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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE AUDIT PLAN

FOR AUDIT YMP-ARC-95-07

OF

LAWRENCE LIVERMORE NATIONAL LABORATORY

LIVERMORE, CALIFORNIA

MARCH 6 THROUGH 10, 1995

Prepared by:

Stephen R. Maslar

Audit Team Leader

Yucca Mountain Quality Assurance Division

Approved by:

Donald G. Horton

Director

Office of Quality Assurance

9502030275

1.0 SCOPE

This full scope 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 (OCRWM). This will be done by verifying implementation and effectiveness of the system in place, as well as verifying compliance with requirements.

In addition to the follow-up on open Corrective Action Requests (CARs), 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 the audit are identified in Section 4.0 of this audit plan.

2.0 AUDIT SCHEDULE

Pre-audit Team/Observer Meeting 8:15 a.m., March 6, 1995

Livermore, California

Pre-audit Conference 9:00 a.m., March 6, 1995

Livermore, California

Audit Activities 10:00 a.m. to 4:00 p.m.

March 6, 1995

Livermore, California

8:00 a.m. to 4:00 p.m.

March 7-9, 1995

8:00 a.m. to 10:00 a.m.

March 10, 1995

Post-audit Conference 11:00 a.m., March 10, 1995

Livermore, California

There will be a daily YMQAD Audit Team/Observer meeting starting at 4:00 p.m. and also a daily Audit Team Leader/Observer/LLNL meeting starting at 8:00 a.m. to discuss potential deficiencies and establish needed liaison.

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 QA Program implementing procedures addressing the OCRWM Quality Assurance Requirements and Description Document (QARD), DOE/RW-0333P, as indicated in the Requirements Traceability Network matrix.
- Applicable Yucca Mountain Site Characterization Project Office Administrative Procedures - Quality.

The conduct of the audit will be guided by the documents (latest revision) listed below:

- Quality Assurance Procedure (QAP) 18.2, "Audit Program"
- OAP 16.1, "Corrective Action"

4.0 ACTIVITIES TO BE AUDITED

Programmatic Elements

- 1.0 Organization
- 2.0 Quality Assurance Program
- 4.0 Procurement Document Control
- 5.0 Implementing Documents
- 6.0 Document Control
- 7.0 Control of Purchased Items
- 12.0 Control of Measuring and Test Equipment
- 13.0 Handling, Storage, and Shipping
- 15.0 Nonconformances
- 16.0 Corrective Action
- 17.0 Quality Assurance Records
- 18.0 Audits

Supplement I, Software

Supplement II, Sample Control

Supplement III, Scientific Investigations

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

- 3.0 Design Control
- 8.0 Identification and Control of Items

9.0 Control of Special Processes

10.0 Inspection

11.0 Test Control

14.0 Inspection, Test, and Operating Status

Supplement IV, Field Surveying

Appendix A, High Level Radioactive Waste Form Production

Appendix B, Transportation

Appendix C, Mined Geological Disposal System

Technical Elements

Selected quality-related work as follows:

- Work Breakdown Structure (WBS) No. 1.2.2.5.1, Metallic Barriers
- WBS No. 1.2.2.4.1, Spent Fuel Dissolution/Oxidation; Cladding
- WBS No. 1.2.3.10.3.2, Thermodynamic Data Determination
- WBS No. 1.2.2.4.2, Glass Testing
- WBS No. 1.2.3.12.4, Small Block Testing

In addition, the technical specialist will evaluate the above activities to determine adequacy in the following areas:

- 1. Technical qualifications of technical personnel.
- 2. Understanding of procedural requirements as they pertain to related work.
- 3. Adequacy of technical procedures, as applicable.
- 4. Development of study plans, scientific investigations, work supporting documents and any related work products.

If the audit identifies a need to verify additional programmatic or technical areas, during the audit, these areas will be added to the audit scope and evaluated accordingly.

5.0 AUDIT TEAM MEMBERS

Stephen R. Maslar, YMQAD, Las Vegas, NV, ATL
James E. Clark, YMQAD, Las Vegas, NV, Auditor
Robert E. Harpster, YMQAD, Las Vegas, NV, Lead Technical Specialist
Kristi A. Hodges, YMQAD, Las Vegas, NV, Auditor
Stephen D. Harris, YMQAD, Las Vegas, NV, Auditor
John R. Matras, YMQAD, Las Vegas, NV, Auditor
Mario R. Diaz, YMQAD, Las Vegas, NV, Auditor
Emily Reiter, Headquarters Quality Assurance Division, Washington, DC, Auditor
-Stephen T. Nelson, Management and Operating Contractor, Las Vegas, NV,
Technical Specialist

6.0 AUDIT CHECKLISTS

YM-ARC-95-07-01, Programmatic Checklist, will be used during the programmatic portions of this audit.

YM-ARC-95-07-02, Technical Checklist, will be used for the examination of technical areas during this audit.

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WASHINGTON, D.C.							
	QUALITY ASSURANCE CHECKLIST						
LLNL DATES C	[x] EXTERNAL [x] AUDIT [SOF EVALUATION] (95 through 3/10/95		PREPARED BY S. R. Maslar	DATE <u>2/16/95</u>			
CONTRO	DELING DOCUMENT (Title, Nu	mber, Revision)		ACTIVITY EVALUATED			
ITEM NO.	CHARACTER	RISTICS TO BE EVALUA	ATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
	ATL - Tom Rodgers - 1 Auditor - Steve Harris - Auditor - Emily Reiter - Auditor - Jim Clark - 4 Auditor - Bob Harpster - Auditor - Kristi Hodges Auditor - John Matras - Auditor - George Vaslos Auditor - Van Ekambaram See Checklist	- 2 , 7, 18 - Lead Technical Spe - 5, 6, 12 13, Supplements II - 15, 16, 17	and III				

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

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-1.0, Revision 4, and CHANGE NOTICE (CN) 1.0-4-1, 1.0-4-2, and 1.0-4-3, ORGANIZATION		
1-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
1-2	Verify that the organizational structure shown is current and correct. (Para. 1.0.1, 0.3.2, Exhibits A and B)		
1-3	Verify that the Project Leader approves all technical publications and reports prior to transmittal. (Para. 1.0.3.4)		
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CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
Verify that Technical Area Leader approves the QA controls applied to items and activities and recommends QA controls for the various plan activities. (Para. 1.0.3.6)		
Verify that the QA Manager reviews the selection of QA controls applied to items and activities. (Para. 1.0.3.8)		
	Verify that Technical Area Leader approves the QA controls applied to items and activities and recommends QA controls for the various plan activities. (Para. 1.0.3.6) Verify that the QA Manager reviews the selection of QA controls	Verify that Technical Area Leader approves the QA controls applied to items and activities and recommends QA controls for the various plan activities. (Para. 1.0.3.6) Verify that the QA Manager reviews the selection of QA controls

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
• .	LLNL-033-YMP-QP 2.0, REVISION 2, ASSURANCE					
2-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN Matrix.					
2-2	Verify the QA Manger's responsibilities and authorities include verification that the YMP QA Program remains responsive to requirements, is implemented correctly, and continues to be effective. (2.06)					

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	QUALITY ASSURANCE CHEC	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
	LLNL-033-YMP-QP-2.1, Rev 6, CHANGE NOTICE 2.1-6.1, PREPARATION, APPROVAL, & REVISION OF PROCEDURES, REQUIREMENTS, PLANS AND THE QUALITY ASSURANCE PROGRAM DESCRIPTION		
2-3	Verify that all quality affecting work performed in support of YMP is accomplished in accordance with controlled procedures and documents. (2.1.1)		
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2-4	Verify that implementing documents meet the minimum format requirements of Paragraph 2.1.4.2.		

