OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

QUALITY ASSURANCE AUDIT PLAN

FOR AUDIT YMP-94-10

OF

LAWRENCE LIVERMORE NATIONAL LABORATORY

LIVERMORE, CALIFORNIA

SEPTEMBER 19 THROUGH 23, 1994

Prepared by: Thomas E. Rodgers Date: 8/12/94
Thomas E. Rodgers
Audit Team Leader
Yucca Mountain Quality Assurance Division

Approved by: Donald G. Horton Date: 8/16/94
Donald G. Horton
Director
Office of Quality Assurance

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, adequacy, and effectiveness of systems in place, as well as verifying compliance with requirements.

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

The programmatic and technical elements to be audited during this full scope audit are identified in Section 4.0 of this audit plan.

2.0 AUDIT SCHEDULE

Pre-audit Team/Observer Meeting	8:30 a.m., September 19, 1994 Livermore, California
Pre-audit Conference	9:00 a.m., September 19, 1994 Livermore, California
Audit Activities	10:00 a.m. to 4:00 p.m. September 19, 1994 Livermore, California
	8:00 a.m. to 4:00 p.m. September 20 through 22, 1994
	8:00 a.m. to 10:30 a.m. September 23, 1994
Post-audit Conference	11:00 a.m., September 23, 1994 Livermore, California

There will be a daily Audit Team/Observer meeting at 4:00 p.m. and also a daily Audit Team Leader (ATL)/Observer/LLNL meeting starting at 8:15 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 programmatic and technical checklists. These checklists will be developed from the latest available revision of the following documents:

- OCRWM Quality Assurance Requirements and Description Document
- LLNL Quality Assurance implementing procedures
- Applicable Yucca Mountain Site Characterization 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"
- QAP 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 and Services
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 Investigation

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. 1.2.2.3.1.1, Oven Dry Bath Oxidation
- WBS No. 1.2.2.3.1.1, Spent Fuel/UO_2 Flow Thru Saturated Dissolution
- WBS No. 1.2.2.3.1.2, HLW Glass Unsaturated 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 team 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

Thomas E. Rodgers, YMQAD, Las Vegas, Nevada, ATL
Amelia I. Arceo, YMQAD, Las Vegas, Nevada, Auditor
Sandra D. Bates, YMQAD, Las Vegas, Nevada, Auditor
Mario R. Diaz, YMQAD, Auditor
John A. Gray, YMQAD, Las Vegas, Nevada, Auditor
Robert L. Howard, YMQAD, Las Vegas, Nevada, Auditor
Vance Cannaday, Headquarters Quality Assurance Division (HQAD), Auditor
Hugh Lentz, HQAD, Auditor
Technical Specialist to be determined

6.0 AUDIT CHECKLISTS

The following checklists will be used during the audit:

YMP-94-10-01, Programmatic Checklist
YMP-94-10-02, Technical Checklist

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

AUDIT/SURVEILLANCE
NO YMP-94-10-01

QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED	[x] EXTERNAL	[x] AUDIT	PREPARED BY See Below	DATE 9/12/94 JER
LLNL	[ ] INTERNAL	[ ] SURVEILLANCE		
DATES OF EVALUATION				
9/19 - 23/94				

CONTROLLING DOCUMENT (Title, Number, Revision)	ACTIVITY EVALUATED

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	ATL - THOMAS E. RODGERS - QP 2.3 & 18 ATL-IN-TRAINING - CYNTHIA A. HUMPHRIES AUDITOR - AMY ARCEO - 13, 15, 16, 17 & 18 AUDITOR - SANDRA BATES - 2 AUDITOR - MARIO DIAZ - 1, 4 & 7 AUDITOR - JOHN GRAY - 5 & 6 AUDITOR - VANCE CANNADAY - SUPPLEMENT I & 8 AUDITOR - HUGH LENTZ - SUPPLEMENTS II & III		

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

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-1.0, REVISION 4, ORGANIZATION		
1-1	Verify that the Project Leader approves all technical publications and reports prior to transmittal. (Para. 1.0.3.4)		
1-2	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)		

