



# STANDARD REVIEW PLAN (SRP)

## FACILITY SOFTWARE QUALITY ASSURANCE (SQA) FOR CAPITAL PROJECT CRITICAL DECISIONS REVIEW MODULE



### CORPORATE CRITICAL DECISION (CD) REVIEW AND APPROVAL FRAMEWORK ASSOCIATED WITH NUCLEAR FACILITY CAPITAL AND MAJOR CONSTRUCTION PROJECTS

MARCH 2010

**OFFICE OF ENVIRONMENTAL MANAGEMENT**

**Standard Review Plan (SRP)**

**Facility Software Quality Assurance (SQA)**

**for Capital Project Critical Decisions**

**Review Module**

Critical Decision (CD) Applicability					
CD-0	CD-1	CD-2	CD-3	CD-4	Post Operation
✓	✓	✓	✓	✓	



**March 2010**

## FOREWORD

The Standard Review Plan (SRP)<sup>1</sup> provides a consistent, predictable corporate review framework to ensure that issues and risks that could challenge the success of Office of Environmental Management (EM) projects are identified early and addressed proactively. The internal EM project review process encompasses key milestones established by DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets*, DOE-STD-1189-2008, *Integration of Safety into the Design Process*, and EM's internal business management practices.

The SRP follows the Critical Decision (CD) process and consists of a series of Review Modules that address key functional areas of project management, engineering and design, safety, environment, security, and quality assurance, grouped by each specific CD phase.

This Review Module provides the starting point for a set of corporate Performance Expectations and Criteria. Review teams are expected to build on these and develop additional project-specific Lines of Inquiry, as needed. The criteria and the review process are intended to be used on an ongoing basis during the appropriate CD phase to ensure that issues are identified and resolved.

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<sup>1</sup> *The entire EM SRP and individual Review Modules can be accessed on the EM website at <http://www.em.doe.gov/pages/safety.aspx>, or on EM's Intranet portal at <https://ido.e.doe.gov/portal/server.pt> in the Programmatic/Project Management subdirectory.*

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## ABBREVIATIONS, ACRONYMS, and DEFINITIONS

ASME	American Society of Mechanical Engineers
CD	Critical Decision
CD-(N)	Critical Decision (Number)
CFR	Code of Federal Regulations
EM	Office of Environmental Management
FPD	Federal Project Director
IPT	Integrated Project Team
ISMS	Integrated Safety Management System
LOI	Lines of Inquiry
MS	Microsoft
NQA-1	Nuclear Quality Assurance-1
NRC	Nuclear Regulatory Commission
PEP	Project Execution Plan
PNNL	Pacific Northwest National Laboratory
QA	Quality Assurance
QAP	Quality Assurance Plan
QAR	Quality Assurance Review
QIP	Quality Assurance Implementation Plan
RM	Review Module
Safety Software.	Includes the following. <p>(1) <u>Safety System Software</u>. Software for a nuclear facility<sup>2</sup> that performs a safety function as part of a structure, system, or component and is cited in either (a) a DOE approved documented safety analysis or (b) an approved hazard analysis per DOE P 450.4, <i>Safety Management System Policy</i>, dated 10-15-96, and the DEAR clause. (DOE O 414.1C)</p> <p>(2) <u>Safety and Hazard Analysis Software and Design Software</u>. Software that is used to classify, design, or analyze nuclear facilities. This software is not part of a structure, system, or component (SSC) but helps to ensure the proper accident or hazards analysis of nuclear facilities or an SSC that performs a safety function. (DOE O 414.1C)</p> <p>(3) <u>Safety Management and Administrative Controls Software</u>. Software that performs a hazard control function in support of nuclear facility or radiological safety management programs or technical safety requirements or other software that performs a control function necessary to provide adequate protection from nuclear facility or radiological hazards. This</p>

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<sup>2</sup>Per 10 CFR 830, quality assurance requirements apply to all DOE nuclear facilities including radiological facilities (see 10 CFR 830, DOE STD 1120, and the DEAR ISMS clause).

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software supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in 10 CFR 830, 10 CFR 835, and the DEAR ISMS clause. (DOE O 414.1C)

SME Subject Matter Expert

SNL Sandia National Laboratory

Software Computer programs, procedures, and associated documentation and data pertaining to the operation of a computer system. (DOE O 414.1C, NQA-1-2000)

SQA Software Quality Assurance

SQAP Software Quality Assurance Plan

SQAR Software Quality Assurance Review

SSC Structure, System, or Component

STD Standard

## I. INTRODUCTION

As required by DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets*, Quality Assurance (QA) begins at project inception and continues through the project's life cycle. Each EM capital project is responsible for planning and implementing a Quality Assurance Program (QAP) for the project. This QAP must address the quality requirements and activities as they relate to software. Appropriate aspects of software quality assurance (SQA) need to be considered during the planning and preparation of project documents and execution of project activities. The project's application of SQA is typically an element of the organizational or project-specific QAP or the approved Quality Assurance Implementation Plan (QIP). Lower level plans, referred to as software quality assurance plans (SQAP), may provide details specific to software.

EM-QA-001, *Office of Environmental Management Quality Assurance Plan*, October 2008 (EM Corporate QAP) identifies the foundation for SQA. The EM QAP captures the QA requirements of 10 CFR 830 Part A, *Quality Assurance Requirements*, DOE O 414.1C, *Quality Assurance*, and American Society of Mechanical Engineers (ASME) NQA-1 2004, *Requirements for Quality Assurance Programs for Nuclear Facilities*, and addenda through 2007, and a series of management expectations. Collectively, they provide the technical basis for assessing the SQA activities for preparing Critical Decision documents and conducting project activities, as required by DOE O 413.3.A.

## II. PURPOSE OF THIS REVIEW MODULE

The purpose of this Software Quality Assurance for Capital Project Critical Decision Review Module (SQA RM) is to identify, integrate, and clarify, in one EM document, the SQA performance objectives, criteria, and guidance needed to review project documents and activities. Additionally, the purpose of this RM is to ensure that the deliverables developed during a particular CD phase and the criteria to ensure those activities are completed and have been performed satisfactorily. For each capital project, the SQA RM can be used as a starting point for both desktop and field reviews. It is expected that project-specific LOI are developed to supplement those of this RM.

This review module is applicable to software used in analysis and design of a facility as well as software used in and in support of the facility operations and maintenance processes. Software includes computer programs, procedures, and associated documentation and data pertaining to the operation of computer systems. Software may be developed or acquired for DOE use. Software includes spreadsheets, utility calculations, and database applications built using acquired software tools such as MS Excel and MS Access. This review module can be used standalone for a review specific to software quality assurance or in conjunction with other standard review modules. The primary objectives of this review module are:

- Assure that the results of software developed, acquired or configured for use in the analysis or design of a structure, system, or component (SSC) are correct and will not negatively affect the proper design or operation of the SSC.

- Assure that the software developed, acquired or configured for use in or in support of facility operations will perform as expected in the operational environment
- Assure that the software developed, acquired or configured is maintainable for its life time

### III. ROLES AND RESPONSIBILITIES

A critical element of Software Quality Assurance Review (SQAR) is the qualifications, training and most importantly, the experience of the personnel selected to conduct the review. To the maximum extent possible, the personnel selected to participate in the software quality assurance review should have “on the ground”, first-hand experience in software quality assurance and software engineering. Although the scope of the review may not include safety software, as a minimum personnel assigned to lead the SQAR team should have completed the *Department of Energy (DOE) Quality Assurance Functional Area Qualification Standard*, DOE-STD-1172-2003.

