. Joseph Ziegler) - Enclosure 4)

The primary points of Mr. Ziegler's presentation were:

- The OMII approach has been revised to strengthen the earlier document;
- Additional resources have been added and efforts increased to achieve additional buy-in down to the supervisory level;
- Actions are being taken to strengthen corrective actions;
- As part of developing the revised version, reviews were done against the documents originally intended for input to confirm that the plan, as revised, addresses the issues and the needed corrective actions;
- A cross-walk has been developed to identify the relationship between the OMII Action Summaries and Objectives and the original documents that identified issues and needed corrective actions (including the root cause analyses);
- Clear defined schedules for implementation of actions in the OMII will be included as part of the OMII;
- Performance metrics will be an integral part of the OMII to measure both progress in implementation and effectiveness;
- The OMII is a Program initiative that involves representatives from each program team member and requires that all of the Program/Project organizations act as a team in carrying out the actions of the OMII.

Aspects of the DOE program and reporting on its progress and results will be made visible to the project at large -- not just to managers. Responsible managers have been named at both DOE (Mr. Ziegler) and BSC (Ms. Nancy Williams). The intent is for this to be one program and for involved personnel to treat it as a single cooperative program. Part of the intent of the revision is to assure that results of the root cause analysis were properly included. When done, the outcome of OMII should be greater than the sum of its parts.

The NRC observed that the original January submittal did not meet NRC expectations as was confirmed by a team assisting the onsite representatives in evaluating the action summaries. It

now appears (with the April 5, 2002 letter) that OMII is back on track, but the NRC is awaiting the results.

Mr. Ziegler offered that his goal was to complete the OMII by the end of April, however, Dr. Dyer told Mr. William Reamer (NRC) that the "next few months" would be reasonable, that DOE is committed to do it right.<sup>2</sup>

Mr. Reamer asked whether a lessons learned was being done on the way the OMII was handled earlier. Dr. Dyer confirmed that that was the case, and that he expected input within a month.

Mr. Latta (NRC) asked how DOE would update the NRC on the status of corrective actions, which Dr. Dyer essentially took under advisement.

Mr. Latta asked whether the OMII would include detailed schedules for implementation, to which Mr. Ziegler replied affirmatively.

Mr. Latta asked about an audit schedule to verify the implementation of corrective actions. Mr. Ziegler responded that the OMII will require quarterly audits with established schedules and semi-annual management assessments.

Mr. Latta asked about whether the intent is for OMII to be a "living" document (which was alluded to in pre-revision discussions), to which Mr. Ziegler replied his expectation is that the OMII will take DOE where it needs to go, at which time regular processes would follow. It is not expected to take on a life of its own, but will probably be ongoing for one to two years.

Mr. Wes Patrick (of the Center for Nuclear Waste Regulatory Analysis) raised a question regarding techniques for ownership and accountability. Mr. Ziegler replied that this effort had already begun with a kick-off meeting led by senior management and attended by key middle management representatives. He also discussed the use of a core team and sub-groups. In addition, the people getting the assignments are helping develop plans.

Mr. Patrick asked about incentives for personnel; Mr. Ziegler responded that incentives and measurements in performance plans are, in general, contained in the Human Performance objective.

Status of Data, Model, and Software Corrective Action Reports (presented by Ms. Nancy Williams, BSC Manager of Projects) – Enclosure 5<sup>3</sup>

<sup>2</sup> In subsequent discussion on the NRC/DOE Quarterly Management Meeting on April 19, 2002, John Greeves (NRC) requested that the submittal be made at least 30 days prior to the next Management Meeting.

<sup>3</sup> It was discovered immediately following the meeting that the footnote on slide 5 has errors; the footnote should indicate:

- "Accepted (860)" instead of "Accepted (863)"
- "Source VL1 (352)" instead of "Source VL1 (332)"
- "Total Data Citations (1212)" instead of "Total Data Citations (1195)"

The overall theme is that DOE is making changes to ensure the infusion of quality attributes earlier in the processes (rather than later as has been the case previously). The focus is on effectiveness and timeliness of corrective action. New modeling procedures being developed will be consistent with the guidance in NUREG-1636. Additionally, self-assessments will be performed during the model development process focusing on validation, planning and execution.

Desktop guidance is being prepared to facilitate the process. The draft is scheduled for late next week; users have been consulted in the process. Currently DOE is using a "traveler" to implement guidance. In addition, a commercial process has been purchased to assist in the software effort.

Mr. Latta stated that he recognized all data was qualified, but asked about the status of software? Ms. Williams discussed DR-88 that had identified 4 pieces of software requiring qualification; two are now complete, the remaining two are being finalized. She indicated that there is no impact on the TSPA-SR.

Mr. Latta asked if the project had an established plan for lifting the management stand-down on software development. Ms. Williams responded to Mr. Latta that lifting the management stand down hinges on procedure revision and training (Procedure AP-SI.1Q) and that the Technical Work Planning (TWP) process has been proceduralized and was in place in December (with the procedure revision).

A question was raised by a member of the public as to whether the models are available to the public. DOE responded that the models for supporting the LA are still under development, but once completed will be available to the public.

Mr. Mike Markley (NRC) asked about how quality assurance would address software models and software reliability specifically with regard to common mode failures. Responding to this question will be a new action item.

