

Kennedy, J.

ATTACHED PLEASE FIND THE REVISED QA PROGRAM
CHECKLIST FOR YMP AUDIT 89-6 OF LLNL. PLEASE
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YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 2 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
1-1 (cont.)		2. Verify that the QA Manager assures that independent verification of quality attainment, QA program implementation and its continued effectiveness is accomplished.			
		3. Verify that the YMP Leader defines procedures and requirements necessary to assure achievement of quality objectives.			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 8 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
2-4	NNWSI/88-9, Rev. 2, Sec. II, Para. 1.7	<p>A QAPP that complies with the requirements of this document, NNWSI/88-9, shall be established by each NNWSI Participant at the earliest practicable time consistent with the schedule for accomplishing the activities. Each QAPP shall assure that procedures required to implement the requirements of this document are properly documented, controlled, and mandated through a policy statement or equivalent document signed by a responsible official. The QAPP shall be applied throughout the life of the NNWSI Project in accordance with the established policies, procedures and instructions. The QAPP shall apply to all items and activities affecting quality. It also shall identify the major organizations participating in the project and the designated functions of these organizations. The QAPP shall provide control over activities that affect quality of the identified structures, systems, and components to an extent consistent with their importance. The activities that affect quality shall be accomplished suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity and assurance that prerequisites for the given activity have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality and the need for verification of quality by inspection, test, peer review, or a combination of these. The program shall provide for indoctrination and, as necessary, training of personnel performing activities that affect quality to assure that suitable proficiency is achieved and maintained.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 9 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
2-4 (cont.)	033-YMP-QP 2.0, Rev. 0, Para. 1.7	<p>The YMPO shall regularly assess the status and adequacy of the QA programs of the Participating Organizations and NTS Support Contractors by means of overview, surveillance, and audit activities.</p> <ol style="list-style-type: none"> 1. Verify that the YMP QAPP complies with the requirements of the DOE Project Office QAP and that the procedures required to implement the requirements are properly documented, controlled, and mandated through a policy statement. 2. Verify that the QAPP applies to and provides control over all items affecting quality. 3. Verify that the established YMP QA program consists of a three tiered system, i.e. (1) Quality Assurance Program Plan (QAPP) requirements generally applicable to the work performed for the DOE Project Office, (2) Quality Procedures (QPs) and/or Administrative Procedures (APs) formulated to meet QAPP requirements, and (3) Scientific Investigation Plans (SIPs) work plans and Technical Implementing Procedures (TIPs) generic or specific technical procedures used to plan or direct specific work activities, for the control and documentation of work done for various sponsors. 4. Verify that requirements and procedures are reviewed and approved as described in Procedure 033-YMP-QP 2.1 "Preparation, Approval and Revision of Quality Procedures and Requirements." 			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 17 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
3-3	YMP-88-9, Rev. 2, Sec. III, Para. 1.4.1, & 1.4.2 LLNL-033-YMP- QP 3.0, Rev. 0, Para. 3.0.13	<p>Interpretation/analysis shall be performed in a planned, controlled, and documented manner. Interpretation/analysis shall be performed and documented in sufficient detail as to purpose, method, assumptions, input, references, and units such that a technically qualified person may review, understand, and verify the analysis without recourse to the originator. These documents shall be legible and in a form suitable for reproduction, filing, and retrieval. Calculations shall be identifiable by subject, originator, reviewer, and date.</p> <p>DOCUMENTATION OF INTERPRETATION/ANALYSIS</p> <p>Documentation of interpretation/analysis shall include the following:</p> <ul style="list-style-type: none"> a. Definition of the objective of the interpretation/analysis. b. Definition of input and their sources. c. A listing of applicable references. d. Results of literature searches or other background data. e. Identification of assumptions. f. Identification of any computer calculation, including computer type, program name, revision, input output, evidence of program verification, and the bases of application to the specific problem. g. Signatures and dates of review and approval by appropriate personnel. 			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 19 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
3-4	YMP-88-9, Rev. 2, Sec. III, Para. 1.6.2	a. Detailed technical implementing procedures together with appropriate logbooks and other supporting documents, shall be used whenever the work is repetitive.			
	LLNL-033-YMP- QP 3.0, Rev. 0, Para. 3.0.5	b. Requirements and acceptance or rejections criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the scientific investigation, unless otherwise designated.			
	LLNL-033-YMP, QP 5.0, Rev. 0, Para. 5.0.5.11, 5.0.5.6, and 5.0.5.4	c. Prerequisites such as calibrated instrumentation, adequate appropriate equipment and instrumentation, suitable and controlled environmental conditions, and provisions for data collection and storage. For activities of long duration, specific provisions shall be established and documented for instrumentation whose calibration interval is shorter than the expected duration of the activity. Such provisions are to be designed to ensure validity of data throughout the scientific investigation.			
	d. Special training or qualification requirements for personnel performing the scientific investigation.				
