

**QUALITY PLAN IMPLEMENTING MATRIX
 CRITERION 1, “PROGRAM”**

Item No.	Requirement	Source Document*	Implementation Location
General Requirements			
1.	<p>A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following:</p> <p>1) Implements QA criteria as defined in Item 3, Suspect/Counterfeit Items (S/CI) prevention requirements as defined in Item 4, and safety software as defined in Item 5, using a graded approach and describing how the QA criteria and graded approach are applied.</p>	DOE O 414.1C, Attachment 2, Section 2(a)(1)	ISD-330-1.0, <i>Graded Approach for Work Activities</i> meets this requirement.
2.	<p>A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following:</p> <p>2) Uses the appropriate national or international consensus standard where practicable and consistent with contractual or regulatory requirements, and identifies the standard used. Appropriate standards include:</p> <p>a) ASME NQA-1-2000, <i>Quality Assurance Requirements for Nuclear Facility Applications</i> (for nuclear-related activities).</p> <p>b) ANSI/ISO/ASQ Q 9001-2000, <i>Quality Management System: Requirements</i> (for non-nuclear activities).</p> <p>c) ANSI/ASQ Z 1.13, 1999, <i>Quality Guidelines for Research</i> (for non-nuclear research activities).</p>	DOE O 414.1C, Attachment 2, Section 2(a)(2)	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Section 2.0, Purpose and Scope, addresses this requirement.

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3.	<p>A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following:</p> <p>3) Applies additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory). [NOTE: These standards are sometimes referred to as “voluntary standards.” However, once the practicable standard(s) is adopted through regulation, code, contract, QAP, or procedure, compliance with the standard is required and is not voluntary.]</p>	DOE O 414.1C, Attachment 2, Section 2(a)(3)	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Section 2.0, Purpose and Scope, addresses this requirement.
4.	<p>A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of a QAP that does the following:</p> <p>4) Integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in this CRD, the S/CI prevention process and Safety Software Quality Requirements with other quality or management system requirements in DOE directives and external requirements, including, where applicable –</p> <ul style="list-style-type: none"> a) DOE P 450.4, <i>Safety Management System Policy</i>, dated 10-15-96. b) DOE P 450.5, <i>Line Environment, Safety and Health Oversight</i>, dated 06-26-97. c) NNSA <i>Quality Management Policy</i>, QC-1, (quality management system for the nuclear weapons complex and weapons-related activities). d) DOE/RW-0333P, DOE Office of Civilian Radioactive Waste Management, <i>Quality Assurance Requirements and Description</i>. e) DOE/CBFO-94-1012, DOE Carlsbad Field Office, <i>Quality Assurance Program Description</i>, (for the Waste Isolation Pilot Plant and related activities). 	DOE O 414.1C, Attachment 2, Section 2(a)(4)	The requirements of DOE/CBFO-94-1012, DOE Carlsbad Field Office, <i>Quality Assurance Program Description</i> , were considered for the remediation activities resulting in waste packages destined for the Waste Isolation Pilot Plant; however, these requirements were determined to be unnecessary at this time.

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5.	The contractor must submit a QAP to DOE for approval before beginning work under a DOE contract.	DOE O 414.1C, Attachment 2, Section 2(b)(1)	N/A – The Environmental Programs Directorate Quality Assurance Plan is consistent with the LANL Institutional QA Program, which was approved by DOE in November 2005.
6.	The contractor must implement the QAP as approved and modified by DOE.	DOE O 414.1C, Attachment 2, Section 2(b)(2)	The Environmental Programs Directorate describes implementation of its QAP within the Quality Assurance Plan, the Quality Plan Implementing Matrices (QPIMs), and the Standard Operating Procedures referenced within the QPIMs.
7.	The contractor must indicate in the submittal any third-party certification affecting the QAP.	DOE O 414.1C, Attachment 2, Section 2(b)(3)	N/A – there is no third-party certification related to the Environmental Programs Directorate QAP.
8.	The contractor must revise an existing QAP that was approved in accordance with previous versions of this CRD (e.g., CRD to DOE O 414.1B, <i>Quality Assurance</i> , dated 04-29-04) to address enhancements required by this CRD.	DOE O 414.1C, Attachment 2, Section 2(b)(4)	The Environmental Programs Directorate QAP is based on DOE O 414.1C.
9.	The contractor must regard a QAP as approved by DOE 90 calendar days after DOE receipt, unless approved or rejected by DOE at an earlier date, and include any modification made or directed by DOE.	DOE O 414.1C, Attachment 2, Section 2(b)(5)	N/A – the LANL QA Program requires approval by DOE; however, the Environmental Programs Directorate QAP does not.