Ms. Susan Zimmerman Lynch (state of Nevada) asked who the IT experts were, where they had come from and where they were assigned while on the project. It was agreed that responding to this question would be a new action item.

Mr. Larry Campbell (NRC) asked about new models and internal audit schedules: would OQA audits be performance-based or compliance/programmatic-based? Ms. Williams responded that audits would likely be scheduled when sufficient work was completed to make the audits valuable (likely not sooner than another three months). Audits will encompass both compliance and performance issues using Chief Science Office staff personnel (who are independent of those who are actually conducting the work) as technical experts. Mr. Murthy also addressed this issue and responded that OQA will continue to conduct performance and compliance-based audits, and emphasized that performance-based audits will be conducted on

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The body of the slide is unchanged.

OMII and CAR-related committed actions. Campbell restated his understanding that OQA would be conducting performance based audits.

The NRC requested an audit schedule (for Analysis Model Reports) for planning purposes.

DOE expects audit schedules to be available based on the results of the OMII and LA planning.

Ms. Williams stated that DOE would revisit the qualification processes for data used for LA.

Metal Specimens Issues (presented by Dr. Mark Peters, BSC Manager, Science and Engineering Testing) – Enclosure 6

The Metal Specimens issue involves incorrect fabrication of test specimens intended for use in corrosion testing and loss of traceability of material provided to the supplier to be used during the fabrication. This problem resulted in four Deficiency Reports (three of which are closed) and one Corrective Action Report (now closed). The corrective actions include removing the supplier from the Qualified Supplier List, increased attention to supplier quality (including improvements in clarity of communication to suppliers), development of materials/samples acceptance plans, and establishment of hold points during the fabrication process.

At the conclusion of the presentation, a question was raised regarding whether a lessons learned had been conducted on these issues. The response is that a lessons learned has not been done at this time, but is scheduled in conjunction with a scheduled June 2002 self-assessment. Another question regarded what the samples were used for if they did not impact the SR (as was stated in the presentation). The samples were to be used to support planned LA work. Another NRC question was whether the situation would impact satisfactory completion of the KTI Agreement Items. Dr. Peters responded that they will not have an impact; this schedule issue has already been considered.

The Center asked if these were the 1-1/2" square corrosion samples numbered D-1 through D-75. It was agreed that providing a response to this question would be an action item from the meeting.

Action Items (presented by Ms. April Gil, DOE)

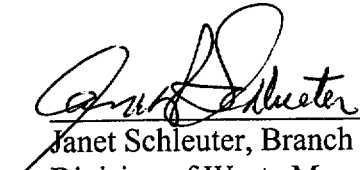
This covered the status of action items from the last meeting and identified new actions from this meeting. The action items and their status are shown on Enclosure 7.

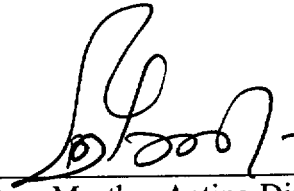
Closing Remarks

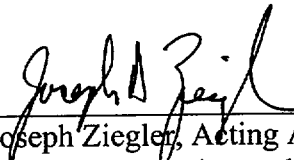
The NRC commented in closing that this meeting is not the end point of the resolution but may mark beginning of resolution. Dr. Chu commented that she expected the upcoming

period to be challenging and that she is expecting steady improvement. Dr. Dyer indicated that the proof will be in DOE performance on YMP.

The NRC invited members of the public to provide comments via the Public Meeting Comment Forms which were available.

 date 5/3/02  
Janet Schleuter, Branch Chief  
Division of Waste Management  
Office of Nuclear Material  
Safety and Safeguards  
U.S. Nuclear Regulatory Commission

 date 4/30/02  
Ram Murthy, Acting Director  
Office of Quality Assurance  
Office of Civilian Radioactive  
Waste Management  
U. S. Department of Energy

 date 4/30/02  
Joseph Ziegler, Acting AMOLRC  
Office of Licensing and  
Regulatory Compliance  
Yucca Mountain Site  
Characterization Office  
U.S. Department of Energy



**List of Enclosures  
For  
April 18, 2002  
QA Meeting Summary**

<b>Enclosure</b>	<b>Description</b>
1	Agenda
2	Attendance List
3	Quality Assurance Program Status
4	OCRWM Management Improvement Initiatives
5	Status of Data, Model and Software Corrective Action Reports
6	Metal Specimens Issues
7	Action Items

**ENCLOSURE 1**

**Agenda**  
**DOE/NRC Quarterly QA Meeting**  
**April 18, 2002**  
**9:00 AM – 12:00 PM (PT)**  
**12:00 Noon – 3:00 PM (ET)**

**BSC**  
**Room 915**  
**9960 Covington Cross**  
**Las Vegas, NV**

*And via Videoconference to:*

**U.S. Department of Energy**  
**Forrestal Building, Room 7F-091**  
**1000 Independence Avenue, SW**  
**Washington, DC 20585**

