

OFFICE OF RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE AUDIT PLAN

FOR AUDIT YMP-93-14

OF

LAWRENCE LIVERMORE NATIONAL LABORATORY

LIVERMORE, CALIFORNIA

JULY 19-23, 1993

Prepared by: Richard L. Weeks Date: 6/1/93
Richard L. Weeks
Audit Team Leader
Yucca Mountain Quality Assurance Division

Approved by: Donald G. Horton Date: 6/3/93
Donald G. Horton
Director
Office of Quality Assurance

1.0 SCOPE

This audit, to be performed by a team of auditors from the Yucca Mountain Quality Assurance Division (YMQAD), will evaluate the Lawrence Livermore National Laboratory (LLNL) Quality Assurance (QA) Program to determine whether it meets the requirements and commitments imposed by the Office of Civilian Radioactive Waste Management. This will be accomplished by verifying implementation and effectiveness of the system in place, as well as verifying compliance with requirements.

In addition to follow-up on open Corrective Action Requests, a representative sample of deficiencies identified during previous QA audits and surveillances of LLNL, will be included in the scope of this audit to determine the effectiveness of LLNL corrective actions.

The programmatic and technical elements to be audited, as well as those programmatic elements not included in this audit, are identified in Section 4.0 of this audit plan.

2.0 AUDIT SCHEDULE

Pre-Audit Team/Observers Meeting	8:30 a.m. July 19, 1993 Livermore, CA
Pre-Audit Conference	9:00 a.m. July 19, 1993 Livermore, CA
Audit Activities	10:00 a.m. to 4:00 p.m. July 19, 1993
	8:00 a.m. to 4:00 p.m. July 20-22, 1993
	8:00 a.m. to 10:30 a.m. July 23, 1993
Post Audit Conference	11:00 a.m. July 23, 1993

There will be a daily Audit Team Leader/observer/LLNL meeting starting at 8:30 a.m. to discuss potential deficiencies and establish needed liaison, and also a daily YMQAD audit team/observer meeting starting at 4:00 p.m. Both daily meetings will be held at locations provided by LLNL.

3.0 REQUIREMENTS TO BE AUDITED AND APPLICABLE REFERENCES

The requirements to be audited will be contained in the programmatic and technical checklists. These checklists will be developed from the latest available revision of the following documents:

- LLNL Quality Assurance Program Plan (QAPP) and implementing procedures
- Applicable Yucca Mountain Site Characterization Project Office Administrative Procedures - Quality

The conduct of the audit will be in accordance with the documents (latest revision) listed below:

- Quality Assurance Administrative Procedure (QAAP) 18.2, "Audit Program"
- QAAP 16.1, "Corrective Action"

4.0 ACTIVITIES TO BE AUDITED

QA Program Elements:

- 3.0 Scientific Investigation Control
- 4.0 Procurement Document Control
- 7.0 Control of Purchased Items
- 8.0 Identification and Control of Items, Samples and Data
- 13.0 Handling, Storage and Shipping
- 15.0 Nonconforming Items

QA Program Elements 19.0, "Computer Software" and 20.0, "Scientific Investigations" are included in QA Program Element 3.0 in accordance with the current revision of the LLNL QAPP. LLNL has no responsibility for Design Control at this time.

The following QA program elements were considered during development of this audit plan and found to be not applicable, since the current LLNL QA Program has no activities for which these elements apply:

- 10.0 Inspection
- 11.0 Test Control
- 14.0 Inspection Test and Operating Status

Technical Areas by Work Breakdown Structure (WBS) No./Activity No.

WBS 1.2.2.3.1.1/D-20-45, Lo Temperature Oven Method for SF Oxidation

WBS 1.2.2.3.1.1/D-20-53a, Flow-through Dissolution Tests on UO₂

WBS 1.2.2.3.1.1/D-20-53b, Flow-Through Dissolution Tests on SF

WBS 1.2.2.3.1.2/D-20-27, Unsat Test on Glass

5.0 AUDIT TEAM MEMBERS

Richard L. Weeks, Audit Team Leader, YMQAD, Las Vegas, Nevada

Kenneth T. McFall, Lead Technical Specialist, YMQAD, Las Vegas, Nevada

Mario R. Diaz, Auditor, YMQAD, Las Vegas, Nevada

Thomas J. Higgins, Auditor, YMQAD, Las Vegas, Nevada

John E. Therien, Auditor, YMQAD, Las Vegas, Nevada

6.0 AUDIT CHECKLISTS

The following checklists will be used during the audit:

YMP-93-14-01, Programmatic Checklist

YMP-93-14-02, Technical Checklist

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QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED LLNL	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Richard Weeks</u> DATE <u>7/13/93</u>
DATES OF EVALUATION 7/19-23/93			