	1. Verify that TIP are used.				
	2. Verify that requirements for acceptance or rejection criteria and prerequisites as above are being implemented.				
	3. Verify training of personnel performing scientific investigation.				
(9) Auditor Signature				(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 20 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
3-5	YMP-88-9, Rev. 2, Sec. III, Para. 1.6.4.1	<p>Where appropriate, and prior to initiation of the experiment or research, the following entries, as a minimum, shall be made.</p> <ul style="list-style-type: none"> a. Title of the experiment or research. b. Name of the qualified individual or individuals performing the experiment or research. c. Description of the experiment's objective and the the proposed approach or procedure for achieving these objectives. This may be accomplished by reference to the appropriate study plan or other scientific investigation planning document which controls the work. d. Equipment and materials to be employed during the experiment or research, including any necessary design or fabrication of experimental equipment and any need characterization of starting material. e. Calibration requirements. f. Dated signature of the individual or individuals making the initial entries. g. Special training or qualification requirements. h. Documentation of suitable and controlled environmental conditions, if applicable. i. Required levels of precision and accuracy shall be identified. j. The potential sources of uncertainty and error in scientific investigations which must be control- 			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 26 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
3-10	YMP-88-9, Rev. 2, Sec. III, Para. 1.10.1 LLNL-033-YMP- QP 18.1, Rev. 0, Para. 18.1.5.1	<p>The QA organization within the Participating Organization shall perform surveillances of all scientific investigations, as may be deemed appropriate for the purposes and the complexity of the work. The QA surveillance team for a scientific investigation shall consist of one or more qualified technical individuals and one or more QA personnel. The timing and the number of surveillances shall be determined by the QA surveillance team that is formed for this work.</p> <ol style="list-style-type: none"> 1. Verify that surveillances are scientific investigations are performed as described above. 2. Verify QA surveillance team is made of qualified personnel as described above. 			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 29 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
3-13	YMP-88-9, Rev. 2, Sec. III, Para. 2.2.1	Applicable design input, such as site characterization data, criteria letters, design bases, performance and regulatory requirements, codes, standards, manufacturer's design data, and quality standards, shall be identified, documented, and their selection reviewed and approved by the responsible design organization and the responsible QA organization. The purpose of the QA review is to assure that the documents are prepared, reviewed, and approved in accordance with documented procedures and quality assurance requirements.			
3-13	LLNL-033-YMP- QP 3.1, Rev. 0, Para. 3.1.5.2	1. Verify that design input has been approved by design organization and QA organization.			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 34 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
3-18	NNWSI/YMP-88-9, Para. 3.1.1	<p>Each organization participating in the NNWSI project shall prepare a description of their software design, test and configuration management system, and submit it to the next higher program organizational level for review and approval. The description shall:</p> <ul style="list-style-type: none"> o Provide criteria for application of the requirements of this section based on the complexity and importance of the software used to perform analysis in support of the design of a geologic repository. o Indicate the methods to be used to develop computer program requirements, to translate those requirements into a detailed design, and to implement that design in executable code. o Relate the types of documentation to be prepared, reviewed, and maintained during software design, code implementation, test, and use. o Identify the methodology for establishing software baselines and baseline updates (changes) and for tracking changes throughout the life of the software. o Specify the process to be used for verification and validation of software developed or applied to geologic repository design analysis. o Identify the procedure for reporting and documenting software discrepancies, including sources, evaluating impacts of discrepancies on previous calculations, and determining appropriate corrective action. 			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 38 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(8) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(6) PERSON CONTACTED
3-21	NNWSI-88-9, Para. 3.1.7 LLNL-033-YMP-R-3, Para. 3.1.7	Verification and validation procedures shall assure that the software adequately and correctly performs all intended functions and that the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system. 1. Verify that procedures are available.			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 45 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
4-1	YMP-88-9, Rev. 2, Sec. IV, Para. 2.1	<p>Procurement issued at all tiers of procurement shall include provisions for the items listed below, as deemed necessary by the purchaser:</p> <p>2.1.1 SCOPE OF WORK</p> <p>A statement of the scope of the work to be performed by the supplier shall be in the procurement documents.</p> <p>2.1.2 TECHNICAL REQUIREMENTS</p> <p>Technical requirements shall be specified in the procurement documents. Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto that describe the items or services to be furnished. The procurement documents shall provide for identification of test, inspection, and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance.</p> <p>2.1.3 QA REQUIREMENTS</p> <p>2.1.3.1 Procurement documents shall require that the supplier have a documented QA program that implements either portions or all of the requirements of this document. Quality Assurance Program Plans (QAPPs) and documents of subcontractors for Quality Assurance Level I purchases shall be reviewed and approved by the procuring Project participant. Those which do not adequately define QA requirements, as judged by the QA representative of the Project participant, shall be corrected prior to initiation of activities specified by the purchase order or contract. The extent of the program required shall</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 46 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