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10.	<p>The contractor must submit QAP changes made the previous year annually to DOE for review and approval. In the submittal, identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this CRD.</p> <p>[NOTE: The contractor may make changes to an approved QAP at any time. Editorial changes made to correct spelling, punctuation, grammar, etc., do not require explanation.]</p>	DOE O 414.1C, Attachment 2, Section 2(b)(6)	N/A – see the response to Item 9 above.
11.	<p>The contractor must consider QA guidance in developing and implementing a QAP, specifically the following:</p> <ul style="list-style-type: none"> • DOE G 414.1-1A, <i>Management Assessment and Independent Assessment Guide for Use with 10 CFR, Part 830, Subpart A, and DOE O 414.1A; Quality Assurance</i>; DOE P 450.4, <i>Safety Management System Policy</i>; and DOE P 450.5, <i>Line ES&H Oversight Policy</i>, dated 5-31-01; • DOE G 414.1-2A, <i>Quality Assurance Management System Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements and DOE O 414.1C, Quality Assurance</i>, dated 6-17-05; • DOE G 414.1-3, <i>Suspect/Counterfeit Items Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance</i>, dated 11-03-04; • DOE G 414.1-4, <i>Safety Software Guide for use with 10 CFR 830, Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance</i>, dated 6-17-05. 	DOE O 414.1C, Attachment 2, Section 2(c)	<p>The Environmental Programs Directorate considered the following four guidance documents in developing the QAP:</p> <ul style="list-style-type: none"> • DOE G 414.1-1A, Management Assessment and Independent Assessment Guide; • DOE G 414.1-2A, Quality Assurance Management System Guide; • DOE G 414.1-3, Suspect/Counterfeit Items Guide; and • DOE G 414.1-4, Safety Software Guide.
12.	The contractor must address the management, performance and assessment criteria of DOE O 414.1C.	DOE O 414.1C, Attachment 2, Section 3	The Environmental Programs Directorate revised the QAP to incorporate DOE O 414.1C requirements.

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13.	Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.	10CFR830.122 (a)1 AND DOE O 414.1C Attachment 2, Section 3(a)(1)	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.2, Roles and Responsibilities, addresses this requirement.
14.	Establish management processes, including planning, scheduling, and providing resources for the work.	10CFR830.122 (a)2 AND DOE O 414.1C Attachment 2, Section 3(a)(2)	Management processes for the Environmental Programs Directorate are described within the SOPs and captured in Statements of Work.
Basic Requirements			
15.	Responsibilities for the establishment and implementation of the quality assurance program shall be defined.	ASME NQA-1-2000, Requirement 1, Organization, 100, Basic	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.2, Roles and Responsibilities, addresses this requirement.
16.	The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.	ASME NQA-1-2000, Requirement 1, Organization, 100, Basic	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.2, Roles and Responsibilities, addresses this requirement.

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Suspect/Counterfeit Items (S/CIs)			
17.	An S/CI prevention process must be developed and implemented as a part of the contractor's QA Program (QAP) and must be commensurate with the facility/activity hazards and mission impact.	DOE O 414.1C, Attachment 2(4)(a)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Section 1.3, Purpose, addresses this requirement.
18.	The QAP must be applied to identifying, analyzing, and removing S/CIs and preventing them from being supplied to DOE/NNSA and its contractors.	DOE O 414.1C, Attachment 2(4)(a)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Section 1.3, Purpose, addresses this requirement.
19.	The QAP must address the following elements for S/CI prevention: 1) Preventing the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned process controls.	DOE O 414.1C, Attachment 2(4)(a)(1)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Section 1.3, Purpose, addresses this requirement.
20.	The QAP must address the following elements for S/CI prevention: 2) Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).	DOE O 414.1C, Attachment 2(4)(a)(2)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Section 5.1, Training Requirements, addresses this requirement.
21.	The QAP must address the following elements for S/CI prevention: 3) Identifying and disposing of S/CIs onsite.	DOE O 414.1C, Attachment 2(4)(a)(3)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Sections 4.2.1, Identifier, and 4.3.3, RLM or Designee, address this requirement.
22.	The QAP must address the following elements for S/CI prevention: 4) Restricting S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process.	DOE O 414.1C, Attachment 2(4)(a)(4)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Sections 4.3.2(b), TSME, and 4.10.1, RLM or Designee, address this requirement.

