

**QUALITY PLAN IMPLEMENTING MATRIX
 CRITERION 4, “DOCUMENTS AND RECORDS”**

Item No.	Requirement	Source Document*	Implementation Location
Documents and Records - General			
1.	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	10CFR830.122(d)1 AND DOE O 414.1C Attachment 2(3)(d)(1)	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , addresses this requirement.
Document Control - Basic Requirements			
2.	The preparation, issue, and change of documents that specify quality requirements or prescribe quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to assure that correct documents are being employed.	ASME NQA-1-2000, Requirement 6, 100, Basic	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , addresses this requirement.
3.	Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.	ASME NQA-1-2000, Requirement 6, 100, Basic	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , addresses this requirement.
4.	Documents must be prepared and revised using the formal process in IMP 311, <i>Institutional Policies, Implementation Procedures and Related Documents</i> , and ISD 311-1, <i>Manual for Preparing Policies, Procedures, and Related Documents</i> .	IP 330.0, LANL Quality Assurance Program, Section 4.2.1.2, Preparing Documents	ISD 311-1.0, <i>Manual for Preparing Policies, Procedures, and Related Documents</i> , addresses this requirement.
5.	The following controls shall be applied to documents and changes thereto: a) for the identification of controlled documents; b) for the specified distribution of controlled documents for use at the appropriate location; c) for the identification of individuals responsible for the preparation, review, approval, and distribution for controlled documents; d) the review of controlled documents for completeness, and approval prior to distribution; and e) a method to ensure the correct documents are being used.	ASME NQA-1-2000, Requirement 6, 200(a), Document Control	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , addresses this requirement.

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Document Changes			
6.	Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. AND Changes to controlled documents must be subjected to commensurate levels of review and approval as the original document.	ASME NQA-1-2000, Requirement 6, 301, Major Changes AND IP 330.0, LANL Quality Assurance Program, Section 4.2.1.3, Controlling Documents	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , Section 4.2, addresses this requirement.
7.	The reviewing organization shall have access to pertinent background data or information upon which to base their approval.	ASME NQA-1-2000, Requirement 6, 301, Major Changes	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , Section 2.1, addresses this requirement.
8.	Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original document.	ASME NQA-1-2000, Requirement 6, 302, Minor Changes	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , Subsection 4.2.1, addresses this requirement.
9.	To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated.	ASME NQA-1-2000, Requirement 6, 302, Minor Changes	EP-DIR-SOP-4001, Revision 2.0, <i>Document Control</i> , Subsection 4.2.1, addresses this requirement.
Document Storage			
10.	Documents, recording media, or electronic documents under specific control systems or with proliferation restrictions (e.g., classified removable electronic media [CREM]) must be subjected to additional institutional requirements.	IP 330.0, LANL Quality Assurance Program, Section 4.2.1.4, Document Storage	EP-DIR-SOP-4001, Revision 3.0, <i>Document Control</i> , Section 4.7, addresses this requirement.
Records Management – General Requirements			
11.	Specify, prepare, review, approve, and maintain records.	10CFR830.122(d)2 AND DOE O 414.1C Attachment 2(3)(d)(2)	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , addresses this requirement.
Records Management - Basic Requirements			
12.	Quality Assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.	ASME NQA-1-2000, Requirement 17, 100, Basic	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 2.1, addresses this requirement.

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13.	A records management plan must be written for each LANL division in accordance with the requirements in ISD 1020-1, <i>Laboratory Records Management</i> .	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.1, Identifying and Preparing of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , meets this requirement.
14.	Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. AND Divisions generating records are responsible for identifying, preparing, validating, categorizing, and designating the retention period of the record.	ASME NQA-1-2000, Requirement 17, 100, Basic AND IP 330.0, LANL Quality Assurance Program, Section 4.2.2.1, Identifying and Preparing of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , addresses this requirement.
15.	Requirements and responsibilities for these activities shall be documented. [NOTE: The term <i>records</i> , used throughout this section, is to be interpreted as <i>quality assurance records</i> .	ASME NQA-1-2000, Requirement 17, 100, Basic	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , addresses this requirement.
16.	Upon completion and designation as a record requiring retention, the record must be transmitted to long-term storage in accordance with the approved division or institutional procedure for records management.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.1, Identifying and Preparing of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 4.6.2, Retention and Disposition of Records, addresses this requirement.

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Generation of Records			
17.	Records shall be legible. <p style="text-align: center;">AND</p> Acceptable records must be legible, authenticated by a valid signature, and must have retention schedules based on record type and expected future use.	ASME NQA-1-2000, Requirement 17, 200(a) Generation of Records AND IP 330.0, LANL Quality Assurance Program, Subsection 4.2.2.2, Receiving, Indexing, and Classifying of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.1.2, Process Record(s), addresses these requirements.
18.	Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.	ASME NQA-1-2000, Requirement 17, 200(b) Generation of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 2.1, addresses this requirement.
Authentication			
19.	Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.	ASME NQA-1-2000, Requirement 17, 300 Authentication of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.1.11, addresses this requirement.