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 that the Task Leader prepares the procedures pertinent to the Technical Leader's area of responsibility. (Para. 1.0.3.7)		
1-4	Verify that the QA Manager reviews the selection of QA controls applied to items and activities. (Para. 1.0.3.8)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1-5	Verify that the Resource Planning and Control Manager (RPCM) reporting relationship is shown in Exhibit A as required by Paragraph 1.0.3.2 (QA Records).		
1-6	Verify that the RPCM does review all procurement documents and ensures that QA requirements are involved in those documents. Additionally, that he maintains the files of procurement documents. (Para. 1.0.3.9)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	QARD, SECTION 2.0, QUALITY ASSURANCE PROGRAM LLNL-033-YMP-QP-2.1, REVISION 5, CHANGE NOTICE 2.1-5.1, PREPARATION, APPROVAL, AND REVISION OF PROCEDURES, REQUIREMENTS, PLANS, AND THE QUALITY ASSURANCE PROGRAM DESCRIPTION		
2-1	Verify that LLNL-YMP completed or is completing a YMPO supplied QARD requirements matrix for each portion of the QARD that LLNL-YMP implements. (Para. 2.1.4.1)		
2-2	Verify that procedure review is conducted by at least one independent reviewer who is qualified in the subject area and independent of the work being performed. (Para. 2.1.4.3.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-3	Verify that quality affecting documents are reviewed by LLNL-YMP personnel identified and specified in Exhibit A. (Para. 2.1.4.3.2)		
2-4	Verify that comment resolution is either achieved or the document is elevated to the YMP leader for final disposition. (2.1.4.3.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-5	Verify that after LLNL approval, Scientific Investigation Plans (SIPs) and changes thereto are transmitted to YMSCO for approval. Verify that Study Plans are transmitted to YMPO for approval by YMPO and OCRWM. (Para. 2.1.4.5.)		
2-6	Verify that changes made to a current revision or change notice are identified by a vertical bar in the right-hand margin (including areas of deletion). (Para. 2.1.5.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-7	Verify that change notices are reviewed and approved by those authorized to approve the original document prior to issuance. (Para. 2.1.5.4.s2)		
	LLNL-033-YMP-QP-2.2, REVISION 1, PEER REVIEW		
2-8	Verify that the requirements of this procedure are adhered to when a Peer Review is conducted by LLNL-YMP.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP-2.4, REVISION 1, TECHNICAL REVIEW		
2-9	Verify that Technical Reviews are performed by qualified individuals other than those who performed the work. (Para. 2.4.4.2)		
2-10	Verify that the Task Leader or designee prepares a checklist for review board consideration which addresses the following: - Applicable input - Input changes - Investigation/design (Para. 2.4.4.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-11	Verify that each review board member signs one technical review approval sheet attesting that the applicable aspects of Section 2.4.4.5, Technical Review, have been considered. Verify that the Technical Area Leader signs the review approval sheet signifying concurrence with the conclusions of the technical review board. (Para. 2.4.4.8)		
2-12	Verify that the following quality assurance records are maintained in accordance with Procedure No. 033-YMP-QP 17.0. - Documentation attesting that applicable personnel were familiar with their duties as described in this procedure. (See 2.4.4.2.) - Technical review approval sheet(s) (see 2.4.4.8), - Review comment records and comment resolution. (Para 2.4.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP-2.5, REVISION 1, CHANGE NOTICE 2.5-1-1, ACCEPTANCE OF DATA NOT GENERATED UNDER THE CONTROL OF THE QARD		
2-13	Verify that qualification of existing data is accomplished by use of one or a combination of the four following methods: - Implementation of the peer review process in accordance with provisions of Procedure No. 033-YMP-QP 2.2, "Peer Review." - Use of corroborating data to support or substantiate other existing data. - Use of a confirmatory testing program conducted in accordance with the provisions of Procedure No. 033-YMP-QP 3.0. - A quality assurance program meeting the requirements of the QARD was utilized for the collection of the data being reviewed. (Para. 2.5.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-14	Verify that Exhibit A, Data/Data Interpretation Acceptance Review Form, is completed, signed and dated, as required. (Para. 2.5.5.3)		
2-15	Verify that upon completion of the review, the reviewer signs and dates the Appendix Sheet (Exhibit C). (Para. 2.5.5.4.13.)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-16	Verify that for data or data interpretation from a Technical Journal, Exhibit E is completed, signed, and dated, as required. (Para. 2.5.5.5.5.)		
2-17	Verify that after YMPO approval, the review package is submitted to Document Control for distribution and incorporation into the quality assurance records system. (Para. 2.5.5.6.s3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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		
2-18	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. (Para. 2.6.4.1.11.)		
2-19	Verify that a master log of unique Readiness Review identification numbers and description information is maintained by Document Control. (Para. 2.6.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-20	Verify that the summary memorandum of Readiness Review meeting(s) and an approved Readiness Review Checklist are maintained as quality assurance records in accordance with Procedure No. 033-YMP-QP 17.0. LLNL-033-YMP-QP-2.6, REVISION 1, CHANGE NOTICE 2.7-1-1, STOP WORK ORDER		
2-21	Verify that the requirements of this procedure are adhered to when Stop Work Orders are issued.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP-2.8, REVISION 3, QUALITY ASSURANCE GRADING		
2-22	Verify that new technical activities have been graded in accordance with this procedure prior to start of work. (Para. 2.8.5.1)		
2-23	Verify that subsequent to the QA Grading Review, QA Grading Reviewers complete, sign and date Exhibit A, Quality Assurance Grading Report. Verify that the Project Leader signs Exhibit A. (Para. 2.8.5.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-24	Verify that controlled copies of Exhibit A are provided to the Task Leader, Technical Area Leader, Project Leader and Quality Assurance Manager. (Para. 2.8.5.6)		
2-25	Verify that Exhibits A through D with attachments are maintained as quality assurance records. (Para. 2.8.7)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	LLNL-033-YMP-QP-2.9, REVISION 5, INDOCTRINATION AND TRAINING		
2-26	Verify that new personnel assigned to the LLNL-YMP have received Quality Assurance Indoctrination that includes training to the following documents: - Quality Assurance Requirements and Description - Applicable implementing procedures and work instructions including job responsibilities and authority - Regulations (10 CFR 60, 10 CFR 960 and 40 CFR 191) - Project level documents (Para. 2.9.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-27	Verify that a training matrix is maintained and that LLNL personnel receive all training identified on the matrix, unless exempted in writing by the TAL. (Para. 2.9.5)		
2-28	Verify that as required by training matrix, training to a change notice or revision is provided due to any of the following: - A change in responsibilities of people addressed in the procedure, - A change in technical requirements of the procedure, - A change in the scope of the procedure. (Para. 2.9.7)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-29	Verify that training materials are prepared by the Instructor and/or Training Coordinator (TC) and approved by the TC prior to use. (Para. 2.9.10.1)		
2-30	Verify that following completion of training, all relevant records are remitted to the LRC. (Para. 2.9.12)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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, QUALIFICATION OF PERSONNEL		