CONTROLLING DOCUMENT (Title, Number, Revision)	ACTIVITY EVALUATED
------------------------------------------------	--------------------

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-1	<p>033-YMP-QP 2.8, REVISION 3, QUALITY ASSURANCE GRADING</p> <p>Para. 2.8.5.1</p> <p>Each individual technical activity must be graded. Subordinate parts of these graded activities may be graded separately.</p> <p>Verify that technical activities are graded.</p>		

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (NA)

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3-2	<p>Para. 2.8.5.1</p> <p>New technical activities must be graded prior to start of work.</p> <p>Verify that new technical activities are graded prior to the start of work.</p>		
3-3	<p>Para. 2.8.5.2</p> <p>QA Grading is documented by the Task Leader on forms such as those shown in Exhibits B, C and D. (If another format issued to document the process, all information on the sample exhibits must be addressed.)</p> <p>Verify that the information on Exhibits B, C, and D is addressed on grading forms.</p>		

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3-4	<p>Para. 2.8.5.2.2</p> <p>Application of the following list of characteristics illuminate the issues. Documentation of this process is done using Exhibit C, and this documentation is mandatory.</p> <ul style="list-style-type: none"> a. Reproducibility or Replacement b. Complexity c. Quality History d. Standardization e. Available Codes and Standards f. Need for Process Control g. Special Handling, Shipping, or Storage <p>Verify documentation of the above.</p>		

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3-5	<p>Para. 2.8.5.3</p> <p>QA Grading Review is accomplished by the appropriate Technical Area Leader (TAL), the Project Leader (PL) or designee, and the QA Manager (QA). If the TL and TAL are the same person, QA Grading Review is accomplished by the PL or designee, and the QA.</p> <p>Verify the above has been implemented.</p>		
3-6	<p>Para. 2.8.5.6</p> <p>After the QA Grading Review has been completed, all necessary documentation is collected in a documentation package. The PL or designee is responsible for assembling the documentation. Once all documentation is in final form, the QA Grading Reviewers sign and date Exhibit A.</p> <p>Verify that the documentation is assembled as required,</p>		

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3-7	<p>Para. 2.8.6</p> <p>Any changes to QA grading are handled through the same process used to perform the original grading.</p> <p>Verify that changes to QA grading are handled the same as the original</p>		
3-8	<p>Para. 2.8.7</p> <p>QA records include Exhibits A through D with attachments.</p> <p>Verify that QA records include Exhibits "A" through "D."</p>		

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3-9	<p>QP 3.0, REVISION 2, SCIENTIFIC INVESTIGATION CONTROL</p> <p>Para. 3.0.4</p> <p>Before work begins, i.e. before data is generated, analysis is performed or conclusions are reached, the work is planned, reviewed and approved by preparation of one or more of the following work planning documents:</p> <ul style="list-style-type: none"> o Scientific Investigation Plans o Study Plans (for Site Characterization activities) o Activity Plans <p>Verify that one of the above is used prior to starting work.</p>		
3-10	<p>Para. 3.0.4.1</p> <p>All quality affecting activities subject to the QA grading process are identified in the SIP.</p> <p>Verify compliance with the above requirement.</p>		

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3-11	<p>Para. 3.0.4.1</p> <p>The intent to use scientific notebooks and the purpose for their use is identified in the SIP.</p> <p>Verify compliance with the above requirement.</p>		
3-12	<p>Para. 3.0.4.4</p> <p>For field tests in the Yucca Mountain area or in the ESF, a Test Planning Package (TPP) must be prepared. YMPO must approved the TPP. Following approval of the TPP, a Job Package must be prepared and approved by the YMPO prior to conduct of the test.</p> <p>Verify the above for the Fran Ridge heated block test.</p>		

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3-13	<p>Para. 3.0.6</p> <p>The scientific notebook (SN) will be used to record data, information, analysis and work progress on a daily or as appropriate basis.</p> <p>Verify the use of SNs.</p>		
3-14	<p>Para. 3.0.6</p> <p>The extent of documentation of the SN is such that another qualified scientist can use the SN to retrace the investigation and confirm the results or repeat the experiment without recourse to the original investigator.</p> <p>Verify compliance with the above requirement.</p>		

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3-15	<p>Para. 3.0.9</p> <p>The PI/Task Leader will identify the hold points in the Activity Plan.</p> <p>Verify the inclusion of hold points and their disposition.</p>		
3-16	<p>Para. 3.0.9</p> <p>Waiver of a specified hold point is approved by the QA Manager and documented before work can proceed beyond the designated hold point.</p> <p>Verify the documentation of hold point waivers.</p>		
3-17	<p>Para. 3.0.10</p> <p>The method of transmittal of information or items, including samples of natural or man-made materials, across interfaces are documented.</p> <p>Verify the documentation of information transmittal.</p>		

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3-18	<p>Para. 3.0.12</p> <p>Results of activities are documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer and date.</p> <p>Documentation of interpretation/analysis includes the following:</p> <ul style="list-style-type: none"> o Summary of results. o Definition of the objective of the interpretation/analysis. o Discussion of whether the work's objectives as outlined in the planning document(s) were achieved. 		