**U. S. Nuclear Regulatory Commission**  
**Room O-3B4**  
**11545 Rockville Pike**  
**Rockville, MD**

***INTERESTED PARTIES MAY PARTICIPATE VIA TELECON BY CALLING 702-295-6081***

<b>9:00 AM</b>	<b>Introduction</b> <ul style="list-style-type: none"><li>• Opening Remarks</li></ul>	<b>DOE/NRC</b>
<b>9:20 AM</b>	<b>QA Program</b> <ul style="list-style-type: none"><li>• QA Organization</li><li>• Status of Open CARs and DRs</li><li>• Trending Results</li><li>• Other Emerging Issues</li><li>• QARD Status</li></ul>	<b>Murthy</b>
<b>9:50 AM</b>	<b>OCRWM Management Improvement Initiative</b>	<b>Ziegler</b>
<b>10:20 AM</b>	<b>Model and Software CARs</b> <ul style="list-style-type: none"><li>• Steps to Prevent Recurrence</li><li>• Status of Data and Software Qualification</li><li>• Model Validation</li></ul>	<b>N. Williams</b>
<b>10:50</b>	<b>OQA Oversight of CARs and OMII</b>	<b>Murthy</b>
<b>11:00</b>	<b>Break</b>	<b>ALL</b>
<b>11:15 AM</b>	<b>Metal Sample Supplier QA Issues</b>	<b>Peters</b>
<b>11:30 PM</b>	<b>Action Item Status</b>	<b>Gil</b>
<b>11:45 PM</b>	<b>Closing Remarks</b>	<b>ALL</b>
<b>12:00 N</b>	<b>Adjourn</b>	

**ENCLOSURE 2**

QA: N/A

**ATTENDANCE LIST**  
**DOE - NRC Quarterly Quality Assurance Meeting**  
**Las Vegas, NV**  
**April 18, 2002**

Name	Organization	Telephone
Robert Hartstern	BSC QA	702-295-2675
DONALD T. KRISHA	BSC QA	702-295-6242
John Hosmer	MANATHON Consulting	630-9223299
Bill Wagner	BSC Perf. Assmt	295-5556
Roxie Underhill	BSC SEET	295-5779
Tish Morgan	MTS	794-1463
RML Latta	US NRC	794-5048
Wilfred Nabake	LPPSR	(660)276-1034
PHILIP JUSTUS	U.S. NRC	702 794 5057
Mark Peters	BSC / Testing / LANC	702-295-3644
Stan ECHOLS	ECG	202-537-1468
Joe Rivers	JASON	251-8055 x212
Jean Younk	BSC	702 295 5497
April Gil	DOE / YMP / OLRC	794-5578
ALI HAGHI	BSC / DEES	702 295 4019
ROBERT MURRAY	MTS	702 794 5566
S.J. CEREGHINO	BSC	702 295 3944
R.B. HESS	BSC	702-295-0502
Suzy MELLINGTON	DOE	702-794-1454
NANCY WILLIAMS	BSC	702-295-5143
DON BECKMAN	BSC	702-295-4358

QA: N/A

**ATTENDANCE LIST**  
**DOE - NRC Quarterly Quality Assurance Meeting**  
**Las Vegas, NV**  
**April 18, 2002**

Name	Organization	Telephone
Atef Elzefrawy (Kenny)	Las Vegas Paint & Trim	300-3493
MYRLE RICE	INTERTECH / Lincoln County	702-263-6583
George Pannell	BSC WLO	702-295-3935
ROBERT HASSON	NQS/OQA	702-794-5023
William GLASS	NQS/OQA	702-794-5014
F. Harvey Dove	NQS/OQA	(702) 794-5025
Jim Schmitt	NQS/OQA	702-794-1472
Susan Lynch	State of Nevada	775-687-3744
TIM GUNTER	DOE/OLRC	702-794-1343
Mal Murphy	Nye Cty	360-978-5610
George Allstrom	DOE/CCO	702-794-1419
Bob Clark	DOE	702-794-5583
VANDAH	BSC	702-295-5520
Bob Gaynor	MTS	702-794-1440
Bob Bradburn	MTS	702-794-5424
Kristi A. Hodges	NQS/OQA	702-794-1464
SAM HOBBS	BSC/LAP	702-295-4031
Rod McCullum	NEI	202-739-8082
Colin Heath	Self	702-243-2486
DONALD G. HODGSON	DOE/VMFD	702-794-1301
S.H. HANAUER	DOE/YMSCO	702-794-1358

**QA: N/A**

**ATTENDANCE LIST**  
**DOE - NRC Quarterly Quality Assurance Meeting**  
**Las Vegas, NV**  
**April 18, 2002**

[illegible]

**QA: N/A**

**ATTENDANCE LIST**  
**DOE - NRC Quarterly Quality Assurance Meeting**  
**Las Vegas, NV**  
**April 18, 2002**

[illegible]



**CENTER FOR NUCLEAR WASTE REGULATORY ANALYSES**  
**MEETING ATTENDANCE**

SUBJECT OF MEETING *NRC/DOE Quarterly QA Meeting*  
 DATE: *4/18/2002* LOCATION: *SWAB Bldg 189, Room N132, Tice in To Las Vegas, NV and Washington, DC, and Arlington*

[illegible]

**DOE/NRC QA Meeting  
April 18, 2002 DOE HQ**

[illegible]



ENCLOSURE 3



U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Quality Assurance Program Status

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Ram Murthy**

**Acting Director, Office of Quality Assurance  
Office of Civilian Radioactive Waste Management  
Yucca Mountain Site Characterization Office**