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23.	<p>The QAP must address the following elements for S/CI prevention:</p> <p>5) Collecting, maintaining, disseminating, and using the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources, including the following:</p> <ul style="list-style-type: none"> • Government-Industry Data Exchange Program (www.gidep.org); • Institute of Nuclear Power Operations (www.inpo.org); • DOE Occurrence Reporting and Processing System (http://www.eh.doe.gov/paa/orps.html); • DOE S/CI Web site (http://www.eh.doe.gov/sci/). 	DOE O 414.1C, Attachment 2(4)(a)(5)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Section 4.4.1(a), SCIL, addresses this requirement.
24.	<p>The QAP must address the following elements for S/CI prevention:</p> <p>6) Identifying the management point of contact responsible for these activities to ensure that the DOE Office of Environment, Safety and health has a viable recipient for S/CI information notices.</p>	DOE O 414.1C, Attachment 2(4)(a)(6)	LANL ISD 330-9.1, <i>Suspect/Counterfeit Items</i> , Section 3.2, Suspect/Counterfeit Items Management POC, addresses this requirement.
Structure and Responsibility			
25.	<p>The organizational structure and responsibility assignments shall be such that:</p> <p>a) senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result;</p> <p>b) quality is achieved and maintained by those assigned responsibility for performing work;</p> <p>c) quality achievement is verified by those not directly responsible for performing the work; and</p> <p>d) those responsible for verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function.</p>	ASME NQA-1-2000, Requirement 1, Organization, 201, General	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.2, Roles and Responsibilities, addresses this requirement.

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26.	The assignment of responsibilities must be based on requirements that ensure that safety, reliability, and performance are maximized through the application of management systems that minimize risks and hazards posed by the work.	IP 330.0, LANL Quality Assurance Program, Section 1.2, Process Requirements	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , addresses this requirement as does ISD 781-1.0, <i>Conduct of Training Manual</i> .
27.	The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under ASME NQA-1-2000 may delegate any or all of the work to others but shall retain responsibility therefore.	ASME NQA-1-2000, Requirement 1, Organization, 202, Delegation of Work	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Statement of Policy and Subsection 5.1.3, Interface Controls, address this requirement.
Organization - Management			
28.	Responsible managers must ensure that, as applicable: <ul style="list-style-type: none"> • work requirements are fully planned and documented using LANL-approved industry standards, current information, and documentation; • work performed by subcontractors and suppliers is monitored; • procedures are developed and approved prior to performance of work; • activity hazards are identified according to hazard analysis and controlled through prescribed procedures or integrated work control documents; • qualified and trained workers are assigned to conduct work operations; • permits and authorizations are identified and completed consistent with institutional requirements; and • materials and equipment are controlled to ensure risks to mission, safety, security, and the environment is managed (e.g., master equipment list (MEL) for nuclear activities, special processes). 	IP 330.0, LANL Quality Assurance Program, Subsection 5.2.1, Ensuring Availability of Standards, Procedures, Personnel, Facilities, and Equipment	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.2, Roles and Responsibilities, addresses this requirement.
Interface Control			
29.	Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.	ASME NQA-1-2000, Requirement 1, Organization, 300, Interface Control	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.3, Interface Controls, addresses this requirement.

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30.	The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.	ASME NQA-1-2000, Requirement 1, Organization, 300, Interface Control	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Subsection 5.1.3, Interface Controls, addresses this requirement.
Quality Assurance Program			
31.	A documented quality assurance program shall be planned, implemented, and maintained in accordance with ASME NQA-1-2000 or portions thereof.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Section 2.0, Purpose and Scope, addresses this requirement.
32.	The program shall identify the activities and items to which it applies.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	EP-DIR-QAP-0001, Revision 0.0, <i>Quality Assurance Plan for the Environmental Programs Directorate</i> , Section 2.0, Purpose and Scope, addresses this requirement.
33.	The program shall provide control over activities affecting quality to an extent consistent with their importance.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	ISD-330-1.0, <i>Graded Approach for Work Activities</i> addresses this requirement.
34.	The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	PD 033.000, <i>Surveillances</i> , addresses this requirement.
35.	The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	The QAP and SOPs were re-written when the DOE requirements and New Mexico State regulations recently changed.

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36.	The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. [NOTE: 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.]	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	The SOPs describe any specific environmental conditions required for accomplishing the work.
37.	The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	Special controls and equipment are described within each SOP.
38.	The organization shall establish and implement processes to detect and correct problems.	ASME NQA-1-2000, Requirement 2, 100, Basic(a)	ISD 322-4.2, <i>Issues and Corrective Action Management Process</i> , addresses this requirement.
39.	The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to assure that suitable proficiency is achieved and maintained.	ASME NQA-1-2000, Requirement 2, 100, Basic(b)	ISD 781-1.0, <i>Conduct of Training Manual</i> , addresses this requirement.

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