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Classification			
20.	<p>Records shall be classified as <i>lifetime</i> or <i>nonpermanent</i> by the Owner, or his agent when authorized, in accordance with the following criteria:</p> <p>[NOTE: Lifetime records are those that meet one or more of the following criteria:</p> <ul style="list-style-type: none"> a) those which would be of significant value in demonstrating capability for safe operation; b) those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; c) those which would be of significant value in determining the cause of an accident or malfunction of an item; d) those which provide required baseline data for in-service inspections.] <p>[NOTE: Lifetime records are required to be maintained by or for the plant Owner for the life of the particular item while it is installed in the plant or stored for future use.]</p> <p>[NOTE: Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.]</p>	ASME NQA-1-2000, Requirement 17, 400, Classification	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 2.1, addresses this requirement.
Receipt Control and Retention of Records			
21.	Records shall be retained in accordance with the above classifications.	ASME NQA-1-2000, Requirement 17, 500, Receipt Control and Retention of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.6.1, addresses this requirement.

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22.	The retention period for nonpermanent records shall be established in writing.	ASME NQA-1-2000, Requirement 17, 500, Receipt Control and Retention of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.6.1, addresses this requirement.
23.	Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records.	ASME NQA-1-2000, Requirement 17, 500, Receipt Control and Retention of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 1.0, addresses this requirement.
24.	The designee shall be responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage.	ASME NQA-1-2000, Requirement 17, 500, Receipt Control and Retention of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 1.0, addresses this requirement.
25.	Completed records must be reviewed for acceptability and uniquely identified.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.2, Receiving, Indexing, and Classifying of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 4.1, addresses this requirement.
26.	This identification must be entered into a database or log, which identifies the record type (e.g., epidemiological, radiological, medical, human resources, security, etc.) and the record located within the record system.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.2, Receiving, Indexing, and Classifying of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.4.6, addresses this requirement.
Storage			
27.	Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: a) natural disasters such as winds, floods, or fires; b) environmental conditions such as high and low temperatures and humidity; c) infestation of insects, mold, or rodents.	ASME NQA-1-2000, Requirement 17, 600, Storage	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.5.5, addresses this requirement.

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28.	Dual facilities, containers, or combination thereof shall be provided for records storage if a single facility, container, or combination thereof is not capable of providing adequate protection.	ASME NQA-1-2000, Requirement 17, 600, Storage	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.5.5, addresses this requirement.
Disposition			
29.	Record retention periods shall be documented.	ASME NQA-1-2000, Requirement 17, 700, Disposition	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.6, addresses this requirement.
30.	Records shall be maintained for their retention periods.	ASME NQA-1-2000, Requirement 17, 700, Disposition	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 4.6, Records Protection, addresses this requirement.
31.	Each division must maintain and store its own records.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.3, Storing, Preserving, and Safekeeping of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , addresses this requirement.
32.	Access to records must be limited to workers authorized on a need-to-know basis.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.3, Storing, Preserving, and Safekeeping of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.5.3, addresses this requirement.
33.	Records transferred to archival or long-term storage must be processed in accordance with the requirements contained in ISD 1020-1, <i>Laboratory Records Management</i> , and division record management plans.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.3, Storing, Preserving, and Safekeeping of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.5.6, Note, addresses this requirement.

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Maintenance of Records			
34.	Records shall be protected from damage or loss.	ASME NQA-1-2000, Requirement 17, 800, Maintenance of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.5.2, addresses this requirement.
35.	Records shall be retrievable.	ASME NQA-1-2000, Requirement 17, 800(b), Maintenance of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Section 4.2, and EP-DIR-SOP-4004, <i>Record Transmittal and Retrieval Processes</i> , address this requirement.
36.	The methods for record changes shall be documented.	ASME NQA-1-2000, Requirement 17, 800(c), Maintenance of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 4.1.13, addresses this requirement.
37.	Provisions shall be made for specially processed records (such as radiographs, photographs, negatives, microform, and magnetic and optical media) to prevent damage from excessive light, stacking electromagnetic fields, temperature, and humidity.	ASME NQA-1-2000, Requirement 17, 800(d), Maintenance of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsections 4.5.2 and 4.5.5, addresses this requirement.
38.	Computer hardware and software that are used to prepare, store, maintain, index, and access records must be controlled to ensure records protection from loss or damage and to ensure that the records are accounted for and retrievable.	IP 330.0, LANL Quality Assurance Program, Section 4.2.2.3, Storing, Preserving, and Safekeeping of Records	EP-DIR-SOP-4003, Revision 1.0, <i>Records Management</i> , Subsection 2.1, addresses this requirement.

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