2-31	Verify the following for LLNL personnel or subcontract personnel working under the direction of LLNL-YMP to Quality Procedures. Personnel Qualification Records documentation packages are prepared, reviewed and approved by Technical Area Leaders. These packages consist of the following records: - Position Description (Exhibit A) - Personnel Resume (Exhibit B) - Management Certification (Exhibit C) - Management Recertification, as applicable (Exhibit D) (Paras. 2.10.4.1; 2.10.4.2; 2.10.4.3; 2.10.4.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-32	Verify that Position Descriptions, Personnel Resumes, Management Certification and Recertification, Training documentation, and documentation for verification of personnel resumes are maintained as lifetime Quality Assurance Records. (Para. 2.10.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	033-YMP-QP-2.3, REVISION 1, MANAGEMENT ASSESSMENTS Based on the most recently performed Management Assessment, verify implementation and effectiveness of the following LLNL procedural requirements.		
2-33	Management Assessments are conducted at least once a year to evaluate the performance of the LLNL YMP in the following five areas: (Para. 2.3.2) - Adequacy of the personnel qualification and training program. - Adequacy and effectiveness of the QA program. - Adequacy of the QA program management information tracking, evaluation, and reporting system. - Adequacy of the organizational structure and staff. - Effectiveness of the nonconformance and corrective action program.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-34	Assessment areas selected for review will be identified on Management Assessment Worksheets to document the assessment and results. (Para. 2.3.4)		
2-35	The management assessment team utilizes, as appropriate, the following methods: (Para. 2.3.4) a. Interviews with management and staff personnel. b. Review of audit, surveillance, corrective action, nonconformance, and QA and project reports and supporting documentation. c. Evaluation of training documentation. d. Review of budget and other statistical information regarding the availability of resources and their use.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-36	The results of the assessment activities are documented in a report. The assessment report includes the following information: (Para. 2.3.4) a. Identification of the management assessment individual(s). b. A description of the assessment activities. c. The scope of the management assessment. d. Identification of personnel interviewed during the assessment. e. Management Assessment Worksheets. f. A summary of results of the assessment. g. A description of any adverse conditions identified during the management assessment.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2-37	Input is solicited from management of other organizations participating in the LLNL-YMP QA Program concerning the status and adequacy of that part of the program that they are executing. (Para. 2.3.4)		
2-38	The assessment report is signed by each individual who participated in performing the assessment. Minority or dissenting comments are appended to the management assessment report. (Para. 2.3.4)		
2-39	The Deputy Associate Director for Fission Energy and Systems Safety Program is responsible for reviewing and approving the management assessment report. (Para. 2.3.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-40	The QA Manager will track assigned action items from management assessment reports to closure, and will provide memo(s) to the Deputy Associate Director for Fission Energy and Systems Safety Program and file upon closure. (Para. 2.3.4)		
2-41	Copies of the management assessment report are distributed to the DOE YMPO Project Manager, the DOE YMPO QA Division Director, the responsible YMP Leader, the Deputy Project Leader, the Associate Project Leader, the Assistant Project Leader, the YMP QA Manager, and the Technical Area Leaders. (Para. 2.3.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2-42	QA Records include the following: (Para. 2.3.5) - Memo designating the management assessment team members and approving the assessment scope. - The management assessment worksheets. - The management assessment report. - The closure memo(s).		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 3.0, REVISION 4, SCIENTIFIC INVESTIGATION CONTROL		
3-1	Verify that before work begins, work is planned, reviewed, and approved. (Para. 3.0.4) Scientific Investigations Plans (SIPs) Study Plans (SPs) Activity Plans		
3-2	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS *Record objective evidence reviewed, method of verification, personnel contacted*	* RESULTS
3-3	Verify that SPs are prepared in accordance with AP-1.10Q and approved by OCRWM. (Para. 3.0.4.2)		
3-4	Verify that Activity Plans, used to described how an activity is to be performed, are reviewed and approved by the TAL. (Para. 3.0.4.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-5	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)		
3-6	Verify that Test Planning Packages (TPPs)/Job Packages (JPs) are approved by YMPO prior to conducting the test. (Para. 3.0.4.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-7	Verify that SIPs, SPs, Activity Plans, and TIPs are handled as controlled documents and that the QA Manager transmits the SIP/SP to the DOE Project Office for approval. (Para. 3.0.8)		
3-8	Verify that Activity Plans identify: Hold 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 Representativeness of Results In-Process Documentation Interfaces Schedule Technical Implementing Procedures Software		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-9	Verify that interface controls between LLNL-YMP and other Participating Organizations are in accordance with requirements defined by YMPO. (Para. 3.0.10)		
3-10	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-11	Verify that field changes to Activity Plans are authorized in writing (TAL) and provided to the YMP Leader and QA Manager. (Para. 3.0.11)		
3-12	Verify that field changes are documented in the appropriate SN and a copy of the notebook pages are provided to the TAL and QA Manager by the end of the following day. (Para. 3.0.11)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-13	Verify that documentation of results includes: (Para. 3.0.12) Summary of results Definition of objective Discussion of whether objectives achieved Definition of inputs Listing of references Statement of assumptions Identification of computer calculation Signatures/dates of review/approval Use and validation of models		
3-14	Verify that QA records include: (Para. 3.0.13) Planning documents Data records Analyses Planning document reviews Comment resolution meetings Verification records Interface control records SNs with field changes		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP 3.2, REVISION 2, SOFTWARE QUALITY ASSURANCE		
3-15	Identify the software packages currently in use and/or planned for use by LLNL in quality-affecting work. Record its full title, classification, date of approval of use in quality-affecting work (if approved), or current status toward approval. Also document if the software package was acquired or modified/developed by LLNL.		
3-16	Ensure that an individual lifecycle plan, defined by control points for documenting baseline elements, has been documented and approved for each software item prior to development or modification of software or the qualification of acquired software. (Lifecycles shall be defined in the ISP and not in an ISP child document) (3.2.2.1.A and 3.2.2.1.B)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-17	Verify that for each software item developed within LLNL, a lifecycle plan prescribes the documentation requirements of 3.2.2.6. (3.2.2.1.D)		
3-18	Verify that the software baselines are reviewed, and that they are performed and documented at the software control points which are defined in the lifecycle plan. Following approval of each baseline element, ensure that it is placed under configuration management controls. (3.2.2.1.E and 3.2.2.7)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-19	Verify that LLNL developed or modified SES and for qualification of acquired SES, a software V&V is performed prior to release for use in quality-affecting work (approved SES) by or reviewed by an independent organization or individual. (3.2.2.2.A.1 and 3.2.2.2.C)		
3-20	Ensure that software V&V plans within the ISP or ISP child documents describe the methods to be used for V&V (such as review, inspection, analysis, demonstration and test). (3.2.2.2.B)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-21	Verify the documentation of software verification performed at the end of each lifecycle phase to ensure that the products of the lifecycle phase meet the established requirements. (3.2.2.3)		