The core review team personnel should include individual(s) possessing qualification and experience in the following areas:

- Software Quality Assurance for DOE nuclear facilities
- Software Development
- Software Control and Monitoring Applications
- Analysis and Design Software
- Spreadsheets and database applications used as Engineering tools/aids

The core team will normally consist of one or more Subject Matter Experts (SMEs) independent of the project. If necessary, each team member will receive indoctrination and training associated with the project mission prior to conducting the evaluation. This core team can be augmented with additional technical personnel selected to complement any specific concerns of the project being reviewed (e.g. Chemical, Structural, Seismic, Instrument, Process, Mechanical Engineering, Construction, Decommissioning, Demolition, etc.).

Management support is another necessary component to a successful SQAR. Field element managers, as well as the Federal Project Director, must recognize the importance of the SQAR and facilitate the resources necessary for its execution. This also requires appropriate interfaces with EM headquarters personnel who may direct or participate in the SQAR process.

The structure, roles, and responsibilities of the individual review team members and others involved in the SQAR must be clear and consistent with the requirements of DOE O 413.3A, Change 1. The table below provides a compilation SQAR roles and responsibilities. The SQAR will typically be conducted in conjunction with a Quality Assurance review (QAR). However, it should not be limited to this approach. Should the SQAR be included with a QAR, the roles and responsibilities will be the same as the QAR roles and responsibilities.



The roles and responsibilities for all involved in the QA review must be clear and consistent. Table 1 provides a compilation of SQA review roles and responsibilities.

**Table 1 - Software Quality Assurance Review Roles and Responsibilities**

<b>Position</b>	<b>Responsibility</b>
Field Element Manager	Provides support and resources to the Federal Project Director and Review Team Leader in carrying out the review.
	Facilitates the conduct of the review. Assigns office space, computer equipment, and support personnel to the team as necessary to accomplish the review in the scheduled time frame
Federal Project Director	Identifies the need for a review and determines the scope of the review effort.
	In conjunction with the Contractor Project Manager, develops the briefing materials and schedule for the review activities.
	Coordinates the review team pre-visit activities and follows up review team requests for personnel to interview or material to review.
	Coordinates the necessary training and orientation activities to enable the review team members to access the facility and perform the review.
	Unless other personnel are assigned, acts as the site liaison with the review team. Tracks the status of requests for additional information.
	Coordinates the Federal site staff factual accuracy review of the draft report.
	Leads the development of the corrective action plan if required. Tracks the completion of corrective actions resulting from the review.
Review Team Leader	In coordination with the Federal Project Director, selects the areas to be reviewed.
	Based on the areas selected for review, project complexity and hazards involved, selects the members of the review team.
	Verifies the qualifications: technical knowledge; process knowledge; facility specific information; and independence of the Team Members.
	Leads the review pre-visit.
	Leads the review team in completing the Review Criteria for the various areas to be reviewed.
	Coordinates the development of the data call and forwards to the Federal Project Director, a list of documents, briefings, interviews, and presentations needed to support the review.
	Forwards the final review plan to the FPD and EM management for approval.

Position	Responsibility
	Leads the on-site review.
	Ensures the review team members complete and document their portions of the review and characterizes the findings.
	Coordinates incorporation of factual accuracy comments by Federal and Contractor personnel on the draft report.
	Forwards the final review report to the FPD and EM management for consideration in making the decision to authorize start of construction.
	Participates, as necessary in the closure verification of the findings from the review report.
Review Team Member	Refines and finalizes the criteria for assigned area of the review.
	Develops and provides the data call of documents, briefings, interviews, and presentations needed for his/her area of the review.
	Completes training and orientation activities necessary for the review. Conducts any necessary pre visit document review.
	Participates in the on-site review activities, conducts interviews, document reviews, walk downs, and observations as necessary.
	Based on the criteria and review approaches in the Review Plan, assesses whether his/her assigned criteria have been met.
	Documents the results of the review for his/her areas. Prepares input to the review report.
	Makes recommendations to the Review Team Leader for characterization of findings in his/her area of review.
	Resolves applicable Federal and Contractor factual accuracy comments on the draft review report.
	Prepares the final review report for his/her area of review.

#### IV. REVIEW SCOPE AND CRITERIA

The SQAR should be conducted in accordance with the process and criteria outlined in this review module. A project-specific assessment plan, based on the scope and nature of project activities will be prepared for each assessment. If the SQAR is included with the QAR, the SQA based scope and nature of the activities should be included in the QAR assessment plan. A separate assessment plan is not needed.

For consistency, this guide provides specific review topics and general lines of inquiry (LOI) to guide the overall review process. The Critical Decision review topics are described in the sections below. General lines of inquiry/principles for a Software Quality Assurance program

for facility operations are contained in Appendix A. These LOI have been developed from DOE O 413.3A, DOE O 414.1C, DOE G 413.3-14, DOE G 414.1-4 and NQA1-2004 including Addendum 2007. The LOI should be used as guidance when developing the project-specific detailed review plan.

*Review Topic CD-0, Project Approval of Mission Need*

This review topic focuses on the project documents and activities to adequately address software quality attributes and activities prior to CD-0 Approval of Mission Need. The review areas include: Pre-Conceptual Planning; Tailoring Strategy; and Mission Validation Independent Project Review. SQA activities conducted prior to the approval of CD-0 would include

Infrastructure software such as project scheduling tools and spreadsheets associated with project management are typically procured, validated, installed and approved for use in preparation for approval of CD-0.

*Review Topic CD-1, Approval of Alternative Selection and Cost Range*

This review topic focuses on the project documents and activities to adequately address software quality attributes and activities prior to CD-1 approval of Alternative Selection and Cost Range. The review areas include: Conceptual Design Report preparation; Acquisition Strategy preparation; Preliminary Project Execution Plan preparation; selection of the FPD; establishment of the IPT; and preparation of safety documents.

Typical software applications used in preparation for CD-1 approval determine the hazard categorization of the facility. This software may be simple spreadsheets created by MS Excel or databases build within MS Access. In addition to SQA activities performed for hazard categorization software, establishment of an SQA program and planning of SQA activities is conducted prior to the CD-1 approval.

*Review Topic CD-2, Approval of Performance Baseline*

This review topic focuses on the project documents and activities to adequately address software quality attributes and activities prior to CD-2 approval of Performance Baseline. The review areas include: Earned Value Management System preparation; design documents preparation, QAP preparation; safety documents preparations; and NEPA documents preparation.

In this CD phase, SQA planning, operational software specification, procurement of software used for hazard analysis and SSC design, and long lead procurements associated with software used during operations are initiated. The long lead procurements may include acquisition of development hardware and software for operational software such as the digital control system.

Software used in the hazard analysis and SSC design is frequently acquired software from either commercial vendors, other DOE sites such as Pacific Northwest National Laboratory (PNNL) or Sandia National Laboratory (SNL), other government agencies such as Nuclear Regulatory Commission (NRC) or Environmental Protection Agency (EPA) or the contractor's corporate

organization. In the instances when software is developed by the contractor's corporate organization, the software typically is considered custom-developed software.