**April 18, 2002**

**Las Vegas, Nevada**

# Outline

- **QA Organization Status**
- **Corrective Action Report (CAR) Status**
- **Trending Results/Emerging Issues**
- **QARD Revisions**
- **Summary**



# QA Organization Status

- **The Department of Energy (DOE), as the potential licensee, is responsible for the OCRWM QA functions including the establishment and maintenance of the QA Program and verification of program implementation, as specified in 10 CFR Part 63.142**
- **DOE may delegate authority but not responsibility**



# QA Organization Status

(Continued)

- **DOE Office of Quality Assurance (DOE OQA) and Bechtel SAIC Company, LLC (BSC QA) perform QA activities. Each organization has unique roles and responsibilities**
- **DOE OQA is responsible for oversight of all Affected Organizations performing work in accordance with the OCRWM QARD**





# QA Organization Status

(Continued)

- The BSC contract was recently modified to include the performance of internal audits and surveillance of BSC activities; including vendors, the USGS, and National Laboratories that support the BSC work scope
- BSC QA currently performs surveillance of BSC activities
- DOE OQA will observe selected BSC QA surveillance and in the future will observe BSC audits



# Corrective Action Report (CAR) Status

- **Modeling CAR (BSC-01-C-001) - Response accepted**
- **Software CAR (BSC-01-C-002) - Awaiting amended response**
- **Training CAR (BSC-02-C-001) - Response accepted and will be in OQA verification by the end of April 2002**
- **Metal Samples CAR (BSC(V)-02-C-002) - closed April 4, 2002**



# **Trending Results/Emerging Issues**

## **(July 1, 2001 - December 31, 2001)**

- **The OCRWM Trend Report (Second Semester 2001) identified two emerging issues**
- **Supplier Deficiencies**
  - **Similar conditions identified at several BSC suppliers in several program areas; e.g., Training, Procurement Document Control, Control of M&TE, Audits, etc.**
  - **Not a repeat condition at one supplier**
  - **BSC has taken prompt management action**
  - **OQA will verify effective implementation of actions taken**



# **Trending Results/Emerging Issues**

## **(July 1, 2001 - December 31, 2001)**

(Continued)

- **Cause Code - Personnel Error (Inattention to Detail)**
  - **Personnel errors due to inattention to detail have been increasing; however:**
    - ♦ **Individually, these conditions are not significant**
    - ♦ **Majority are compliance type. No impact on products**
    - ♦ **Trend is notice of early concern**
    - ♦ **DOE and BSC Senior Management has initiated management actions**
    - ♦ **OQA will monitor this cause code quarterly to evaluate trend**



# OCRWM QARD Revisions

- **Revision 11 strengthened requirements for model validation utilizing NUREG-1636 as the basis document**
- **Revision 12 will address QA organizational changes**
- **Revision 13 will address new Yucca Mountain Review Plan**



# Summary

- **QA organization changes will ensure that the effectiveness of the QA program is enhanced**
- **QA trending has resulted in the early identification of emerging issues and management actions were taken**
- **QARD Revision 11 is approved**



ENCLOSURE 4



U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# OCRWM Management Improvement Initiative

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Joseph Ziegler**

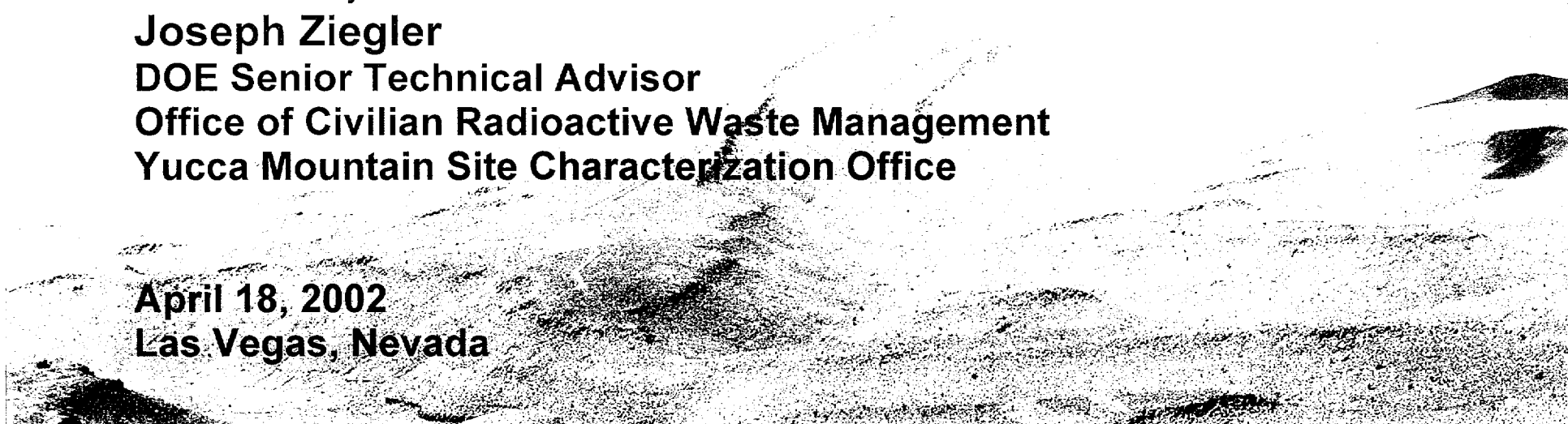
**DOE Senior Technical Advisor**

**Office of Civilian Radioactive Waste Management**

**Yucca Mountain Site Characterization Office**

**April 18, 2002**

**Las Vegas, Nevada**





# Objective

- **Present the revised approach and restructuring of the OCRWM Management Improvement Initiative (OMII)**
- **Reiterate Management commitment and involvement in the OMII development and implementation**
- **Present mechanism for tracking and communicating results of OMII implementation**



