



**Department of Energy**  
 Office of Civilian Radioactive Waste Management  
 Yucca Mountain Site Characterization Office  
 P.O. Box 98608  
 Las Vegas, NV 89193-8608

OCT 11 1996

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 Technical Project Officer  
 for Yucca Mountain  
 Site Characterization Project  
 TRW Environmental Safety Systems, Inc.  
 Bank of America Center, Suite P-110  
 101 Convention Center Drive  
 Las Vegas, NV 89109

**VERIFICATION OF CORRECTIVE ACTION AND CLOSURE OF DR YM-96-D-079  
 RESULTING FROM OFFICE OF QUALITY ASSURANCE SUPPLIER AUDIT  
 OQA-SA-96-020 OF FRAMATOME COGEMA FUELS**

The Yucca Mountain Quality Assurance staff has verified the corrective action to Deficiency Report (DR) YM-96-D-079 and determined the results to be satisfactory. As a result, the DR is considered closed.

If you have any questions, please contact either Mario R. Diaz at (702) 794-1489 or Richard L. Maudlin at (702) 794-1302.

Richard E. Spence  
 Yucca Mountain Quality Assurance

YMQA:MRD-0083

Enclosure:  
 DR YM-96-D-079

cc w/encl:  
 T. A. Wood, DOE/HQ (RW-14) FORS  
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RECIP: NMSS/PAHC



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

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**PERFORMANCE/DEFICIENCY REPORT RESPONSE**

**14 Remedial Actions:**

The action required to correct the specific conditions noted in block 6 are as follows:  
The inputs to the Waste Package Filler Material Testing Report will be specified as unqualified because of the conditions listed in block 6. The FCF procedure QCR-64 is being revised to eliminate the requirements for this data. This will require that any further work specify in the implementing document that the calibration records contain all information required by the QARD.

**15 Extent of Condition: (Not required for PR)**

The condition is isolated to the Filler Material Test Program and the related document. This was the only program or product associated with Framatome Cogema Fuel in Lynchburg. A review of a number of calibration records reveals the same condition exists but this does not impact the quality of the report because the purpose was to prove the feasibility of adding shot to the waste package and the tolerance of the test far exceeds the problem that could exist with the calibration of equipment.

**16 Root Cause Determination: (Not required for PR)**

Required  Yes  No

The root cause determination is that the implementing document failed to make it clear that the program was to be performed to the requirements of the QARD and not only to the FCF QA program. The certificate information issue was determined to be human error. (See attached root cause analysis). The procedure requires a review of the records upon receipt of the instrument. This is verified by internal audits which will increase the focus on this in the future.

**17 Action to Preclude Recurrence: (Not required for PR)**

Required  Yes  No

The program has been concluded so no action is necessary for this project. If future work is to be done at this facility, the implementing document will specify the areas where the FCF QA program and the QARD differ. These areas will be specifically detailed to obtain the correct documentation as required by the QARD. These will include the use of qualified suppliers for calibration of instruments, the information required on the calibration record, and submission of these records to Waste Package Development for inclusion in the records package.

**18 Corrective Action Completion Due Date:**

30 SEPT 96 *9/1/96*

\*. Review with J. COGAR

**19 Response by:**

Initial

Amended

*Ying 1 Moof for A. Segrest*

Date *9-03-96* Phone *794-1924*

**20 Response Accepted**

QAR

*[Signature]*

Date *9/12/96*

**21 Response Accepted (N/A for PR):**

AQQAM

*Robert B. Constable*

Date *9-20-96*

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6 Description of Condition: (Continued)

Calibration Certification from Satec, Certificate for calibration of FCF 044-1135 (QC-519) performed on 6/20/96, did not include the next calibration due date of the supplier's standard and a statement of accuracy of the standards used in performing the calibration.

Calibration Certification from the Commonwealth of Virginia, dated 2/6/96, Test No. VA-96-6270, did not include a reference to the specific standard used, the last and next calibration due date of the supplier's standard used, and a statement of accuracy of the standards used in performing the calibration.

- C. Calibration records of instruments used to perform work for the CRWMS M&O were not being maintained in a 1 hour fire rated facility or dual storage.

10 Recommended Action: (Not required for PR)(Continued)

- B. Determine and document the impact on quality due to: (1) The lack of calibration records not meeting the procurement documents; and (2) Using unqualified suppliers to perform calibrations.
- C. Identify and document the cause of the conditions adverse to quality described in Block 6.
- D. Identify and document the actions taken to preclude recurrence.

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Refer to Subsection 5.2 and 5.3 of AP-16.4Q for amplification of information.

1. Identify the adverse condition.
  - A. The Commonwealth of Virginia was used for the calibration of FCF standards and had not been evaluated in accordance with QARD Section 7.0.
  - B. Calibration certification documentation did not include the required information.
  - C. Calibration records of instruments used to perform work for the CRWMS M&O were not being maintained in a 1 hour fire rated facility or dual storage.
  