3-22	Verify that software validation activities are integrated into the software lifecycle and that testing is the primary method used for validation. (3.2.2.4.A and 3.2.2.4.B)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-23	Verify that software validation performed for modifications to released software items include regression testing. (3.2.2.4.C)		
3-24	Verify that the test plans and test cases are documented in a software validation plan. (3.2.2.4.C)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-25	Verify that acquired SES is documented sufficiently to demonstrate the ability of the software to meet the needs of LLNL. (3.2.2.5)		
3-26	Ensure that for acquired software that was not developed in accordance with this procedure, its qualification shall include: (3.2.2.5.A) - Verification to an approved plan, to ensure that software meets the requirements for its intended use. - Placement under the configuration management controls of this procedure.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-27	Verify that qualification of acquired software that was developed or modified in accordance with the procedure or its predecessors (if accepted under previous OCRWM QA Program) include the following: (3.2.2.5.B) - Installation testing to ensure that software performs as required in the operational environment. (TIP-YM-15) - Confirmation that documentation information exists to support that appropriate requirements were met. - Placement under the configuration management control of this procedure.		
3-28	Review the requirements information to ensure the documentation sufficiently addresses the ability of the software to meet the needs of the affected organization. (3.2.2.6.A) (acquired and modified/developed software) - Description of the overall nature and purpose of the software. - Requirements for its intended use.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-29	Review the user information to ensure the documentation sufficiently addresses the ability of the software to meet the needs of the affected organization. (3.2.2.6.B) (acquired and modified/developed software) - Description of how to use the software item including: Input and output options; data files; input and output data; defaults and file formats; anticipated errors and how the user can respond; the hardware and software environments; and a description of the allowable and tolerable ranges for inputs and outputs. - Available sample problems. - Changes since the last release that affect the user. - Installation procedures.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-30	Review the validation information to ensure the documentation sufficiently addresses the ability of the software to meet the need of the affected organization. (3.2.2.6.C) (acquired and modified/developed software) - The validation plan which includes a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software validation. - A record of the results of the execution of planned software validation including the extent to which the results agree with the specified acceptance criteria.		
3-31	Review the documentation to ensure that it includes a record of reviews of software baselines. (3.2.2.6.D) (acquired and modified/developed software)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-32	Review the requirements and design information to ensure that the documentation sufficiently addresses the ability of the software to meet the need of the affected organization. (3.2.2.6.E) (acquired and modified/developed software) - Functional requirements. - Performance requirements and design constraints. - Interfaces with external data, hardware, or other software. - Applicable software and hardware operation issues to include programming languages and versions, portability, maintainability, reliability, and efficiency. - A description of the major software items as they relate to the functional requirements. - A description of the software structure including software internal interfaces, control logic, and data structure and flow. - A description of models and numerical methods.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-34	Verify that acquired software meets the documentation requirements reflected in checklist Items 14, 15, 16 and 17. (3.2.2.5.C)		
3-35	Verify that a configuration identification within the software configuration management system includes: (3.2.2.7.D) - A definition of the baseline elements of each software baseline. - A unique identification of software items to be placed under software configuration management. Each version or revision of a software item is uniquely identified and lableled; and where feasible, included with the genrerated output.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-36	Ensure that configuration identification assigns unique identifiers that relate baseline documents to their associated software items. A cross-reference must be maintained between baseline documents and associated software. (3.2.2.7.D)		
3-37	Verify that configuration control include a release and control process for baseline elements. (TIP-YM-11)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-38	Verify that changes to baseline elements, including retirement and withdrawal, are beig formally controlled and documented with a description of the change. The rationale for the change, and the identification of affected baseline elements. (3.2.2.7.D)		
3-39	Ensure that the change is being formally evaluated and approved by the organization responsible for approving the baseline element. (3.2.2.7.E.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-40	Verify that only approved changes are being made to software baselines and information concerning approved changes are being transmitted to all organizations affected by the changes. (3.2.2.7.E.3)		
3-41	Verify that software verifications are being performed for the changes as necessary to ensure the change is appropriately reflected in software documentation and to ensure that document traceability is maintained. (3.2.2.7.E.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS *Record objective evidence reviewed, method of verification, personnel contacted*	RESULTS
3-42	Verify that software validation is being performed as necessary for the change. (3.2.2.7.E.5)		
3-43	Verify that configuration status accounting includes the following: (3.2.2.7.F) - A listing of the approved baseline elements and unique identifiers. - The status of proposed and approved changes to the baseline elements. - A brief chronology of the software items, including desriptions of the changes made between versions of software items.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-44	Verify that the defect reporting and resolution system is being integrated with the software configuration management system to ensure formal processig of deficient resolutions. (3.2.2.8.A)		
3-45	Verify that software defect reporting and resolution system includes the following controls: (3.2.2.8.A) - Documentation and resolution of defects. - Defects shall be accessed for their impact on previous applications. - Review and approval of resolutions before changes are made to baseline elements. - Notification of affected organizations.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-46	Verify that when a defect is identified in software that adversely impacts previous applications, conditions adverse to quality are being documented and controlled in accordance with QP 16.0. (3.2.2.8.A)		
3-47	Verify that completed/released software items to the media are being contolled to prevent inadvertent damage or degradation. (3.2.2.9.A)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-48	Verify that LLNl has established procedures for controlling and documenting the use of released software and that the procedures are sufficient to allow an independent repetition of the use of the software. (3.2.2.10.B.1)		
3-49	Verify that software uses are being approved and independently reviewed to ensure that the software selected is applicable to the problem being solved and that inputs and assumptions are valid and traceable. (3.2.2.10.B.2)		
3-50	Verify that if the use of a software item fails outside the range of validation, further validation is being performed prior to use. (3.2.2.10.C.1)		