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3-18 Cont'	<ul style="list-style-type: none"> o Definition of input and their sources. o A listing of applicable references. o Results of literature searches or other background data. o Statement of assumptions. o Identification of any computer calculation, including computer type, program name, revision, input, output, evidence of program verification, and the basis of application to the specific problem. o Signatures and dates of review and approval by appropriate personnel. <p>Verify that results are documented as required.</p>		

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3-19	<p>033-YMP-QP 3.3, REVISION 2, REVIEW OF TECHNICAL PUBLICATIONS AND DATA</p> <p>Para. 3.3.4</p> <p>When draft reports are ready for publication, they must be submitted to a formal, controlled, and thoroughly traceable review process.</p> <p>Verify that drafts of publications are submitted for review.</p>		
3-20	<p>Para. 3.3.4.2</p> <p>One technical reviewer must be independent of technical efforts that resulted in the report. A peer who works for the same programmatic supervisor (usually the Task Leader [TL]), but who did not perform the technical work, is considered independent. The next higher programmatic supervisor (usually the TAL) who did not perform the technical work is also considered independent. The responsible programmatic supervisor who did not perform the technical work is not considered independent and cannot be a technical reviewer unless the LLNL-YMP Leader or designee documents, in advance, that another reviewer cannot be identified.</p> <p>Verify the independence of technical reviewers.</p>		

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3-21	<p>Para. 3.3.4.5</p> <p>The Publications Manager retains all review documentation in a fire resistant cabinet until distribution of the printed publication is completed. The Publications Manager completes the proper forms and submits the review packages, along with a copy of the printed report, to the LRC.</p> <p>Verify compliance with the above requirements.</p>		

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3-22	<p>QA records include the following documents, as applicable:</p> <p>Publication Review:</p> <ul style="list-style-type: none"> o the original draft; o completed "technical Data, Milestones, and Records Form" (Exhibit A); o completed "Technical Report Review Record for YMP Reports" (Exhibit B); o completed "Technical Reviewer's Comment Form(s)" (Exhibit C); o documentation of comment resolution, if applicable (usually a second Exhibit C); o copy of transmittal letter to YMPO with manuscript, if different from the original; o all supporting documentation from YMPO reviews; o YMPO approval letter; o any documentation of disputed comments and their resolution by the LLNL-YMP Leader; and o published technical report. 		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-22 Cont'	<p>Data Review:</p> <ul style="list-style-type: none"> o the original draft (paper or other approved media); o completed "Technical Reviewer's Comment Form(s) for Technical Data Submittal" (Exhibit D); o completed "Technical Review Record for YMP Technical Data Submittal" (Exhibit E); o documentation of comment resolution, if applicable (usually a second Exhibit D); o documentation of disputed comments and their resolution by the LLNL-YMP Leader, if applicable; o final version of the data document (paper or other approved media); and o copy of the transmittal letter and TDIF to the appropriate database administrator. <p>Verify the inclusion of the above QA records.</p>		

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3-23	<p>033-YMP-QP 3.4, REVISION 2, SCIENTIFIC NOTEBOOKS</p> <p>Para. 3.4.5.1</p> <p>The LRC shall keep a record of the SN Custodian, the unique identifier, and the date of issue of each SN; and</p> <p>The LRC must be informed regarding which SN has been reassigned, to whom, and when.</p> <p>Verify LRC compliance with the above requirements.</p>		

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3-24	<p>Para. 3.4.5.2.1</p> <p>The Investigator is responsible for entering the following initial SN entries:</p> <ul style="list-style-type: none"> o The title, number and version of the applicable Activity Plan or any other Plan such as an individual Software Plan) and the number and version of a Technical Implementing Procedure (TIP[s]) to be used with their SN, if any. <p>Plans and TIPs may be used in conjunction with SNs but are not required to make SNs acceptable. Plans and TIPs may be referenced in the initial entry or in subsequent entries of the SN. If Plans and TIPs are not referenced or if these documents did not contain the following items, the initial SN entries must describe the following subject areas to the extent known at the time the initial entries are made: The research objective, proposed approach, equipment to be used, any starting material characterization required, calibration requirements, training/qualification requirements, environmental requirements, accuracy and precision requirements, and potential sources or error.</p>		