*Review Topic CD-3, Approval of Start of Construction*

This review topic focuses on the project documents and activities to adequately address software quality attributes and activities prior to CD-3 approval of prior to Start of Construction. The review areas include: final design documents preparation; safety documents preparation; and updating of project management documents.

Typical software applications used in the preparation for CD-3 approval are used to identify the hazards and to design the facility and structures, systems, and components (SSC). Common SQA activities performed for the hazard analysis and SSC design software are validation and approval for use, configuration control, and approval for use.

Safety analysis and design software can be software developed using programming languages (e.g., C, Java, and FORTRAN) or software tools such as MS Excel. Frequently software is developed to interface between different software applications. A typical use for this type of software is to convert the output from one code modeling application such as GTSTRUDL to another such as SASSI. Other software applications may manipulate the output from an analysis or design code to display the output data in a different graphical representation than the original modeling code.

Spreadsheets are frequently used to support engineering calculations for the design of SSCs. These spreadsheets are software. However, depending upon the frequency of use, the validation of the results from these spreadsheets, company procedures, and other characteristics these spreadsheets may be exempt from some SQA activities.

Operational software, such as digital control systems and equipment surveillance databases need to be identified, functional requirements defined, software procurement options evaluated, and long lead procurements initiated.

*Review Topic CD-4, Approval of Start of Operations and Project Completion*

This review topic focuses on the project documents and activities to adequately address software quality attributes and activities prior to CD-4 approval of Start of Operations and Project Completion. The review areas include: conduct of Readiness Assessment or Operational Readiness Review; Commissioning Planning preparation; final safety documents preparation; Lessons Learned preparation; and conduct of Post Implementation Review.

Typical software applications that are involved in the activities prior to CD-4 approval are operational software applications and any software used to validate design changes. This software can include software developed or configured and downloaded to PLCs from the vendor or contractor, facility operator and maintenance staff human machine interfaces, equipment maintenance databases such as technical safety requirements maintenance schedules

& reporting, facility access control, personnel training databases, and worker and public safety monitoring systems.

## **V. REVIEW PLANS AND DOCUMENTATION**

The following activities should be conducted as part of the SQA review plan development and documentation/closure of the review. These activities can be conducted as part of a larger Quality Assurance review.

- Subsequent to the selection, formation and chartering of the review team and receipt and review of the prerequisite documents; assignment of responsibilities for the development of specific lines of inquiry should be made.
- The review team members should develop specific lines of inquiry utilizing the topics and areas listed in the respective appendices of this guide.
- The individual lines of inquiry should be compiled and submitted to the manager authorizing the review for concurrence prior to starting the review. Once approved by the manager they should be provided to the organization being reviewed along with a schedule for the planned assessment.
- The project-specific review plan should be compiled with a consistent and uniform numbering scheme that provided for a unique identifier for each line of inquiry, arranged by subject area such that the results of each line of inquiry can be documented and tracked to closure.
- The lines of inquiry should be satisfied via document review and personnel interviews and any combination of these methods. For the field assessment, these techniques are augmented by the direct observation of work to verify procedure execution as appropriate. The method used the basis for closure/comment/finding and the result of the inquiry should all be documented and tracked.

## **VI. REFERENCE MATERIAL**

1. 10 CFR 830, Subpart A, *Quality Assurance Requirements*
2. ASME NQA-1 2004, Part I: *Requirements for Quality Assurance Programs for Nuclear Facilities*, and addenda through 2007
3. ASME NQA-1 2004, Part II, Subpart 2.7: *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*, and addenda through 2007
4. DOE Guide 200.1-1, *Software Engineering Methodology*
5. DOE Guide 413.3-14, *Information Technology Project Guide*

6. DOE Guide 414.1-4, *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance*
7. DOE O 200.1A, *Information Technology Management*
8. DOE O 413.3A, Change 1, *Program and Project Management for the Acquisition of Capital Assets*
9. DOE O 414.1C, *Quality Assurance*

## **APPENDIX A: SQA Performance Objectives and Criteria for Review of Critical Decision (CD) Documents and Activities**

### **I. PURPOSE**

The purpose of this Appendix is to provide a breakdown of the key requirements/deliverables for projects as identified in DOE O 413.3A, Table 2 and the roles and responsibilities with regard to each of these items. The Performance Objectives and LOIs provided in this Chapter are organized by CD as they are identified in the DOE Order. Each of the key deliverables for the CD is then identified and the role or application of SQA to the evaluation of the adequacy of the specific deliverable is defined in the Performance Objectives and LOIs.

### **II. APPLICATION**

This Appendix can be applied in a variety of ways; however, its structure is particularly focused on application to the review of deliverables for review and approval of a particular CD. Should there be a desire to broaden the review the coordination of this chapter with the subsequent chapters will provide a simple means to evaluate the SQA program and the adequacy of its integration into the project and associated deliverables.

**Table 2: Legend of Software Quality Assurance Review Topics**

<b>Review Topical Area</b>	<b>Identifier</b>
Project Approval of Mission Need	CD-0
Approval of Alternative Selection and Cost Range	CD-1
Approval of Performance Baseline	CD-2
Approval of Start of Construction	CD-3
Approval of Start of Operations and Project Completion	CD-4



ID #	Performance Objectives and Criteria	Met?
<i>Project Approval of Mission Need</i>		
CD-0	<i>Software Project Management and Quality Planning</i>	
	<i>Criterion 1 – Program. For performing <b>Pre-Conceptual Planning</b> activities, is software project management integrated as part of the system level project management and quality planning? (CD-0.1)</i>	
	<i>Criterion 1 – Program. Does the Pre-Conceptual Planning address at a minimum software used to support engineering and safety calculations and the acquisition, development, configuration, testing and installation of software used during facility operations (i.e., digital control system, TSR surveillances)? (CD-0.2)</i>	
	<i>Criterion 1 – Program. For performing <b>Mission Validation Independent Project Review</b> is SQA expertise included? (CD-0.3)</i>	

ID #	Performance Objectives and Criteria	Met?
<i>Approval of Alternative Selection and Cost Range</i>		
CD-1	<i>Software Project Management and Quality Planning</i>	
	<i>Criterion 1 – Program. Does the <b>Project Execution Plan</b> incorporate policies and procedures to manage and control the major software activities? (CD-1.1)</i>	
	<i>Criterion 1 – Program. Do project management and quality plans identify upper level tasks associated with the software development, use and acquisition, including procurement of services, estimate of the duration of the tasks, resources allocated to the task, and any dependencies? (CD-1.2)</i>	
	<i>Criterion 1 – Program. Does the <b>Quality Assurance Program</b> address all applicable requirements from 10 CFR 830 and DOE O 414.1C as they are applied to software? (CD-1.3)</i>	
	<i>Criterion 1 – Program. Do quality plans address acquired, custom developed, and embedded (i.e., firmware, PLC) software, including safety software (as defined in DOE Order 414.1C paragraph 7.0)? (CD-1.4)</i>	
	<i>Graded Approach</i>	
	<i>General Requirements. Do quality plans include a grading system to be applied to all software? (CD-1.5)</i>	
	<i>General Requirement. Is that grading system to be applied to safety software equivalent to the Level A, B, and C grading criteria in DOE Guide 414.1-4 Section 2.2? (CD1-6)</i>	
	<i>Software Risk Management</i>	
	<i>Criterion 1 – Program. Do plans, (e.g., <b>Project Execution Plan</b> and <b>Risk Management Plan</b>) for risk management activities address risks associated with software? (CD-1.7)</i>	
	<i>Criterion 1 – Program. Do plans, (e.g., <b>Project Execution Plan</b> and <b>Risk Management Plan</b>) include special emphasis on tracking the software risks associated with costs, resources, schedules, and technical aspects of the project? (CD-1.8)</i>	
	<i>Software Configuration Management</i>	
	<i>Criterion 5 – Work Processes. Are software configuration management work activities applied beginning at the point of DOE’s or its contractor’s control of the software, including the creation of or receipt of software documentation? (CD-1.9)</i>	