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

AUDIT/SURVEILLANCE
NO YMP-94-10-01

QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED	[x] EXTERNAL	[x] AUDIT	PREPARED BY ~~See Below~~	DATE 9/12/94
LLNL	[ ] INTERNAL	[ ] SURVEILLANCE		JER
DATES OF EVALUATION				
9/19 - 23/94				

CONTROLLING DOCUMENT (Title, Number, Revision)	ACTIVITY EVALUATED

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	033-YMP-QP 3.3, REVISION 2 REVIEW OF TECHNICAL PUBLICATION AND DATA		
3-51	Determine the number (obtain list) of technical publication and technical data reviews performed. (General)		
3-52	Verify that reviewers are qualified and appropriately independent. (Paras. 3.3.4.2 and 3.3.5)		

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

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-53	Verify that technical data is reviewed by LLNL-YMP QA and LLNL-YMP Leader. (Para. 3.3.5)		
3-54	Verify that reviewer comments are resolved (disputed comments resolved by the LLNL-YMP Leader are retained as QA records). (Para. 3.3.4.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-55	Verify that publication drafts are submitted to YMPO for approval. (Para. 3.3.4.3)		
3-56	Verify that YMPO approved drafts are reviewed for final signature and record by LLNL-YMP management and QA. (Para. 3.3.4.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-57	Verify that subcontractors follow procedure for submittal of technical documents/data. (Para.3.3.6)		
3-58	Verify that original drafts, forms, comment resolution documents, transmittals, and YMPO approval letters are retained as QA records. Also: Final version of document/data Documentation of disputed comments		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	SCIENTIFIC NOTEBOOKS, 033-YMP-QP3.4, REVISION 3		
3-59	Verify that the LRC maintains a record of the Scientific Notebook custodian, the unique identifier, and the notebook's date of issue. (Para. 3.4.5.1)		
3-60	Verify that the investigator makes the following initial entries: Title, number and version of plan, TIP, or description of subject area to the extent known. List of personnel using notebook date and signature of investigator and Task Leader (TL) (Para 3.4.5.2.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-61	Verify that Scientific Notebook entries include the following: Be recorded in Table of Contents Be in ink that is legible Have loose materials securely fastened LRC has signed statement identifying markouts as being during process Include references to LRC Records Include investigators signature/initials and date for each entry (Para. 3.4.5.2.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-62	Verify that final Scientific Notebook entries include the following: Signature of notebook custodian Signature of Task leader, when appropriate Signature of Independent Technical Reviewer (Para. 3.4.5.2.3)		
3-63	Verify that the LRC maintains a log of notebook references including any interim storage location. (Para. 3.4.5.2.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3-64	Verify that the Scientific notebook is reviewed by the TL annually, at the completion of the notebook and at completion of activity by signing and dating the review. (Para. 3.4.5.3.1)		
3-65	Verify that the Scientific Notebook is reviewed by an Independent Technical reviewer who is selected by the TL. The reviewer signs and dates the entry. (Para. 3.4.5.3.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-66	Determine, if independent technical reviewer is the direct supervisor, that the rationale for using supervisor is documented and approved. (Para 3.4.5.3.3)		
3-67	Verify that all interim technical reviews are documented, signed, and dated. (Para 3.4.5.3.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-68	Verify that the Scientific Notebook or copy is submitted to the LRC annually, or when notebook is full. (Note: Third generation photo copies are not acceptable). (Para. 3.4.6)		
3-69	Verify that the custodian submits notebook to LRC as QA Record when it is complete or no longer needed. (Para. 3.4.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-70	Verify that Scientific notebook decontrolled by the LRC or the custodian is logged; supervisor annotates, technical value, signs, and dates entry; and supervisor's entry is retained as a QA Record. (Para. 3.4.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	CONTROL OF INTERNAL TECHNICAL INTERFACES, 033-YMP-QP3.5, REVISION 1		
3-71	Verify that technical/scientific information/response to request are transferred on a Technical Information Transmittal Form (TITF). (Para. 3.5.5.1)		
3-72	Verify that Document Control assigns a unique identifier and maintains a TITF status log (Para. 3.5.5.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3-73	Verify that the originating organization Task Area Leader (TAL) and the affected organization TAL approve the TITF. (Paras. 3.5.5.6 and 3.5.5.7)		
3-74	Verify that Document Control assigns interface number, maintains distribution lists and distributes information provided on the TITF. (Para. 3.5.5.10, 3.5.5.11, and 3.5.5.12)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	• RESULTS
3-75	Verify that TITF with attached input are retained as QA Records. [note: lifetime or nonpermanent] (Para. 3.5.7)		
3-76	Verify that changes are approved and transmitted in the same manner as the original TITF/information. (Para. 3.5.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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 the Requester has completed the Purchase Requisition (PR) and assured that the Technical Requirements include or reference, as appropriate, specific: 1. Drawings 2. Specifications 3. Codes 4. Standards 5. Regulations 6. Procedures 7. Instructions 8. Applicable tasks, inspections, or acceptance requirements to be used to monitor and evaluate the performance of the supplier. 9. Documentation to be submitted to the LLNL-YMP for information, review, or approval; document submittal schedules shall be identified.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4-2	Verify that the PR includes or references, as appropriate, the QA requirements addressed in Paragraph 4.0.5.1.C, 1 through 8.		
4-3	Verify that when a procurement is for a Technical Services 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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4-4	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. (Para. 4.0.5.1)		
4-5	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	033-YMP-QP-4.1, REVISION 3, PREPARATION OF QUALITY ASSURANCE REQUIREMENTS SPECIFICATIONS AND APPROVAL OF SUBCONTRACTOR QA PROGRAMS		
4-6	Verify that the QA Requirements Specification(s) have been reviewed and approved by the Technical Area Leader and the QA Manager. (Para. 4.1.5.2.2 and 3)		
4-7	Verify that as a prerequisite to approve the Subcontractor QA Program, a pre-qualification QA Surveillance of the subcontractor facility was performed. (Para. 4.1.5.3)		
4-8	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	QP-5.0, REVISION 3, CN 5.0-3-1, TECHNICAL IMPLEMENTING PROCEDURES		
5-1	Check sampled TIPs for any case where a TIP was performed by other than qualified personnel, verify that no QA requirements were implemented or required by the procedure, during procedure performance. (Section 5.0.2)		
5-2	Verify the following for each of the sampled TIPs: (Section 5.0.3) - Documentation that the TIP was prepared by a PI, TL, or written designee.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-2 Cont'	- Documented evidence of completion of training, or special training, required by the TIP for personnel performing the procedure, prior to actual procedure performance. - Documented evidence of verification of procedural required personnel qualification by the PI, TL, or written designee.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5-2 Cont'	- Documented evidence that the next level of Project Management above the individual(s) performing work to a TIP has checked that the data collected and/or analysis performed met the objectives of the TIP and led to a supportable conclusion. - Sampled TIPs were reviewed by Technical Area Leader against required review criteria including verification that the TIP(s) has met the objectives of the associated SIP(s) or project planning document(s). Also verify approval of TIP(s) by same individual.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-3	For sampled TIPs, verify entries that address training, special training, or qualification requirements are made for personnel performing the procedure. (Section 5.0.5) Verify that "Limits and Precautions" are addressed in TIPs that have prerequisites for TIP implementation.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-3 Cont'	Verify that details of provisions in sampled TIPs comply with applicable sections of the following QPs: - 033-YMP-QP 8.0 - 033-YMP-QP 9.0 - 033-YMP-QP 10.0 - 033-YMP-QP 11.0 - 033-YMP-QP 12.0 - 033-YMP-QP 13.0 - 033-YMP-QP 14.0 Verify identification of lifetime and non-permanent QA Records generated by sample TIPs.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-4	Verify that any procedural deviations made to TIPs during implementation were authorized and documented on a change notice (CN). (Section 5.0.6) Check TIPs for any deviations made due to conditions adverse to quality; verify corrective action taken.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-5	Verify sample TIPs were approved in accordance with Exhibit A of 033-YMP-QP 2.1. (Section 5.0.8.)		
5-6	Verify that the method of documenting work progress is identified in the TIPs sampled. (Section 5.0.9)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5-6 Cont'	Verify that when a Scientific Notebook (SN) is used during TIP implementation, that the following information is included, as applicable: - Date and name of individual making the entry. - Description of the activity attempted, including detailed step-by-step process followed. Verify that any modifications made to a TIP without review or approval: - Fell within allowable reasons in Section 5.0.9.2. - Generated a CN per QP 6.0, Section 6.0.5.6.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5-6 Cont'	For any sampled TIP where work could not be accomplished as described in the TIP, verify: - The work was stopped. - Work did not resume until the TIP was changed to reflect current work practices (per QP 6.0, Section 6.0.5.6). - The work stoppage and resumption was documented.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5-7	Verify the following QA Records have been retained for sampled TIPs: (Section 5.0.10) - Current and previously issued TIPs and CNs. - Returned draft review copies with major comments. - Disposition of comments.		