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3-24 Cont'	<ul style="list-style-type: none"> o A list of personnel using the notebook and examples of their signatures and initials. o Any other information necessary to understand the research to be documented. In general, this will be information not in the referenced documents. o Date and signature of an Investigator and of the TL. If the Investigator is a TL or TAL, a second signature is not required; however, the Investigator may solicit a review/signature from a technically qualified reviewer. o Other entries if appropriate. o If an activity requires more than one SN before it is completed, the Investigator may enter the initial SN entries on the first SN only and may refer to such entries at the beginning of every subsequent or linked SN. <p>Verify the inclusion of these SN entries.</p>		

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3-25	<p>Para. 3.4.5.2.2</p> <p>All SN Entries shall:</p> <ul style="list-style-type: none"> o Be recorded in the Table of Contents (TOC). If entries are made in the SN more frequently than once per week, one consolidated TOC entry per week is acceptable. o Be in permanent ink that is legible after photocopying. o Have loose materials securely fastened so they cannot be removed without detection. o Blank pages or substantial blank space on a page shall be identified as either blank or reserved for a purpose. o Have errors corrected by single line-through the incorrect entry which leaves the incorrect entry readable. Each correction must be initialed and dated. o Make reference to changes in the initial entries or the referenced documents as they apply to the work covered by the SN. o Include the Investigator's name/initials and date for each entry. <p>Verify compliance with the above requirements.</p>		

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3-26	<p>Para. 3.4.5.2.3</p> <p>Final SN entries shall include signatures of the SN custodian and a Technical Reviewer prior to the final submittal of the SN to the LRC.</p> <p>Verify the existence of the above signatures.</p>		
3-27	<p>Para. 3.4.5.3.1</p> <ul style="list-style-type: none"> o The SN shall be reviewed by the TL at least annually, at the completion of the SN, and at completion of the activity. o The TL shall sign and date the review and indicate that the entries were read and understood. o If the Investigator is a TL or TAL, a TL review is not required. <p>Verify compliance with the above requirements.</p>		

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3-28	<p>Para. 3.4.5.3.2</p> <ul style="list-style-type: none"> o SNs shall be technically reviewed by a SN Technical Reviewer who is selected by the TL. o The Reviewer indicates that the SN has been reviewed and understood, then signs and dates the entry. <p>Verify compliance with the above requirements.</p>		
3-29	<p>Para. 3.4.6</p> <p>The SN is submitted to the LRC for photocopying annually or when the SN is full. Alternatively, the SN may be copied by the Investigator and these copies submitted to the LRC. If the SN contains photocopies of original data, then the SN must be submitted since third generation photocopies are not acceptable. The SN will be returned to the Custodian after photocopying.</p> <p>Verify compliance for retained documentation.</p>		

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4-1	<p>PROCUREMENT DOCUMENT CONTROL 033-YMP-QP-4.0, REVISION 3, CHANGE NOTICE 4.0-3-1</p> <p>Para 4.0.5.1 Verify that the Requester includes the scope of work, technical requirements, and QA requirements in Purchase Requisitions (PR).</p>		
4-2	<p>Verify that The Task Leader prepares a Procurement Document Review (PDR) form if the procurement is quality affecting and/or a Technical Services Contract and that the Task Leader indicates whether the procurement is quality affecting.</p>		

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4-3	Verify that the RPCM reviews the package for completeness, accuracy, and compliance with LLNL and YMP procurement requirements.		
4-4	Verify that the QA reviews the procurement package to assure that necessary Quality Assurance requirements are included. The QA returns the package to the RPCM. The RPCM attaches the YMP Procurement Action Form and submits the package to the LLNL Procurement Department.		

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4-5	Verify that LLNL procurement notifies the QA when the final purchase document has been completed and that for quality-affecting procurement, the QA signs the QA Procurement Action form prior to final placement.		
4-6	Para 4.0.5.2 Verify that memorandums initiating SANL procurement address: <ul style="list-style-type: none"> a. Workscope b. Amount Requested c. Period of Performance d. Account Number e. Technical contact at LLNL and the contracted organization f. Applicable QA Requirements 		

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4-7	Verify that the QA signs the Procurement Action form for quality-affecting SANL procurement.		
4-8	Para 4.0.5.3 Verify that items or services obtained internally from other LLNL organizations have documentation that specify applicable technical and quality requirements.		

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4-9	<p>Verify that Memorandum of Agreement between LLNL-YMP and other LLNL entities are approved by the TAL, YMP Leader, and QA.</p> <p>PREPARATION OF QUALITY ASSURANCE REQUIREMENTS SPECIFICATIONS AND APPROVAL OF SUBCONTRACTOR QA PROGRAMS 033-YMP-QP 4.1, REVISION 2, CHANGE NOTICE 4.1-2-1</p> <p>Para. 4.1.5.1.1</p>		
4-10	<p>Verify that the QA prepares the Generic QA Requirements Specification and that it is approved by the YMP Project Leader.</p>		

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4-11	<p>Para. 4.1.5.2.3</p> <p>Verify that Subcontract QA Requirements Specifications are approved by the cognizant Technical Area Leader, the QA, and the Project Leader.</p>		
4-12	<p>Para. 4.1.5.3.2</p> <p>Verify that QA reviews Subcontractors Quality Assurance Program Manual for inclusion of the requirements specified in the Subcontract QA Requirements Specification.</p>		

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4-13	Para. 4.1.5.3.3 Verify that the QAM conducts a Pre-qualification QA Surveillance of the subcontractor's facilities.		
4-14	Para. 4.1.5.3.6 Verify that the cognizant Task Leader provides a letter to the subcontractor indicating that the QA Program is approved.		

