



QA: QA

Mark T. Peters, Manager  
Science & Engineering Testing  
Bechtel SAIC Company, LLC  
1180 Town Center Drive  
Las Vegas, NV 89144

VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DEFICIENCY REPORTS  
(DR) BSC(V)-02-D-024, -025, -026, -027, AND -028 RESULTING FROM THE BECHTEL  
SAIC COMPANY, LLC (BSC) QUALITY ASSURANCE AUDIT BSC-SA-01-030 OF  
LAMBDA RESEARCH, INC.

BSC Quality Assurance has verified implementation of corrective action for DRs  
BSC(V)-02-D-024, -025, -026, -027, and -028 and determined the results to be satisfactory. As a  
result, the DRs have been closed.

If you have any questions, please contact either Richard L. Hand at (702) 295-4406 or  
Daniel A. Klimas at (702) 295-2665.

A handwritten signature in black ink, appearing to read 'D. T. Krisha'.

Donald T. Krisha, Manager  
Quality Assurance

3/21/02

Date Signed

RLH:bw-0313021797

Enclosures:  
DR BSC(V)-02-D-024,-025, -026, -027, and -028

*Nmsso7  
WM-11  
Add: Melissa  
Wyatt*

March 21, 2002

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cc w/encl:

L. H. Barrett, DOE/HQ (RW-2) FORS  
L. W. Bradshaw, Nye County, Pahrump, NV  
J. R. Dyer, DOE/YMSCO, Las Vegas, NV  
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R. L. Hand, BSC, Las Vegas, NV  
S. H. Horton, BSC, Las Vegas, NV  
D. A. Klimas, BSC, Las Vegas, NV  
B. R. Kornegay/B.L. Wilson, BSC, Las Vegas, NV  
D. T. Krishna, BSC, Las Vegas, NV  
Robert Latta, NRC, Las Vegas, NV  
S. W. Lynch, State of Nevada, Carson City, NV  
Ram Murthy, DOE/OQA, Las Vegas, NV  
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N. K. Stablein, NRC, Rockville, MD  
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H. E. Adkins, BSC, Las Vegas, NV  
R. L. Hand, BSC, Las Vegas, NV  
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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT

NO. BSC(V)-02-D-024

PAGE 1 OF 5  
QA: QA

**DEFICIENCY/CORRECTIVE ACTION REPORT**

1. Controlling Document: Lambda Research, Inc. QA Manual, 1M1000\_8 (Version 8), 12/29/99

2. Related Report No.: BSC-SA-01-030

3. Responsible Organization: BSC S&ET/Lambda Research, Inc.

4. Discussed With: Marie Marawi, Lambda Research, Inc./Ahmed Monib, BSC/Mark Peters, BSC/Howard Adkins, BSC

5. Requirement: Training

- Lambda QA Manual, 1M1000\_8, Section 5.1.1, *Laboratory Technician*, requires a Laboratory Technician to have either a four year degree in a technical or scientific field or a two year technical/science degree and two years equivalent experience.
- Lambda Procedure 6T1006\_02, *Training Procedure*, identifies training required for each position.

6. Description of Condition:

- Lambda Procedure 6T1005\_03 and 6T1004\_02 conflict with the QA Manual. 6T1004\_02 allows high school or two years of college or associates degree for Lab Technician. 6T1005\_03 allows high school plus 6 months to a 1 year for a level 1.
- The Laboratory Technician performing work for the Yucca Mountain Project only has a high school degree.
- The Director of Laboratory Operations is a Level III, but there is no evidence that he has completed all required training.

7. Initiator: *R. F. Hartstern* Date: *11/12/01*  
Robert F. Hartstern

9. Does a stop work condition exist? (Not required for a DR)  
 Yes  No  
If Yes, Check One:  A  B  C  D

10. Recommended Actions:

- Resolve conflict between the education and experience requirements in the three documents.
- Based on the action resulting from 1., determine the Laboratory Technician's qualifications to meet education and experience requirements.
- Have the Director of Laboratory Operations complete all required training.
- Determine if there was any impact on YMP work as a result of the above deficiencies.

11. QA Review: *Richard L. Hand* Date: *11/13/01*  
QAR Richard L. Hand

12. Response Due Date:  
10 Working Days From Issuance

13. DOQA Issuance Approval:  
Printed Name Donald T. Krishna Signature *D. T. Krishna* Date *11/15/01*

22. Corrective Actions Verified: QAR *Richard L. Hand* Date *3/13/02*

23. Closure Approved by: DOQA *D. T. Krishna* Date *3/21/02*

TYPE RESPONSE:

- Initial
- Complete
- Amended

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DR/CAR NO. BSC(V)-02-D-024

PAGE *X2* OF *5* QA  
*12/13/02* QA: *X* *12/16*  
*12/19/01*

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**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

- 1) The Laboratory Technician will be restricted from performing YMP QA work until his or her qualifications can be reviewed and determined to be acceptable.
- 2) As of 12/06, Lambda had initiated a review of the referenced documents to determine which shows the position requirements that are actually needed for the Laboratory Technician position.
- 3) Lambda will initiate a review of the referenced training requirements for the Director of Laboratory Operations position, to determine if they accurately reflect the actual training needs for the position.