4-1 (cont.)	YMP/88-9, Rev. 2, Sec. IV, Para. 2.1	<p>Depend upon the type and use of the item or service being procured. The procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.</p> <p>2.1.3.2 In developing QA requirements for test and other equipment, consideration should be given to whether proper performance of that equipment can be determined during or after its use (i.e., whether failure or malfunction of the equipment can be detected.)</p> <p>2.1.4 RIGHTS OF ACCESS</p> <p>At each tier of procurement, the procurement documents shall provide for access to the suppliers' facilities and records for inspection or audit by the purchaser, appropriate WMPO personnel, or other WMPO authorized representatives. WMPO access to subtier contractor facilities shall be arranged by the contracting organization.</p> <p>2.1.5 DOCUMENTATION REQUIREMENTS</p> <p>The procurement documents at all tiers shall identify the documentation required to be submitted to the purchaser. The time of submittal shall also be established. If the purchaser requires the supplier to maintain specific QA records, then the retention times and disposition requirements shall be specified in accordance with Section XVII of this QA Plan.</p> <p>2.1.6 NONCONFORMANCE</p> <p>The procurement documents shall prescribe the purchaser's requirements for reporting and approving disposition of nonconformances.</p>			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 47 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
		<p>2.1.7 SPARE AND REPLACEMENT PARTS</p> <p>The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies and the appropriate delineation of the technical and quality related data that are required for ordering these parts or assemblies. The technical and quality requirements shall be equal to or better than the original. If QA or technical requirements of the original item cannot be determined, then an engineering evaluation shall be conducted by qualified individuals to establish the requirements. The evaluation shall consider the interchangeability, function, and safety of the item. The evaluation shall be documented.</p> <p>Review procurement documents and verify that if the procurement supports a QA Level I or II activity, the requester identifies the QA Level on the procurement document and attaches a Procurement Document Review Form (Exhibit E). The following specifications are included in the procurement package:</p> <p>A. Scope of Work - The scope of work defines the work to be accomplished and includes a statement and schedule of deliverables and their documentation.</p> <p>B. Technical Requirements - the technical requirements include specifications, standards, codes, and procedures that are to be followed. In-process reviews and acceptance tests necessary to evaluate conformance of an item or service to the technical requirements are specified.</p> <p>C. Subcontractor Quality Assurance Requirements - Subcontractors are to provide or follow a quality assurance program consistent with pertinent provisions of the YMP QAPP. The quality assurance program re-</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 52 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
4-2 (cont.)	033-YMP-QP 4.0, Par. 4.0.5.4	<p>Verify that the Resource Planning and Control Manager reviews the Procurement Document Review Form to verify that all appropriate information has been entered by the Task Leader. Questions concerning this information are resolved with the Task Leader. The Resource Manager completes and signs the Procurement Document Review Form.</p>			
		<p>If the procurement action is for technical services pertaining to a scientific investigation, then the document package is forwarded to the YMP Project Leader for review and approval. Approval is indicated by signature on the Procurement Document Review Form. The document package is then returned to the Resource Manager.</p>			
		<p>(Note: Verify that resolutions to questions concerning the Procurement Documents are documented and signed.)</p>			
	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.5	<p>Verify that the QA Manager reviews all procurement document packages to assure each is identified with the appropriate activity and the attendant Level of Quality Assurance or exempt status.</p>			
		<p>Verify that the QA Manager assures that the required information prescribed by this procedure is contained in the procurement package, including:</p>			
		<p>a. For QA Level I and II procurements, provisions for reviewing and approving QA Program Plans of subcontractors are provided.</p>			
		<p>b. For commercial grade procurements, provisions for verifying technical characteristics of items are provided.</p>			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 53 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
4-2 (cont.)	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.5	<p>Verify that when the document package satisfies the requirements of this procedure, the QA Manager signs the Procurement Document Review Form. For QA Level I and II, and commercial grade procurement, the QA Manager stamps the procurement document with a request that the Procurement Department return copies of the contract award documents to YMP Quality Assurance. SANLs are stamped with a message that the Special Materials Office is to return copies of processed SANLs to the Resource Manager.</p> <p>Verify that for QA Level III and Exempt procurements, the QA Manager verifies that the assigned status is consistent with the activity for which procurement is being conducted. If it is not, the responsible Task Leader is notified and the issue is resolved.</p> <p>(Note: Verify that resolutions to questions concerning the procurement documents are documented and signed.)</p> <p>Verify that for QA Level I and II procurements, and commercial grade procurements, the QA Manager creates and maintains a separate folder (the procurement action folder) for each procurement action. The QA Manager makes a copy of the procurement document package and places it in the appropriate folder.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 55 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
