



STANFORD UNIVERSITY
SLAC National Accelerator Laboratory
 Operated by Stanford University for the U.S. Department of Energy



DOE Order 414.1D, Admin Chg. 1, Quality Assurance (05/08/2013)
Site Compliance Plan (final rev., 07/11/2016)

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Introduction

This Site Compliance Plan (SCP):

- a) corresponds with the version of the DOE Order on Occurrence Reporting and Processing of Operations Information listed in the Prime Contract,
- b) states how the Laboratory complies with applicable requirements as tailored to the risks at the Laboratory,
- c) identifies CRD sections that do not apply, and
- d) documents DOE-approved methods of compliance for applicable requirements and recurring deliverables*.

Impact on the Contract:

Under the SCP, sections of the CRD are incorporated into the Contract as-is, unless the SCP indicates that a section or portion thereof is inapplicable, or the section has been changed. Thus, for example, if “In compliance” is listed next to a CRD section, that section is incorporated into the Contract as-is. However, where an SCP indicates that a section or portion thereof is inapplicable, the section or portion thereof is excluded from the Contract. In addition, where a section or portion thereof is applicable, but changes to the section have been agreed by the Parties, the section, as modified by the Parties, shall be incorporated into the Contract. The SCP also memorializes the Parties’ agreement on how SLAC will comply with sections of the CRD (whether or not modified).

Contractor Requirements Document (CRD) (Attachment 1)

Regardless of the performer of the work, the contractor is responsible for complying with the requirements of this CRD. The contractor is responsible for flowing down the applicable requirements of this CRD, to the extent necessary, to subcontractors at any tier, as well as vendors and suppliers, to ensure the contractor’s compliance with the requirements and the safe performance of work. When the contractor conducts activities or provides items or services that affect or may affect the safety of DOE (including National Nuclear Security Administration [NNSA]) nuclear facilities, it must conduct work in accordance with the quality assurance (QA) requirements of 10 C.F.R. Part 830 Subpart A and the additional requirements of this CRD, unless the work falls within one or more of the exclusions found in 10 C.F.R. § 830.2. Requirements of this CRD that overlap or duplicate Nuclear Regulatory Commission (NRC) requirements are not applicable to facilities or activities (including design, construction, operation, deactivation and decommissioning) subject to a NRC license (including construction authorization) and related NRC regulatory authority. Other requirements in this CRD may be applied to the extent determined appropriate by the responsible Program Office. In addition to the requirements set forth in this CRD, Attachments 2, 3 and 4 to DOE O 414.1D are made a part of this CRD and provide program requirements and/or information applicable to contracts in which this CRD is inserted.

*Deliverables: Data delivered to DOE or other external agency (e.g., recurring reporting, external database entries)