Compliance Date: January 18, 2002

14. Remedial Actions:

- 1) Lambda will revise all affected documents to ensure that they consistently define the requirements for the Laboratory Technician position.
- 2) Lambda will revise the Training procedure to ensure that it accurately reflects the training requirements for the Director of Laboratory Operations position.
- 3) If any other inconsistencies are found, Lambda will revise all affected documents to ensure that they accurately reflect position and training requirements.
- 4) Lambda will initiate a review of all other positions involved with YMP QA work, to ensure that their position descriptions and training requirements accurately reflect practice.

15. Extent of Condition:

Extent of Condition will be determined as part of the Remedial Actions described in 14) above.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

Failure to update Lambda procedures to accurately reflect current practice in position qualification and training.

17. Action to Preclude Recurrence:

Lambda will retrain all affected personnel to the revised documents.

18. Due Date: February 18, 2002

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B. Reynolds* *Put* *T.B. BSC QA*  
*Mad Hete* *12/17/01* *K3* *RF* *12/18/01*  
 Date *12/17/01* Phone *295-5215*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Richard G. Hunt* Date *12/19/01*

21. Concurrence:

*Robert P. Kelleher*  
 DOQA *D. T. KRISHA* Date *12/21/01*

TYPE RESPONSE:

- Initial
- Complete
- Amended

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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

DR/CAR NO. BSC(V)-02-D-024  
PAGE 13 OF 15 3/6/02  
3/6/02 QA: KQA

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JBR 3/6/02

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:  
See Initial Response.

Compliance Date:

14. Remedial Actions:

- 1) Lambda has revised Section 5.1.1 of the Quality Manual (1M1000\_9) to state that the education and training requirements for the Laboratory technician and Director of Laboratory Operations positions are found in 6T1004 (Basic Training Requirements, Section 1) and 6T1005 (Training levels Based Upon ANSI/ASME N 45.2.6).
- 2) Lambda has completed a review of the qualifications of the Laboratory Technician, and also the position and training requirements for the Laboratory Technician and the Director of Laboratory Operations. The Laboratory Technician meets the requirements of 6T1004, (a high school diploma, high school math and science, and a score above 70 on the Lambda Research aptitude test). These are the acceptable minimal requirements for employment at Lambda Research as a Lab Staff employee.

15. Extent of Condition:

A review of the Lambda Technical Staff Training Matrix has been made. It was determined that during the time that YMP projects were in the lab, the personnel that were in the lab and performing the work were adequately trained. YMP work was performed by Lambda research personnel who were trained on the procedures specific to the tests performed. Therefore, there is no impact to Yucca Mountain Quality Affecting work.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

Failure to update Lambda procedures to accurately reflect current practice in position qualification and training, due to oversight.

17. Action to Preclude Recurrence:

The documents have been revised and the affected personnel (Lambda President) have been formally notified.

18. Due Date: 3/08/02

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B Reynolds*  
Date 3/6/02  
Phone 5-5215  
ROS BSC QA 03/06/02  
PJ for YMP  
3/6/02

20. Evaluation:  Accept  Partially Accept  Reject

QAR *[Signature]* Date 3/7/02

21. Concurrence:

DOQA *[Signature]* Date 3/21/02

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8.  DR/CAR  
 Stop Work Order

NO. BSC(V)-02-D-024/02  
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DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

14a) Remedial Actions Continued:

2) The identified Laboratory Technician, C. Salyer, as of 8/98 had been trained and qualified to perform the procedures that affect the quality work that may be performed for the Yucca Mountain Project as follows:

- 3P1002 "Strain Gage and Sectioning Procedure"
- 3P1051 "Incremental Ring Core Technique for the Determination of the Residua Stress Distribution"
- 3P1070 "Determining Residual Stresses by the Hole-Drilling Strain gage Method"

3) The Director of Laboratory Operations, D. Hornbach, has achieved Level 3 status at Lambda Research as a lab staff employee. He has an engineering degree and nearly ten years of experience at Lambda Research. He has written programs and assisted in the research and development of test methods for Lambda Research. Mr. Hornbach, has had training in, developed or implemented the following test methods/ procedures that may be performed for YMP work:

- |   |                |
|---|----------------|
| 3P1002, "Strain Gage and Sectioning Procedure"                                  | Training       |
| 3P1051 "Incremental Ring Core Technique"  | R&D/program    |
| 3P1070 " Determining Residual Stresses by the Hole-Drilling Strain gage Method" | Implementation |

15. Extent of Condition

There is no impact on YMP work, because the qualifications and training of all affected personnel were reviewed prior to the performance of YMP quality affecting work. Per Lambda Research Procedure 6T1005, the education, experience, or research and development work of an individual can be taken into consideration to assess their qualification and training for the the laboratory employment levels indicated.

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8.  DR/CAR  
 Stop Work Order

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QA: *XQA*

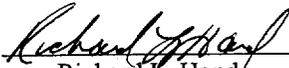
DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

A BSC Quality review has verified completion of corrective action. The following information was reviewed and verified.

1. Verified the Lambda QA Manual, Rev. 9 dated 1/7/02, has been revised to reference internal procedures for education and training requirements. The requirement details have been removed from the QA Manual.
2. Training procedures 6T1005.03, Training Levels Based Upon ANSI/ASME N 45.2.6, and 6T1005.02, Basic Training Requirements, provide details for qualification and training. These were in effect at the time of the audit. The requirement is that the technician has to have a high school education, as a minimum, which the technician has. The QA Manual was in conflict with this requirement. Verified conflict was corrected by revision of the QA Manual.
3. Verified the Director has completed the required training for Level III through review of the training matrix which shows training status of all employees.