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Alternative Selection and Cost Range</i></b>		
	<p><i>Criterion 4 – Documents and Records.</i> Do software quality plans or procedures address the following software configuration management activities: (1) configuration identification, (2) configuration control, (3) configuration status accounting, and (4) configuration audits and reviews? <b>(CD-1.10)</b></p> <ul style="list-style-type: none"> <li>• the methods used to control, uniquely identify, describe, and document the configuration of each version or update of software and its related documentation should be described in the software quality plans?</li> <li>• documentation should include criteria for configuration identification, change control, configuration status accounting, and configuration reviews and audits.</li> <li>• a baseline labeling system that uniquely identifies each configuration item, identifies changes to configuration items by revision, and provides the ability to uniquely identify each configuration should be described in the software quality plans.</li> </ul>	
<b><i>Procurement and Supplier Management</i></b>		
	<p><i>Criterion 4 – Documents and Records.</i> Do procurement plans or procedures include software procurement controls that are based upon the level of control DOE or its contractors have on the quality of the software or software service being procured and the complexity of the software? <b>(CD-1.11)</b></p> <ul style="list-style-type: none"> <li>• The grading levels in procurement plans should match the grading levels in the quality planning documents</li> </ul>	
	<p><i>Criterion 4 – Documents and Records.</i> Do procurement plans or procedures identify the requirements for suppliers to report problems to the supplier, any required supplier response, and the method for the purchasers to report problems to the supplier? <b>(CD-1.12)</b></p>	
	<p><i>Criterion 7 – Procurement.</i> Does the <b>Acquisition Strategy</b> address software used for process and safety controls? <b>(CD1.13)</b></p>	
<b><i>Software Requirements Identification and Management</i></b>		
	<p><i>Criterion 5 – Work Processes –</i> Does the <b>Conceptual Design Report</b> describe clearly and concisely how software, including software embedded within equipment, will be used within the facility? <b>(CD-1.14)</b></p>	
	<p><i>Criterion 4 – Documents and Records.</i> Do software quality plans or procedures state that software requirements include functional; performance; security (including user access control); interface and safety requirements; and installation considerations and design constraints where appropriate? <b>(CD-1.15)</b></p>	

ID #	Performance Objectives and Criteria	Met?
<i>Approval of Alternative Selection and Cost Range</i>		
	<i>Software Safety</i>	
	<i>Criterion 5 – Work Processes.</i> As part of the conceptual design stage, does the <b>Preliminary Hazard Analysis Report</b> identify and evaluate potential failures in software for their consequences of failure and probability of occurrence? <b>(CD-1.16)</b>	
	<i>Verification and Validation</i>	
	<i>Criterion 4 – Documents and Records.</i> Do software quality plans or procedures address the need for verification to be performed throughout the life-cycle of the safety software? <b>(CD-1.17)</b>	
	<i>Criterion 4 – Documents and Records.</i> Do software quality plans or procedures require validation activities to be performed at the end of the software development or acquisition processes to ensure the software meets the intended requirements? <b>(CD-1.18)</b>	
	<i>Criterion 4 – Documents and Records.</i> Do software quality plans or procedures require V&V activities to be performed by competent staff other than those who developed the item being verified or validated? <b>(CD-1.19)</b>	
	<i>Criteria 6 – Design.</i> Does the <b>Conceptual Design Review</b> include a review of the software associated with the process and safety control systems? <b>(CD-1.20)</b>	
	<i>Problem Reporting and Corrective Action</i>	
	<i>Criterion 1- Program.</i> Is software problem reporting and corrective action part of the overall quality system problem reporting and corrective action system? <b>(CD-1.21)</b>	
	<i>Criterion 3 – Quality Improvement.</i> Does the reporting and corrective action system cover (1) methods for documenting, evaluating and correcting software problems; (2) an evaluation process for determining whether a reported problem is indeed a defect or an error; and (3) the roles and responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation? <b>(CD-1.22)</b>	
	<i>Training of Personnel</i>	
	<i>Criterion 2 –</i> Does the <b>Integrated Project Team</b> charter include at least 1 member to address the technical and quality aspects required for software used in SSC design and facility operations? <b>(CD-1.23)</b>	

ID #	Performance Objectives and Criteria	Met?
<i>Approval of Alternative Selection and Cost Range</i>		
	<i>Criterion 2 – Personnel Training and Qualification.</i> Do quality plans identify training needs for the analyst, development and test teams, application users, and operations staff involved with safety software? <b>(CD-1.24)</b>	
	<i>Consensus Standards</i>	
	<i>General Requirements –</i> Do quality plans identify the consensus standard(s) to be applied to software development, use and acquisition? <b>(CD-1.25)</b>	
	<i>General Requirements –</i> For safety software, do these consensus standard(s) meet the requirements in DOE O 414.1C Attachment 2, Section 5? <b>(CD-1.26)</b>	

ID #	Performance Objectives and Criteria	Met?
<i>Approval of Performance Baseline</i>		
CD-2	<b><i>Software Project Management and Quality Planning</i></b>	
	<i>Criterion 1 – Program.</i> Does the <b>Performance Baseline</b> include key performance parameters, costs and schedule for the facility’s major software systems (e.g., digital control system)? <b>(CD-2.1)</b>	
	<i>Criterion 1 – Program.</i> Are the software project management and quality plans for both the software used in designing and operating the facility updated to identify lower level tasks associated with the software development and procurement, including procurement of services, description of task, estimate of the duration of the tasks, resources allocated to the task, and any dependencies? <b>(CD-2.2)</b>	
<b><i>Graded Approach</i></b>		
	<i>General Requirements.</i> Is the grading system defined and approved during CD-1, effectively applied to all software? <b>(CD-2.3)</b>	
<b><i>Software Risk Management</i></b> <sup>3</sup>		
	<i>Criterion 5 – Work Processes.</i> Has the Risk Management Plan or other software specific risk management plan been updated to reflect new or modified risks and their mitigation approaches and any changes in priorities? <b>(CD-2.4)</b>	
<b><i>Software Configuration Management</i></b>		
	<i>Criterion 5 – Work Processes.</i> Do software configuration management work activities for software continue to be applied at the point of DOE’s or its contractor’s control of the software? <b>(CD-2.5)</b>	
	<i>Criterion 5 – Work Processes.</i> Is a baseline labeling system that uniquely identifies each configuration item, identifies changes to configuration items by revision, and provides the ability to uniquely identify each configuration been implemented? <b>(CD-2.6)</b>	
	<i>Criterion 4 – Documentation and Records.</i> Do software change procedures require proposed changes to the software to be documented, evaluated, and approved for release? <b>(CD-2.7)</b>	
	<p><i>Criterion 5 – Work Processes.</i> Are software verification activities performed after a change to ensure the change was implemented correctly? <b>(CD-2.7)</b></p> <ul style="list-style-type: none"> <li>• verification should include changes to the software documentation.</li> </ul>	

<sup>3</sup> This activity does not apply to commercial design and analysis safety software.