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ITEM		REMARKS	•
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2-5	Verify that quantitative or qualitative acceptance criteria is included, where appropriate. (2.1.4.3.1)		
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2-6	Verify that quality affecting documents are reviewed by LLNL-YMP personnel identified and specified in Exhibit A. (2.1.4.3.2)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
2-7	Verify that comment resolution is either achieved or the document is elevated to the YMP Leader for final disposition.				
2-8	Verify that LLNL-YMP approval, Scientific Investigation Plans (SIPs) and changes thereto are transmitted to YMPO for approval. Verify that Study Plans are transmitted to YMPO for approval by YMPO and OCRWM. (2.1.4.5)				

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ı		QUALITY ASSURANCE CHECKLIST (continuation sheet)					
	ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
	2-9	Verify changes or revision impacting specific organizations or disciplines are reviewed by those organizations or disciplines. Verify the QA Organization reviews changes to documents if they					
		reviewed the previous version regardless of whether the QA Organization is affected by the changes. (2.1.5.7)					
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
	LLNL-033-YMP-QP- 2.2, REVISION 1, PEER REVIEW				
2-10	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN Matrix.				
2-11	Verify that the Technical Area Leader notifies the Project Leader and QA Manager by memorandum when a Peer Review is to be conducted. (2.2.5.1)				

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	QUALITY ASSURANCE CHECKLIST (Continuation sneet)				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS		
2-12	Verify that the QA manger identifies a QA representative to serve as Secretary of the Peer Review and notifies the TAL of the selection in writing. (2.2.5.1)				
2-13	Verify that prior to beginning of the Peer Review, the Chairman submits a memorandum to the Project Leader and the TAL attesting to the qualifications of the selected peers. (2.2.5.2.d)				
2-14	Verify that the Peer Review Chairman and the TAL develop a plan for conducting the Peer Review. (2.2.5.3)				
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	ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
		LINL-033-YMP-QP-2.3, REVISION 1, CN 2.3-1-2, MANAGEMENT ASSESSMENTS					
2	-15	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN Matrix.					
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2	:-16	Verify Management Assessments are conducted at least once a year. (2.3.2)					
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
2-17	Verify that the Management Assessment Team evaluated the adequacy and effectiveness of:				
	- Personnel and training program				
	 QA Program (including nonconformance and corrective action program) 				
	 QA program management information tracking, evaluation, and reporting system 				
·	- Organizational structure and staff				
2-18	Verify Deputy Associate Director for Fission Energy Systems Safety Program's review and concurrence of the Management Assessment. (2.3.4)		:		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
2-19	Verify that the QA Manger tracks assigned action items from management assessment reports to closure and provides a memo to the Deputy Associate Director for Fission Energy and Systems Safety Program. (2.3.4)			
2-20	Verify Management Assessments are identified and processed as Quality Assurance Records. (2.3.5)			

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-2.4, REVISION 1, TECHNICAL REVIEW		
2-21	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
2-22	Verify that independent technical reviews of study documents (Scientific Notebooks, drawings, calculations, specifications, analysis, reports, etc.) included a checklist (Para. 2.4.4.3) and a signed approval sheet attesting to the applicable aspects of Section 2.4.4.5.		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-23	Verify that the technical area lead signed the review approval sheet signifying concurrence with the conclusions of the technical review board. (Para 2.4.4.8)		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 2.5, REVISION 1, CN 2.5-1-1, ACCEPTANCE OF DATA NOT GENERATED UNDER THE CONTROL OF THE QARD		
2-24	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
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2-25	Verify that data to be qualified meets the requirements of YAP-SIII.1Q, Revision 0, Qualification of Existing Data.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP 2.6, REVISION 2, READINESS REVIEWS		
2-26	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN Matrix.		
2-27	Verify that when a Readiness Review is scheduled, a Readiness Review Checklist is approved by signatures of the Readiness Review Team Leader and Technical Area Leader. (2.6.4.1.11)		
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	QUALITY ASSURANCE CHECKLIST (continuation sheet)				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
2-28	Verify that a master log of unique Readiness Review identification numbers and description information is maintained by Document Control. (2.6.5)				
2-29	Verify that the Readiness Review Team Leader transmits written recommendations to the Project Leader. (2.6.4.3.21)				
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	QUALITY ASSURANCE CHECKLIST (continuation sheet)				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
2-30	Verify that the summary memorandum of Readiness Review meeting(s) and an approved Readiness Review Checklist are identified and processed as quality assurance records. (2.6.5)	·			
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP, 2.7, REVISION 1, CN 2.7-1-1, STOP WORK ORDER		
2-31	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD section identified in the RTN Matrix.		
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2-32	Verify any Stop Work Orders issued since the last audit are performed in accordance with applicable requirements.		
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		LLNL-033-YMP-QP 2.9, REVISION 5, CN-2-9-5-1, INDOCTRINATION AND TRAINING			
2-	33	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD section identified in the RTN Matrix.		,	
- I					
2-	34	Verify Technical Area Leaders assure that required indoctrin- ation and training is accomplished and for notifying the Trainin Coordinator (TC) whenever new personnel are assigned so that indoctrination and training can be scheduled. (2.9.3.1)	g		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-35	Verify that the YMP Quality Manager reviews all procedures and revisions to determine if training or retraining is required. (2.9.3.2)		
2-36	Verify that the TC reviews and approves indoctrination and training materials and training settings for effectiveness. (2.9.3.3)	,	

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	GUALITY ASSURANCE CHECKLIST (COMMINATION SHEET)				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
2-37	Verify that the TC collects, stores, and maintains training QA records in a locked, fire-resistant repository. Verify TC forwards completed records to the LRC. (2.9.3.3)				
2-38	Verify that YMP personnel complete all assigned training before				
2-30	any quality affecting work is performed or within 60 days of the effective date of the procedure or change notice, whichever comes first. (2.9.3.4)				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS
2-39	Verify personnel receive technical training (including training to applicable Technical Implementing Procedures) prior to performing activities that affect quality. (2.9.6)		
2-40	Verify retraining (refresher training), necessary to maintain or regain proficiency is provided to project personnel at the discretion of the TAL to preclude recurrence of nonconformances or as part of corrective action. (2.9.8)		

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ITI N	EM O.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-4	1	Verify Exemptions to training have been documented by the TAL (2.9.9)		
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2-4	,	Verify classroom training is conducted when a new procedure is		
		written or when a procedure is revised so extensively that the result is a complete rewrite. (2.9.10.1)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP-2.10, REVISION 5, CN 2.10-5-1		
2-43	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements for the QARD sections identified in the RTN Matrix.		
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2-44	Verify a written Position Description, prescribing minimum qualification requirements that include education, experience, and skills is prepared and approved by the responsible Project position. (2.10.4.1)		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
2-45	Verify the relevant education and experience history is verified by LLNL-YMP Management. (2.10.4.2)			
2-46	Verify the TPO provides a statement of assigned justification when minimum education and experience cannot be specifically verified. (2.10.4.2)			

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		REMARKS	
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-47	Verify the TAL completes a Management Certificate for each individual verifying training and experience are commensurate with the position description upon initial assignment to the project of when there is a change in position description. (2.10.4.3)		
2-48	Verify the TAL performs and documents an Annual Management Recertification for each person assigned to participate in the YMP. (2.10.4.4)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-49	Verify personnel qualification records are prepared, processed and retained as Lifetime quality assurance records for each person assigned to participate in the YMP. (2.10.5)		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
	033-YMP-QP 4.0, REVISION 4, PROCUREMENT DOCUMENT CONTROL			
4-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.			
4-2	Verify that the Requester has completed the Purchase Requisition (PR) and assured that the Technical Requirements include or reference, as appropriate, specific:			
	 Drawings Specifications Codes Standards Regulations Procedures Instructions Applicable tasks, inspections, or acceptance requirements to be used to monitor and evaluate the performance of the supplier. Documentation to be submitted to the LLNL-YMP for information, review, or approval; document submittal schedules shall be identified. 			

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4-3	Verify that the PR includes or references, as appropriate, the QA requirements addressed in Paragraph 4.0.5.1.C, 1 through 8.		
4-4	Verify that when a procurement is for a Technical Service Contract, it has been reviewed and signed by the LLNL-YMP Leader, RPCM and QA Manager. Otherwise, the RPCM and QA Manager are required only. (Para. 4.0.5.1)		
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I	QUALITY ASSURANCE CHECKLIST (CONTINUATION SHEET)			
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
4-5	Verify that changes to scope of work, technical requirements, QA program requirements, documentation requirements have been subject to the same degree of control as used in the preparation of the original documents.			
4-6	Verify that when procurement actions are completed, the procurement package becomes QA Records and stored and maintained in accordance with 033-YMP-QP 17.0. (Para. 4.0.6)			

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
-7	033-YMP-QP 4.1, REVISION 3, PREPARATION OF QUALITY ASSURANCE REQUIREMENTS SPECIFICATION AND APPROVAL OF SUBCONTRACTOR QA PROGRAMS		
	Verfiy that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
-8	Verify that the QA Requirements Specification(s) have been reviewed and approved by the TAL and the QA Manager. (Para. 4.1.5.2.2 and 3)		
I -9	Verify that as a prerequisite to approve the Subcontractor QA Program, a pre-qualification QA surveillance of the subcontractor's facility was performed. (Para, 4.1.5.3)		