All conditions were reviewed by Lambda and determined there was no impact to YMP work. After review of the supporting information noted above, the BSC QAR concurs with this determination.

These actions are considered acceptable and adequate for closure of this deficiency and this DR is considered closed.

  
Richard L. Hand

3/20/02  
Date

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8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT

NO. BSC(V)-02-D-025

PAGE 1 OF 4  
QA: QA

**DEFICIENCY/CORRECTIVE ACTION REPORT**

1. Controlling Document: Lambda Research, Inc. QA Manual, 1M1000_8 (Version 8), 12/29/99 and BSC Subcontract 24540-160-TSA-0109, Mod. 04, Statement of Work, Rev. 3	2. Related Report No.: BSC-SA-01-030
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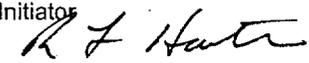
3. Responsible Organization: BSC S&ET/Lambda Research, Inc.	4. Discussed With: Marie Marawi, Lambda Research, Inc./Ahmed Monib, BSC/Mark Peters, BSC/Howard Adkins, BSC
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5. Requirement:  
Document Control/QA Records

- Lambda QA Manual, 1M1000\_8, Section 8.1.1 *Procedures*, last paragraph, states, "The procedures used at Lambda Research are listed in the Table of Contents of the QA Procedures Manual 3."
- The Statement of Work, Rev. 3, Section III, *Quality Assurance*, Page 5 of 6, first paragraph states in part, "...Records for this procurement shall be ..... and identifiable to the items(s) or activity(s) to which they apply..."
- The Statement of Work, Rev. 3, Section III, *Quality Assurance*, Page 5 of 6, second paragraph states in part, "...corrections to completed Records shall be made by drawing a single line through the changed or incorrect information and inserting the new or correct information. The correction shall include the initials or signature of the individual authorized to make the correction and the date the correction was made. Lambda Procedure 1M1000\_8 requires changes to be initialed.

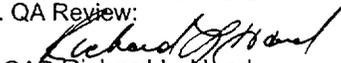
6. Description of Condition:

- The following procedures were incorrect:
  - 3P1016 is actually Rev. 10, but index lists as Rev. 9
  - 3P1051\_2 has incorrect title in the index
- The two job files for the YMP scope of work contain a sheet with only the strain gage batch/lot numbers used to perform the test. The strain gage batch/lot numbers are not recorded on the test data sheets. If the sheet with the strain gage numbers was removed from the job file, there is no traceable number to identify it to the test data sheets or the job file.
- A number of changes to data sheets and other records were identified with a line through and the corrected input added, however, there were no initials or date on some and some with initials had no date. Examples are the audit report for audit of Procedure 3P1051\_01, dated 7/9/01, and Job File 824-10037 set-up data sheet, neither of which had an initial or date with the corrections.
- Lambda Procedure 1M1000\_8 does not require the changes to be dated.

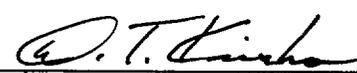
7. Initiator:  Robert F. Hartstern	Date: 11/12/01	9. Does a stop work condition exist? (Not required for a DR) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
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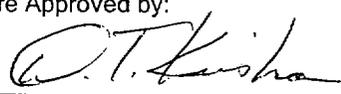
10. Recommended Actions:

- Review the index for correct titles and revisions and correct as necessary
- Record the strain gages used on each data sheet and require it for all future YMP work.
- Assign a responsible individual that can authorize changes, review all records associated with YMP and ensure changes are acceptable and initial and date when review accomplished.
- Change procedure to require date as well as initials for all changes to records for YMP work.
- Determine if any impact to quality resulted to the deficiencies.

11. QA Review:  QAR Richard L. Hand	Date: 11/13/01	12. Response Due Date: 10 Working Days From Issuance
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13. DQQA Issuance Approval:

Printed Name: Donald T. Krisha      Signature:       Date: 11/15/01

22. Corrective Actions Verified: QAR  Date: 3/13/02	23. Closure Approved by: DQQA  Date: 3/21/02
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TYPE RESPONSE:

- Initial
- Complete
- Amended

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DR/CAR NO. BSC(V)-02-D-025

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12/19/01

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

Not applicable

Compliance Date: N/A

14. Remedial Actions:

- 1) Lambda will update the index to reflect current procedure titles and revisions.
- 2) Lambda will edit affected data sheets to add the appropriate strain gage number that was used in the acquisition of those data.
- 3) Lambda will review the affected documentation in the YMP project files, to determine if all editorial corrections were made with initials and dates.
- 4) Lambda will identify and implement a process to ensure that special project requirements are effectively communicated, such as dating editorial corrections.

15. Extent of Condition:

Extent of Condition will be determined as part of Remedial Action 14) above.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

The requirement to date editorial corrections is a special requirement unique to YMP work. The current Lambda process to communicate special requirements transmitted this requirement but did not ensure that it was carried out.

17. Action to Preclude Recurrence:

Lambda will revise their process for transmitting special project requirements, and retrain affected personnel.