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Performance Baseline</i></b>		
	<i>Criterion 4 – Documentation and Records.</i> Do software configuration management procedures define the level of configuration control based upon the results of software grading? <b>(CD-2.8)</b>	
	<b><i>Procurement and Supplier Management<sup>4</sup></i></b>	
	<i>Criterion 7 – Procurement.</i> Do software procurement activities include controls that are based upon the level of control DOE or its contractors have on the quality of the software or software service being procured and the complexity of the software? <b>(CD-2.9)</b> <ul style="list-style-type: none"> <li>• The grading levels in procurement plans should match the grading levels in the quality planning documents</li> </ul>	
	<i>Criterion 7 – Procurement.</i> Do procurement documents identify the requirements for purchasers to report problems to the supplier, the method for the purchasers to report problems to the supplier, and any required supplier response? <b>(CD-2.10)</b>	
	<i>Criterion 7 – Procurement.</i> Do procurement documents require that procurement documentation include the technical and quality requirements for the safety software? <b>(CD-2.11)</b>	
	<i>Criterion 7 – Procurement.</i> Are procurement documents assessed for completeness, and to ensure the quality of the software being purchased? <b>(CD-2.12)</b>	
	<b><i>Software Requirements Identification and Management<sup>5</sup></i></b>	
	<i>Criterion 5 - Work Processes.</i> Do software requirements identify functional; performance; security (including user access control); interface and safety requirements; and installation considerations and design constraints where appropriate? <b>(CD-2.13)</b>	
	<i>Criterion 7 - Procurement.</i> Are software requirements traceable to software procurement documents? <b>(CD-2.14)</b>	
	<i>Criterion 5 – Work Processes.</i> Are software requirements traceable to software life cycle documents? <b>(CD-2.15)</b>	
	<b><i>Software Design and Implementation</i></b>	
	<i>Criterion 5 – Work Processes.</i> Is the preliminary software design complete and sufficient to satisfy the software requirements? <b>(CD-2.16)</b>	

<sup>4</sup> Levels A, B, and C software applications are required to fully meet these items but application can be graded based upon complexity and importance to safety

<sup>5</sup> Software requirements identification management and traceability applies to Level A, B, and C software applications and should fully meet this requirement (no grading in this topic)

ID #	Performance Objectives and Criteria	Met?
<b>Approval of Performance Baseline</b>		
	<i>Criterion 5 – Work Processes.</i> Does the preliminary software design identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and design constraints? <b>(CD-2.17)</b>	
	<i>Criterion 4 – Documentation and Records.</i> Do software development procedures state that software developers should perform unit testing prior to system level V&V techniques, including acceptance testing? <b>(CD-2.18)</b>	
	<i>Criterion 4 – Documentation and Records.</i> Do software procedures implement a grading system that requires all elements of software design engineering to be implemented for Levels A, B, and C custom developed software applications? <b>(CD-2.19)</b>	
	<b>Software Safety</b>	
	<i>Criterion 6 – Design.</i> Do preliminary designs for software with a grade level equivalent to Level A custom developed safety software include simplicity of modules that perform safety functions and isolation of those modules as a design consideration? <b>(CD-2.20)</b> <ul style="list-style-type: none"><li>• Custom developed, configurable, and acquired software with a grade level equivalent to Level B or Level C software applications may be graded</li></ul>	
	<i>Criterion 6 – Design.</i> Do preliminary software application designs include identification of hazards (i.e., abnormal conditions and events) that have the potential for defeating a safety function and the implementation of design strategies to eliminate or mitigate those hazards? <b>(CD-2.21)</b>	
	<i>Criterion 6 – Design.</i> Do preliminary designs include methods to mitigate the consequences of software failures? <b>(CD-2.22)</b>	
	<i>Criterion 6 – Design.</i> Do software design concepts include integration with safety analysis to identify and evaluate potential software failures for their consequences of failure and probability of occurrence? <b>(CD-2.23)</b>	
	<i>Criterion 6 – Design.</i> Do preliminary software designs separate software modules performing functions important to safety from non-safety modules? <b>(CD-2.24)</b>	
	<i>Criterion 6 – Design.</i> Do preliminary software designs include process flow analysis, data flow analysis, path analysis, interface analysis, and interrupt analysis? <b>(CD-2.25)</b>	



ID #	Performance Objectives and Criteria	Met?
<b>Approval of Performance Baseline</b>		
	<b>Verification and Validation</b>	
	<i>Criterion 5 – Work Processes.</i> Are verification activities being performed for software? <b>(CD-2.26)</b>	
	<i>Criterion 8 – Inspection and Acceptance Testing.</i> Do procedures require validation activities to be performed at the end of the software development or acquisition processes to ensure the software meets the intended requirements? <b>(CD-2.27)</b>	
	<i>Criterion 2 – Personnel Training and Qualification.</i> Are V&V activities performed by competent staff other than those who developed the item being verified or validated <b>(CD-2.28)</b> ?	
	<i>Criterion 5 – Work Processes.</i> Are software requirements traced to the software design? <b>(CD-2.29)</b>	
	<i>Criterion 7 – Procurement.</i> Do V&V activities include supplier assessments where appropriate? <b>(CD-2.30)</b>	
	<i>Criterion 4 – Documents and Records.</i> Are software tests described in test plans containing objective acceptance criteria? <b>(CD-2.31)</b>	
	<i>Criterion 5 – Work Processes.</i> Are test activity documents placed under configuration management? <b>(CD-2.32)</b>	
	<i>Criterion 8 – Inspection and Acceptance Test.</i> When new versions of software tools are obtained are predetermined and ad-hoc test cases and procedures performed to validate that, the system meets the requirements and does not perform any unintended functions? <b>(CD-2.33)</b>	
	<p><i>Criterion 5 – Work Processes.</i> Is grading properly applied to V&amp;V activities? <b>(CD-2.34)</b></p> <ul style="list-style-type: none"> <li>• Software with a grading equivalent to Level A safety software all deliverables should be reviewed using V&amp;V methods, and traceability of the requirements to the design and from requirements to test cases should be performed</li> <li>• Software with a grading equivalent to Level B safety software, deliverables that include requirements, test plans and procedures, and test results should be reviewed using V&amp;V methods</li> </ul>	