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L		QUALITY ASSURANCE CHECKLIST (continuation sheet)				
	ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	3	
4	I - 10	Verify that generic QA Requirements Specifications are reviewed each time that the QARD was revised in order to ensure that it contains current requirements identified in the QARD. (Para. 4.1.5.4.1)				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS
	033-YMP-QP 5.0, REVISION 4, TECHNICAL IMPLEMENTING PROCEDURES		
5-1	Verify that all sections of the QP evaluated in this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
	Because Audit YMP-94-10-01 focused exclusively on TIPs to determine adequacy of Criterion 5, only a minimal effort will be taken to verify implementation of this procedure. The basis for determining Criterion 5 adequacy will focus primarily on implementation of 033-YMP-QP-2.1, "Preparation, Approval, and Revision of Procedures, Requirements, and Plans." This procedure is covered in checklists prepared for Criterion 2, but will be completed, in part, to verify Criterion 5 implementation.		
5-2	Ensure that a list of materials to be used is included in TIPs. (Section 5.0.5)		
5-3	Determine whether for an activity of long duration, specific provisions (including provisions for storage limits and precautions) are established for instrumentation (M&TE) whose calibration interval is shorter than the expected duration of the activity. (Section 5.0.5)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-4	Where the ability to detect failure/malfunction of instrumentation is questionable, verify that procedures include special provisions for configuration, installation, and use that reduce risk. (Section 5.0.5)		
5-5	Verify that any procedural deviations made to TIPs during implementation were authorized and documented on a CN. (Section 5.0.6) Determine how LLNL meets requirement for stopping work when it can not be accomplished as described in the implementing document.		
5-6	Determine how an activity is controlled and documented when existing procedures; e.g. ASTM, supplier manuals, equipment maintenance instructions, or approved drawings are utilized in lieu of approved LLNL implementing procedures. (Section 5.0.7)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-7	Verify that if/when a CN is generated which impacts an Activity Plan that a revision/change of the Activity Plan is accomplished. (Section 5.0.9.2)		
	Note: Determine whether work may continue based upon a change to the TIP prior to a change to the Activity Plan. Also, ensure that impacted Activity Plans are changed/revised when/if TIPs are revised.		
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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-6.0, REVISION 4,CN 6.0-4-2, DOCUMENT CONTROL		
6-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN Matrix.		
6-2	Verify controlled distribution of selected Activity Plans, Individual Software Plans, QA Grading Reports, Quality Procedures, QARD Requirements Matrix, QA Requirements Specifications, Scientific Investigation Plans, and Technical Implementing Procedures. (Section 6.0.5.2, 6.0.5.3)		
6-3	Verify LLNL-YMP Project Administrator (or designee) approval of the Table of Contents. (Section 6.0.5.3.1)		
6-4	Verify that the Revision History reflects the reason for each revision and for CNs to the current revision. (Section 6.0.5.3.3)		

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TEM NO. CHARACTERISTICS TO BE EVALUATED REMARKS Record objective evi of verification, perso Verify removal of obsoleted/superseded documents of selected document holders. (Section 6.0.5.4)	idence reviewed, method RESULTS
Verify that CNs are reviewed and approved by those who are authorized to approve the original document prior to issuance. (Section 6.0.5.6)	
Verify in accordance with 033-YMP-QP 2.1, Revision 6, Exhibit A, "Responsibilities for Review and Approval of Controlled Project Documents."	

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CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
Verify that changes that did not require the review or approval of authorized technical personnel meet the established criteria for a minor change. (Section 6.0.5.6)		
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Determine whether any preliminary documents containing unverified data or conclusions have been issued for information or use. Verify a "Release Prior to Verification Form" approved, with justification, by the LLNL-YMP Leader and QA Manager prior to transmittal. (Section 6.0.5.7)		
	·	
	Verify that changes that did not require the review or approval of authorized technical personnel meet the established criteria for a minor change. (Section 6.0.5.6) Determine whether any preliminary documents containing unverified data or conclusions have been issued for information or use. Verify a "Release Prior to Verification Form" approved, with justification, by the LLNL-YMP Leader and QA Manager prior to transmittal.	CHARACTERISTICS TO BE EVALUATED Record objective evidence reviewed, method of verification, personnel contacted Verify that changes that did not require the review or approval of authorized technical personnel meet the established criteria for a minor change. (Section 6.0.5.6) Determine whether any preliminary documents containing unverified data or conclusions have been issued for information or use. Verify a "Release Prior to Verification Form" approved, with justification, by the LLNL-YMP Leader and QA Manager prior to transmittal.

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NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6-9	Verify that a distribution list indicating all receipts have been returned and copies of any "Decontrol Notices of Controlled Document" forms are authenticated and transmitted to the LRC when completed. (Section 6.0.7)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 7.0, REVISION 1, CONTROL OF PURCHASED ITEMS AND SERVICES		
7-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identifed in the RTN matrix.		
7-2	Verify that for quality-affecting procurements, source evaluations were conducted and the results of these were documented and maintained in a file. (Para. 7.0.5.2)		
7-3	Verify that the Technical Representative and the QA Manager are verifying the supplier's performance in accordance with Paragraph 7.0.5.3.A, Steps 2 through 6, plus B and C.		
7-4	Verify that supplier generated documents are controlled, processed, and accepted in accordance with the requirements established in the procurement documents and the submittal of these documents is maintained by LLNL to ensure that it is accomplished accordingly. (Para 7.0.5.4A and B)		

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ITEM NO,	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7-5	Verify that procured item(s) acceptance is done by the Technical Representative through one of the following: (Para. 7.0.5.5.1)		
	a. Certificate of Conformance b. Source Verification		
	c. Receiving Inspection d. Post-installation Testing		
	·		
- 6	Verify that the Technical Representative accepts technical services using one of the following methods: (Para. 7.0.5.5.3)		
	a. Verifying the data or results produced.b. Conducting a surveillance and/or audit of the activity.		
	c. Reviewing objective evidence for conformance with the requirements specified in the procurement documents.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7-7	Verify that QA Records are identified as lifetime or non- permanent QA Records in accordance with QARD requirements of Section 5.2.2.H.		
7-8	Verify that supplier nonconformances are controlled and processe	d	
	following the requirements established by same paragraph. (Para. 7.0.5.6)		

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	GUALITY ASSURANCE CHECKLIST (Continuation sheet)				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
	033-YMP-QP 12.0, REVISION 6, CONTROL OF MEASURING AND TEST EQUIPMENT (M&TE)				
12-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.				
12-2	Review latest issue of the M&TE Status List to identify M&TE authorized for YMP use.				
	Obtain printout of current data base listing for comparison.				
12-3	Verify that "User Calibrations" are performed by individuals in accordance with approved calibration procedures.				
·	Verify documented training to these calibration procedures.				