18. Due Date: February 18, 2002

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

Mark H. [Signature] WDR Thomas B Reynolds TSR 12/19/01  
 Date 12/18/01 KB Phone 295-5215 BSC

20. Evaluation:  Accept  Partially Accept  Reject

QAR [Signature] Date 12/19/01

21. Concurrence:

[Signature]  
 DOQA D. T. KRISHA Date 12/21/01

TYPE RESPONSE:

- Initial
- Complete
- Amended

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QA: ~~X~~ QA

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TBR 3/6/0

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:  
Not applicable

Compliance Date:

14. Remedial Actions:

- 1) The procedure index has been corrected to reflect the actual revision number and title for the subject procedures.
- 2) a) The PStrain data sheet 5F1032 has been revised to include sections to record gage lot # and location.  
b) The strain gage type and lot numbers used for jobs 824-10037 and 1181-10221 were recorded on identifiable data sheets contained in the job file.
- 3 & 4) Laboratory personnel were trained on acceptable corrections per 1M1000, Section 10.4.2, and on BSC purchase order requirements. The job files 824-10037 and 1181-10221 were reviewed for corrections. A review of the YMP project files was made. All data sheets that had editorial corrections were reviewed to determine if the changes affected the job adversely. The corrections were dated and initialed. Editorial corrections were confirmed to be appropriate and did not affect the job.

15. Extent of Condition:

- 1) The index for Manual 3 procedures was reviewed and compared to the actual procedures and revision numbers. The index is correct and verified. All procedures are correct and verified. The error in the index did not affect YMP work since the most current version of the procedure was in the procedural manual and available at the workstation.
- 2) The extent of condition is limited to job numbers 824-10037 and 1181-10221. There is no impact to YMP QA work, because the strain gage type and batch/lot numbers were recorded in several places in both job records. The type and batch numbers were also part of the report and were contained in tables in the appendices.
- 3 & 4) The job files 824-10037 and 1181-10221 were reviewed for corrections. There was no impact to YMP QA work.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

- 1) The error for 3P1016 was a clerical typo. The error for 3P1051 occurred when the second revision was issued. A word in the title (trepanning) had been changed to ring core. The failure to carry this to the index was an oversight since the revision number was updated, but the title change (which is rare) was not updated.
- 2) The location of measurement and corresponding strain gage/batch lot were not clearly recorded in the job files.
- 3) Technicians were not making corrections per Lambda Research procedure and BSC purchase order special requirements.
- 4) Lambda Research's quality system is based on ISO Guide 25 (now ISO/IEC 17025). This standard does not require changes to be dated.

17. Action to Preclude Recurrence:

- 1) Isolated oversight - no need for action to preclude recurrence.
- 2&3) A Supplementary Instruction Sheet has been created to accommodate and comply with client requirements that vary from the normal work or procedures at Lambda Research. This includes requirements such as initialing and dating corrections. Affected personnel will be trained by 3/08/02, on using the Supplementary Instruction Sheet to communicate and document special project requirements
- 4) Isolated oversight - no action needed

18. Due Date: 3/08/02

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B. Reynolds* *TBR BSC QA*  
*TBR* *AK* *3/6/02* *WWD*  
Date *3/6/02* Phone *5-5215*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Richard G. Haddad* Date *3/7/02*

21. Concurrence:

DOQA *C. T. Krishna* Date *3/21/02*

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RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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8.  DR/CAR  
 Stop Work Order

NO. BSC-D-02-025  
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QA: *YGT* *3/20/02*

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

A BSC Quality review has verified completion of corrective action. The following information was reviewed.

1. Reviewed the revised procedure index, QA Manual 3, dated 2/2/02, and verified correction of the procedure title and revision number.
2. Reviewed the software V&V data sheet for "pstrain" and verified the required information is recorded. The data sheet form 5F1032\_3.doc, dated 2.26.01, now includes the strain gage type and lot numbers.
- 3 & 4. Verified training attendance sheet dated 11/15/01, for training relative to acceptable methods to make changes to data sheets. This training addresses special requirements in the BSC purchase order. Supplemental instruction sheet, form 5F1011.01, addresses client requirements not addressed in Lambda procedures.

All conditions were reviewed by Lambda and determined not to impact the YMP work. BSC Quality concurs with this determination. The proposed action to prevent recurrence is acceptable.

These actions are considered acceptable and adequate for closure of this deficiency and this DR is considered closed.

*Richard L. Hand*  
Richard L. Hand

*3/20/02*  
Date

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RADIOACTIVE WASTE MANAGEMENT  
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8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT

NO. BSC(V)-02-D-026

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QA: QA

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**DEFICIENCY/CORRECTIVE ACTION REPORT**

1. Controlling Document: Lambda Research, Inc. QA Manual, 1M1000\_8 (Version 8), 12/29/99  
2. Related Report No.: BSC-SA-01-030

3. Responsible Organization: BSC S&ET/Lambda Research, Inc.  
4. Discussed With: Marie Marawi, Lambda Research, Inc./Ahmed Monib, BSC/Mark Peters, BSC/Howard Adkins, BSC

5. Requirement:  
Corrective Action  
1. Lambda QA Manual, 1M1000\_8, Section 1.6 *Audits*, last paragraph states, "Any nonconformity to the Quality System discovered during a Quality Audit shall be monitored for corrective action and resolution through the management group."  
2. Lambda QA Manual, 1M1000\_8, Section 12.3, *Corrective Action of Testing Procedures*, identifies that immediate action will be taken when testing reveals a problem in the accuracy or precision of the data. It requires that a "QA Incident Report" will be used to document the problem and resolution.