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CRD §	Requirements from CRD, Attachment 1	Compliance Status	Method of Compliance	Deliverables* (managed through SLACTrak)			
				Item	Frequency	Due Date(s)	Recipient (e.g., SSO)
1.	QUALITY ASSURANCE PROGRAM DEVELOPMENT AND IMPLEMENTATION. The contractor must identify and assign an individual to have responsibility, authority, and accountability to ensure the development, implementation, assessment, maintenance, and improvement of the QAP. The contractor, using a graded approach, must develop a QAP and conduct work in accordance with the approved QAP that meets the requirements of this CRD. The QAP must do the following:	In compliance	The Quality Assurance Program (QAP) is managed by the SLAC Director of Contractor Assurance and Contract Management who reports directly to the SLAC Laboratory Director. The methods to manage the QAP are outlined in the sections below.	n/a	n/a	n/a	n/a
1.a.	Describe the graded approach used in the QAP.	In compliance	Section 3 of the QAP includes a description of the graded approach.	n/a	n/a	n/a	n/a
1.b.	Implement QA criteria as defined in Attachment 2, as well as the requirements in Attachment 3 for all facilities, and the requirements in Attachment 4 for nuclear facilities, and describe how the criteria/requirements are met, using the documented graded approach. Note: This requires that all software meet applicable QA requirements in Attachment 2, using a graded approach.	In compliance	Section 4 of the QAP covers the implementation of criteria in Attachment 2, Quality Assurance Criteria, and Attachment 3, Suspect/Counterfeit Items Prevention. Attachment 4, Safety Software Quality Assurance Requirements for Nuclear Facilities, does not apply to SLAC.	n/a	n/a	n/a	n/a
1.c.	Use appropriate national or international consensus standards consistent with contractual and regulatory requirements, and Secretarial Officer direction. Clearly identify which standards, or parts of the standards, are used. When standards do not fully address the CRD requirements, the gaps must be addressed in the QAP. Select and document the appropriate choice below.	In compliance	ISO 14001, Environmental Management Systems is used when appropriate as a means of supplementing this Order's CRD.	n/a	n/a	n/a	n/a
1.c. (1)	For Hazard Category 1, 2 and 3 nuclear facilities: (a)-(c)	SLAC is not a Category 1, 2 or 3 nuclear facility; 1.c.(1) does not apply to SLAC.					
1.c. (2)	For other activities and facilities (e.g., less than hazard category 3, non- nuclear, or chemically hazardous) use in whole or in part appropriate standards. Examples of appropriate standards	In compliance	ISO 14001, Environmental Management Systems is used when appropriate as a means of supplementing this Order's CRD	n/a	n/a	n/a	n/a

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	include: (a) ASME NQA 1-2008 with the NQA-1a 2009 addenda, <i>Quality Assurance Requirements for Nuclear Facility Applications</i> , Part I and applicable requirements of Part II; (b) ASME NQA 1-2000, <i>Quality Assurance Requirements for Nuclear Facility Applications</i> , Part I and applicable requirements of Part II; (c) ANSI/ISO/ASQ Q9001-2008, <i>Quality Management System: Requirements</i> ; and, (d) ANSI/ASQ Z 1.13-1999, <i>Quality Guidelines for Research</i> .						
2.	QUALITY ASSURANCE PROGRAM APPROVALS AND CHANGES. The contractor must:						
2.a.	Submit a QAP to DOE for approval within 90 days of being awarded a DOE contract.	In compliance	SLAC's QAP has been approved by DOE.	n/a	n/a	n/a	n/a
2.b.	Review the QAP annually, and update as needed. Submit a summary of the annual review of the QAP and, if necessary, also submit the modified QAP to the DOE approval authority. Editorial changes, that do not reduce or change commitments, do not require approval.	In compliance	The QAP is reviewed annually as part of SLAC's Quality and Improvement procedures. A review summary is provided to SSO by 9/30 annually.	Revised QAP and Summary of Annual Review	Annual	9/30	DOE SSO CO
2.c.	Regard a QAP as approved by DOE, 90 calendar days after receipt by DOE, unless approved or rejected by DOE at an earlier date. Receipt includes acknowledgement by the receiving organization, and every official submittal to DOE restarts the 90 day clock.	In compliance	Outlined in Attachment 1, Section 2.a of this SCP.	n/a	n/a	n/a	n/a
2.d.	For subcontractor, vendor, and supplier activities that are not governed by the contractor's DOE-approved QAP, evaluate their program to ensure they meet applicable QA requirements.	In compliance	SLAC Supply Chain Management ensures compliance through DOE-approved SMC program description.	n/a	n/a	n/a	n/a

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Quality Assurance Criteria (Attachment 2)

Note: Criteria 1 -10 are addressed in SLAC's Quality Assurance Program document, Section 4, Quality Assurance - Criteria