4-4	YMP/88-9, Rev. 2, Sec. 4.0, Para. 2.4 033-YM)-QP 4.0, Rev. 0, Para. 4.0.5.5 033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.6	<p>Participating Organizations and NTS Support Contractors shall forward to the SAIC/T&MSS Project QA Department (QA Verification Division Manager), a copy of purchase documents, and changes thereto, as issued, when purchases involve Quality Assurance Level I items or services. Only those purchase documents which identify the vendor, describe the scope of work, and detail when work is to start are required to be submitted to the SAIC/T&MSS Project QA Department.</p> <p>Verify that the QA Manager retains the original Procurement Document Review Form in the appropriate folder. When purchases involve Quality Quality Assurance Level I and II items and services, a copy of procurement documents identifying the vendor, the scope of work, and when work is to start is sent to the DOE Project Office QA Manager and the T&MSS Project QA Department.</p> <p>Verify that the DOE Project Office QA Manager is sent copies of changes to QA Level I procurement documents relating to vendor identification, work scope, or work start schedule.</p> <p>(Note: Are changes to procurement documents also sent to the T&MSS project QA Department?)</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 68 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-1 (cont.)		<p>1.2.3 MEASURES FOR EVALUATION AND SELECTION OF PROCUREMENT SOURCES</p> <p>Measures for evaluation and selection of the results thereof, shall be documented and shall include one or more of the following items:</p> <ul style="list-style-type: none"> o Evaluation of the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability. o Supplier's current quality assurance records supported by documented qualitative and quantitative information that can be objectively evaluated. o Supplier's technical and quality capability as determined by a direct evaluation of their facilities and personnel and the implementation of his QA program. 			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 69 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-1 (cont.)	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.8	<p>Verify that the determination of the supplier's capabilities is conducted and documented prior to the award. The determination of the supplier's capabilities is made by qualified personnel (as determined and verified by the technical representative) based on one or more of the following:</p> <ul style="list-style-type: none"> a. Evaluating the supplier's history of providing an identical or similar product that performs satisfactorily in actual use. Current capability of the supplier is evaluated; b. Conducting a pre-award survey of the supplier's technical and quality capabilities; and c. Evaluating the supplier's current quality assurance records supported by documented qualitative and quantitative information that can be objectively evaluated. <p>Verify that the method of determining the supplier's capabilities is documented by the requestor (or technical representative) and the Procurement Department Contract Administrator. The documentation is provided to Quality Assurance for inclusion in the procurement action folder.</p> <p>Verify that a qualified supplier's list is maintained by the YMP Program. Each evaluation of a supplier is documented and maintained in a file accessible by appropriate index identities.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 72 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-4	YMP/88-9, Rev. 2, Sec. VII, Para. 1.4.1	<p>The purchaser of items and services shall establish measures to interface with the supplier. The measures shall include the following:</p> <ul style="list-style-type: none"> o Documentation of the understanding between purchaser and supplier of the provisions and specifications of the procurement documents. o Requiring the supplier to identify planning techniques and processes to be utilized in fulfilling procurement document requirements. o Reviewing supplier documents that are generated or processed during activities fulfilling procurement document requirements. o Identifying and processing necessary change information. Measures to control changes in procurement documents shall be established, implemented and documented in accordance with the requirements of this QA plan. o Establishing methods of document information exchange between purchaser and supplier. 			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 75 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-5	YMP-88-9, Rev. 2, Sec. VII, Para. 1.4.2.1	<p>The purchaser of items and services shall establish measures to verify supplier's performance, as deemed necessary by the purchaser. The measures shall establish the extent of source surveillance and inspection activities.</p> <p>Note: When a Participating Organization, or Nevada Test Site (NTS) Support Contractor, utilizes another Participating Organization or NTS Support Contractor for NNWSI activities for which they are responsible, the user organization shall initiate a request to WMPO to conduct a WMPO surveillance of the organization performing the work. The surveillance shall be conducted to determine that the item or activity is being produced or performed in accordance with the user organization's requirements. These surveillances may utilize NTS Support Contractor or Participating Organization personnel as technical advisors.</p> <p>The extent of verification activities, including planning, shall be a function of the relative importance, complexity, and quantity of the item or services procured and the supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the suppliers' activities. These verification activities shall be conducted as early as practicable. However, the purchaser's verification activities shall not relieve the supplier of their responsibilities for verification of quality achievement.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 76 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-5 (cont.)	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.9	Verify that as specified in the procurement document package, the technical representative and the QA Manager conduct in-process evaluations of the supplier's performance.			
	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.9	(Note: Examples of methods that can be used include: (a) Requiring the supplier to identify planning techniques to fulfill the procurement objective; (b) Reviewing supplier documents that were created to fulfill the procurement objective; (c) Establishing the extent of in-process source surveillance and inspections; and (d) conducting audits.)			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL (2) Page 77 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-6	YMP-88-9, Rev. 2, Sec. VII, Para. 1.4.2.2	Activities performed to verify conformance to requirements of procurement documents shall be recorded.			
	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.9	Verify that the technical representative and the QA Manager prepare documentation of the in-process monitoring activities.			
	Verify that the technical representative sends a copy of this documentation to Quality Assurance for inclusion in the procurement action folder.				