# Revised Approach - OMII

- **Re-evaluate OMII to strengthen the approach and ensure effective actions to prevent recurrence**
- **Develop and incorporate lessons learned from previous corrective actions and management initiatives**
- **More comprehensive to include clearly defined actions, schedules and metrics**
- **Reissue as “Q” document and implement in accordance with AP-5.1Q, *Plan and Procedure Preparation, Review and Approval***



# Revised Approach – OMII

(Continued)

- **Require assessment of completion and effectiveness by responsible managers, DOE & BSC QA, and senior management**
- **Implement management tool to track and communicate results to project staff**



# Management Commitment

- **DOE senior manager assigned full-time responsibility for developing the revised OMII**
- **Executive leadership team will monitor performance on a weekly basis**
- **Director of OCRWM will track progress on a weekly basis**



# Management Commitment

(Continued)

- **Joint DOE/BSC (including National Labs and USGS) leadership for initiatives**
  - **Development of action summaries including:**
    - ♦ **Remedial actions and actions to preclude recurrence for the Model and Software CARs**
    - ♦ **Other planned actions not directly part of CAR corrective actions, but within NRC regulatory purview and subject to DOE QARD**
    - ♦ **Additional improvements from project business practices that are appropriate to support overall performance**
  - **Overall effectiveness reviews after implementation**
  - **Ownership and accountability of results**
  - **Integration sessions to achieve alignment on actions, problems, causes and path forward**
- **Firm commitment by management from all program participants to ensure buy-in and ownership of all actions**



# Model/Software CARs and OMII Interface

- **Considers management actions necessary to specifically address lack of timely identification of actions to preclude recurrence of conditions adverse to quality**
- **Parallel information in CARs and OMII**
- **CAR focus**
  - **Corrective actions to address specific deficiencies**
  - **Corrective actions to address causes and recommendations**
  - **Performance measures for progress and effectiveness**



# Model/Software CARs and OMII Interface

(Continued)

- **OMII focus**

- **Corrective actions related to management functions, such as human performance and project management, in addition to quality issues**
- **Performance measures for progress and effectiveness**
- **Detailed action summaries**
- **Overall achievement of plan objectives**



# Concluding Remarks

- **Dedicated DOE Senior Management assigned for OMII planning activities**
- **DOE & BSC (including National Labs and USGS) Management team commitment and ownership of implementation**
- **Comprehensive incorporation of lessons learned, management initiatives and CAR Corrective Action Plans**
- **Actions, schedules, results, and performance metrics tracked and communicated to internal and external organizations**





**ENCLOSURE 5**



U.S. Department of Energy  
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# Status of Data, Model and Software Corrective Action Reports

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

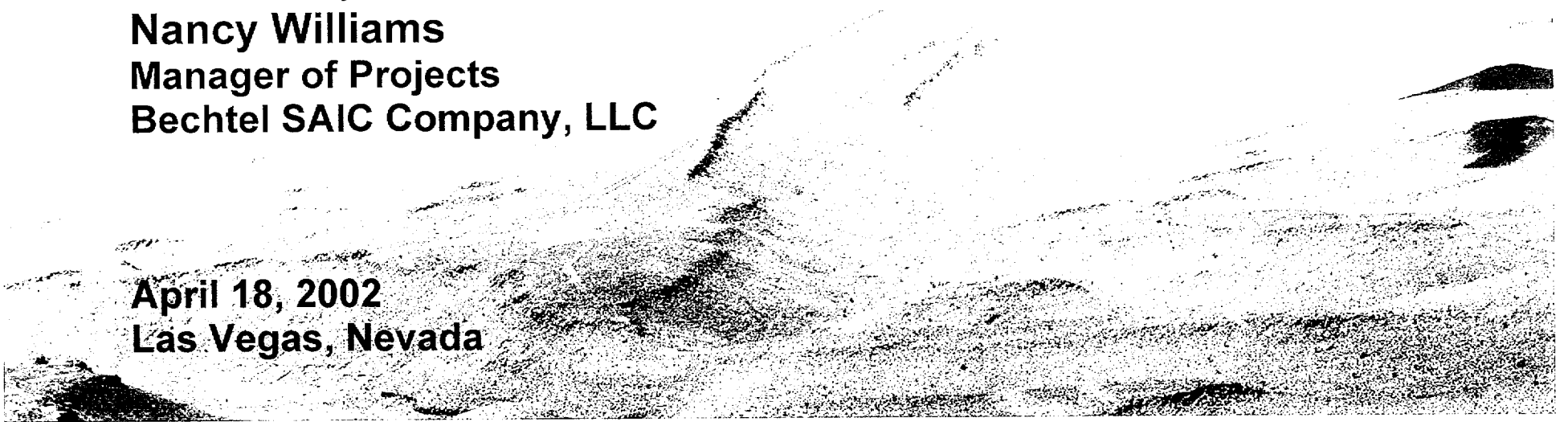
**Nancy Williams**

**Manager of Projects**

**Bechtel SAIC Company, LLC**

**April 18, 2002**

**Las Vegas, Nevada**



# Objective

- **Provide overview of data strategy and planning for License Application (LA)**
- **Provide status of CAR actions taken since March 2002**