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-4	Verify that the accuracy of calibration standards are greater than the accuracy of the M&TE being calibrated.		
12-5	Determine whether a 25% uncertainty is exceeded, and if so, whether justification is provided by the TAL.		
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		REMARKS	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-6	Verify that standards are traceable to NIST or equivalent and that this traceability reflects a documented, unbroken chain.	·	
•	(Coordinate with auditor reviewing procurement documents to ensure that this requirement is passed on to external laboratories that calibrate LLNL M&TE.)		
12-7	Determine whether M&TE has been documented as "out-of-tolerance" by a user-calibration or by an external lab. If so, verify that the TL (or designee) generates an Out-of-Tolerance Report (OOTR) for impact evaluations.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-8	Verify that calibrated M&TE is labeled/marked or documented to indicate due date or interval for the next calibration.		
	Note: YMP stickers: (white) indicates a calibrated instrument that is currently on the master list; (yellow) indicates the instrument is used for YMP, but does not require calibration; (orange) indicates the instrument must be calibrated before each use.		
12-9	Ensure that "out-of-calibration" M&TE removed from the Master Status List is also removed from service. Evaluate methods used to prevent use of this equipment.		
12-10	Ensure an evaluation to determine the acceptability for previously collected data, processes monitored, or items previously inspected or tested is performed and documented when M&TE is found to be out-of-calibration.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS		
12-11	Review the calibration documentation for M&TE to ensure that the following information is documented (QARD, Section 12.2.6):				
	- Identification of the M&TE calibrated.				
	- Traceability to the calibration standard used for calibration.				
	- Calibration data.				
	- Identification of the individual performing the calibration.				
	 Identification of the date of calibration and the recalibration due date or interval, as appropriate. 	•			
	 Results of the calibration and statement of acceptability. 				
	 Reference of any actions taken in connection with out-of-calibration or nonconforming M&TE including evaluation results, as appropriate. 				
	 Identification of the implementing document (including revision level) used in performing the calibration. 				
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ITEM		REMARKS	*
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method	RESULTS
		of verification, personnel contacted	
	033-YMP-QP 13.0, REVISION 1, HANDLING, STORAGE, AND SHIPPING		i
1.			
13.1	Verify that all sections of the QP evaluated by this checklist		
	adequately reflect the applicable requirements of the QARD		ļ
	sections identified in the RTN matrix.		Į
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13.2	Verify that written instructions state how items, sample, and		
13.2	equipment are handled, stored, and shipped to prevent damage,		
	deterioration, or loss and are incorporated within TIPs,		Į.
٠.	procurement documents, shipping documents, etc. which include		
	verification of requirements. (Para. 13.0.4.1)		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
13-3	Verify that special handling tools and equipment are controlled, inspected, and tested in accordance with documented procedures and at specified time intervals. (Para 13.4.4.2)		
13-4	Verify that special instructions provide for marking and labeling for packaging, shipping, handling, and storage as necessary, and shall identify, maintain, and preserve the item.		
	(Para. 13.0.4.2)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
13-5	Verify that when special equipment requires specially trained and experienced operators, those are specified and verified by LLNL personnel. (Para 13.0.4.2)				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
	033-YMP-QP-15.0, REVISION 3, CN 15.0-3.1 and 3-2, NONCONFORMANCES				
15-1	Verify that all section of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.				
15-2	Determine if Nonconformance Reports (NCRs) were initiated by LLN personnel since the last audit, September, 1994.	L			
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 16.0, REVISION 5, CN 16.0-5.1 AND 16.0-5.2, CORRECTIVE ACTIONS		
16.1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
16-2	Verify that Corrective Actions Reports (CARs) are initiated when a condition adverse to quality is identified, such as:		
	a. An adverse trend identified as a result of trend analysis.		
	b. A situation when a QARD or implementing document requirement is not met.		
	c. Repeated nonconformances of engineered items or M&TE.		
	d. Other adverse conditions reported to the QA Manager.		
	(Para. 16.0.5.1.1)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method	RESULTS
16-3	Verify that the QA Manager evaluates whether the identified adverse condition is "Significant to Quality" or "Not Significant." (Para. 16.0.5.1.3)	of verification, personnel contacted	
16-4	Verify that if the QA Manager disapproves the recommended action, the disapproval and basis for that decision are documented and attached as a continuation of the CAR. The CAR is returned to the originator who will review the recommended action and, if appropriate, resubmit the CAR to the QA Manager. (Para. 16.0.5.1.3)		
16-5	Verify that the CARs are distributed to the YMP Leader, Deputy Project Leader, Associate Project Leader, Assistant Project Leader, and to the cognizant supervisor(s). (Para. 16.0.5.1.4)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16-6	Verify that actual corrective action taken is documented on Items 15 and 16 of the CAR.		
16-7	Verify that the QA Manger indicates concurrence with the actual corrective action taken in Item 17. If the corrective action is unacceptable, the QA Manager requires additional action to be taken by returning the CAR to the initiator unsigned with a Memo explaining the requirements. (Para. 16.0.5.3.2)		
16-8	Verify that the QA organization verifies completion and adequacy of the specified corrective action and completes for closure all related documentation in a timely manner. If acceptable, Items 18 and 19 of the CAR are completed. (Para. 16.0.5.4.1)		

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÷.	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16-9	Verify that the QA Manger indicates closure of the CAR by signing Item 20. A copy of the completed CAR is sent to the YMP Leader, Deputy Project Leader, Associate Project Leader, Assistant Project Leader, the cognizant supervisor(s), and to the Director, QA Division - YMP. (Para. 16.0.5.4.2)		
16-10	Verify that the Cognizant Supervisor or other individual documents proposed changes to CARs (such as changes in corrective action or extension of completion date) by sending a memorandum to the QA Manager for approval. (Para. 16.0.5.5.1)		
16-11	Verify that the QA organization monitors the status of open CARs until satisfactory resolution through the use of the "QA Action Item List" which lists the status of CARs, NCRs, YMPO CARs, and delinquent receipt acknowledgments. The QA Action Item List also notifies affected managers of significant conditions adverse to quality and lessons learned.		
	This list is issued to the YMP Leader, Deputy Project Leader, Associate Project Leader, Assistant Project Leader, and all Technical Area Leaders and Task Leaders. (Para. 16.0.5.6.2)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16-12	Verify that completed CARs and supporting documentation are sent to the LRC as QA Records. (Para. 16.0.6)		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
	033-YMP-QP 16.1, REVISION 2, CN 16.1-2.1 AND 16.1-2.2, PROCESSING EXTERNALLY ORIGINATED CORRECTIVE ACTION DOCUMENTS			
16-13	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.			
16-14	Verify that externally originated corrective action documents are entered into the QA Action Item List.	-		
16-15	Verify that the response documentation is completed prior to the specified due date.			

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
16-16	Verify that if the corrective action cannot be completed by the specified due date, the QA Manger is notified and a revised completion date is coordinated with the originating organization.			
16-17	Verify that the QA Action Item List lists the status of CARs, NCRs, YMPO CARs and delinquent receipt acknowledgments.			

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-16.2, REVISION 4, TREND ANALYSIS		
6-18	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
6-19	Verify that trend analysis contains pertinent information from CARs, NCRs, externally originated corrective action document (ECA), subcontractor furnished corrective action document (CCA), surveillance deficiency corrected during the surveillance (SDC), and audit deficiencies corrected during the audit (ADC). (Para. 16.2.4.1)		
.6-20	Verify that, upon identification of a trend, the YMP QA Manager made a determination to document the trend on a CAR justification for not initiating a CAR, or the Trend Analysis Report (TAR). (Para. 16.2.4.3)		

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	TEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS
16	-21	Verify that the TAR contains the following information:		
		 a. Trend Analysis Period b. Trends Identified (if any) c. Reference to CAR initiated (if any) d. Justification (if initiation of a CAR is determined to be unnecessary) 		
	. *	(Para. 16.2.4.4)		
16	-22	Verify that TARs are submitted as QA Records to the LRC 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
	033-YMP-QP-17.0, REVISION 6, CN 17.0-6-1, QUALITY ASSURANCE RECORDS	<u>.</u>	
17-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.	·	
17-2	Verify that QPs and TIPs have "QA Records" section which lists the QA Records. {Para. 17.0.6}		
17-3	 Verify that the Record Source: a. Submit QA records and QA records packages to the LRC no later than 20 working days after authentication. b. Privileged records are identified as "PRIVILEGED" on the first page of either the individual record or the records package table of contents. c. Notify the LRC by submitting documentation for one-of-a-kind records that are completed but still in use and being temporarily stored by the records source. If the record should be part of a record package, but is still in use, a complete description and the storage location of the record is provided to the LRC. (Attachment 4A) 		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
17-4	Verify that the LRC checks records and records packages to ensure they are legible, identifiable, complete, suitable for microfilming, are authenticated, and the records are as designated and in agreement with the Table of Contents. (Attachment 4, B.1.a)		
17-5	Verify that corrections to completed records are made by the Record Source in accordance with Attachment 2, Paras. 2 & 3.		
17-6	Verify that a log of rejected record transmittals is maintained by the LRC. (Attachment 4.B.1.a)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
17-7	Verify that records accepted by the LRC are logged using a computer based document logging system in accordance with Attachment 4, B.1.c		
17-8	Verify that revision of a previously accepted record or package is required, only the corrected or supplemented page is submitted, and at the top of the page the accession number is identified (*Correction (or Supplement) to accession *]. This statement shall be dated and reauthenticated by the record source originating organization. If an entire record/records package is superseded, the new record/records package identified the accession number of the record/records package it is superseding, and is dated and reauthenticated by the record source originating organization. (Attachment 2, 3.a, b)		
17-9	Verify, that for QA records that cannot be replaced, the record source documents the condition in a Corrective Action Report, including a statement on the impact of the missing records on work accomplished and /or future work. (Attachment 5, A.2)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
17-10	Verify that the LRC transmits records to the CRWMS M&O using the LRC Record Transmittal Form, Exhibit D written three months of receipt. (Attachment 4, B.2)		
17-11	Verify that the Record Source ensures that documents and other materials that may become records are protected from deterioration, loss or damage prior to submittal to the LRC. (Attachment 5, A.1)		
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	QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method` of verification, personnel contacted	RESULTS			
17-12	Verify that LRC stores in-process records in one-hour, fire-resistant containers deemed appropriate for fire protection by the LLNL Fire Chief and meet UL requirements for one-hour fire rating. (Attachment 5, B.1)					
17-13	Verify that QA records are protected from damage, deterioration or loss at the LRC in accordance with Attachment 5, B.1)					
17-14	Verify that LRC maintains a list of personnel who have access to the privileged files. Also that assigned LLNL-YMP personnel and unauthorized personnel are under constant surveillance by LRC personnel. (Para. 17.0.5.2)					

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
•	033-YMP-QP 18.0, REVISION 5, CN 18.0-5.2, AUDITS		
18-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
18-2	Verify that all applicable program elements for project activities are audited at least annually or at least once during the life of the activity, whichever is shorter. The audit schedule addresses all applicable elements of the QA program and quality elements not applicable are documented. (Para 18.0.5.1)		
18-3	Verify that subcontractors are audited on at least a triennial basis when supplemented by annual evaluations. (Para. 18.0.5.1.3)		