	(9) Auditor Signature			(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 78 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-7	YMP-88-9, Rev. 2, Sec. VII, Para. 1.6.1.1	<p>When a certificate of conformance is used, the following minimum criteria shall be met:</p> <ul style="list-style-type: none"> o The certificate shall identify the purchased material or equipment, such as by the purchase order number. o The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, or other specifications. This may be accomplished by including a list of the specific requirements or by providing at the point of receipt, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment. o The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means by which to resolve the nonconformances. o The certificate shall be attested to by a person who is responsible for this QA function and whose function and whose function and position are described in the purchaser's or supplier's QA program. o The certificate system, including the procedures to be followed in filling out a certificate and the administrative procedures for the review and approval of the certificates, shall be described in the purchaser's or supplier's QA program. 			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 83 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-9 (cont.)	033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.11A(C) 033-YMP-QP 4.0, Rev. 0, Para. 4.0.5.11A(C)	<p>Verify that a receiving inspection ("end item") is performed at the destination (i.e., location of receipt) to evaluate an item for shipping damage, loss of parts, or any other problem that might affect the item's performance.</p> <p>Verify that a receiving inspection is performed by qualified personnel whose qualifications are determined and verified by the technical representative.</p> <p>Verify that receiving inspections are performed using written procedures that specify the requirements and criteria for acceptance of an item.</p> <p>Verify that all receiving inspections are documented by the technical representative.</p>			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 86 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
7-12	YMP-88-9, Rev. 2, Sec. VII,	<p>1.8 CONTROL OF SUPPLIER NONCONFORMANCES</p> <p>1.8.1 METHODS</p> <p>The purchaser and supplier shall establish and document methods for disposition of items and services that do not meet procurement requirements. These methods shall include the following provisions:</p> <p>1.8.1.1 EVALUATION</p> <p>Provisions for evaluation of non-conforming items.</p> <p>1.8.1.2 SUBMITTAL</p> <p>Provisions for submittal of nonconformance notice to purchaser by supplier as directed by the purchaser. These submittals shall include supplier recommended disposition (e.g., us-as-is or repair) and technical justification. Nonconformances to the procurement requirements or purchaser approved documents, which consist of one or more of the items listed below shall be submitted to the purchaser. Approval of the recommended disposition shall be in accordance with documented procedures.</p> <p>o Technical or material requirement is violated.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 92 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
8-1	NNWSI/88-9, Rev. 2, Sec. VIII, Part A, Para. 1.1 033-YMP-QP 8.0, Para. 8.0.4.1 (033-YMP-QP 3.0) (033-YMP-QP 5.0)	Items of production shall be identified from the initial receipt and fabrication of the items up to and including installation and use. Physical identification shall be used to the maximum extent possible. 1. Verify Technical Implementing Procedures (TIP) or Study Plans have identified specific identification and control measures for materials, parts, and components. Note: 033-YMP-QP 8.0 provides for physical identification "where practical" (Para. 8.0.4.1.1) instead of "to the maximum extent possible" required by NNWSI/88-9, Sec. VIII, Part A, Para. 1.1.1. Note: 033-YMP-QP 8.0, Para. 8.0.4.1.4 provides for documentation of damaged or deteriorated identifiers. Identify whether or not such discrepancies are processed as nonconformances per 033-YMP-QP 15.0. (See also QP 8-3).			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 94 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
8-3	NNWSI/88-9, Rev. 2, Sec. VIII, Part B, Para. 1.1 033-YMP-QP 8.0, Para. 8.0.4.2 .(033-YMP-QP 3.0) (033-YMP-QP 5.0)	<p>Samples shall be identified by placing the identification directly on the sample, on their (sic) container, or on records traceable thereto...methods shall be described and implemented to assure that samples are not mixed with like samples, and that correct identification of samples is verified and documented prior to release for use.</p> <p>Verify Technical Implementing Procedures (TIP) or Study Plans have identified specific identification and control measures for samples.</p> <p>Note: 033-YMP-QP 8.0 merely reiterates the requirements of NNWSI/88-9, but provides no specific measures for consistent sample identifiers, methods of marking, or documentation of verifications prior to release of samples.</p> <p>Note: 033-YMP-QP 8.0, Para. 8.04.2.6 provides for documentation of damaged or deteriorated identifiers. Identify whether or not such discrepancies are processed as nonconformances per 033-YMP-QP 15.0. (See also QP 8-1).</p>			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 96 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