ID #	Performance Objectives and Criteria	Met?
<i>Approval of Performance Baseline</i>		
	<b><i>Problem Reporting and Corrective Action<sup>6</sup></i></b>	
	<i>Criterion 3 – Quality Improvement.</i> Are software problem and corrective action reports included in the overall quality system problem reporting and corrective action system? <b>(CD-2.35)</b>	
	<p><i>Criterion 3 – Quality Improvement.</i> Does the software problem reporting and corrective action system: <b>(CD-2.36)</b></p> <ul style="list-style-type: none"> <li>• Include methods for documenting, evaluating and correcting software problems;</li> <li>• Include an evaluation process for determining whether a reported problem is indeed a defect or an error;</li> <li>• Include the roles and responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation;</li> <li>• correlate the error with the appropriate software engineering elements; <ul style="list-style-type: none"> <li>– identify the potential impacts and risks to past, present, and future developmental and operational activities;</li> <li>– support the development of mitigation strategies; and</li> </ul> </li> <li>• apprise all users of errors to ascertain any impacts upon safety basis decisions?</li> </ul>	
<b><i>Training of Personnel in Safety Software</i></b>		
	<i>Criterion 2 – Personnel Training and Qualification.</i> Are training needs for the analyst, development and test teams, and application users identified? <b>(CD-2.37)</b>	
	<i>Criterion 2 – Personnel Training and Qualification.</i> Are training plans commensurate with the scope, complexity, and importance of the tasks and the education, experience, and proficiency of the individual? <b>(CD-2.38)</b>	
	<i>Criterion 2 – Personnel Training and Qualification.</i> Is completion of training, education, and/or qualification requirements for all staff involved in the development, testing, use, and evaluation of custom developed or configurable software graded as Level A, B, or C documented and periodically reviewed? <b>(CD-2.39)</b>	

<sup>6</sup> This activity should be fully implemented for all Level A and B software types (custom developed, acquired, configurable, and commercial design and analysis) and for Level C custom developed. A graded approach that reduces the formality of documenting problem reports and approving corrective actions taken may be applied for Level A and B utility calculation safety software and all Level C software applications except custom developed.

ID #	Performance Objectives and Criteria	Met?
<b>Approval of Performance Baseline</b>		
	<p><i>Criterion 2 – Personnel Training and Qualification.</i> Is completion of training, education, and/or qualification requirements for all staff involved in the procurement, testing, use, and evaluation of acquired or utility calculation software graded as Level A documented and periodically reviewed? <b>(CD-2.40)</b></p>	
	<p><b>Software Identification &amp; Registry</b></p>	
	<p><i>General Requirements.</i> Is all software to be used during the project design and construction phases identified? Does this identification contain the following: unique identifier, software name, version identifier, safety software designation, any grade level description, and responsible individual? <b>(CD-2.41)</b></p> <ul style="list-style-type: none"> <li>• Safety software is the only software required to be included in an inventory with the above attributes. However, best practices necessitate the identification of software to perform the proper level of quality assurance.</li> </ul>	
	<p><i>General Requirements.</i> Is this inventory maintained? <b>(CD-2.42)</b></p> <ul style="list-style-type: none"> <li>• Safety software is the only software required to be included in an inventory with the above attributes. However, best practices necessitate the identification of software to perform the proper level of quality assurance.</li> </ul>	
	<p><i>General Requirement.</i> What consensus standard(s) are being applied to software that will be developed, maintained, or procured and used during the project design and construction phases? <b>(CD-2.43)</b></p> <ul style="list-style-type: none"> <li>• For safety software, the consensus standard must be either ASME NQA-1-2000, ASME NQA-1-2008, or other DOE approved consensus standard.</li> </ul>	
	<p><i>General Requirement.</i> Have DOE guides for quality assurance and software quality assurance been considered for use? <b>(CD-2.44)</b></p>	

ID #	Performance Objectives and Criteria	Met?
<b>Approval of Start of Construction</b>		
CD-3	<b>Software Project Management and Quality Planning<sup>7</sup></b>	
	<i>Criterion 1 – Program.</i> Do software project management and quality plans reflect all tasks associated with the software development and procurement; including procurement of services, estimate of the duration of the tasks, resources allocated to the task, and any dependencies? <b>(CD-3.1)</b>	
	<b>Graded Approach</b>	
	<i>General Requirements:</i> Is the grading system applied to all software? <b>(CD-3.2)</b>	
	<i>General Requirements.</i> Is the system for grading safety software equivalent to Levels A, B, and C per DOE Guide 414.1-4? <b>(CD-3.3)</b>	
	<b>Software Risk Management<sup>8</sup></b>	
	<i>Criterion 5 – Work Processes.</i> Has the Risk Management Plan or other software specific risk management plan been updated to reflect new or modified risks and their mitigation approaches and any changes in priorities? <b>(CD-3.4)</b>	
	<b>Software Configuration Management</b>	
	<i>Criterion 5 – Work Processes.</i> Do software configuration management work activities for software continue to be applied at the point of DOE’s or its contractor’s control of the software? <b>(CD-3.5)</b>	
	<i>Criterion 5 – Work Processes.</i> Has a process for identifying, controlling, and validating software to be used during operations been defined and implemented? <b>(CD-3.6)</b>	
	<i>Criterion 5 – Work Processes:</i> Are software configuration items associated with software to be used during operations identified? <b>(CD-3.7)</b>	
	<i>Criterion 5 – Work Processes.</i> Has a baseline labeling system that uniquely identifies each configuration item, identifies changes to configuration items by revision, and provides the ability to uniquely identify each configuration been developed and implemented? <b>(CD-3.8)</b>	
	<i>Criterion 3 – Quality Improvement.</i> Are proposed software changes documented, evaluated, and approved for release? <b>(CD-3.9)</b>	

<sup>7</sup> does not apply to commercial design and analysis software because the project management and quality planning activities associated with commercial design and analysis software are performed by the service supplier

<sup>8</sup> This activity does not apply to commercial design and analysis safety software.

ID #	Performance Objectives and Criteria	Met?
<b>Approval of Start of Construction</b>		
	<i>Criterion 3 – Quality Improvement.</i> Are only approved changes made to the software that has been baselined? <b>(CD-3.10)</b>	
	<i>Criterion 5 – Work Processes.</i> Is software verification performed after a change to ensure the change was implemented correctly? <b>(CD-3.11)</b>	
	<i>Criterion 5 – Work Processes.</i> Do verification activities include changes to the software documentation? <b>(CD-3.12)</b>	
	<i>Criterion 5 – Work Processes.</i> Are software configuration audits or reviews performed to verify that the software product is consistent with the configuration item descriptions in the requirements and that the software, including all documentation, being delivered is complete? <b>(CD-3.13)</b>	
	<i>Criterion 5 – Work Processes.</i> Are software configuration management activities implemented based upon the results of software grading? <b>(CD-3.14)</b>	
	<i>Criterion 6 - Design.</i> Are authorized users lists implemented to ensure that use of operational software is limited to those persons trained and authorized to use the software? <b>(CD-3.15)</b>	
	<b><i>Procurement and Supplier Management<sup>9</sup></i></b>	
	<i>Criterion 7 – Procurement.</i> Do software procurement activities include controls that are based upon the level of control DOE or its contractors have on the quality of the software or software service being procured and the complexity of the software? <b>(CD-3.16)</b>	
	<i>Criterion 7 – Procurement.</i> Do the grading levels in procurement plans match the grading levels in the quality planning documents? <b>(CD-3.17)</b>	
	<i>Criterion 7 – Procurement.</i> Do procurement documents identify the requirements for purchasers to report problems to the supplier, the method for the purchasers to report problems to the supplier, and any required supplier response? <b>(CD-3.18)</b>	
	<i>Criterion 7 – Procurement.</i> Do procurement documents include the technical and quality requirements for safety software? <b>(CD-3.19)</b>	
	<i>Criterion 4 - Inspection and Acceptance Testing.</i> Are evaluations performed on purchased software to ensure that the delivered software completely meets the software requirements specified in the procurement documents? <b>(CD-3.20)</b>	