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	·
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
18-4	Verify that audits are performed by personnel qualified IAW, procedure 033-YMP-QP 18.2. (May include technical specialist who are independent of any direct technical responsibility for the organization to be audited.) (Para 18.0.5.2)		
18-5	Verify that the Lead Auditor documents on the "Audit Planning Worksheet," Exhibit A, the assessment that assigned personnel have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.		
18-6	Verify that an audit plan is prepared IAW the format shown in Exhibit B, "Audit Plan Format" for each audit. (Para. 18.0.5.4		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
18-7	Verify that audit reports are signed by the Lead Auditor and issued no later that 30 calendar days after the closing meeting. The audit report contains the requirements listed in Paragraph 18.0.5.6.				
8-9	Verify that the following are transmitted to the LRC as QA Records:				
	a. Audit Schedule b. Audit Planning Worksheet c. Audit Plan d. Completed Audit Checklist e. Audit Report				

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Ì.	GOALITT ASSUMANCE OTEORIEST (COMMIDATION SHEET)					
	ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
		033-YMP-QP 18.1, REVISION 5, CN 18.1-5.1, SURVEILLANCES				
	•	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.				
	18-9	Verify that surveillance schedule for each fiscal year identify those YMP and subcontractor activities for which surveillances are planned. (Para. 18.1.5.2.1)				
	18-10	Verify that checklists have been used for the conduct of surveillances except as specified in Paragraph 18.1.5.4.2.				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
18-11	Verify that surveillance reports contain information required by Paragraph 18.1.5.7.1, approved by the QA Manager and issued no later than 20 calendar days after completion of the surveillance. (Paras. 18.1.5.7.1.and 18.1.5.7.2)				
18-12	Verify that the following are transmitted to LRC as QA Records:				
	 a. Surveillance Schedules b. Completed Surveillance Checklists, if applicable c. Surveillance Reports 	J			

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 18.2, REVISION 3, QUALIFICATION OF QUALITY ASSURANCE AUDIT PERSONNEL		
18-13	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
,	Based on a sample of QA audit personnel, verify implementation and effectiveness of the following LLNL procedural requirements.		
18-14	The YMP QA Manager is responsible for training auditors to perform the various audit functions by one or both the methods given below: (Para 18.2.4.1)		
	a. Orientation and training in audit performance		
	 On-the-job training and guidance under the direct super- vision of a Lead Auditor. 		
18-15	The Lead Auditor is responsible for indoctrinating technical specialists and other non-auditor personnel in audit techniques (as a minimum) and for documenting the indoctrination. (Para 18.2.4.1)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
18-16	The QA Manager maintains a file for each auditor to document training and audit participation. (Para 18.2.4.1)		
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18-17	The QA Manager maintains a file for each technical specialist or other non-auditor team member to document qualifications, indoctrination, and audit participation. Applicable technical knowledge is documented on a resume or by reference to a YMP Personnel Qualification Record. The YMP Leader and the QA Manager review and accept the technical qualifications of technical specialists and other non-auditor team members. (Para. 18.2.4.1)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
18-18	Each candidate for YMP Lead Auditor is evaluated by the YMP QA Manager in accordance with criteria described below. The evaluation for each candidate is documented. (Para 18.2.4.2)		
	a. Communication Skills b. Training		
	c. Evaluation of Education/Training and General Auditing Experience		
,	d. Nuclear Auditing Experience e. Lead Auditor Examination		
18-19	An Auditor is certified by the YMP QA Manager as a Lead Auditor when the criteria in Section 18.2.4.2 are met. The certification which is valid for one year, is documented. (Para. 18.2.4.3)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
18-20	The YMP Manager reviews the certification for each Lead Auditor annually and either extends or cancels the certification.		
	These reviews are documented. (Para. 18.2.4.4)		
18-21	Lead Auditors who fail to maintain their proficiency for a		
	period of two years or more must requalify. (Para. 18.2.4.4)		
10.00			
18-22	QA Records include the following: (Para 18.2.4.5) - Auditor training records,		
	 Audit participation records, YMP Lead Auditor Qualification Form and supporting documents, and 		
·	 Evaluation memo of adequacy of Lead Auditor examination and added supplemental documents if examination is determined to be inadequate. 		
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·	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
	033-YM-QP 3.2, REVISION 3, SOFTWARE QUALITY ASSURANCE			
I-1	Verify all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of QARD sections identified in the RTN matrix.			
1-2	Identify the software used at LLNL for quality-affecting work since the last audit 9/94.			
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QUALITY ASSURANCE CHECKLIST (continuation sheet)			
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1-3	Verify documentation of a specific life cycle plan for each software prior to development, modification, or qualification. (3.2.2.1A) QP 3.2, page 6.		
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I-4	Verify documentation of category selection for LLNL quality related SES. If it is affirmative, assure it includes a declaration of whether the software is to be treated as Blue SES or not. (3.2.2.1.A.3) QP 3.2, page 6.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
I-5	Verify the life cycle plan to the end user (or other s/w documentation) reflects changes to auxiliary software. (3.2.2.1.A.1) QP 3.2, page 7, [Distribution Package].		
I-6	Verify distribution of any software packages partially meeting QP 3.2 requirements are labeled as to the status		
	(check READ.ME file). (3.2.2.1.A.2) QP 3.2, page 7.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS
I-7	Verify the Task Leader makes a formal determination of software as SES that is approved by Technical Area Leader. It is to be a permanent record. (3.2.2.1.A.3) QP 3.2, page 8.		
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I-8	Verify the PI prepares an Individual Software Plan for each software package prior to development, modification, or qualification activities. Acquisition or use does not require an ISP. (3.2.2.1.A.4) QP 3.2, page 8.		

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ITEM NO,	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
I-9	Verify for any Blue SES developed or modified the ISP for code-to-code comparison or in a separate ISP. For acquired Blue SES verify the version number or other ID is documented. (3.2.2.1.A.4) QP 3.2, page 9.		
r -1 0	Verify the life cycle definition in an ISP (not child) by control points for software baseline elements. Verify review of all revisions. (3.2.2.1A.4 & 3.2.2.1.B) QP 3.2, pages 9 & 10.		

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	QUALITY ASSURANCE CHEC	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
I-11	Verify in the ISP the development line is described by successiv numbers. (3.2.2.1.B) QP 3.2, page 10.	е	
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I - 12	Verify for developed or modified software the ISP or ISP child document includes a description of plans for meeting documentation requirements of section 3.2.2.6. (3.2.2.1.D) QP 3.2, page 11.		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
I - 13	Verify review of Software Baselines at Control Points. (3.2.2.1E) QP 3.2, page 11. Assure documentation of this review is entered in the Master File Folder.		,
I - 14	Verify Software Verification and Validation plans describe methods and are included in an ISP or child. (3.2.2.2.B) QP 3.2, page 12.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
1-15	Verify software verification and validation activities are documented in an ISP or ISP child document, and carried out or reviewed by an independent individual or organization. (3.2.2.2.C) QP 3.2, page 12.				
I-16	Verify software verification review addresses any changes related to porting or installation. (3.2.2.3) QP 3.2, page 13.				
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QUALITY ASSURANCE CHECKLIST (continuation sheet) REMARKS ITEM Record objective evidence reviewed, method RESULTS **CHARACTERISTICS TO BE EVALUATED** NO. of verification, personnel contacted Verify software validation activities are integrated into the 1-17 software life cycle as described in an ISP or ISPs. (3.2.2.4A) QP 3.2, page 14. I-18 Verify the primary method of validation is testing which is described in a test case library. (3.2.2.4.A) QP 3.2, page 14. I-19 Verify regression testing is performed during validation of software modifications to released software. (3.2.2.4.C) QP 3.2, page 15.

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	ACQUIRED SOFTWARE		
1-20	Verify for acquired not modified software:		-
	1) Validation to a plan in an ISP for intended use		
•	2) Place under CM		
	3) A, B, C, D, E, of 3.2.2.6		
	(3.2.2.5.A & 3.2.2.5.C) QP 3.2, page 16.		
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1-21	Verify for acquired software modified:		
	1) Installation testing		
	 Documentation of meeting appropriate requirements (A, B, C, D, E, F, of 3.2.2.6) a) Review by independent party. 		
	3) Placing software under CM		
	(3.2.2.5.B & 3.2.2.6) QP 3.2, page 16.		

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	QUALITY ASSURANCE CH	HECKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
r -22	Verify for Blue SES that such software is mentioned in validation documentation for SES code-to-code comparison. (3.2.2.6) QP 3.2, page 16.		
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ПЕМ		REMARKS	•
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	CONFIGURATION MANAGEMENT		
I - 23	Verify the TL has a CM system for each SES for which he is responsible. (3.2.2.7.A) QP 3.2, page 20.		
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I - 24	Verify the Project Leader maintains a master list of all quality-affecting SES which notes the responsible TL. (3.2.2.7.A) QP 3.2, page 20.		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
I - 25	Verify configuration management for acquired SES is placed under LLNL-YMP CM, but not change control unless it is being developed/modified. (3.2.2.7.A) QP 3.2, page 20.				
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1-26	Verify placement of software under CM as each baseline element is certified in accordance with 3.2.2.11. (3.2.2.7.B) QP 3.2, page 20.				