<p>Criterion 1— Management/Program.</p> <ul style="list-style-type: none"> a. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. b. Establish management processes, including planning, scheduling, and providing resources for the work.
<p>Criterion 2— Management/Personnel Training and Qualification.</p> <ul style="list-style-type: none"> a. Train and qualify personnel to be capable of performing their assigned work. b. Provide continuing training to personnel to maintain their job proficiency.
<p>Criterion 3— Management/Quality Improvement.</p> <ul style="list-style-type: none"> a. Establish and implement processes to detect and prevent quality problems. b. Identify, control, and correct items, services, and processes that do not meet established requirements. c. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning. d. Review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement.
<p>Criterion 4— Management/Documents and Records.</p> <ul style="list-style-type: none"> a. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. b. Specify, prepare, review, approve, and maintain records.
<p>Criterion 5— Performance/Work Processes.</p> <ul style="list-style-type: none"> a. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means. b. Identify and control items to ensure proper use. c. Maintain items to prevent damage, loss, or deterioration. d. Calibrate and maintain equipment used for process monitoring or data collection.
<p>Criterion 6— Performance/Design.</p> <ul style="list-style-type: none"> a. Design items and processes using sound engineering/scientific principles and appropriate standards. b. Incorporate applicable requirements and design bases in design work and design changes. c. Identify and control design interfaces. d. Verify or validate the adequacy of design products using individuals or groups other than those who performed the work. e. Verify or validate work before approval and implementation of the design.
<p>Criterion 7— Performance/Procurement.</p> <ul style="list-style-type: none"> a. Procure items and services that meet established requirements and perform as specified. b. Evaluate and select prospective suppliers on the basis of specified criteria. c. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.
<p>Criterion 8— Performance/Inspection and Acceptance Testing.</p> <ul style="list-style-type: none"> a. Inspect and test specified items, services, and processes using established acceptance and performance criteria. b. Calibrate and maintain equipment used for inspections and tests.
<p>Criterion 9— Assessment/Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.</p>
<p>Criterion 10— Assessment/Management Assessment.</p> <ul style="list-style-type: none"> a. Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. b. Establish sufficient authority and freedom from line management for independent assessment teams. c. Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.



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Suspect/Counterfeit Items Prevention (Attachment 3)

CRD §	Requirements from CRD, Attachment 3	Compliance Status	Method of Compliance	Deliverables*(managed through SLACTrak)			
				Item	Frequency	Due Date(s)	Recipient (e.g., SSO)
1.	<p>PURPOSE. To set forth requirements for DOE and its contractor organizations, as part of their QAPs, to establish, document and implement effective controls and processes that will:</p> <p>(1) ensure items and services meet specified requirements;</p> <p>(2) prevent entry of Suspect/Counterfeit Items (S/CIs) into the DOE supply chain; and</p> <p>(3) ensure detection, control, reporting, and disposition of S/CIs.</p>						
2.	<p>REQUIREMENTS. The organization's QAP must:</p>						
2.a	<p>Include a S/CI oversight and prevention process commensurate with the facility/activity hazards and mission impact.</p>	In compliance	<p>SLAC has instituted measures to prevent the purchase of S/CI, as well as to detect and dispose of S/CIs. These details of the process are documented in SLAC's Suspect/Counterfeit Items program. The program consists of identification of items, inspection during procurement, inspection during installation, and disposition and reporting of S/CI parts.</p>	n/a	n/a	n/a	n/a
2.b	<p>Identify the position responsible for S/CI activities and for serving as a point of contact with the Office of Health, Safety, and Security.</p>	In compliance	<p>The POC for SC/I activities and for the Office of Health, Safety and Security is SLAC's Quality Manager.</p>	n/a	n/a	n/a	n/a
2.c	<p>Provide for training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs).</p>	In compliance	<p>Proper training of the S/CI program and its processes are defined in Section 3.0 of the S/CI program document in accordance with this Implementation Plan.</p>	n/a	n/a	n/a	n/a
2.d	<p>Prevent introduction of S/CIs into DOE work by:</p> <p>(1) engineering involvement:</p> <p>(a) in the development of procurement specifications;</p> <p>(b) during inspection and testing; and</p> <p>(c) when maintaining, replacing, or modifying equipment;</p> <p>(2) identifying and placing technical and QA requirements in procurement specifications;</p> <p>(3) accepting only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices; and</p> <p>(4) inspecting inventory and storage areas to identify, control, and disposition for S/CIs.</p>	In compliance	<p>The process is defined in Section 3.0 of SLAC's S/CI program document.</p>	n/a	n/a	n/a	n/a