# Scientific Data Status

- **All data for Site Recommendation Qualified and/or Verified**
- **Developing plans and processes to manage data needs for LA**
  - **Identifying qualification needs for data to support LA Design and Total System Performance Assessment (TSPA) updates**
  - **Developing approach for**
    - ♦ **Ensuring defensibility of data used in LA**
    - ♦ **Dispositioning unused/unneeded data**
- **Will keep NRC apprised of progress**



# TSPA-SR PMR Data Status

PMR	% Data Qualified	% Data Verified
Biosphere	100	100
Disruptive Events	100	100
EBS	100	100
ISM	100	100
Near Field	100	100
SZ F&T	100	100
UZ F&T	100	100
Waste Form	100	100
Waste Package	100	100
Total	100	100

Data status as of 04/15/2002

Percent completion for data figures are based upon Data Tracking Numbers contained in locked Document Input Reference System for TSPA-SR Rev 0, ICN 1.



# Verification/Qualification Status-TSPA-SR 04/15/02

	<u>Total</u>	<u>Completed</u>	<u>To-Go</u>	
VL1 DIRS (Verif. Checklists)	250	250	0	(Q-TBV) ("actual citations")
VL1 Sources (Verif. Checklists)	352	352	0	(Q-TBV) ("daughters")
VL2 (No Verification Checklists)	182	182	0	(Q-TBV)
Accepted Data (Fact)	78	78	0	(e.g., handbooks, textbooks)
Accepted Data approved by Assistant Manager, Office of Project Execution	32	32	0	(e.g., non-project source)
Qualified by procedures established after 6/30/99	36	36	0	
Unqualified DTNs qualified per AP-SIII.2Q	282	282	0	
Totals	1212	1212	0	

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Percent of Total Data Citations	100%	0%
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Notes: Document Input Reference System VL1+VL2+AP-SIII.2Q+Accepted (863) + Source VL1 (332) = Total Data Citations (1195)  
VL1 = Principal Factor Related DTN      VL2 = Non-Principal Factor Related DTN

Percent completion for data figures are based upon Data Tracking Numbers contained in locked Document Input Reference System for TSPA-SR Rev 0, ICN 1.



# Models Validation Status

## Model Validation Corrective Action Report (CAR) (BSC-01-C-001)

- **Corrective Actions to Prevent Recurrence (CATPR) essentially complete**
- **CATPR re-evaluated and expanded slightly to ensure root causes adequately addressed; Actions in progress**
- **Remedial actions will be applied to models carried forward to LA; Model planning and development in progress**



# **Status of Model Validation Corrective Actions**

- **Corrective Actions completed include:**
  - **Chief Science Office assigned functional management responsibility**
  - **Complete revision of AMR procedure into 2 new procedures**
    - ♦ **AP-SIII.10Q - Models**
    - ♦ **AP-SIII.9Q - Scientific Analyses**
  - **Training on new modeling procedure by CSO subject matter expert completed by 12/21/2001**
  - **Training included testing on information presented**
  - **Model workshop conducted during training session**
  - **Line and Functional Management involved in training sessions**





# **Model Validation Corrective Actions**

## **What's Different**

- **Model validation is integral part of model development**
  - Begins at model conception, not as a final action following model development / documentation
  - Technical Work Plan defines validation approach and criteria to ensure plans for model validation are appropriate
  - “Plan the work / Work the plan” concept
- **Chief Science Office assigned functional management responsibility**
  - Validation interpretive authority and procedure owner (subject matter expert)
  - Reviews model validation plan (pre-AMR development or revision), draft and final model validation documentation as developed by the line organization



# **Model Validation Corrective Actions What's Different**

(Continued)

- **Timely self-identification of validation issues from CSO reviews allows Line Management to focus resources**
- **New modeling procedure developed consistent with NUREG 1636**
- **Self-assessments to be performed of model development process, focusing on validation planning and execution**



# Software CAR Status

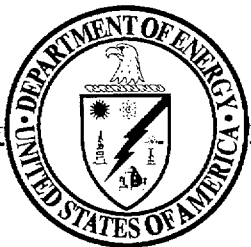
- **Software Quality Assurance CAR (BSC-01-C-002)**
- **Remedial actions complete**
- **CATPR reviewed and partially accepted with OQA comments; action plan rework underway**
- **CATPR in progress**
  - **Software summits with users and developers**
  - **External expertise retained**
  - **New procedures in development**
  - **Improved tools for software configuration management process being implemented**
  - **Interim controls from Software Stand-down enhanced**



# Summary

- **Data Verification and Qualification**
  - Data required to support TSPA-SR, Rev 0, ICN 01 was completed to support SR
  - Planning underway to ensure that data required to support LA meets QARD data qualification requirements
- **Software and Model Validation CAR Preventive Action implementation in progress**
  - Revising CAR and OMII actions plans
  - Under Line Management Review
  - Obtaining OQA Approval
  - Continuing Implementation
  - No impact to SR