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4-15	Para. 4.1.5.4.3 Verify that Task Leaders Review existing subcontract QA Requirements Specifications each time there is a change to the Generic QA Requirements Specification.		

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8-1	IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA 033-YMP-QP 8.0, REVISION 1 Para. 8.0.4.1 Verify that identification of items is related to documentation specified in the same paragraph.		

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8-2	<p>Para. 8.0.4.1.1</p> <p>Verify that physical identification used where practical otherwise, other methods are used to maintain traceability.</p>		
8-3	<p>Para. 8.0.4.2</p> <p>Verify that samples are identified and controlled in a manner consistent with their intended use. Additionally, when samples are no longer needed, they are archived in accordance with requirements of the same paragraph.</p>		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-4	<p>Para. 8.0.4.2.2</p> <p>Verify that samples have their identifications (ID) attached or traceable. Additionally the ID of samples is verified and documented prior to release for use by LLNL personnel</p>		
8-5	<p>Para. 8.0.4.2.4</p> <p>Verify that samples are adequately stored in order to maintain their physical conditions and do not degrade during long-term storage.</p>		

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8-6	<p>Para. 8.0.4.2.6</p> <p>Verify that a record is kept for all locations and types of environments of the sample identifiers plus additional requirements described in the same paragraph.</p>		
8-7	<p>Para. 8.0.4.2.7</p> <p>Verify that identifiers specify the use limitations or the maximum life expectancy of the samples.</p>		

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8-8	<p>Para. 8.0.4.3.1</p> <p>Verify that identification of data includes a reference to the origin of the data (e.g. task, test, experiment, report or publication) and the QC imposed on the activity which produced the data.</p>		
8-9	<p>Para. 8.0.4.3.3</p> <p>Verify that the data resulting from scientific investigations involving more than one organization are annotated to show which organization produced what portion of the data.</p>		

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8-10	<p>Para. 8.0.5</p> <p>Verify that QA records of samples and data are handled in accordance with YMP-QP 17.0.</p>		
13-1	<p>HANDLING, STORAGE AND SHIPPING 033-YMP-QP 13.0, REVISION 1</p> <p>Para. 13.0.4.1</p> <p>Verify that samples are handled, stored, and shipped in accordance with written instructions or Technical Implementing Procedures.</p>		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
13-2	Para. 13.0.4.2 Verify that when special equipment requires specially trained or experienced operators, those are specified and verified by LLNL personnel.		
13-3	Verify that records dealing with handling, storage and shipping activities are handled in accordance with QP 17.0.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
15-1	<p>NON-CONFORMING ITEMS 033-YMP-QP 15.0, REVISION 3</p> <p>Para. 15.0.5.1</p> <p>Verify that the originator clearly identifies and describes the characteristics that do not conform to specified criteria and submits the original NCR to the LLNL-YMP QA Manager.</p>		
15-2	<p>Para. 15.0.5.2.</p> <p>Verify that after assigning a number to the NCR, a file folder containing documentation relevant to the NCR is maintained.</p>		

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15-3	<p>Para. 15.0.5.2</p> <p>Verify that in case an NCR is voided, the grounds for voiding the report are documented on a continuation sheet to the NCR.</p>		
15-4	<p>Para. 15.0.5.3</p> <p>Verify that non-conforming items are tagged. Additionally, verify that the QA Manager determines if the NCR is of a significant nature, and so indicates the determination in Item 7 of the NCR.</p>		

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15-5	Para. 15.0.5.4 Verify that proposed dispositions to NCR are provided to the YMP Leader within 30 days after assignment.		
15-6	Para. 15.0.5.4 Verify that disposition of NCR do contain the requirements detailed in the same paragraph.		