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QUALITY ASSURANCE CHECKLIST (continuation sheet) REMARKS ITEM Record objective evidence reviewed, method CHARACTERISTICS TO BE EVALUATED **RESULTS** NO. of verification, personnel contacted CONFIGURATION IDENTIFICATION I-27 Verify configuration identification includes definition of baseline elements for each SES and a unique identifier for the software items. (3.2.2.7.D) QP 3.2, page 21. Verify, for complex branching, the rationale is described I-28 and the system for documentation contained in an ISP, TIP, or memo to Master File Folder. (3.2.2.7.D.1) QP 3.2, page 23. I-29 Verify the TL documents the true software configuration items, in a software package and defines for each the file(s) which comprise it. This is to be in the Configuration Item List. (3.2.2.7.D.2) QP 3.2, page 25.

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
. •	DISTRIBUTION PACKAGES		
I - 30	Verify in Distribution package the exact revisions of the software components are identified. Also, verify identification of documentation components. (3.2.2.7.D.3) QP 3.2, pages 25-26.		
1-31	Verify the TL maintains a Configuration Item List (CIL) for each development or acquisition line. It includes:		
· · · · · · · · · · · · · · · · · · ·	1) List of all true software items in the package.		
	2) The software distribution package.		
	(3.2.2.7.D.5) QP 3.2, page 27.		
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ITEM		REMARKS	•
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
I -3 2	Verify each software distribution package contains the software package name and corresponding version # in the READ.ME text file required in 3.2.2.7.D.7. (3.2.2.7.D.6) QP 3.2, page 28.		
:-33	Verify each text file also contains the software package name and the distribution package version number. Also, major code documents shall contain the software distribution package version number in their titles. (3.2.2.7.D.6) QP 3.2, page 28.		

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	QUALITY ASSURANCE CHECKLIST (continuation sneet)				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
	CONFIGURATION CONTROL				
I-34	Verify implementation and documentation of configuration control by the use of:				
	 File folders, Software Development log - opened before development or modification, and Software Distribution log - opened prior to internal or external distribution 				
	(3.2.2.7.E.1) QP 3.2, page 29.				
I-35	Verify the Master File Folder contains items 1-5 (bottom of page 30) unless the condition is not applicable. (3.2.2.7.E.1.a) QP 3.2, page 30.		-		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
- 36	Verify the Software Development log contain a record of revision-by-revision development of each of the primary true software components and a list of each component whose development is controlled using this log. (3.2.2.7.E.1.b) QP 3.2, page 31.		
:-37	Verify the use of the software development log by the developer to include:		
	1) Revision signed out 2) Name or initials of developer signing out 3) Date signed out 4) Revision signed in 5) Name or initials of party signing in 6) Date signed in		
	7) Check mark indicating log entry of Summary of Work Done. (3.2.2.7.E.1.b) QP 3.2, page 32.		

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		REMARKS	•
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
r-38	Verify the Summary of Work Done contains:		
	1) Name of software component modified 2) The development line 3) Revision or stage number of the modified component 4) Developer's name or initials 5) Date of completion 6) Short summary of development or modification, if any 7) Summary of testing conducted, if any 8) Rationale for the changes (if not elsewhere) (3.2.2.7.E.1.b) QP 3.2, page 32.		
-39	Verify the Software Distribution log contains:		
	 Names and addresses of receiving parties Version # of the software distribution package Date of distribution Signature or initials or person making distribution If appropriate, platform identifier(s) for the distribution package 	d n	
	(3.2.2.7.E.1.c) QP 3.2, page 33.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
,	APPROVAL OF CHANGES		
1-40	Verify the TL evaluates and approves all changes to software developed or modified by means of:		
	 ISP or child document. Defect reporting and resolution system documentation. Memoranda entered in the Master File Folder or other File Folder. 		
	(3.2.2.7.E.2) QP 3.2, page 33		
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I-41	Verify information concerning approved changes are transmitted to organizations affected by the change as identified in the Software Distribution Log. (3.2.2.7.E.3) QP 3.2, page 34		

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	QUALITY ASSURANCE CHE	ECKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
I-4 2	Verify software verification and validation is performed for changes to software. (3.2.2.7.E.4 £ 5) QP 3.2, page 34		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	STATUS ACCOUNTING		
-43	Verify Configuration Status Accounting includes:		
	 A listing of approved baseline elements and unique identifiers. 		
	 A status of approved and proposed changes to baseline elements. 		
	3) A brief chronology of software items and descriptions of changes.		
	(3.2.2.7.F) QP 3.2, page 34		
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-44	Verify a defect reporting system is in place for SES and is integrated into the SCM system.		
.	(3.2.2.8) QP 3.2, pages 34 and 35		
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	QUALITY ASSURANCE CHECKLIST (CORUMNIZATION SHEEL)				
ITEM NO.	REMARKS CHARACTERISTICS TO BE EVALUATED Record objective evidence reviewed, method of verification, personnel contacted REMARKS Record objective evidence reviewed, method of verification, personnel contacted				
I - 45	Verify backup of software under development at least monthly. (3.2.2.9.C) QP 3.2, page 37				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	SOFTWARE USE	or vormoution, personner contacted	
I-46	Verify the following is documented for software used:		
	- Date of use - Software Package name - Distribution Package version - Platform - Operating system name and version - Compiler name and version		
	(3.2.2.10.B) QP 3.2, page 38		
I-47	Verify the use of software in an approved study plan, scientific investigation plan, ISP or child, or Scientific Notebook entry. (3.2.2.10.B) QP 3.2, page 39		

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REMARKS					
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
- 4 .8	Verify, for SES outside the previous range of validation, further validation is performed. (3.2.2.10.C) QP 3.2, page 39				
-49	Verify software certification in accordance with 3.2.2.11. (3.2.2.11) QP 3.2, page 39				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 8, REVISION 2, IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES AND DATA		
11-1	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
11 -2	Determine what is meant by an "item" and identification and		
	control of the items. (Para. 8.0.4)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
11-3	Determine if controls are developed and implemented to ensure samples are identified and controlled. Controls should include (Para. 8.0.4.2)		
	a) Special measure for handling, etc.		
	b) Identifying special environments		
	c) Special equipment/environment		
	d) Special handling tools/equipment		
	1) inspected/tested 2) operator experience/training		
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II-4	Verify that a physical identification of samples is maintained or samples can be traced to appropriate documentation. (Para. 8.0.4.2.2)		

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	GONLITT ASSUMMOE OREONLIST (CONTINUATION SHEET)					
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
II-5	Verify that samples are identified on the sample, container or on records. (Note: Ensure identification prevents samples from being mixed). (Para. 8.0.4.2.2)					
II-6	Verify that controls are developed/implemented to ensure methods produce the intended sample (meet technical objectives). (Para. 8.0.4.2.3)					

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
11-7	Verify that samples are maintained in a predetermined physical condition (long term storage appropriate treatment). (Para. 8.0.4.2.4)				
11-8	Verify that samples are transported in appropriate (?) containers to preclude damage. (Para. 8.0.4.2.5)				

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	QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
II-9	Verify that measures are developed/implemented to maintain sample identification during storage. (Para. 8.0.4.2.6)					
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11-10	Verify that a record is kept of all locations and environment of the sample identifiers replaced and traceability is maintained from original identifier through replacements. (Para. 8.0.4.2.6)					
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
II-11	Verify that methods have been established to preclude using samples beyond intended use or storage life. (Para. 8.0.4.2.7)		
II-12	Verify that controls are developed/implemented to ensure the data are identified to assist in the determination of correct use. Identification includes: (Para. 8.0.4.3)		
	- Origin of data		
	- Quality control imposed - Verification prior to release for use		

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	REMARKS .						
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS				
	TIP-YM-3, REVISION 3, LABELING, TRACKING, AND SHIPPING OF SAMPLES						
II-13	Verify that all section of the TIP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.	·					
· .							
II-14	Verify that samples are labeled to assure traceability as follows: (Para. 3.5.1.1)						
	1) Labels are located on the sample itself or the container.						
	Labels are securely attached to avoid loss during handling, storage, or shipping.						
	Labels do not affect the characteristics or end use.						
	4) Labels are legible.		1				