2. Indicate *Where* the condition was found.

The condition was found at Framatome Cogema Fuels during an OCRWM audit.
  
3. Note *When* the condition was first found.

The condition was found during an audit of Framatome Cogema Fuels conducted on 25 and 26 July 1996.
  
4. Select which major program element(s) was affected. (Waste Acceptance, Storage, Transportation, or Repository.)

Repository
  
5. Denote the specific area(s) or discipline(s) of the major program element the condition occurred.  
(e.g., engineering, design, ES&H)  
Engineering development
  
6. Determine if the condition is isolated or recurring.

The condition is isolated to this development program.
  
7. Determine if the condition is hardware (item) or programmatic (procedures, personnel) related or both.

The condition is procedure related.
  
8. Denote what organizations are affected by this condition (M&O, USGS, Weston, OCRWM, etc.).

M&O

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9 Document the changes that have taken place that could have caused the condition.  
The change that has taken place is the attempt to conduct a development program using "home office" support and conducting the program under their QA program as a qualified vendor.

10. Determine the need for sketches or photographs.  
N/A

11. Determine the need for laboratory tests.  
N/A

12. Identify the physical evidence examined.  
The physical evidence examined includes purchase orders and calibration records.

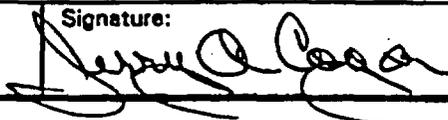
13. Note the relevant documents reviewed.  
Relevant documents reviewed include the FCF QA manual, purchase orders for calibration, and the calibration certificates.

14. Document any other information that may be pertinent to supporting the selection of the correct root cause.  
N/A

15. Interviews conducted:  Yes  No  
If Yes, refer to page 3 of this attachment.

RI or designee: (Print)  
Jerry A. Cogar

Signature:



Date:

9/3/96

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TELEPHONE OR PERSONAL INTERVIEW RECORD

Person interviewed: (Print) C. A. Armontrout		Title: Manager of Quality Assurance	
Organization/Location: FCF/Lynchburg Va.	Telephone No.: (804) 832-5043	Date/Time: 07/24/96	CAR No./DR No.: DR YM-96-D-079

Interview Details:

Mr. Armontrout was interviewed at the time of the audit. He concluded that the development program was conducted under FCF's QA program as specified in the implementing document. He also stated that the calibration certificates did not contain the required information as required by FCF's QA manual and procedures.

Jerry A. Cogar

Interviewer

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Root Cause Code:  
(1)(B)(d), (1)(C)(g), (8)(C)(c)

CAR No./DR No.:  
DR YM-96-D-079

Root Cause:

The implementing document failed to make it clear that the program was required to meet all of the QARD requirements and not just be performed to meet only the FCF QA program. The incorrect information on the certificate was a result of the responsible individual not reviewing the certificate as required.

Justification or Rationale for Selected Root Cause:

The root cause was selected because the FCF QA manager admitted that he understood the differences in the FCF QA program and the QARD. He stated that it was his understanding that the program was to be conducted under the FCF QA program.

The calibration issue occurred because the responsible individual did not closely review the certificates against what was required by the procedures.

Designee: (Print)  
Jerry A. Cogar

Signature:



Date:

9/3/96

RI: (Print)

Signature:

Date:

**Interoffice Correspondence**  
**Civilian Radioactive Waste Management System**  
**Management & Operating Contractor**



TRW Environmental  
Safety Systems Inc.

WBS: 1.2.2.3.4  
QA: L

**Subject**  
Required wording for future  
TGD's (SCPB: N/A)

**Date**  
August 23, 1996  
LV.WP.JAC.08/96-208

**From**  
H. A. Benton

**To**  
A. M. Segrest

**cc**  
J. A. Cogar  
R. L. Maudlin HL-455  
RPC

**Location/Phone**  
TES3/423  
(702)794-5387

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In order to assure that future development work at Framatome Cogema Fuels (FCF) or Framatome Technologies Incorporated (FTI) is performed in the correct manner, specific words will be included in the specific QA requirements section of the technical guidelines document. A sample is provided on the following pages of this IOC and are in bold print for identification purposes.

The words on the following pages will be discussed with Framatome Cogema Fuels or Framatome Technologies Incorporated QA and shop personnel prior to the start of any future work at either of these facilities. This will be done by Waste Package Development personnel to assure that the people performing the work have a full understanding of the QARD requirements before the project is started.