QUALITY ASSURANCE CHECKLIST (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 controlled distribution of sampled TIPs per this action. (Section 6.0.5.3)		
	Verify sampled TIPs distributed to, and used at, the work location.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6-1 Cont'	Verify that Document Control considers training requirements for sampled TIPs prior to establishing their effective date.		
	Verify that changes made to sampled TIPs are listed on the title pages and are current.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6-2	Verify document master lists are current and distributed to the recipients (check effectiveness of the "quarterly" distribution practice). (Section 6.0.5.4)		
6-3	Verify major changes to sampled TIPs were reviewed by the organizations affected. (Section 6.0.5.6) Verify major changes to sampled TIPs were reviewed and approved by the YMP Leader.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6-4	Verify a "Release Prior to Verification" form was completed for issuance of any document containing data or conclusions that were not verified. (Section 6.0.5.7) Verify that the "unverified" portion of the document was identified by the TL/Record Source, and that the document was stamped "unverified" by the LRC.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
6-5	Verify that a distribution list indicating all receipts have been returned and copies of any "Decontrol Notice of Controlled Document" forms are authenticated and transmitted to the LRC when completed. (Section 6.0.7) Verify that the release prior to verification forms and log, along with a stamped copy of the document, is retained in Records and a copy was transmitted to the YMSCO.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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 for quality-affecting procurement, a bid evaluation team established a written evaluation criteria that included, as appropriate, the following subjects: (Para. 7.0.5.1.3) a. Technical consideration b. QA requirements c. Supplier's personnel d. Supplier's production capabilities or research facilities e. Supplier's experience or past performance f. alternates g. Exceptions h. Other criteria as appropriate		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7-2	Verify that prior to the contract being awarded, the QA Manager resolves, or obtains commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation. (Para. 7.0.5.1.3)		
7-3	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7-4	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.		
7-5	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7-6	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		
7-7	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		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7-8	Verify that QA Records are identified as lifetime or nonpermanent QA Records in accordance with QARD requirements of Section 5.2.2.H.		
7-9	Verify that supplier nonconformances are controlled and processed following the requirements established by same paragraph. (Para. 7.0.5.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	033-YMP-QP 8.0, REVISION 2, IDENTIFICATION AND CONTROL OF ITEMS, SAMPLES, AND DATA		
8-1	Determine if any items require identification and control. (General)		
8-2	Determine how items are being identified and controlled. (Para. 8.0.4.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8-3	Verify that items are identified when they are received, fabricated, stored, worked on, or shipped. (Para. 8.0.4.1)		
8-4	Verify that items tested in accordance with ILPs are identified, controlled, and dispositioned. (Para. 8.0.4.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-5	Verify that records used for identification are traceable to actual item. (Para. 8.0.4.1.1)		
8-6	Verify that identification markings are clear and legible. (When items are subdivided, markings are transferred to each part.) (Para. 8.0.4.1.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8-7	Verify that measures are defined to require unambiguous identification (correct identification is verified and documented prior to release for use). (Para. 8.0.4.1.3)		
8-8	Verify that items are handled and stored to prevent damage to item identifier. (Para. 8.0.4.1.4)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8-9	Verify that records are kept on all damaged identifiers and traceability is maintained from all original identifiers through all replacements. (Para. 8.0.4.1.4)		
8-10	Verify that items having limited shelf life are identified and controlled. (Para. 8.0.4.1.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-11	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		
8-12	Verify that physical identification of samples is maintained or samples can be traced to appropriate documentation. (Para. 8.0.4.2.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-13	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)		
8-14	Verify that controls are developed/implemented to ensure collection methods produce the intended sample (meet technical objectives). (Para. 8.0.4.2.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-15	Verify that samples are maintained in a predetermined physical condition (long term storage receives appropriate treatment). (Para. 8.0.4.2.4)		
8-16	Verify that samples are transported in appropriate (what is?) containers to preclude damage. (Para. 8.0.4.2.5)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-17	Verify that measures are developed/implemented to maintain sample identification during storage. (Para. 8.0.4.2.6)		
8-18	Verify that a record is kept of all locations and environments of the sample identifiers replaced and traceability is maintained from original identifier through replacements. (Para. 8.0.4.2.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-19	Verify that methods have been established to preclude using samples beyond intended use or storage life. (Para. 8.0.4.2.7)		
8-20	Verify that samples that do not meet requirements are handled in accordance with QP 15.0, Nonconforming Items. Verify that disposition is identified as "use-as-is," "limited use," or "discard." (Para. 8.0.4.2.10)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8-21	Determine if 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 controls imposed - Verification prior to release for use		
8-22	Verify that the following records are retained as QA Records: (Lifetime or non-permanent) (Para. 8.0.5) - Records establishing items, sample, and data identification - Sample collection records		