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
11-15	Verify that unique sample number is assigned that consists of a primary number and sub-numbers. Verify that there is a reference to the pertinent Scientific Notebook. Verify this information is contained in the Scientific Notebook. (Para. 3.5.1.2)		
II-16	Verify the Notebook contains the following information: (Para. 3.5.2.1)		
	- sample label information		
. '	<pre>- date sample is received/transmitted (including sub- divided samples)</pre>		
	- from/to whom the sample was received/transmitted - description of tests, preparation procedures and results		
	·		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)				
II-17	Verify that subdivide samples are relabeled and is traceable. (Para. 3.5.2.2)			
II -1 8	Determine how physical identification relative to the location that was sampled is maintained. (QP 8.0, Para. 8.0.4.1.1)			
	that was sampled is maintained. (Mr 0.0, rata. 0.0.4.1.1)			
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QUALITY ASSURANCE CHECKLIST (continuation sheet) REMARKS ITEM Record objective evidence reviewed, method CHARACTERISTICS TO BE EVALUATED **RESULTS** NO. of verification, personnel contacted 033-YMP-QP 3.0, REVISION 4, CN 3.0-4-1, SCIENTIFIC INVESTIGATION CONTROL III-1 Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix. III-2 Verify that before work begins, work is planned, reviewed and approved. (Para. 3.0.4) Scientific Investigation Plans (SIPs) Study Plans (SPs) Activity Plans

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
111-3	Verify that SIPs contain QA requirements, quality-affecting activities subject to the QA grading process, previous work including QA controls, and activity numbers for SIPs with more than one activity. (Para 3.0.4.1)		
	·		
III-4	Verify that SPs are prepared in accordance with AP-1.1Q and approved by OCRWM and YMPO. (Para. 3.0.4.2)		
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QUALITY ASSURANCE CHECKLIST (continuation sheet)

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
III-5	Verify that Activity Plans, used to describe how an activity is to be performed, are reviewed and approved by the Technical Area Lead. (Para. 3.0.4.3)		
III-6	Verify that Test Plans are linked to an approved Activity Plan and that the Test Plan has been provided to the LLNL-YMP Technical Representative. (Para. 3.0.4.3)		

III-7

(Para. 3.0.4.4)

Verify that Test Planning Packages (TPPs)/Job Packages (JPs)

are approved by YMPO prior to conducting the test.

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ITEM	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method	RESULTS
NO.		of verification, personnel contacted	
111-8	Verify that Activity Plans identify:		
	Eold Points (Para. 3.0.9)		
	Interface controls (Para. 3.0.10)		
	Methods of transmittal (Para. 3.0.10)		
	and are prepared appropriately in accordance with Appendix A:		
. "	Scientific Investigation Plan		•
	Scope, Purpose, and Objectives		
	Activity Description Precision, Accuracy, and Results		
'	In-Process Documentation		
	Interfaces		
	Schedule		
	Technical Implementing Procedures		
	Software		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
III-9	Verify that field changes made to Activity Plans are incorporated by the end of the month following the date of change (Para. 3.0.11), are authorized by the TAL (Para. 3.0.11), and the field changes are documented in the Scientific Notebook . (Para. 3.0.11).		
III-10	Verify that the documentation includes a discussion of why the data was selected and the suitability of the data for intended application. (Para. 3.0.12, last bullet)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
III-11	Verify the model validation included justification for intended use and that validation was accomplished by comparing results data against acquired from laboratory or field experiments or observations. (Para. 3.0.12)		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 3.3, REVISION 3, CN 3.3-3-1, REVIEW OF TECHNICAL PUBLICATIONS AND DATA		
III-12	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix		
III-13	Verify that the technical reviewer of data is independent of the technical efforts. (Para. 3.3.4.2)		
III-14	Verify that existing data is validated to establish the adequacy and suitability of the data for it's intended use. (QARD III.2.4C. and QP 3.3 Para. 3.3.5)		

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CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
Verify that all data, including data submitted to the CRF or GEMBOCHS, (not only data submitted to the RIB or YMP TDB) are reviewed for technical adequacy. (Para. 3.3.5)		
Wanter that the Emerical Designate Council Days		
Technical Data Submittal, (Exhibit D) is complete for technical data reviews.		
	Verify that all data, including data submitted to the CRF or GEMBOCHS, (not only data submitted to the RIB or YMP TDB) are reviewed for technical adequacy. (Para. 3.3.5) Verify that the "Technical Reviewer's Comment Form for Technical Data Submittal," (Exhibit D) is complete for	Verify that all data, including data submitted to the CRF or GEMBOCHS, (not only data submitted to the RIB or YMF TDB) are reviewed for technical adequacy. (Para. 3.3.5) Verify that the "Technical Reviewer's Comment Form for Technical Data Submittal," (Exhibit D) is complete for

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 3.4, REVISION 3, CN 3.4-3-2, SCIENTIFIC NOTEBOOKS		
III-17	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		
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111-18	Verify that Scientific Notebooks are:		
,	issued by the LRC		
	with a unique identifier and		
	that the Scientific Notebook Custodian maintains this information		
	along with date of issue and		
	name of assigned personnel. (Para. 3.4.5.1)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
III-19	Verify that initial Scientific Notebook entries include:		
	title, Activity Plan number and version, TIP(s) number and version, subject area, 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 of error personnel using Notebook - signatures - initials date and signature of investigator and TL sample id and M&TE used. (Para 3.4.5.2.1)		

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		REMARKS	
NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
11-20	Verify Scientific Notebook entries are made in accordance with Section 3.4.5.2.2 specifically:		
	investigator's signature/initials and date for each entry,		
	Technical Reviewer can retrace the investigation,		
	discuss deviations from planned activities.		
	·		
II - 21	Verify that an independent review is performed when the Notebook is full or activity complete.		
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ı		QUALITY ASSOCIATION OF LONGING SHEET						
	ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS				
		033-YMP-QP 3.5, REVISION 1, CONTROL OF INTERNAL INTERFACES						
	III-22	Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.						
	III - 23	Verify the application of Technical Information Transmittal Forms (TITF) in quality affecting activities.						
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<u> </u>	QUALITY ASSUMANCE OFFICIALIST (Continuation sheet)							
ITE!	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS					
	YAP-SIII.2Q, REVISION 0, TECHNICAL INFORMATION FLOW TO AND FROM THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT TECHNICAL DATA BASE							
111-	Verify that data flow to and from the technical data base is done in accordance with YAP-SIII.2Q.							

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	QUALITY ASSURANCE CHECKLIST (continuation sheet)							
ITEM NO. CHARACTERISTICS TO BE EVALUATED REMARKS Record objective evidence reviewed, method of verification, personnel contacted								
	YAP-SIII.3Q, REVISION 0, CONTROL AND TRANSFER OF TECHNICAL DATA ON THE YUCCA MOUNTAIN SITE CHARACTERIZATION PROJECT							
III - 25	Verify that data transfers are done in accordance with YAP-SIII.3Q.							
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	QUALITY ASSURANCE CHECKLIST								
ORGANIZATION EVALUATED [X] EXTERNAL [X] AUDIT [] INTERNAL [] SURVEILLANCE 3/6/95 through 3/10/95 CONTROLLING DOCUMENT (Title, Number, Revision)		PREPARED BY Robert A. Harpster ACTIVITY EVALUATED	DATE 2	/17/95					
CONTRO	OLLING DOCUMENT (TRIB, NU	mber, Revision)		ACTIVITY EVALUATED					
ITEM NO.	CHARACTER	RISTICS TO BE EVALUA	ATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS			
2-1	LLNL-033-YMP-QP 2.8, REVISION 3, QUALITY ASSURANCE GRADING Verify that all sections of the QP evaluated by this checklist adequately reflect the applicable requirements of the QARD sections identified in the RTN matrix.		·						
2-2 Are the technical activities reviewed by the Technical Specialist graded by the Task Leaders? (Para. 2.8.5.1, page 4)									

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

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-3	Is the grading process documented on forms such as those shown in Exhibits B? (Para. 2.8.5.2.2, page 5)	·	
2-4	Exhibit C? (Para. 2.8.5.2.2, page 5)		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-5	Exhibit D? (Para. 2.8.5.2.3, page 6)		
	·		
2-6	Is the grading review documented using Exhibit A? (Para. 2.8.5.3 - 2.8.5.6, page 7)		
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	QUALITY ASSUMANCE CHECKLIST (Continuation sheet)					
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
2-7	Are the specified records maintained as Quality Assurance Records? (Para. 2.8.7, Page 8)					

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	GOALITI ASSUNANCE OILECKLIST (COMMINGATION SHEET)				
ITEM NO.	EM IO. CHARACTERISTICS TO BE EVALUATED REMARKS Record objective evidence reviewed, method of verification, personnel contacted				
	GENERAL				
2-8	What is the relative importance of glass and spent fuel dissolution to the source term considering the likely abundance of both waste forms in a repository and their performance based on experiments and models to date?				
2-9	What is meant by 'model' in the context of ongoing testing programs?				
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-10	What is the purpose of testing both UO2 and spent fuel in both oxidation and dissolution experiments?		
2-11	How sensitive is release in the experiments or models to the presence of man-made materials (cements, steel, etc,) that may alter water chemistry entering the waste package?	·	
2-12	How sensitive is oxidation rate and radionuclide release to grain size? Does oxidation change grain size? What is the inherent variation in grain size for spent fuels?	•	