8-4	NNWSI/88-9, Rev. 2, Sec. VIII, Part B 033-YMP-QP 8.0, Para. 8.0.4.2.4, Para. 8.0.4.2.5	<p>Storage methodology shall be developed and implemented to assure that samples are maintained in predetermined physical conditions commensurate with their intended purpose. Samples intended for long term storage shall receive appropriate treatment to assure they do not degrade during storage.</p> <p>Verify that the storage and transportation methods developed to maintain sample integrity have been procedurally documented, and that "long term storage" has been defined.</p> <p>Note: 033-YMP-QP 8.0 merely reiterates the requirements of NNWSI/88-9, but provides no specific measures for storage, transportation, or handling.</p> <p>Note: Neither NNWSI/08-9, nor 033-YMP-QP 8.0 define "long term storage;" as a result, there is no consistent project level identification of when samples must be protected to prevent deterioration, degradation, or change in characteristics during storage.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 102 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
11-2	NNWSI/QAP-88-9, Rev. 2, Sec. XI, Para. 2.0, LLNL-033-YMP-R-11, Rev. 0, Para. 2.0; LLNL-033-YMP-QP, 11.0, Rev. 0, Para. 11.0.4	Test requirements and acceptance or rejection criteria, including required levels of precision and accuracy, shall be provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated. Required tests, including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests shall be controlled. Test requirements and acceptance or rejection criteria shall be based upon specified requirements contained in applicable design or other pertinent technical documents. 1. Verify that test procedures are prepared, controlled. 2. Verify that there are test requirements acceptance/rejection criteria for the pertinent technical documents and design.			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 109 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S. X. N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
11-9	NNWSI/QAP-88-9, Rev. 2, Sec. 11.0, Para. 5.0 LLNL-033-YMP-R-11, Rev. 0, Para. 5.0; LLNL-033-YMP-QP 11.0, Rev. 0, Para. 11.0.5	Test records shall, as a minimum, identify the following: <ul style="list-style-type: none"> o Item tested o Date of test o Tester or data recorder identification o Type of observation o Results and acceptability o Action taken in connection with any deviations noted o Person evaluating results 1. Verify that test records identify the items above.			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 110 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
12-1	NNWSI/88-9, Rev. 2, Sec. XII, Para. 2.1, 2.3 033-YMP-QP 12.0, Para. 6.1, 6.2, Para. 12.0.4.2	<p>The type range, and accuracy of a measuring device shall be documented in test and inspection documents. Each device shall have a unique identification number. This number shall be recorded on the data sheet, log, etc., along with the measurement taken, to ensure traceability to the measurement of the device that was used to take the measurement.</p> <p>The method and interval of calibration for each item shall be defined, based on the type of equipment, stability characteristics, required accuracy, precision, intended use, degree of usage, and other conditions that affect measurement control.</p> <p>Verify M&TE subject to calibration and control is identified on calibration data records, which identify the equipment by serial number or unique control number, equipment description or type, last calibration date, and calibration frequency.</p> <p>Note: 033-YMP-QP 12.0 merely reiterates the requirements of NNWSI/88-9, but provides no details on how calibration will be performed, what documentation is required, or who is responsible for the overall control of M&TE.</p>			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 111 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
12-1 (cont.)		<p>Note: 033-YMP-QP 12.0, Para. 12.0.4.3 provides for calibration interval to be defined based on a number of conditions, but contains no measures for actually establishing the intervals.</p> <p>Note: Review supplier approval status for calibration services and procurement provisions to obtain "as found" calibration.</p>			
				(9) Auditor Signature	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 113 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
12-2 (cont.)		Note: Review availability of manufacturers' equipment manuals or instructions for maintenance, repair calibration (including recommended intervals, if identified), and use.			
		Note: Review specific measures for calibration recall and for evaluation of out of tolerance (OOT) conditions.			
		Note: 033-YMP-QP 12.0 does not identify specific documentation to report calibration document discrepancies to calibration suppliers, or to evaluate out of tolerance conditions.			
		Note: Review any controls for justification of use of equipment with the same accuracy for calibration of "working" M&TE.			
(9) Auditor Signature				(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 114 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
13-1	NNWSI/QAP-88-9, Rev. 2, Sec. 13.0, Para. 1.0	Measures shall be established to control the packaging, handling, storage, shipping, cleaning, and preservation of material and equipment to prevent damage, loss, or deterioration. Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.			
	LLNL-033-YMP-R-13, Rev. 0, Para. 1.0	1. Verify that written instructions state how items and equipment are handled, stored, and shipped.			
	LLNL-033-YMP-QP 13.0, Rev. 0, Para. 13.0.4.1	2. Verify that these instructions are incorporated with- in procurement documents, shipping documents, etc.			
(9) Auditor Signature		(10) Date			

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 115 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
13-2	NNWSI/QAP-88-9, Rev. 2, Sec. 13.0, Rev. 0, Para. 1.1 LLNL-033-YMP-R-13, Para. 1.1; LLNL 033- YMP-QP-13.0, Rev. 0 Para. 13.0.4.2	1.0 SPECIAL EQUIPMENT AND PROTECTIVE ENVIRONMENTS When required for particular items, special equip- ment (e.g., containers, shock absorbers, and ac- celerometers) and special protective environments (e.g., an inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided, and their existence shall be verified. 1. Verify that particular items are specified and verified.			