**Specific QA requirements are as follows:**

- 1. The work described in this Technical Guidelines Document shall be performed under the controls described in the Framatome Technologies, Inc (FTI) QA Program Manual, Rev 02, dated 01/02/96 and shall only use the Safety Related portion of the manual. The Framatome Technologies, Inc QA Program shall be accepted by the M&O prior to the performance of work described in this document. Any changes or revisions to the Framatome Technologies, Inc QA Program shall be identified to the M&O, in writing, prior to the implementation of the revision.**
- 2. The M&O, OCRWM, its agents or assigns, shall have the right to inspect and evaluate Framatome Technologies, Inc facilities, records and activities at any time during the performance of the work described herein. This right shall extend to sub-tier suppliers and shall be coordinated through Framatome Technologies, Inc.**
- 3. Framatome Technologies, Inc shall be responsible for assuring that all sub-tier suppliers implement a QA program commensurate with the services rendered. When a sub-tier supplier is used to satisfy the specific actions defined in this technical guidelines document, all technical and quality requirements imposed in this document and its supplements shall be transmitted to the sub-tier suppliers. All purchase orders shall specify the Safety Related QA requirements and be review by FTI QA for compliance.**
- 4. All records and reports shall reference or be traceable to this technical guidelines document and shall be of sufficient quality to be reproduced legibly, be microfilmable, and be dated and bear the title and signature of a qualified individual who is attesting to the authenticity of the record content.**
- 5. Documentation retention times shall be in accordance with the Framatome Technologies, Inc QA Program as accepted by the M&O with the exception that any records classified by FTI as non-permanent or not stored in dual storage facilities will be submitted to Waste Package Development with the data package for inclusion into the records package.**
- 6. Deliverables and work performed that do not meet the requirements of this technical guidelines document shall be reported and evaluated in accordance with the Framatome Technologies, Inc nonconformance system.**
- 7. Framatome Technologies, Inc shall submit a report of nonconformance to the M&O including recommended disposition and technical justification for the dispositions of "Use-As-Is" or "Repair". Additionally, Framatome Technologies, Inc shall comply with the provisions of the Code of Federal Regulation, Title 10, Part 21, Reporting of Defects and Noncompliance (10 CFR 21) (Ref 15).**
- 8. Data reports, final reports, and test results provided to the M&O under the terms and conditions of this Technical Guidelines Document shall include the following, as applicable:**

- a. The number of this Technical Guidelines Document (i.e., BBA000000-01717-2500-00001 Rev 02)
- b. Name of organization (company) performing the test or analysis
- c. Unique identification of the sample or material analyzed
- d. Name or identification of the person(s) performing the analysis
- e. Unique identification of the instruments used in the performance of the analysis
- f. Unique identification of the reference standard used in the analysis
- g. Procedure or instruction, and revision, used to perform the analysis

9. A Certificate of Conformance is required for all hardware or services performed. The Certificate of Conformance shall contain the following as a minimum:

- a. Identification of the material, equipment, or service provided
- b. Identification of the specific Technical Guidelines requirements that are met. Requirements identified shall include any approved changes, waivers, or deviations. Where maintenance or rework has been performed, include description of principal activity performed and identification of specific part(s) or hardware replaced.
- c. Identification of any Technical Guidelines requirements that have not been met, together with an explanation and the means for resolving the nonconformance(s)
- d. Signature or authentication otherwise by a person responsible for this QA function and whose function and position are described in the Framatome Technologies, Inc QA Program.

10. Proposal Evaluation Criteria have not been listed because the work is considered to be "home office support".

11. Measuring and test equipment shall be calibrated by an audited and approved organization and or may be done in-house using standards that were calibrated by an organization audited and approved by FTI and the calibration documentation shall include the following information:

- A. Identification of the measuring or test equipment calibrated.
- B. Traceability to the calibration standard used for calibration.

- C. Calibration data.**
- D. Identification of the individual performing the calibration.**
- E. Identification of the date of calibration and the recalibration due date or interval, as appropriate.**
- F. Results of the calibration and statement of acceptability.**
- G. References to any actions taken in connection with out-of calibration or nonconforming measuring and test equipment including evaluation results, as appropriate.**
- H. Identification of the implementing document (including revision level) used in performing the calibration.**

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WASHINGTON, D.C.

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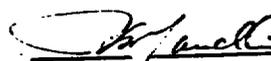
QA: L

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VERIFICATION AND CLOSURE OF PR YM-96-D079

A review of the Waste Package Filler Material Testing Report, dated October 3, 1996, Pages v and 5 reveal that a statement has been added to reflect that the instruments used to take measurements for inputs to this report are unqualified. In addition, a review of Framatome Cogema Fuels procedure QCR-64, Revision 4 revealed that the requirements for calibration documentation had been modified. Based on these actions and the response provided, the conditions in this DR have been satisfactorily resolved. If Framatome Cogema Fuels is given any future work, the implementing document issued to Framatome Cogema Fuels will be evaluated against the draft implementing document provided with the response to this DR.

As a result, no further action is required in resolution to this DR. This DR is considered closed.

  
R.L. Maudlin

10/04/96  
Date