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15-7	<p>Para. 15.0.5.4</p> <p>Verify that QA personnel conducts verification of the completion of the NCR corrective action and copies of the NCR are distributed as per same paragraph.</p>		
15-8	<p>Para. 15.0.7</p> <p>Verify that QA organization monitors the status of open NCRs through the use of QA Action Item List.</p>		

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15-9	Para. 15.0.9 Verify that NCRs and supporting documents are handled as QA records in accordance with 033-YMP-QP 17.0.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1	<p style="text-align: center;">LLNL SOFTWARE QUALITY ASSURANCE PLAN, REVISION 0, SECTION 4.3.1, CHANGE NOTICE 1-REVISION 0</p> <p>Verify that software (S/W) products intended for use in quality affecting work are listed on the Master Log</p>		
2	<p>033-YMP-QP 3.2, REVISION 0, SOFTWARE QUALITY ASSURANCE, SECTION 3.2.4</p> <p>Verify that Software QA Plans are prepared before development, acquisition or application of the software for quality-affecting activities</p>		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	<p>Verify that S/W QA Plans are revision controlled documents that address:</p> <ul style="list-style-type: none"> o Organization responsibilities o Criteria for the requirements of Appendix H o S/W lifecycle model and lifecycle controls o Documentation required o Reviews required o Configuration management system o Verification and Validation o Discrepancy reporting and corrective actions o S/W change control o Control of S/W applications o Control of commercial and acquired S/W <p>033-YMP-QP 3.2, REVISION 0, SOFTWARE QUALITY ASSURANCE, SECTION 3.2.3.3</p>		
4	<p>Verify that the YMP QA Manger meets his/her responsibilities for:</p> <ul style="list-style-type: none"> o Assuring that the applicable Project Quality Procedures are addressed in the S/W planning documents o Approval of S/W planning documents o Performing audits and surveillances to verify compliance with QA requirements 		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5	<p>TIP-YM-11, REVISION 0, SOFTWARE CONFIGURATION MANAGEMENT SYSTEM, SECTION 3.3</p> <p>Verify that the S/W Quality Technician:</p> <ul style="list-style-type: none"> o Obtains the S/W package release number o Assigns each configuration item a unique identifier o Opens SCMS File Folders as stated in the ISP o Maintains an index of File Folders o Maintains a list of documents entered into each File Folder 		
6	<p>TIP-YM-11, REVISION 0, SOFTWARE CONFIGURATION MANAGEMENT SYSTEM, SECTION 5.4</p> <p>Verify that changes to S/W configuration items are formally controlled and documented.</p>		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	Verify that Configuration Item Identifiers follow the prescribed convention. 033-YMP-QP 3.2, REVISION 0, SOFTWARE QUALITY ASSURANCE, SECTION 3.2.2		
8	Verify that each S/W product meets the requirements of the LLNL Software QA Plan, either directly or through its specific Individual Software Plan (ISF)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	<p>033-YMP-R, APPENDIX H, REVISION 0, REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE, SECTIONS 6.0 AND 7.0</p> <p>Verify that the required S/W lifecycle documents have been prepared, reviewed and approved.</p>		
10	<p>033-YM-R, APPENDIX H, REVISION 0, REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WASTE REPOSITORY LICENSE, SECTIONS 4.1</p> <p>Verify that S/W Verification is performed to written procedures relative to specific hardware configurations. Results are documented and reviewed.</p>		

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11	<p>033-YM-R, APPENDIX H, REVISION 0 REQUIREMENTS FOR COMPUTER SOFTWARE USED TO SUPPORT A HIGH-LEVEL NUCLEAR WARE REPOSITORY LICENSE, SECTIONS 4.2</p> <p>Verify that S/W Validation is performed to written procedures relative to specific hardware configurations. Results are documented and reviewed.</p>		
12	<p>003-YMP-QP 3.2, REVISION 0, SOFTWARE QUALITY ASSURANCE, SECTION 3.2.5</p> <p>Verify that Software QA Plans are reviewed, approved and revised in accordance with Quality Procedure 033-YMP-QP 2.1.</p>		

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ORGANIZATION EVALUATED LLNL		<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>J. Kevin McCoy</u> DATE _____	
DATES OF EVALUATION 7/19-23/93					
CONTROLLING DOCUMENT (Title, Number, Revision)			ACTIVITY EVALUATED WBS 1.2.2.3.1.1 and 1.2.2.3.1.2		
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1	ACTIVITY D-20-53A FLOW-THROUGH DISSOLUTION TESTS ON UO SUB 2 Obtain evidence of qualification for Ray Stout, Steven Steward, and Homer Weed (LLNL).				
2	Why should we study unirradiated uranium dioxide? How is its behavior pertinent to that of irradiated spent fuel? What results do we hope to obtain that will not be obtained by our study of spent fuel?				

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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3	Why was carbonate chosen as the primary solute to be controlled? Why were other solutes neglected?		
4	Explain the reasons for status meetings with PNL on Activity D-20-53a. What was the date of the last meeting? What plans have been made for the next meeting?		
5	Describe the correspondence between test conditions used at PNL (for spent fuel) and LLNL (for uranium dioxide).		

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6	Describe the methods you use for controlling systematic errors.		
7	Describe the methods you use for controlling problems due to inexperience. (See section 4.2. of the Activity Plan)		
8	Describe the methods you use for controlling working spreadsheets.		