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 125 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
15-3 (cont.)	033-YMP-QP 15.0, Rev. 0, Para. 15.0.5.4	<p>Verify that if the YMP QA Manager considers the NCR to be of a serious nature (i.e., the matter can adversely affect quality), the YMP Project Leader is notified by memorandum.</p> <p>Verify that the YMP Project Leader assigns an individual or individuals to determine the cause of the NCR and to propose an appropriate disposition.</p> <p>Note: This information is documented by the YMP Project Leader in Part III or the NCR form.)</p> <p>Verify that if the YMP Project Leader concurs with the proposed disposition, the YMP Project Leader completes Parts IV and V of the NCR form and forwards it to the YMP QA Manager for review and approval.</p> <p>Verify that the YMP QA Manager's approval of the proposed disposition is indicated by the signature in Part V of the NCR form.</p> <p>Note: Disagreements concerning the disposition of an NCR are resolved among the YMP Project Leader, the Task Leader, and the YMP QA Manager. In instances where the matter cannot be resolved among these parties, the YMP Project Leader's decision is final.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 126 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
15-3 (cont.)	033-YMP-QP 15.0, Rev. 0, Para. 15.0.5.4	<p>Verify that upon approval of the proposed disposition, the YMP QA Manager notifies the responsible organization to proceed.</p> <p>Verify that when notified by the responsible organization that corrective action has been completed, the YMP QA Manager conducts a verification of the completion of the corrective action and documents his verification in Part VI of the NCR form.</p> <p>Verify that the YMP QA Manager sends copies of the completed NCR to the YMP Project Leader, the cognizant Task Leader, the originator and the DOE Project Office.</p>			
15-4	<p>YMP-88-9, Rev. 2, Sec. XV, Para. 1.4.5</p> <p>033-YMP-QP 15.0, Rev. 0, Para. 15.0.7</p>	<p>In those cases where the responsible organization proposes a disposition of "repair", WMPO shall approve the proposed disposition prior to implementation. In the case of a proposed disposition of "use-as-is", the NCR shall be forwarded to WMPO for approval after all actions necessary to support technical justification of the disposition have been completed. The appropriate WMPO Branch Chief and the WMPO PCM shall approve NCR dispositions involving "repair" or "use-as-is" determinations and conditional release recommendations.</p> <p>Verify that if the disposition of a nonconforming item associated with a Level of Quality Assurance I or II is "repair" or "use-as-is," then the YMP QA Manager forwards the NCR to the Yucca Mountain Project Office (YMP) for approval.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 128 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
15-6	YMP-88-9, Rev. 2, Sec. XV, Para. 2.0	When repetitive or recurring nonconforming conditions are identified, an evaluation shall be made as to whether or not further programmatic corrective action is warranted to preclude repetition. This corrective action shall be beyond the scope of the action taken for the disposition on the existing NCRs, and shall be processed in accordance with corrective action procedures developed by each NNWSI Project participant.			
	033-YMP-QP 15.0, Rev. 0, Para. 15.0.9	Verify that when repetitive or recurring nonconforming conditions are identified, the YMP QA Manager conducts an evaluation of the need for further programmatic corrective action to preclude repetition.			
(9) Auditor Signature				(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 131 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
16-1	YMP-88-9, Rev. 2, Sec. XVI, Para. 1.1	<p>For significant conditions adverse to quality the identification, cause, and corrective action taken to preclude recurrence shall be documented and reported to immediate management and upper levels of management for review and assessment. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or operability. Significant conditions include, but are not limited to breakdowns in the Quality Assurance program and repetitive nonconformances. Upon discovering or receiving notification that a significant condition adverse to quality or unusual occurrence exists, each NNWSI Project Participant shall ensure that:</p> <ul style="list-style-type: none"> o Immediate actions have been taken to remedy the specific condition(s). o Causative factors have been determined. o Controls have been reviewed, implemented, monitored, and revised, if necessary. o Affected managers at all levels have been notified of adverse condition(s) and of lessons to be learned to improve conditions or avoid similar occurrences. <p>Verify that the cause of the condition adverse to quality, including procedural nonconformances, is identified and documented.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 132 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
16-1 (cont.)	033-YMP-QP 16.0, Rev. 0, Para. 16.0.5.2	Verify that the YMP QA Manager assigns a sequential identification number (CAR-001,...CAR-010, etc.) to the CAR and forwards a copy of the CAR to the YMP Project Leader, the appropriate Task Leader, and the DOE Project Office.			
	033-YMP-QA 16.0, Rev. 0, Para, 16.0.5.3	Verify that the YMP QA Manager enters prescribed information regarding the CAR on a Corrective Action Log Sheet, Exhibit B, and creates a separate file folder for maintaining documentation relevant to the CAR.			
		Verify that the Task Leader of the affected work implements the corrective action specified in the CAR.			
		Verify that when the corrective action is implemented, the Task Leader completes Part II of the CAR and sends it to the YMP Project Leader for review. The Project Leader indicates concurrence by his signature in Part II of the CAR. The Project Leader then forwards the CAR to the YMP QA Manager for verification.			