6. Description of Condition:  
1. There is no evidence that corrective action is being monitored to either status actions or ensure timely resolution. Several nonconformities were identified for action in February and are still open. There is no "log" or status report to monitor corrective action or indicate how long they have been open.  
2. The "QA Incident Reports" reviewed were prepared after the corrective action to the incident was complete. There is no documented identification and tracking of the incident when initially identified to ensure that the necessary action is reported to and taken by management.

7. Initiator: *R F Hartstern* Date *11/12/01*  
Robert F. Hartstern  
9. Does a stop work condition exist? (Not required for a DR)  
 Yes  No  
If Yes, Check One:  A  B  C  D

10. Recommended Actions:  
1. Implement a process to identify open conformities and track status, and be more aggressive in the resolution of nonconformities.  
2. Establish method to immediately identify and track problems in testing that may result in an QA Incident Report.

11. QA Review: *Richard L. Hand* Date *11/13/01*  
QAR Richard L. Hand  
12. Response Due Date:  
10 Working Days From Issuance

13. DOQA Issuance Approval:  
Printed Name Donald T. Krisha Signature *D. T. Krisha* Date *11/15/01*

22. Corrective Actions Verified: QAR *Richard L. Hand* Date *3/13/02*  
23. Closure Approved by: DOQA *D. T. Krisha* Date *3/21/02*

TYPE RESPONSE:

- Initial
- Complete
- Amended

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

DR/CAR NO. BSC(V)-02-D-026

PAGE *12* OF *4* QA  
*12/13/02* QA: *Y*

ORIGINAL  
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*12/19/01*

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

Lambda will review open nonconformities and potential QA Incidents, to determine if any are not being closed.

Compliance Date: January 18, 2002

14. Remedial Actions:

- 1) A process already exists to identify and track open non-conformities. Lambda will review ways to more aggressively implement that process, such as monthly status to management.
- 2) A process already exists to identify and track problems that may result in a QA Incident Report. Lambda will review ways to more aggressively and uniformly implement that process.

15. Extent of Condition:

The extent of condition will be determined as a result of the Remedial actions in 14) and 14a) above.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

The processes to identify and track nonconformities and problems that may result in QA Incident Reports are partially informal.

17. Action to Preclude Recurrence:

Lambda will implement modifications to their existing processes, to ensure that those processes are more uniformly and aggressively implemented. Should procedure revisions be necessary, Lambda will train appropriate personnel to the revised procedures.

18. Due Date: February 18, 2002

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B Reynolds*  
*Mark Helton*

Date *12/17/01*

*12/18/01*  
*BSC QA*

Phone *295-5215*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Richard G. Hamel* Date *12/19/01*

21. Concurrence:

DOQA *D. T. KRISHNA* Date *12/21/01*

TYPE RESPONSE:

- Initial
- Complete
- Amended

**OFFICE OF CIVILIAN  
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WASHINGTON, D.C.**

DR/CAR NO. BSC(V)-02-D-026 *RAH*  
PAGE *13* OF *14* *3/13/04*  
*BKH 3/13/04* QA: *XQA*

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*QR 3/6/02*

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

Lambda has reviewed all open nonconformities and potential QA incidents, and has documented them on a Corrective Action Status Log. The Corrective Action status log has been updated and is being implemented.

Compliance Date:

14. Remedial Actions:

- 1) A revised Corrective Action Status Log has been put in place and is being utilized to track and close nonconformities.
- 2) The Corrective Action Status Log now includes eight means by which a corrective action is identified.

15. Extent of Condition:

All open corrective actions have been reviewed for impact on YMP work. YMP work has not been adversely impacted due to open corrective actions, because the open corrective actions are all administrative in nature.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

- 1) The initial Corrective Action Status Log put in place 7/2000 was not effective in documenting corrective actions.
- 2) QA Incident Reports are usually written when erroneous data has been reported to a client or a procedure has blatantly been ignored causing serious problems and requiring corrective action. It is usually handled directly by the President of Lambda Research and Supervisors involved. The details of these incidents are usually documented and followed up elsewhere while they are in the process of corrective action (job record, phone notes, lab notebooks, LABSTAT, QA clipboards, malfunction reports, etc.).

17. Action to Preclude Recurrence:

Lambda has implemented a modified corrective action status log, to ensure that these processes are more uniformly and aggressively implemented. Affected personnel will be trained by 3/08/02.

18. Due Date: 3/08/02

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B Reynolds* *#00 ISSC QA 3/6/02*  
*TK* *PC for MP* *used*  
Date *3/6/02* Phone *5-5215*

20. Evaluation:  Accept  Partially Accept  Reject

21. Concurrence:

QAR *Robert G. [Signature]* Date *3/7/02*

DOQA *D.T. Kirsh* Date *3/21/02*

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RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

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8.  DR/CAR  
 Stop Work Order

NO. BSC-D-02-026  
PAGE 4 OF 4 *CA# 3/20/02*  
QA: *LQA*

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

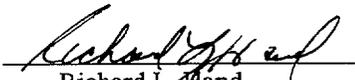
A BSC Quality review has verified completion of corrective action. The following information was reviewed.