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9	Do you plan to vary the flow rate and surface area of the solid to determine where dissolution is controlled by solubility and where it is controlled by dissolution rate? Why or why not?		
10	What data are available on the effects of solutes other than carbonate on the solubility and dissolution rate of uranium dioxide?		
11	How do you clean your tubing? Have you studied contamination of solutions by deposits inside the tubing?		

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12	Visit uranium dioxide dissolution laboratory and examine experimental setup for uranium dioxide dissolution tests, if possible.		
13	Audit checklist YMP-92-21-02, item T-29 discusses changes to experimental setup in response to oxygen diffusion through plastic tubing. (See also Activity Plan D-20-53a, appendix B, page 15.) Were these changes in effect at the time of the audit? If not, examine documentation of changes in experimental setup.		
14	Visit SEM laboratory to observe how work is actually done, if possible.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
15	Examine records for determination of uncertainty in measurement of chemical analysis.		
16	Examine records for determination of uncertainty in measurement of pH.		
17	Examine calibration and alignment records for x-ray diffractometer.		

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18	If you were going to add more TIPs, which measurements would benefit the most from them?		
19	Measurements of solution and gas composition are obviously important to the results and appear to be repeated at least 38 times each (Activity Plan D-20-53a, Appendix B, pp. 16-19), but there are no TIPs for these measurements. Explain.		
20	Dissolution tests in J-13 well water are planned (Activity Plan D-20-53a, Appendix B, p. 19), and a procedure for handling this water (TIP-YM-2) exists, but it is not cited. Explain.		

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21	Examine evidence that water was handled according to TIP-YM-2.		
22	Describe how this activity and activity D-20-53b complement activities D-20-54.1 and D-20-54.2		
23	What has been learned about the release of Tc? What is the effect of oxygen fugacity?		

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24	What information has been relayed to the modeling effort and how is it being utilized?		
25	What different samples of uranium dioxide have been tested? Have single crystal and mineral samples been tested? Are there differences in response?		

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26	Early models have indicated a dependency on carbonate concentration. How has this changed with additional testing?		
27	Comment on the use of the statistical test matrix. Has it been effective in defining major dependencies? Should additional tests be performed?		

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1	ACTIVITY D-20-53B FLOW-THROUGH DISSOLUTION TESTS ON SPENT FUEL Obtain evidence of qualification for Walter Gray (PNL).		
2	Explain how the spent fuel samples were selected. Discuss how selection affects the applicability of the results to performance assessment.		
3	What provisions have been imposed on PNL, for the QA and technical supervision of subcontracted work, by LLNL personnel?		

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4	Obtain copies of all Memoranda of Understanding between LLNL and PNL for work on this activity.		
5	Review Memoranda of Understanding.		
6	Obtain copies of all LLNL procedures for work on this activity.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS <i>Record objective evidence reviewed, method of verification, personnel contacted</i>	RESULTS
7	Obtain copies of all PNL procedures for work on this activity.		
8	Select an appropriate number of LLNL and PNL procedures and review documentation of technical reviews. Obtain names and review qualifications of reviewers. Review technical content of review comments and see how the review was carried out.		
9	Obtain records from audits of PNL work by LLNL to evaluate effectiveness and thoroughness of audits.		

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10	Grain boundary release is expected to exceed that from the matrix for 20000 years (Activity Plan D-20-53b, Appendix A, p. 10), so kinetics of grain boundary release are important to performance assessment. Explain how the results obtained in this activity can be used to find kinetics of grain boundary release.		
11	LLNL will study both acidic (pH = 4 to 6) and alkaline (pH = 8 to 10) environments; PNL will study only alkaline environments. Explain.		
12	J-13 well water contains substantial concentrations of Ca (11.5 to 15 ppm) and Si (26.6 to 31.9 ppm). PNL has measured drops in dissolution rates by two orders of magnitude in response to 1.5 ppm of Si (Activity Plan D-20-53b, Addendum to Appendix A, p. 2.) There are no plans to study effects of Ca and Si on dissolution behavior. Explain.		

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13	The activity plan expresses concern about changing personnel on the experiment (p. 4). Describe past or planned personnel changes.		
14	Describe observed differences between the dissolution behaviors of uranium dioxide and spent fuel.		

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15	What different samples of spent fuel and UO ₂ have been tested? Have single crystal and mineral samples been tested? Are there differences in response?		
16	What plans are there to obtain fuel samples with more burnup poison?		
17	The SIP (Page 33) notes the potential for analysis of C-14. However, the test plans do not mention the collection of C-14. Is the concentration too low to measure? Please explain.		

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18	What release dependencies have been determined from the spent fuel tests? Are they the same or different from those obtained for UO2?		
19	What is the current schedule for testing and completion? The Test Plan (Page 22) notes completion in FY 91.		