			(9) Auditor Signature	(10) Date	

YMPQ AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 134 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
16-3	YMP-88-9, Rev. 2, Sec. XVI, Para. 1.3	Corrective action reports shall be periodically analyzed by the QA organization to show quality trends. Results shall be reported to upper management for review and assessment.			
	033-YMP-QP 16.0, Rev. 0, Para. 16.0.7	Verify that the CAR Log Sheets are reviewed monthly by the YMP QA Manager to assure that corrective actions and the resulting closure are implemented and to analyze trends.			
		Verify that a report is issued monthly by the YMP QA Manager to the YMP Project Leader indicating the status of all open CARs and identifying any adverse quality trends.			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 142 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-1	NNWSI/88-9, Rev. 2, Sec. XVIII, Para. 1.0	<p>All Nevada Nuclear Waste Storage Investigations (NNWSI) Project activities will be subject to planned and scheduled internal and external audits to assure that procedures and activities comply with the overall Quality Assurance (QA) program and to determine their effectiveness. Each NNWSI Project participant shall include in their Quality Assurance Program Plan (QAPP) a system of planned, periodic audits to provide an objective evaluation of the quality-related practices, procedures, instructions, activities, and items including the review of documents and records to ensure that the QA program is effective and properly implemented. The audits shall be performed in accordance with written procedures using checklists by appropriately trained personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented, reported to, and reviewed by responsible management. Tracking systems shall be instituted for audit findings to assure that all findings are appropriately addressed and to identify quality trends. All deficiencies, nonconformances, and potential quality problems identified during the audit are to be documented and monitored until verification of effective corrective action is made. The audited organization shall describe in a formal report the corrective action to be taken to address findings, and shall submit the report to the auditing organization and their own responsible management.</p> <p>Follow up action, including verification of corrective action or reaudit of specific areas, shall be performed.</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 143 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-1 (cont.)	033-YMP-QP 18.0, Rev. 0 NNWSI/88-9, Rev. 2, Sec. XVIII, Para. 1.0 033-YMP-QP-18, Rev. 0, Para. Nos. 18.0.5.1, 18.0.5.1.2, 18.0.5.1.3, 18.0.5.2, 18.0.5.6, 18.0.7	<ol style="list-style-type: none"> 1. Verify that all activities are audited at least once during the life of the activity, whichever is shorter. 2. Verify that a schedule for conduct of internal and external QA audits is issued annually, including planned audits of subcontractors and the requirements against which the audits will be conducted. 3. Verify that the justification for not performing audits of suppliers whose activities are less than four months in duration is documented and approved by the YMP QA Manager. <p>Verify that audits are performed by:</p> <ol style="list-style-type: none"> 4. Personnel qualified in accordance with Procedure No. 033-YMP-QP 18.2 "Qualification of Quality Assurance Audit Personnel," and that the Lead Auditor designated by the YMP QA Manager prepares a pre-audit documented assessment that assigned audit personnel have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. This assessment is to be documented. 5. Verify that the audit reports include a statement concerning the effectiveness of the implementation of the audited QA elements and that the audit report is in the format required by 033-YMP-QP 18.0. 			
			(9) Auditor Signature	(10) Date	

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 146 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
18-2 (cont.)		<p>the activity being surveilled, but are familiar with the SIP that governs the activity. Also verify that the surveillance team determines the number and frequency of surveillances for scientific investigations to which they are assigned.</p> <p>3. Verify that a schedule of planned surveillances for the fiscal year was issued by the YMP QA Manager to the YMP Project Leader, Technical Area Leaders, Task Leaders and to the DOE YMP and subcontractor activities to be surveilled.</p> <p>4. Verify that surveillance plans approved are appropriately numbered and a log maintained to control them and to monitor status of activities.</p> <p>5. Verify that standard formats prescribed in 033-YMP-QP 18.1 for the documentation of surveillance checklists and surveillance reports are being utilized for surveillance activities.</p> <p>6. Verify that the YMP QA Manager analyzes surveillance results to identify adverse trends affecting quality and issues quarterly summaries specifying the status of surveillances in progress and any adverse trends that have been identified for corrective action processing per the provisions of Procedure No. 033-YMP-QP 16.0 "Corrective Action."</p>			
				(9) Auditor Signature	(10) Date

YMPO AUDIT CHECKLIST NO. 89-6-01

N-QA-044
12/88

(1) Organization LLNL

(2) Page 147 of 147

(3) AUDIT ITEM NO.	(4) QUALITY ELEMENT & REFERENCE	(5) STANDARD QUALITY REQUIREMENTS AUDIT GUIDELINES	(6) RESULTS S, X, N/A	(7) SUMMARY OF INVESTIGATION	(8) PERSON CONTACTED
		7. Verify that QA records resulting from surveillance activity are collected, handled, stored, and maintained as required by Procedure No. 033-YMP-QA 17.0, "Quality Assurance Records" including: <ul style="list-style-type: none"> - Surveillance Schedules; - Surveillance logs; - Surveillance Reports; and - Completed Checklists. 			
			(9) Auditor Signature	(10) Date	