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# Oversight of OCWRM Management Improvement Initiative and Corrective Action Reports

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

**Ram Murthy**

**Acting Director, Office of Quality Assurance**

**Office of Civilian Radioactive Waste Management**

**Yucca Mountain Site Characterization Office**

**April 18, 2002**

**Las Vegas, Nevada**

# **OCRWM Management Improvement Initiative (OMII) Oversight**

- **Office of Quality Assurance (OQA) will develop a verification schedule to perform oversight of completed actions including both “Q” and “Non-Q” activities**
- **OQA will conduct selective oversight activities on a phased approach through the use of audits, surveillance, and in-process verifications**
- **BSC QA will also perform in-process surveillance**
- **The schedule will be monitored by OQA and updated on a quarterly basis**



# Corrective Action Report (CAR) Oversight

- **Software**
  - Identify commitments
  - Establish matrix of commitments and completion dates
  - Schedule in-process verification
  - Schedule verification of completed corrective action
- **Modeling**
  - Identify models and validation dates from P-3 Schedule
  - OQA perform verification to ensure product acceptability and process effectiveness



ENCLOSURE 6





U.S. Department of Energy  
Office of Civilian Radioactive Waste Management



# Metal Specimens Issues

Presented to:

**DOE/NRC Quarterly Quality Assurance Meeting**

Presented by:

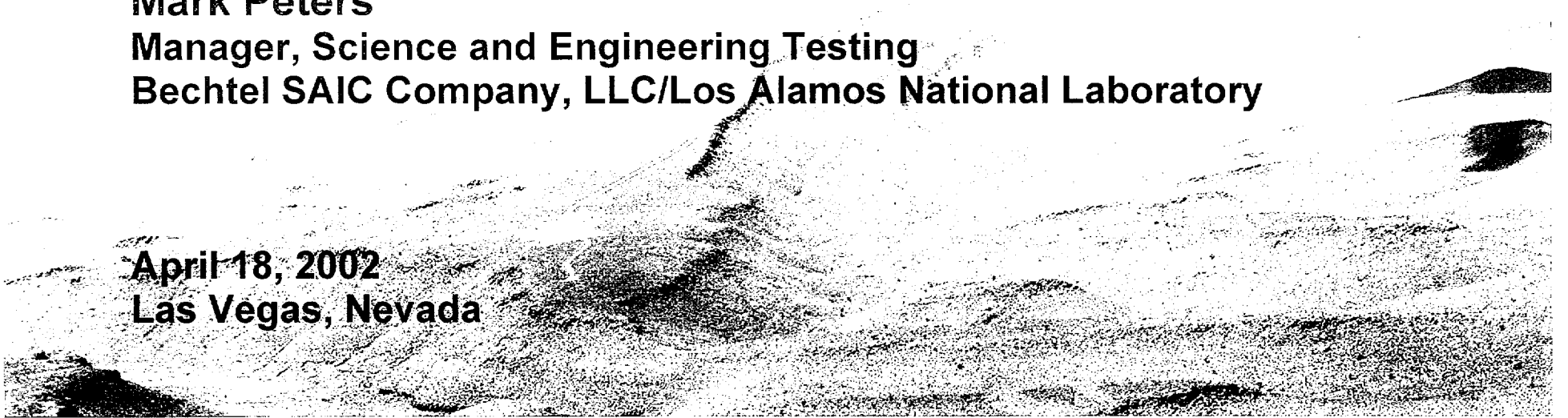
**Mark Peters**

**Manager, Science and Engineering Testing**

**Bechtel SAIC Company, LLC/Los Alamos National Laboratory**

**April 18, 2002**

**Las Vegas, Nevada**



# Historical Perspective

- **Problems**

- **McDermott Technologies, Inc. (MTI) had an un-tested welded specimen lightly etched to look for features of weld defects. MTI found that the specimen consisted of both weld and base metal. This specimen was to be composed entirely of weld metal**
- **This prompted an investigation into the placement of welds for all customer supplied welded Alloy 22 and TiGr7 specimens, fabricated by a supplier on the OCRWM Quality Supplier List (QSL), at Lawrence Livermore National Laboratory (LLNL) and MTI**



# Historical Perspective

(Continued)

- Evaluations at LLNL and MTI revealed that specimens were not fabricated in accordance with the specimen sampling location drawings and sketches included with purchase orders awarded to the supplier
- Investigations performed by Science and Engineering Testing (S&ET) further revealed that a combination of poor planning, lack of communication, and lack of direction by the technical organization contributed to this problem
- Documented in deficiency report BSC(V)-01-D-124 - Closed on December 12, 2001



# Historical Perspective

(Continued)

- During MTI's evaluations of the misplacement of welds, MTI reported 2 specimens as having a notch located in the incorrect location. This prompted the S&ET organization along with BSC QA to observe the supplier's process (at their facility) for fabricating specimens. The outcome of that visit indicated a loss of traceability of customer supplied Alloy 22 and TiGr7 welded plate at receipt at the supplier's facility
  - ♦ The supplier failed to record customer supplied Alloy 22 and TiGr7 welded plate shipped from Framatome Technologies, Inc. to MSC for fabricating test specimens
  - ♦ Documented in corrective action report BSC(V)-02-C-002 - status provided below
    - » Root Cause Analysis Completed