1. Reviewed a copy of the corrected/updated Corrective Action Status Log, form 5F2016\_2, dated 12.21.2001. Verified the log now provides Due Date and Closed Date columns to maintain status and track closure. The corrective action log now identifies documents used to initiate corrective action which includes the QA Incident Report.

2. Verified training on the "QA Corrective and Preventative Action" procedure was conducted on Aug. 9, 2001.

All conditions were reviewed by Lambda and determined there was no impact to YMP work. BSC Quality concurs with this determination.

These actions are considered acceptable and adequate for closure of this deficiency and this DR is considered closed.

  
Richard L. Hand

3/20/02  
Date

**OFFICE OF CIVILIAN  
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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT

NO. BSC(V)-02-D-027

PAGE 1 OF 4  
QA: QA

**DEFICIENCY/CORRECTIVE ACTION REPORT**

1. Controlling Document: Lambda Research, Inc. QA Manual, 1M1000_8 (Version 8), 12/29/99	2. Related Report No.: BSC-SA-01-030
3. Responsible Organization: BSC S&ET/Lambda Research, Inc.	4. Discussed With: Marie Marawi, Lambda Research, Inc./Ahmed Monib, BSC/Mark Peters, BSC/Howard Adkins, BSC

5. Requirement:

Control of Measuring & Testing Equipment  
Lambda QA Manual, 1M1000\_8, Section 6.5.1 states in part, ..."Any instruments found that are defective or that did not pass the calibration check will be blue tagged immediately as specified in Section 6.2.3." and "If a problem exists, all projects will be reviewed from the date of the last acceptable calibration check."

6. Description of Condition:

Gage blocks S/N 861221, 861200, 910313, 820719 were identified as failing to meet Grade 2 requirements. There is no evidence of initiation of the "Out of Calibration/Defective Instrument Report." There was no analysis of impact on the work performed.

Gage blocks were taken out of service but this information is not evident in the logs.

The Instrumentation master list was not dated. It was not evident as to which of the three lists on file was the current list.

7. Initiator: <i>Richard L. Hand</i> Richard L. Hand Date 11/13/01	9. Does a stop work condition exist? (Not required for a DR) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If Yes, Check One: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D
--	---

10. Recommended Actions:

Review the "Blue Tag" log to ensure action taken for equipment identified as out of calibration or defective is identified. Complete an analysis of work done using instruments calibrated using the subject gage blocks. Determine if any of the instruments were used on YMP work and have any impact on the work.

11. QA Review: <i>Richard L. Hand</i> QAR Richard L. Hand Date 11/13/01	12. Response Due Date: 10 Working Days From Issuance
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13. DOQA Issuance Approval: Printed Name Donald T. Krishna Signature <i>D. T. Krishna</i> Date 11/15/01
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22. Corrective Actions Verified: QAR <i>Richard L. Hand</i> Date 3/13/02	23. Closure Approved by: DOQA <i>D. T. Krishna</i> Date 3/21/02
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TYPE RESPONSE:

- Initial
- Complete
- Amended

**OFFICE OF CIVILIAN  
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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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*12/19/02* QA: *Y RJA*  
*12/19/01*

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**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

- 1) As of 12/06, Lambda has reinstated the "Out of Calibration / Defective Instrument Report."
- 2) Lambda will fill out "Out of Calibration / Defective Instrument Reports" for the subject instruments.

Compliance Date: January 18, 2002

14. Remedial Actions:

- 1) Lambda will review the "Blue Tag" log, to ensure that "Out of Calibration / Defective Instrument Reports" are filled out for all instruments reported as defective or out of calibration. If a problem exists, all YMP-related projects will be reviewed from the date of the last acceptable calibration check.
- 2) Lambda will conduct a review to determine if there is any impact to YMP quality affecting work from instruments that did not have "Out of Calibration / Defective Instrument Reports."
- 3) Lambda will date the most current version of the instrumentation master list, and remove all others from the work area.

15. Extent of Condition:

Extent of Condition will be determined during the Remedial Actions described in 14) above.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

Failure to ensure implementation of Lambda instrumentation maintenance requirements.

17. Action to Preclude Recurrence:

Lambda will retrain affected employees to the "Out of Calibration/Defective Instrument" requirements specified in Lambda QA Manual 1M1000\_8, Section 6.5.1..

18. Due Date: February 18, 2002

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B. Reynolds*  
*Mark J. Felto*

Date *12/17/01*

*PWA* BSC & APWS  
*RF* *12/18/01*  
Phone *275-5215*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Cookland* Date *12/19/01*

21. Concurrence:

*Robert P. Kele*  
DOQA *D. T. KRISHA* Date *12/21/01*

TYPE RESPONSE:

- Initial
- Complete
- Amended

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

DR/CAR NO. BSC(V)-02-D-027 *AK*  
PAGE *13* OF *14* *3/13/02*  
*AK 3/13/02* QA: *KQA*

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*F32 3/6/02*

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:  
See Initial Response.

Compliance Date:

14. Remedial Actions:

- 1) The form was revised and reinstated in the forms and formats manual. The blue tag log was reviewed for the need to document the impact on work performed by any blue tagged equipment. A report was recorded for the gage blocks that failed Grade 2 calibration.
- 2) Not applicable. See Cause 2) below.
- 3) A title containing the year was added to the form.