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CR D §	Requirements from CRD, Attachment 3	Compliance Status	Method of Compliance	Deliverables*(managed through SLACTrak)			
				Item	Frequency	Due Date(s)	Recipient (e.g., SSO)
2.e.	Include processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications ¹ and other applications that create potential hazards. Also address the use of supporting engineering evaluations for acceptance of installed S/CI as well as marking to prevent future reuse.	In compliance	Outlined in Attachment 3, Section 2.d of this SCP.	n/a	n/a	n/a	n/a
2.f.	Conduct engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards. Evaluations must consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required).	In compliance	Outlined in Attachment 3, Section 2.d of this SCP.	n/a	n/a	n/a	n/a
2.g.	Perform the evaluation to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place. Disposition S/CIs identified during routine maintenance and/or inspections to prevent future use in these applications.	In compliance	The evaluation process is defined in Section 4 of the S/CI program document.	n/a	n/a	n/a	n/a
2.h.	Report to the DOE Inspector General per paragraph 3. below, and DOE O 221.1A, <i>Reporting Fraud, Waste, and Abuse to the Office of Inspector General</i> , dated 03-22-01 (or latest version).	In compliance	Outlined in Attachment 3, Section 3 of this SCP.	n/a	n/a	n/a	n/a
2.i.	Collect, maintain, disseminate, and use the most accurate, up to date information on S/CIs and suppliers. Sources are identified on the DOE S/CI website (http://www.hss.energy.gov/csa/csp/sci/).	In compliance	If an S/CI item is identified, SLAC has established processes to disseminate information to the appropriate stakeholders. This is described in the S/CI program, Section 3.0.	n/a	n/a	n/a	n/a

¹ Safety applications are those whose failure could adversely affect the environment, safety, or health of the public or workers. This term includes safety systems in nuclear facilities (see 10 C.F.R. § 830.3).



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CRD §	Requirements from CRD, Attachment 3	Compliance Status	Method of Compliance	Deliverables*(managed through SLACTrak)			
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2.j.	Conduct trend analyses for use in improving the S/CI prevention process. Note: DOE O 210.2, <i>DOE Corporate Operating Experience Program</i> , dated 06-12-06 (or latest version) requires review of existing lessons learned reports and submittal of new lessons learned reports for use in improving the S/CI prevention process.	In compliance	SLAC's established tracking and trending metrics for process improvement would be used should an S/CI item be discovered. SLAC participates in DOE Corporate Operating Experience Program monthly conference calls and disseminates information out to stakeholders when appropriate. SLAC also shares pertinent Lessons Learned/Operating Experience via the SLAC Lessons Learned Program and OPEXShare system.	n/a	n/a	n/a	n/a
3.	INSPECTOR GENERAL. Contact the DOE Inspector General (IG), before destroying or disposing of S/CIs and corresponding documentation, to allow the IG to determine whether the items and documentation need to be retained for criminal investigation or litigation.	In compliance	SLAC follows DOE IG protocols whenever applicable.	n/a	n/a	n/a	n/a
4.	OCCURRENCE REPORTING. S/CIs must be reported in accordance with DOE M 231.1-2, <i>Occurrence Reporting and Processing of Operations Information</i> , dated 08-19-03 (or latest version).	In compliance	The DOE approved Implementation Plan for DOE O 232.2 – Occurrence Reporting outlines SLAC's methods of compliance with that Order.	n/a	n/a	n/a	n/a

Safety Software Quality Assurance Requirements for Nuclear Facilities (Attachment 4)

The requirements in Attachment 4 are for Category 1, 2, and 3 Nuclear Facilities and do not apply to SLAC.

Approvals

Name:	Title:	Signature:	Date:
Marc E. Clay	Contractor Assurance and Contract Management Director, SLAC	(on file)	
Dave Osugi	Quality Assurance Program Manager, SSO	(on file)	

Please return signed document to: Contract Management, MS 75