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ITEM	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method	RESULTS
NO.	O DA INTO TO DE ETABORTES	of verification, personnel contacted	TIESOE 10
2-13	How sensitive are dissolution and release rates to oxidation of the UO2 and spent fuel?		
2-14	What variation in release rates have been observed for various components, such as uranuim, iodine, and carbon?		
2-15	How does burnup affect release and oxidation rates?		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
	GLASS TESTING: SITE SPECIFIC TESTS (WBS NO. 1.2.2.4.2)			
2-16	Given what you have learned to date, what are the important processes (equilibrium, kinetic, particulate release, etc.) involved in waste form degradation and radionuclide release? What is their relative importance? Compare and contrast saturated, unsaturated, and vapor-phase tests? Is there any indication that releases will not be solubility limited (i.e. collodial release)?			
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	GOALITY ASSURANCE CHECKLIST (Continuation energy				
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
2-17	Section 1.3 of SIP-WF-02 states that a model will be developed that "accurately predicts" the results of a subset of your experiments. How far along are you in developing such a model? What do you consider to be an "accurate" prediction? What contingencies do you have if this is not achievable?				
2-18	How sensitive is performance to glass composition? How well does your testing program bound probable glass compositions?				

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-19	How does the radiation field affect degradation? How do you account for those effects in modeling?		
2-20	Are saturated, unsaturated, and vapor-phase testing all		
	underway? If not, why not and what are the risks?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-21	This SIP mentions analogs (Section 2.4). What analogs, if any, have been considered?		
2-22	How have you determined what "representative" waters (Section 3.2.1) are? What are the possible impacts of using the "wrong" water? How do you bound this problem?		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-23	To what groundwater parameters is glass performance most sensitive?		
		·	·
2-24	The SIP pays a lot of attention to secondary phases. What are they? What is their importance? To what extent are they likely form colloids?	•	

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-25	How do secondary phases vary with saturated, unsaturated, and vapor-phase testing?		
2-26	How do dissolution and secondary phase formation vary with time of testing?		
2-27	How is the existence (or absence) or colloids as secondary phase established?	s	
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	GOALITI ASSURANCE OILEGRAST (COMMINATION SHEET)			
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
2-28	Why does the SIP indicate that more saturated than unsaturated tests will be performed (Section 3.2.1.2)? Does the larger test matrix for saturated experiments imply that you anticipate that this is a more likely scenario for release?			
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	GLASS TESTING: MODEL DEVELOPMENT TESTS (WBS NO. 1.2.2.4.2)		
2-29	What is the status of improving the match of glass hydration/dissolution theory to experimental results (Section 3.3.2.2)?		
2-30	Is there a difference between the glasses and waters used in		
	these tests and those used in the site specific tests (Section 3.3.3.1)? What is the philosophy behind such differences?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	R	ESULTS
2-31	Have the results to date indicated the need for initiating the activities in Section 3.3.3.3?	·		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	SPENT FUEL TESTING: DISSOLUTION TESTS (WBS NO. 1.2.2.4.1)		
2-32	Why does the SIP indicate that more saturated than unsaturated spent fuel tests will be performed (Section 3.3.1.2)? Does the larger test matrix for saturated experiments imply that you anticipate that this is a more likely scenario for release? Are there differences in the two processes which could lead to substantially different release behavior?		
2-33	What secondary phases, if any, are formed under saturated and unsaturated conditions, respectively? What potential is there for the formation of colloids? Do releases appear to be solubility controlled?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESUL	LTS
2-34	Since spent fuel may somewhat resemble uraninite, how do the results of your studies compare to places like Pena Blanca or other possible analog sites? What is the potential for the use of such analogs in your studies?			
		·		
2-35	How are the solutions analyzed?			
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		CKLIST (COMMUNICATION SHEET)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-36	How are the solid and colloid phases analyzed?		
2-37	Section 3.4 of SIP-WF-01 states that a model will be developed and validated "for the release of radionuclides from the spent fuel waste form under repository conditions. How far along are you in developing such a model? What codes are being considered? What do you consider to be a "valid"		
	prediction? What contingencies do you have if this is not achievable?		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-38	What is the sensitivity of releases to groundwater chemistry for both saturated and unsaturated tests?		
2-39	What criteria are established to determine which fuels are tested?		

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	QUALITY ASSURANCE CHEC		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	SPENT FUEL TESTING: OXIDATION/CLADDING TESTS (WBS NO. 1.2.2.4.1)		
2-40	How do you account for drift in the Thermo Gravimetric Analysis (TGA) balance?		
2-41	What is the effect of humidity on oxidation rate?		
2-42	What is the sequence of phases formed?		
	what is the sequence of phases formed.		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
2-43	How do the results of TGA and oven tests compare?		*	
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	MODELING SPENT FUEL, GLASS DISSOLUTION, AND SOLUBILITY (WBS NO. 1.2.2.4.1)		
2-44	What are the capabilities of EQ3/6 for modeling spent fuel and glass?		
2-45	How do the capabilities of EQ3/6 vary with changes in chemical conditions to be modelled; e.g., modeling solutions with low and high ionic strength?		
2-46	To what extent has EQ3/6 been successful in modeling the behavior of spent fuel and glass (for example, see Section 2.4, key output 3)? What level of uncertainty is acceptable?		•
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
2-47	How complete is the database needed for modeling glass and spent fuel dissolution and degradation?	·		
2-48	What are the "pre-" and "post-" processors mentioned in Section SIP-WF-02, Section 3.3.2.1.?			
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
2-49	How complete is the database for modeling solubility?		
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	THERMODYNAMIC DATA DETERMINATION (WBS NO. 1.2.3.10.3.2)		
2-50	How does this study differ in workscope and philosophy from WBS 1.2.3.4.1.3.1 *Dissolved Species Concentration Limits?*		
	m1.bbb. 2		
2-51	To what extent does your work consider colloids?		
			· .
2-52	The SIP describes measurements from oversaturation (D-20-54.1) and a separate set of measurements from undersaturation		
	(D-20-54.2). What is the rationale for the separate approaches? Why not reverse both sets of experiments?		

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		Sixtio (footinitiation sheet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-53	How will you constrain the size of your test matrix, given the number of possible variables? What elements have you studied/planned to study? What are your selection criteria?		
2-54	Is the orientation of you study to measure solubilities under repository relevant conditions, or to gather the necessary thermodynamic data to allow solubility calculations under a range of possible conditions?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-55	How do you define an adequate match between calculated and measured solubilities?		
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}	GOALITI ASSURANCE ONE	•	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	TESTING OF SMALL BLOCKS: (WBS NO. 1.2.3.12.4)		
2-56	To what extent can the small blocks provide the same information as the Large Block Test itself? Will the small blocks provide the mechanical and chemical information that will not be gathered due to the replanning of the Large Block Test?		
2-57	How relevant will the parameters collected be to the host rock underground, or will they only be representative of the Large Block material itself?		
2-58	How will the geochemical data that are collected be used?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
2-59	How is the characterization of small blocks progressing? To what extent do you anticipate characterizing blocks in this manner for underground tests?			
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ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	METALLIC BARRIERS: (WBS 1.2.2.5.1)		
2-60	What is your strategy to build confidence in the temporal scaling of experiments a few years in length on candidate waste package material to performance over hundreds or thousands of years?		
2-61	What is the current concept for waste package materials in		
2-01	terms of thickness and kind?		

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	QUALITY ASSURANCE ONE	CRLIST (continuation sneet)	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-62	How sensitive is the current concept for waste package materials to the EBS design, e.g, the multi-purpose canister?		
2-63	How are the possible effects of microbially induced corrosion being studied? What are the inputs and interfaces from other parts of the program in this area?		

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		REMARKS	1.
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-64	How are dry oxidation and phase stability of metallic barriers being studied?		
2-65	What boundries for possible groundwater compositions are in your test matrix? Do they conservatively bound waters likely to be present in the near field? What are your interfaces with the near field geochemistry task (WBS 1.2.3.12.1)?		

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ITEM NO.	CHARACTERISTICS TO BE EVALUATED REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
2-66	How do the boundaries for groundwater compositions vary with saturated, unsaturated, and vapor-phase systems?		
2-67	What is the status of model development and confidence building in the models? What constitutes a "valid" model? What level of uncertainty is acceptable?		
2-68	How will the models incorporate crevice corrosion, stress corrosion cracking and hydrogen embrittlement?	·	