15. Extent of Condition:

The blue tag log was reviewed for any work performed by any blue tagged equipment. Except for the referenced gage blocks, there was no other equipment logged during the past 18 months that could potentially have impacted test results. The gage blocks are used to calibrate precision dimensional measuring instruments. There was no impact from the gage blocks because they passed Grade 3 although they failed Grade 2. *Grade 2 tolerance is still greater than the most accurate dimensional measuring instrument to be calibrated.* An out of Calibration/Defective Instrument Report was made for the gage blocks and for all other equipment in the blue tag log for the past 18 months. There was no impact on test results because all failed/defective instruments had been removed from service as part of their placement on the blue tag log. In addition, all of the other equipment besides the gage blocks were removed from service because of routine service or rotation, not because they had failed calibration.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

- 1) The "Out of Calibration/Defective Instrument Report" was part of the quality manual until revision 8 was issued. During Revision 8, forms were removed and placed in the forms and formats manual. This form was erroneously archived.
- 2) The information was recorded in the blue tag log. It did not affect the instrument master list, because the gage blocks that were out of Grade 2 tolerance were replaced completing the gage block set.
- 3) The instrument master list contains a date of revision, but not a title indicating year.

17. Action to Preclude Recurrence:

By 3/8/02, Lambda will retrain affected employees to the "Out of Calibration/Defective Instrument" requirements specified in Lambda QA manual 1M1000\_8 Section 6.5.1

18. Due Date: 3/08/02

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*AK BSC QA 3/6/02*  
*AK Thomas B Reynolds PO for MP 3/6/02*  
Date *3/6/02* Phone *5-5215*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Richard [Signature]* Date *3/13/02*

21. Concurrence:

DOQA *[Signature]* Date *3/21/02*

OFFICE OF CIVILIAN  
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U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

8.  DR/CAR  
 Stop Work Order

NO. BSC-D-02-027

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QA: *LGA*

*3/21/02*

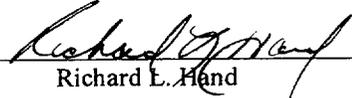
DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

A BSC Quality review has verified completion of corrective action. The following information was reviewed.

1. Verified an "Out of Calibration/Defective Instrument Report", dated 2/15/02, has been written to document the calibration failure of the gauge blocks. The gauge blocks were replaced. The impact analysis statement states that there was no impact on YMP work because the gauge blocks met Grade 3 requirements and that tolerance is greater than required to perform the calibrations.
2. Review of documentation shows that the Out of Calibration/Defective Instrument Report, form 5F2018\_1, dated 1.29.02, has been put back into the Forms Manual and is required by the QA manual in paragraph 6.5.1. Personnel have been notified of the need to implement the "Out of Calibration/Defective Instrument Report" process and Quality Manual requirement 6.5 for "Corrective Action."
3. Verified the calibration schedule, form 2C1307\_8.DOC, dated 1.23.02 now has a date indicating what year it applies to.

All conditions were reviewed by Lambda and determined there was no impact to YMP work. BSC Quality concurs with this determination.

These actions are considered acceptable and adequate for closure of this deficiency and this DR is considered closed.

  
Richard L. Hand

3/21/02  
Date

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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8.  DEFICIENCY REPORT  
 CORRECTIVE ACTION REPORT

NO. BSC(V)-02-D-028

PAGE 1 OF 4  
QA: QA

**DEFICIENCY/CORRECTIVE ACTION REPORT**

1. Controlling Document:  
Lambda Research, Inc. QA Manual, 1M1000\_8 (Version 8), 12/29/99, and  
BSC Subcontract 24540-160-TSA-0109, Mod. 04, Statement of Work, Rev. 3

2. Related Report No.:  
BSC-SA-01-030

3. Responsible Organization:  
BSC S&ET/Lambda Research, Inc.

4. Discussed With:  
Marie Marawi, Lambda Research, Inc./Ahmed Monib,  
BSC/Mark Peters, BSC/Howard Adkins, BSC

5. Requirement:  
Control of Software  
Lambda Procedure 3P4001-2, *Recommended Programming Conventions*, requires that software used in performance of laboratory tests shall be validated to ensure proper functioning.

The Statement of Work, Rev. 3, Section on *Other Documentation*, requires "Software validation records" to be retained.

6. Description of Condition:

- "Restress" software was purchased from Micro Measurement Instrument Division. There is no verification and validation (V&V) documentation available for this program. The V&V of software was identified in the survey and Lambda incorporated the requirement into their procedures, but failed to go back and perform V&V on existing software.
- Documentation for verification of "Trecalc" included pages of data that were not dated or signed to indicate review for acceptability. The "Trecalc" file contained only the latest verification for Rev. 7 but none of the data for previous revisions.

7. Initiator:

*Richard L. Hand*  
Richard L. Hand Date 11/12/01

9. Does a stop work condition exist? (Not required for a DR)

- Yes  No  
If Yes, Check One:  A  B  C  D

10. Recommended Actions:

Obtain verification data from the supplier for "Restress" software or conduct in-house verification of the program. Assess any potential impact on YMP work for any problems identified. If any problems are identified that impact YMP work, repeat stress calculations using corrected program.