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1	<p>ACTIVITY D-20-27 UNSATURATED TESTING OF WVDP AND DWPF GLASS</p> <p>Our copy of the activity plan is 28 months old. The test plans are 30 months old. Are revisions scheduled?</p>		
2	<p>Obtain evidence of qualification for William Bourcier (LLNL), John Bates (ANL).</p>		
3	<p>The glasses under study are ATM-10 (West Valley) and 165A (Savannah River). (See NNWSI-05-036, p. 4 and NNWSI-05-037, p. 4) These are fairly old compositions. How have waste glasses evolved since these glasses were developed? How will these changes affect the applicability of the results? Do you foresee tests on additional glasses?</p>		

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4	What provisions have been imposed on ANL, for the QA and technical supervision of subcontracted work, by LLNL personnel?		
5	Obtain copies of all Memoranda of Understanding between LLNL and ANL for work on this activity.		
6	Review Memoranda of Understanding.		

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7	Obtain copies of all LLNL procedures for work on this activity.		
8	Obtain copies of all ANL procedures for work on this activity.		
9	Select an appropriate number of LLNL and ANL procedures and review documentation of technical reviews. Obtain names and review qualifications of reviewers. Review technical content of review comments and see how the review was carried out.		

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10	Obtain records from audits of ANL work by LLNL to evaluate effectiveness and thoroughness of audits.		
11	Ten reports are cited regarding 165A glass (NNWSI-05-036, p. 10), but none on ATM-10 glass (NNWSI-05-037, p. 10). Explain the lack of publishable results on ATM-10 glass.		
12	The SIP discusses testing at several laboratories. Are tests at LLNL planned to confirm the results obtained at ANL?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
13	How long will the tests be run?		
14	What is the status of the analysis of the N3 batch tests?		
15	What has been learned about colloid generation?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16	How can the test be modified to help understand colloid retardation? Are these modifications planned for the future?		
17	What information has been relayed to the modeling effort and how is it being utilized?		

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1	<p>ACTIVITY D-20-45 LOW-TEMPERATURE OVEN METHOD FOR SPENT-FUEL OXIDATION TESTING</p> <p>The test plan has been essentially unchanged since 1988. Does the lack of changes reflect a desire to maintain consistency or the basic simplicity of the experiments?</p>		
2	<p>Obtain evidence of qualification for Bob Einziger (PNL).</p>		
3	<p>The experiments have included a small number of approved test materials. How well do these represent the oxidation behavior of other fuels?</p>		

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4	What provisions have been imposed on PNL, for the QA and technical supervision of subcontracted work, by LLNL personnel?		
5	Obtain copies of all Memoranda of Understanding between LLNL and PNL for work on this activity.		
6	Review Memoranda of Understanding.		

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7	Obtain copies of all LLNL procedures for work on this activity.		
8	Obtain copies of all PNL procedures for work on this activity.		
9	Select an appropriate number of LLNL and PNL procedures and review documentation of technical reviews. Obtain names and review qualifications of reviewers. Review technical content of review comments and see how the review was carried out.		

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10	Obtain records from audits of PNL work by LLNL to evaluate effectiveness and thoroughness of audits.		
11	PNL-6427 says that LWR fuel "tends to fracture intragranularly" (p. 2.12), but PNL's test plan for Activity D-20-53b says that spent fuel "tends to fracture along grain boundaries" (p. 5). Reconcile these two statements. If PNL's method for separating grains fails, are the measurements of grain boundary inventory reliable?		
12	Some of the fuels seem to be described inconsistently. See Activity Plan D-20-45, Appendix B, pp. 3-4. Is ATM-106 PWR or BWR fuel? Is ATM-IC4 the same as ATM-104?		

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13	The oxidation measurements to date have been made in air. Describe how you expect the oxidation rate will depend on oxygen pressure.		
14	How have the results of the tests affected other experimental programs, such as the TGA experiments?		
15	What information has been relayed to the modeling effort and how is it being utilized?		

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16	A new series of tests has begun at 255 C. Describe the results obtained to date and compare them to those expected.		
17	What data has been collected on the release of C-14 from the spent fuel?		
18	What techniques are available to better define the location of the excess oxygen in the U sub 4 O sub 9 lattice?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
19	What new fuels will be added to the test matrix and when will this be done?		
20	Are there any low-temperature, long-term field data for spent fuel stored in air that could be used to help confirm the laboratory results?		

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21	The Test Plan for BWR spent fuel indicates that the tests "will run for up to two years." (PNL-6427, P.iii) What is the actual elapsed time and when will the tests be terminated?		
22	Explain how surface (rim) versus bulk pellet oxidation effects are being addressed.		
23	What was the basis for selection of Bath 5 for test termination to permit the use of the bath for the 255 C tests? (See Activity Plan D-20-45, Page D-5)		