# Historical Perspective

(Continued)

- **Corrective Actions Taken**

- The supplier has been removed from the OCRWM QSL
- Reassignment of roles and responsibilities in S&ET
- BSC QA implementing processes to improve supplier quality (communication, surveillances, follow-up audits)
- S&ET, BSC QA, and Procurement working together to provide clear and concise direction in supplier contracts and analytical/technical service contracts
  - ♦ Transfer of material between suppliers and across organizations
  - ♦ Development of material/sample acceptance plans
  - ♦ Hold points during fabrication process



# Status of Conditions Adverse to Quality

- **CAR No. BSC(V)-02-C-002 (Loss of Traceability)**
  - Closed April 4, 2002
  - Material to be controlled by NCRs
- **Outstanding Deficiency Reports**
  - BSC(V)-02-D-043, supplier deficient in calibrating roughness standards. The standards have since been calibrated to a master standard and found to be in tolerance. DR is closed (no impact to YMP work)
  - BSC(V)-02-D-044, supplier failed to complete an anomaly report for specimens that were out of tolerance. The specimens are being used for non-Q testing activities. DR is closed (no impact to YMP work)



# Status of Conditions Adverse to Quality

(Continued)

- **BSC(V)-02-D-045, supplier is deficient in evaluating sub-tier suppliers. One outstanding supplier (R&R Gage Co.) still needs to be evaluated. (Evaluation of impact is ongoing)**



# Non-Conformance Reports

- **Two NCRs (YMSCO-02-0021 *Loss of Traceability* and YMSCO-01-0035 *Misplacement of Welds*) were generated to control specimens**
  - **Affected specimens at LLNL and MTI segregated and red-tagged**
    - ♦ **Samples will not be used for any further testing**





# Impact

- **No Impact to SR products**
- **Impact to LA products**
  - **Sufficient samples will be in test to support LA-CA**



# Path Forward

- **Laboratory Testing, Inc. (LTI) to Fabricate Replacement Specimens and Remainder of FY02 Specimens**
  - BSC QA audited LTI December 2001 with emphasis on traceability of customer supplied material - no findings
  - Hold points included in the list of items to LTI's statement of work
  - Surveillance by BSC QA of the fabrication process at LTI's facility scheduled for April 23, 2002
- **S&ET Currently Evaluating Future Specimen Needs**
  - Contract will be awarded through competitive bid process



# Path Forward

(Continued)

- **Self Assessment**
  - **Target Completion Date is June 30, 2002**



**ENCLOSURE 7**

**Combined Action Items  
From The  
December 5, 2001 And The April 18, 2002  
NRC/DOE Quarterly QA Meeting**

<b>Item No.</b>	<b>Description</b>	<b>Status</b>
5Dec01-1	DOE will provide to NRC the project responses to the QAMA recommendations	Completed: DOE provided a copy of the project responses to the QAMA recommendations by letter dated April 15, 2002
5Dec01-2	DOE will provide follow-up information/status to NRC on deficiencies related to metal samples. This will be accomplished via an Appendix 7 meeting if appropriate.	Completed: was discussed in April 2002 Quarterly QA Meeting in lieu of an Appendix 7 meeting.
5Dec01-3	DOE will request the QAMA team to include evaluation of the DOE/BSC performance measures/metrics in the scope of their FY 2002 assessment.	Open: the FY 2002 QAMA Plan was issued on March 11, 2002 without specific provision for including performance measures in the evaluation. A revised scope will be issued to cover this item.
5Dec01-4	Director, OQA, will follow-up with Clark County, NV, regarding information that some labs are not documenting all problems. The State of Nevada will also be informed of the outcome.	Completed: B. Davis closed action with Clark County, NV per email on 1/2/02. Closure with the State of Nevada was completed (also by email) on February 12, 2002.
5Dec01-5	DOE agreed to inform NRC of any changes in OQA/BSC QA responsibilities prior to their implementation.	Open: on March 19, 2002, the NRC was informed by letter of the first step in changing QA responsibilities: BSC's assumption of internal surveillances and internal corrective action activities (with some limitations). These changes were effective on March 25, 2002. It is anticipated that this action item will be completed with the issuance of QARD Rev. 12 prior to implementing further changes; however, if such changes are implemented prior to issuance of Rev. 12, the NRC will be informed prior to implementation.
18Apr02-1	Provide the State of Nevada a list of the external (independent) software experts, where they are from and where they are assigned on the project.	New Action Item

**Combined Action Items  
From The  
December 5, 2001 And The April 18, 2002  
NRC/DOE Quarterly QA Meeting**

18Apr02-2	Respond to Mike Markeley (NRC) question on QA and the potential for software common mode failures.	New Action Item
18Apr02-3	Confirm with regard to the "metal specimens" issue that the sample/plates being discussed were the 1½ in. plates intended for corrosion testing with serial numbers D-1 through D-77 and that all samples were red-tagged.	New Action Item
18Apr02-4	DOE will provide the NRC with an audit schedule (to enable the NRC to facilitate their planning) for Analysis Model Reports when available.	New Action Item