11. QA Review

*Richard L. Hand*  
QAR Richard L. Hand Date 11/13/01

12. Response Due Date:

10 Working Days From Issuance

13. DOQA Issuance Approval:

Printed Name Donald T. Krishna Signature *D. T. Krishna* Date 11/15/01

22. Corrective Actions Verified:

QAR Date

23. Closure Approved by:

DOQA *D. T. Krishna* Date 3/21/02  
2/22/02

TYPE RESPONSE:

- Initial
- Complete
- Amended

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

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*12/13/02* QA: *X*

*CSH*  
*12/19/01*

ORIGINAL  
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**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

- 1) As of 12/06, Lambda has initiated efforts to obtain verification data from the supplier for "Restress" software.
- 2) Lambda will cease any use of "Restress" or "Trecalc" on YMP related quality affecting work, until both programs have successfully completed verification and validation (V&V).

Compliance Date: January 18, 2002

14. Remedial Actions:

- 1) Lambda will complete verification and validation (V&V) of "Restress" software, using data obtained from supplier. Lambda will also assess any impacts to YMP work, based on results of V&V. If necessary, Lambda will repeat any affected calculations using the corrected program.
- 2) Lambda will review the V&V for "Trecalc Rev 7.", and will either V&V any previous versions of "Trecalc" that were used on YMP work, or conduct it if it has not already been done. Lambda will also assess any impacts to YMP work, based on results of V&V. If necessary, Lambda will repeat any affected calculations using the corrected program.
- 3) Lambda will review other software that were used on YMP quality affecting work, to ensure that all such programs have been V&Ved, and have the documentation.

15. Extent of Condition:

Extent of Condition will be determined using the outcome of the Remedial Actions defined in 14) above.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

Failure to uniformly implement referenced requirements documents.

17. Action to Preclude Recurrence:

Lambda will develop and implement a process for ensuring that project requirements are more aggressively identified and tracked. Lambda will retrain applicable personnel on software validation requirements.

18. Due Date: January 18, 2002

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B Reynolds RWA*  
*Mark J. [Signature]*

Date *12/17/01*

*RF*  
*12/18/01*  
*BSC 92*  
Phone *295-5215*

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Richard [Signature]* Date *12/19/01*

21. Concurrence:

*Robert P. [Signature]*  
DOQA *D. T. KRISHNA*

Date *12/18/01*

TYPE RESPONSE:

- Initial
- Complete
- Amended

**OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.**

DR/CAR NO. BSC(V)-02-D-028/2014  
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QA: XQA

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TBR 3/15/02

**DEFICIENCY/CORRECTIVE ACTION REPORT (RESPONSE)**

14a. Immediate Actions:

See Initial Response

Compliance Date:

14. Remedial Actions:

- 1) Verification and validation was performed again on the RESTRESS software.
- 2) The versions prior to version 1.7 were developmental and were not used in any client data.

15. Extent of Condition:

- 1) Verification and validation has historically been performed on both custom and purchased software, prior to installation at Lambda research. Program directories are strictly controlled to prevent changes or modifications. There are no software packages that have not been verified and validated prior to use on YMP QA work.
- 2) It was determined that there was no impact on YMP work since the current version in place (1.7) was validated prior to loading on the system, and has been in use since 07/18/95.

16. Cause: (Attach results of root cause determination prepared in accordance with AP-16.4Q for a significant deficiency.)

- 1) Failure to document verification and validation of purchased software.
- 2) Programs are not loaded onto the system unless they have been validated and verified by the President of Lambda Research. The President is in charge of loading the accepted version on the LAN system. Date modified and author is contained in the program. Signing and dating a copy of the program was overlooked.

17. Action to Preclude Recurrence:

Lambda will retrain applicable personnel on software validation requirements before 3/08/02.

18. Due Date: 3/08/02

- For submittal of complete response
- For completion of corrective action

19. Response by: Thomas B. Reynolds

*Thomas B Reynolds* WTP 3/4/02 NUS BSC QA  
used 3/4/02  
Date 3/4/02 Phone 5-5215

20. Evaluation:  Accept  Partially Accept  Reject

QAR *Richard D. Hood* Date 3/7/02

21. Concurrence:

DOQA *W. T. Keisha* Date 3/21/02

OFFICE OF CIVILIAN  
RADIOACTIVE WASTE MANAGEMENT  
U.S. DEPARTMENT OF ENERGY  
WASHINGTON, D.C.

8.  DR/CAR  
 Stop Work Order

NO. BSC-D-02-028

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QA: XGA

3/21/02

DEFICIENCY/CORRECTIVE ACTION REPORT/STOP WORK ORDER CONTINUATION PAGE

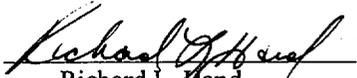
A BSC Quality review has verified completion of corrective action. The following information has been reviewed.

1. Reviewed print out of completed computation for known input, dated 12/3/01. Verified resulting data matches that which the program developer indicates should result.
2. Verified "Trecalc" data has been signed and dated. Revision 1.7 has been validated by Lambda. This is the version presently loaded and used on YMP work. Previous revisions were developmental and not used.

Lambda personnel have been retrained on the requirement for Verification and Validation of Software.

All conditions were reviewed by Lambda and determined there was no impact to YMP work. BSC Quality concurs with this determination.

These actions are considered acceptable and adequate for closure of this deficiency and this DR is considered closed.

  
Richard L. Mand

3/21/02  
Date