QUALITY 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		
12-1	Review the latest issue of the M&TE Master Status List to identify the M&TE which are acceptable for use on YMP.		
12-2	Ensure that the calibration standards have a greater accuracy that the required accuracy of the M&TE being calibrated.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-3	Ensure that for a sample of items on the M&TE Master Status List, the collective uncertainty of the measurement standards used for calibration do not exceed 25% of the acceptable tolerance for each characteristic being calibrated. Justification for use if this uncertainty exceeds 25% must be provided by the Technical Area Leader.		
12-4	Ensure that the basis for calibration acceptance for each calibration performed is documented and authorized by the PI.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-5	Identify any M&TE classified for use on one-time-only applications. Ensure that the calibration is done before and after use.		
12-6	Compare the calibration intervals on the M&TE Master Status List to ensure that they are consistent with the frequency prescribed in the manufacturer's or designer's specifications, or to the Calibration Laboratory's standards.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-7	Ensure that when the accuracy of M&TE becomes suspect or is in error, the M&TE is considered out-of-calibration and a calibration is performed prior to its use.		
12-8	Ensure that calibrated M&TE is labeled/marked or documented to indicate due date or interval for the next calibration.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-9	Verify that M&TE are uniquely identified to provide traceability to its calibration data.		
12-10	Ensure the documentation of the use of M&TE identifies the process monitored, data collected, or items inspected or tested since the last calibration.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12-11	Identify the methods used to prevent use of out-of-calibration M&TE.		
12-12	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.		
12-13	Verify that the M&TE is properly handled and stored to maintain accuracy.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
12-14	Review the calibration documentation for M&TE to ensure that the following information is documented: - Identification of the M&TE calibrated - Traceability to the calibration standard used for calibration - Calibration data - Identification of the individual performing the documentation - Identification of the date of calibration and the recalibration due date or interval, as appropriate - Results of the calibration and statement of acceptability - Reference to 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		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-13.0, REVISION 1, CN.13.0-1-1, HANDLING, STORAGE, AND SHIPPING		
13-1	Verify that written instructions state how items, samples, and equipment are handled, stored, and shipped to prevent damaged, deterioration, or loss and are incorporated within Technical Implementing Procedures (TIPs), procurement documents, shipping documents, etc. which include verification of requirements. (Para. 13.0.4.1)		
13-2	Verify that special handling tools and equipment are controlled, inspected, and tested in accordance with documented procedures and at specified time intervals. (Para. 13.0.4.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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, NONCONFORMANCES		
15-1	Verify if Nonconformance Reports (NCRs) were initiated by LLNL personnel since the last audit, July 23, 1993.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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, CORRECTIVE ACTION		
16-1	Verify that Corrective Action 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)		
16-2	Verify that the QA Manager evaluates whether the identified adverse condition is "Significant to Quality" or "Not Significant." (Para. 16.0.5.1.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16-3	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)		
16-4	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)		
16-5	Verify that actual corrective action taken is documented on Items 15 and 16 of the CAR. (Para. 16.0.5.3.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
16-6	Verify that the QA Manager 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 an Memo explaining the requirements. (Para. 16.0.5.3.2)		
16-7	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)		
16-8	Verify that the QA Manager 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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
16-9	Verify that the Cognizant Supervisor 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)		
16-10	Verify that the QA Manager reviews proposed changes and signs the memo requesting the change, if approved. (Para. 16.0.5.5.2)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
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)		
16-12	Verify that completed CARs and supporting documentation are sent to the LRC as QA Records. (Para. 16.0.6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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		
16-13	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)		
16-14	Verify that, upon identification of a trend, the YMP QA manager made a determination to document the trend on a CAR or justification for not initiating a CAR, or the Trend Analysis Report (TAR). (Para. 16.2.4.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
16-15	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)		
16-16	Verify that the TAR is issued within two months of the end of the calendar year to the following personnel: a. YMP Leader b. Deputy/Associate/Assistant Project Leader c. Technical Area Leader d. Task Leaders e. Project Administrator (Para. 16.2.4.2)		
16-17	Verify that TARs are submitted as QA Records to the LRC in accordance with QP-17.0.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16-20	Verify that if the corrective action cannot be completed by the specified due date, the QA Manager is notified and a revised completion date is coordinated with the originating organization .		
16-21	Verify that the QA Action Item List lists the status of CARs, NCRs, YMPO CARs and delinquent receipt acknowedgments.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
	033-YMP-QP-17.0, REVISION 5, CN.17.0-5.2, QUALITY ASSURANCE RECORDS		
17-1	Verify that QPs and TIPs have "QA Records" section which lists the QA Records. (Para. 17.0.5.2)		
17-2	Verify that the Record Source: (Para. 17.0.5.2) a. Collects and transmits to the LRC records generated when the activity is completed. b. Transmits the records to the LRC not later than 10 working days after the records are completed. c. Verifies that each record is legible, identifiable with the activity if related to, accurate, complete, reproducible and that it is appropriate to the work accomplished. d. Transmits records to the LRC using Records Transmittal form (Exhibit A). e. Transmits record packages to the LRC using Record Package form, table of contents (Exhibit B).		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
17-3	Verify that records transmittals are inspected by the LRC to assure that they are legible, identifiable, complete, suitable for microfilming, and are authenticated per the signature authentication list maintained by the training coordinator. (Para. 17.0.5.3)		
17-4	Verify that corrections to completed records are made by the Record Source in accordance with Paragraph 17.0.5.3.1.		
17-5	Verify that a log of rejected record transmittals is maintained by the LRC. (Para. 17.0.5.3.1)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS *Record objective evidence reviewed, method of verification, personnel contacted*	RESULTS
17-6	Verify that records accepted by the LRC are logged using a computer based document logging system in accordance with Paragraph 17.0.5.3.2.		
17-7	Verify that revision of a previously accepted record or package is identified by referencing the original record or package. The record is identified as a revision, a supplement to a previous record, or as superseding the previous record, and is authenticated by the original record source or by someone with equivalent technical or administrative knowledge and authority. (Para. 17.0.5.3.3)		
17-8	Verify if records have been determined lost or damaged. How were they documented? (Para. 17.0.5.3.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
17-9	Verify that the LRC transmits records to the CRF using the LRC record transmittal form (Exhibit C) approximately once a week, or every two weeks depending on volume of records, but no later than 30 working days after the records are received and accepted. One-of-a-kind records are submitted to the CRF no later than 10 working days after the records are received and accepted by the LRC.		
17-10	Verify that the Task Leader/Record Source assures that from the time of generation/validation of a record until it is delivered to the LRC, the record is protected from damage, deterioration and loss. (Para. 17.0.5.6a)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
17-11	Verify that LRC stores records in a one-hour fire-resistant container until processing is completed. I(Para. 17.0.5.6b)		
17-12	Verify that records are stored in appropriate containers in a manner to prevent damage from moisture, temperature and pressure. Specially processed and one-of-a-kind records are stored in a manner to also prevent damage from excessive light, stacking, electromagnetic fields, temperature and humidity. (Para. 17.0.5.6c)		
17-13	Verify that LRC maintains a list of personnel who have access to the files.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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 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)		
18-2	Verify that subcontractors are audited on at least a triennial basis when supplemented by annual evaluations. (Para. 18.0.5.1.3)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
18-3	Verify that audits are performed by personnel qualified IAW, procedure 033-YMP-QP-18.2, may include technical specialists who are independent of any direct technical responsibility for the organization to be audited. (Para. 18.0.5.2)		
18-4	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.		
18-5	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
18-6	Verify that audit reports are signed by the Lead Auditor and issued no later than 30 calendar days after the closing meeting. The audit report contains the requirements listed in Paragraph 18.0.5.6.		
18-7	Verify that audited organizations respond to adverse audit findings within 30 calendar days of receipt of the audit report or CAR. (Para. 18.0.5.6)		
18-8	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		

QUALITY ASSURANCE CHECKLIST (continuation 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,		
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.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

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 Based on a sample of QA audit personnel, verify implementation and effectiveness of the following LLNL procedural requirements.		
18-13	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. b. On-the-job training and guidance under the direct supervision of a Lead Auditor.		
18-14	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
18-15	The QA Manager maintains a file for each auditor to document training and audit participation. (Para. 18.2.4.1)		
18-16	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
18-17	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		
18-18	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)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
18-19	The YMP QA 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)		
18-20	Lead Auditors who fail to maintain their proficiency for a period of two years or more must requalify. (Para. 18.2.4.4)		
18-21	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.		

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

AUDIT/SURVEILLANCE
NO YMP-94-10-02

QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED	[x] EXTERNAL	[x] AUDIT	
LLNL	[ ] INTERNAL	[ ] SURVEILLANCE	PREPARED BY Thomas E. Rodgers DATE
DATES OF EVALUATION			
CONTROLLING DOCUMENT (Title, Number, Revision)			ACTIVITY EVALUATED

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	WBS 1.2.2.3.1.2 - GLASS TESTING		
1	How long has glass testing been ongoing at Argonne?		
2	What data have been collected during that time?		
3	Have any models been developed to describe the data? If so, describe them.		

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

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4	If models have been developed, what sort of records have been kept of the process for developing the models? Examine records of model development.		
5	If models have not been developed, what plans have been made for developing them?		
6	Which procedures control the development of models? What records will be kept of model development?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	How will glass testing contribute to design and performance assessment?		
8	The effects of iron, copper, and lead on glass degradation have recently been publicized. What plans are there to study the effects of other elements? Have any predictions been made?		
9	In experimental work to date, which activities have been quality-affecting and which have not?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	What glass compositions are under test?		
11	How much variability is expected in glass composition?		
12	How much variation in dissolution behavior is seen as a result of composition variations?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
13	If variability is significant, how will the behavior of other glasses be predicted?		
14	Describe how EQ3/6 models the kinetics of dissolution. (SIP-WF-02, p. 17)		
15	Has validation of EQ3/6 been started? If not, when is it planned? If so, examine procedures for and records of validation.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
16	SIP-WF-02 (pp. 17-18) indicates that validation of EQ3/6 will not be controlled by a procedure. Please describe methods for controlling and documenting this work.		
17	How do test conditions represent conditions expected at Yucca Mountain?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
18	Has screening of data for incorporation into the release model begun? If so, what procedures or controls are used in the screening process?		
19	AP D-20-27, Page 4 states that the unsaturated tests are not intended to represent a miniature waste package. What are they intended to represent?		
20	Are glass samples actually to be retained in the records system? (AP D-20-27, Page 6)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	WBS 1.2.2.3.1.1 - FLOW-THROUGH DISSOLUTION TESTING		
21	What procedures are available to control peer review? (See p. 18 of SIP-WF-01)		
22	Tests are to determine the effects of water chemistry, fission gas release, burnup, grain size, temperature, level of oxidation, and other fuel characteristics. Describe the strategy for addressing each of these. (SIP-WF-01, p. 22)		
23	What pretest and posttest examinations of materials are performed? (SIP-WF-01, p. 23)		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
24	Results published to date on dissolution of UO2 include the effects of pH, carbonate concentration, oxygen activity, and temperature. Describe efforts planned on the effects of particle size and flow rate.		
25	Describe results obtained to date on dissolution of spent fuel.		
26	Describe efforts planned to determine the effects of pH, carbonate concentration, oxygen activity, temperature, particle size, and flow rate of spent fuel dissolution.		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
27	How will additional experiments be used to verify models for UO2 and spent fuel dissolution?		
28	Is determination of uranium concentration in solution now governed by a procedure?		
29	What documentation of gas composition is provided by the supplier?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
30	Have the tests to date suggested any additional directions for future studies?		
31	Examine UO2 dissolution apparatus and provisions for record-keeping.		
32	Dissolution rates for UO2 appear to have substantial scatter. How much of this is due to variability of the material and how much is due to experimental methods?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
33	Has work on spent fuel dissolution been interrupted by hot cell maintenance at PNL? If so, what plans have been made for resumption of work?		
34	What is the origin of the UO2 used in dissolution work? Have efforts been made to ~~assure that~~ determine whether other sources of UO2 will have similar dissolution behavior?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
35	Are additional approved test materials being obtained for the spent fuel effort?		
36	To what extent were experiments at PNL controlled by procedures?		
37	Are additional technical meetings between PNL and LLNL planned for this activity? When was the last meeting and when will the next be?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
38	How will flow through dissolution testing contribute to design and performance assessment?		
39	How do test conditions represent conditions expected at Yucca Mountain?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	WBS 1.2.2.3.1.1 - DRY BATH OXIDATION		
40	What pretest and posttest examinations of materials are performed?		
41	How will additional experiments be used to verify models for UO2 and spent fuel oxidation?		
42	What materials have been chosen for oxidation, and how do they represent the spent fuel to be disposed of?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
43	Can the data obtained to date be used to predict whether a given time-temperature history will result in significant oxidation of fuel? If not, what additional experiments are necessary?		
44	What evidence is available to support or refute the two-step oxidation mechanism? (AP D-20-45, p. 2)		
45	Have the test to date suggested any additional directions for future studies?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
46	Has work on ~~spent fuel dissolution~~ dry bath oxidation been interrupted by hot cell maintenance at PNL? If so, what plans have been made for resumption of work?		
47	How will dry bath oxidation test contribute to design and performance assessment?		
48	How does oxidation behavior depend on fuel type (BWR or PWR), fission gas release, or burnup?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
49	Have any of the oxidized samples been used in dissolution tests?		
50	Are there any plans to oxidize fuels at lower oxygen pressures?		

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
51	What information has been relayed to the modeling effort and how is it being used?		
52	How much scatter is seen from one sample to another of nominally identical material? How closely might you expect to predict behavior with the final model of oxidation?		
53	How do test conditions represent conditions expected at Yucca Mountain ?		