<sup>9</sup> Levels A, B, and C software applications are required to fully meet these items but application can be graded based upon complexity and importance to safety

ID #	Performance Objectives and Criteria	Met?
<b>Approval of Start of Construction</b>		
	<b><i>Software Requirements Identification and Management</i></b>	
	<i>Criterion 6 – Design.</i> Are system requirements translated into requirements specific for the software (i.e. are the requirements generated for software derived from the safety system requirements?) <b>(CD-3.21)</b>	
	<i>Criterion 6 – Design.</i> Do software requirements identify functional; performance; security (including user access control); interface and safety requirements; and installation considerations and design constraints where appropriate? <b>(CD-3.22)</b>	
	<i>Criterion 7 - Procurement.</i> Are software requirements traceable to software procurement documents? <b>(CD-3.23)</b>	
	<i>Criterion 5 – Work Processes.</i> Are software requirements traceable to software life cycle documents? <b>(CD-3.24)</b>	
	<b><i>Software Design and Implementation</i></b>	
	<i>Criterion 6 – Design.</i> Are software design documents complete and describe a design that is sufficient to meet the software requirements? <b>(CD-3.25)</b>	
	<i>Criterion 6 – Design.</i> Do software design documents identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and design constraints? <b>(CD-3.26)</b>	
	<i>Criterion 6 – Design.</i> Do software designs describe how the software will interface with other system components? <b>(CD-3.27)</b>	
	<i>Criterion 6 – Design.</i> Do software developers perform unit testing prior to system level V&V techniques, including acceptance testing? <b>(CD-3.28)</b>	
	<i>Criterion 6 – Design.</i> Are all elements of software design engineering implemented for software with grade levels equivalent to Levels A, B, and C custom developed software applications? <b>(CD-3.29)</b>	
	<b><i>Software Safety</i></b>	
	<p><i>Criterion 6 – Design.</i> Do designs for software with grade levels equivalent to Level A custom developed safety software include simplicity of modules that perform safety functions and isolation of those modules as a design consideration? <b>(CD-3.30)</b></p> <ul style="list-style-type: none"> <li>• Custom developed, configurable, and acquired software with grade levels equivalent to Level B or Level C software applications may be graded</li> </ul>	

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Construction</i></b>		
	<i>Criterion 6 – Design.</i> Do software application designs include identification of hazards (i.e., abnormal conditions and events) that have the potential for defeating a safety function? <b>(CD-3.31)</b>	
	<i>Criterion 6 – Design.</i> Do safety software designs consider principles of simplicity, decoupling, and isolation to eliminate the hazards? <b>(CD-3.32)</b>	
	<i>Criterion 6 – Design.</i> Do designs include methods to mitigate the consequences of software failures? <b>(CD-3.33)</b>	
	<i>Criterion 6 – Design.</i> Do safety software designs include integration with safety analysis to identify and evaluate potential software failures for their consequences of failure and probability of occurrence? <b>(CD-3.34)</b>	
	<i>Criterion 6 – Design.</i> Do software designs separate software modules performing functions important to safety from non-safety modules? <b>(CD-3.35)</b>	
	<i>Criterion 6 – Design.</i> Do software designs include process flow analysis, data flow analysis, path analysis, interface analysis, and interrupt analysis? <b>(CD-3.36)</b>	
<b><i>Verification and Validation</i></b>		
	<i>Criterion 5 – Work Processes.</i> Are verification activities being performed for software in all lifecycle phases? <b>(CD-3.37)</b>	
	<i>Criterion 4 - Inspection and Acceptance Testing.</i> Are validation activities performed at the end of the software development or acquisition processes to ensure the software meets the intended requirements? <b>(CD-3.38)</b>	
	<i>Criterion 2 – Personnel Training and Qualification.</i> Are V&V activities performed by competent staff other than those who developed the item being verified or validated? <b>(CD-3.39)</b>	
	<i>Criterion 5 – Work Processes.</i> Are reviews and inspections being performed on software deliverables, requirement specifications, procurement documents, software design, code modules, test results, training materials, user documentation, and processes that guide the software development activities? <b>(CD-3.40)</b>	
	<i>Criterion 5 – Work Processes.</i> Do V&V activities include traceability of the software requirements into the software design? <b>(CD-3.41)</b>	

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Construction</i></b>		
	<i>Criterion 5 – Work Processes.</i> Have methods for V&V testing for utility calculations (spreadsheets, macros, etc.) been specified? <b>(CD-3.42)</b>	
	<i>Criterion 5 – Work Processes.</i> Has verification of the software design been completed prior to approval of the software for use? <b>(CD-3.43)</b>	
	<i>Criterion 7 – Procurement.</i> Do V&V activities include supplier assessments where appropriate? <b>(CD-3.44)</b>	
	<i>Criterion 5 – Work Processes.</i> Are software tests described in test plans containing objective acceptance criteria? <b>(CD-3.45)</b>	
	<i>Criterion 5 – Work Processes.</i> Have test cases and procedures that refer to the software requirements, including expected results, been created? <b>(CD-3.46)</b>	
	<i>Criterion 5 – Work Processes.</i> Are test activity documents placed under configuration management? <b>(CD-3.47)</b>	
	<i>Criterion 4 - Inspection and Acceptance Testing.</i> When new versions of software tools are obtained are predetermined and ad-hoc test cases and procedures performed to validate that, the system meets the requirements and does not perform any unintended functions? <b>(CD-3.48)</b>	
	<p><i>General Requirements.</i> Is grading properly applied to V&amp;V activities? <b>(CD-3.49)</b></p> <ul style="list-style-type: none"> <li>• For all Level A safety software except utility calculations, acceptance testing work activities should be planned and documented</li> <li>• Level A safety software all deliverables should be reviewed using V&amp;V methods, and traceability of the requirements to the design and from requirements to test cases should be performed</li> <li>• For Level B safety software, deliverables that include requirements, test plans and procedures, and test results should be reviewed using V&amp;V methods</li> </ul>	
<b><i>Problem Reporting and Corrective Action</i></b>		
	<i>Criterion 3 - Quality Improvement.</i> Are software problem reporting and corrective action part of the overall quality system problem reporting and corrective action system? <b>(CD-3.50)</b>	



ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Construction</i></b>		
	<p><i>Criterion 3 – Quality Improvement.</i> Does the software problem reporting and corrective action system: <b>(CD-3.51)</b></p> <ul style="list-style-type: none"> <li>• Include methods for documenting, evaluating and correcting software problems;</li> <li>• Include an evaluation process for determining whether a reported problem is indeed a defect or an error;</li> <li>• Include the roles and responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation;</li> <li>• correlate the error with the appropriate software engineering elements;</li> <li>• identify the potential impacts and risks to past, present, and future developmental and operational activities;</li> <li>• support the development of mitigation strategies; and</li> <li>• apprise all users of errors to ascertain any impacts upon safety basis decisions?</li> </ul>	
<b><i>Training of Personnel in Safety Software</i></b>		
	<p><i>Criterion 2—Personnel Training and Qualification.</i> Are training needs for the analyst, development and test teams, and application users identified? <b>(CD-3.52)</b></p>	
	<p><i>Criterion 2—Personnel Training and Qualification.</i> Are training plans commensurate with the scope, complexity, and importance of the tasks and the education, experience, and proficiency of the individual? <b>(CD-3.53)</b></p>	
	<p><i>Criterion 2—Personnel Training and Qualification.</i> Is completion of training, education, and/or qualification requirements for all staff involved in the development, testing, use, and evaluation of custom developed or configurable software graded as Level A, B, or C documented and periodically reviewed? <b>(CD-3.54)</b></p>	
	<p><i>Criterion 2—Personnel Training and Qualification.</i> Is completion of training, education, and/or qualification requirements for all staff involved in the procurement, testing, use, and evaluation of acquired or utility calculation software graded as Level A documented and periodically reviewed? <b>(CD-3.55)</b></p>	
<b><i>Software Identification &amp; Registry</i></b>		
	<p><i>General Requirements.</i> Is all software to be used during the project design, construction and operations phases identified? Does this identification contain the following: unique identifier, software name,</p>	

ID #	Performance Objectives and Criteria	Met?
<i>Approval of Start of Construction</i>		
	version identifier, safety software designation, any grade level description, and responsible individual? <b>(CD-3.56)</b> <ul style="list-style-type: none"> <li>• Safety software is the only software required to be included in an inventory with the above attributes. However, best practices necessitate the identification of software to perform the proper level of quality assurance.</li> </ul>	
	<i>General Requirements.</i> Is this inventory maintained? <b>(CD-3.57)</b> <ul style="list-style-type: none"> <li>• Safety software is the only software required to be included in an inventory with the above attributes. However, best practices necessitate the identification of software to perform the proper level of quality assurance.</li> </ul>	
<i>Consensus Standard and Guidance Use</i>		
	<i>General Requirement.</i> What consensus standard(s) are being applied to software that will be developed, maintained, or procured and used during the project design and construction phases? <b>(CD-3.58)</b> <ul style="list-style-type: none"> <li>• For safety software, the consensus standard must be either ASME NQA-1-2000, ASME NQA-1-2008, or other DOE approved consensus standard.</li> </ul>	
	<i>General Requirement.</i> Have DOE guides for quality assurance and software quality assurance been considered for use? <b>(CD-3.59)</b>	

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Operations and Project Completion</i></b>		
CD-4	<b><i>Software Project Management and Quality Planning<sup>10</sup></i></b>	
	<i>Criterion 1 – Program.</i> Do the software project management activities align with both integration and startup testing? <b>(CD-4.1)</b>	
	<b><i>Graded Approach</i></b>	
	<i>General Requirements.</i> Are installation, checkout, and acceptance activities for software being performed according to the approved software graded approach? <b>(CD-4.2)</b>	
	<b><i>Software Risk Management<sup>11</sup></i></b>	
	<i>Criterion 5 – Work Processes.</i> Has the Risk Management Plan or other software specific risk management plan been updated to reflect new or modified risks and their mitigation approaches and any changes in priorities? <b>(CD-4.3)</b>	
	<b><i>Software Configuration Management</i></b>	
	<i>Criterion 5 – Work Processes.</i> Do SCM activities identify all functions and tasks required to manage the configuration of the software and its associated configuration items (e.g., data, life cycle documentation, users manual, source code, and software executable) during the operations phase? <b>(CD-4.4)</b>	
	<i>Criterion 5 – Work Processes.</i> Has a baseline labeling system that uniquely identifies each configuration item, identifies changes to configuration items by revision, and provides the ability to uniquely identify each configuration been implemented? <b>(CD-4.5)</b>	
	<i>Criterion 3 – Quality Improvement.</i> Are proposed software changes documented, evaluated, and approved for release? <b>(CD-4.6)</b>	
	<i>Criterion 3 – Quality Improvement.</i> Are only approved changes made to software that has been baselined? <b>(CD-4.7)</b>	
	<i>Criterion 5 – Work Processes.</i> Is software verification performed after a change to ensure the change was implemented correctly? <b>(CD-4.8)</b>	
	<i>Criterion 5 – Work Processes.</i> Do verification activities include changes to the software documentation? <b>(CD-4.9)</b>	

<sup>10</sup> does not apply to commercial design and analysis software because the project management and quality planning activities associated with commercial design and analysis software are performed by the service supplier

<sup>11</sup> This activity does not apply to commercial design and analysis safety software.

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Operations and Project Completion</i></b>		
	<i>Criterion 5 – Work Processes.</i> Are software configuration audits or reviews performed to verify that the software product is consistent with the configuration item descriptions in the requirements and that the software, including all documentation, being delivered is complete? <b>(CD-4.10)</b>	
	<i>Criterion 5 – Work Processes.</i> Are software configuration management activities based upon the results of software grading? <b>(CD-4.11)</b>	
	<i>Criterion 6 - Design.</i> Are authorized users lists implemented to ensure that use of operational software is limited to those persons trained and authorized to use the software? <b>(CD-4.12)</b>	
	<b><i>Procurement and Supplier Management</i></b> <sup>12</sup>	
	<i>Criterion 7 – Procurement.</i> Do procurement documents identify the requirements for purchasers to report problems to the supplier, the method for the purchasers to report problems to the supplier, and any required supplier response? <b>(CD-4.13)</b>	
	<i>Criterion 7 – Procurement.</i> Do procurement documents include the technical and quality requirements for safety software? <b>(CD-4.14)</b>	
	<i>Criterion 4 – Inspection and Acceptance Testing.</i> Are assessments performed on purchased software to ensure that the delivered software completely meets the software requirements specified in the procurement documents? <b>(CD-4.15)</b>	
	<b><i>Software Requirements Identification and Management</i></b> <sup>13</sup>	
	<i>Criterion 5 – Work Processes.</i> Are software requirements traceable to the software design, test cases, and user guide? <b>(CD-4.16)</b>	
	<b><i>Software Design and Implementation</i></b>	
	<i>Criterion 6 – Design.</i> For custom-developed safety software, has techniques such as static analysis, clean room inspections, or reviews been used during implementation to ensure the implementation remains consistent with the design and does not add complexity or functions which could decrease the safe operation of the software? <b>(CD-4.17)</b>	
	<i>Criterion 6 – Design.</i> Do software design documents identify the operating system, function, interfaces, performance requirements, installation considerations, design inputs, and design constraints? <b>(CD-4.18)</b>	

<sup>12</sup> Levels A, B, and C software applications are required to fully meet these items but application can be graded based upon complexity and importance to safety

<sup>13</sup> Software requirements identification management and traceability applies to Level A, B, and C software applications and should fully meet this requirement (no grading in this topic)

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Operations and Project Completion</i></b>		
	<i>Criterion 6 – Design.</i> For custom-developed or configurable safety software (e.g., safety control system), do software design documents describe how the software will interface with other system components? <b>(CD-4.18)</b>	
	<i>Criterion 5 – Work Processes.</i> For custom-developed software, is unit testing of software modifications performed prior to conducting system level V&V techniques? <b>(CD-4.19)</b>	
	<i>Criterion 6 – Design.</i> Are all elements of software design engineering implemented for safety software using grade levels equivalent to Levels A, B, and C custom developed applications? <b>(CD-4.20)</b>	
	<b><i>Software Safety</i></b>	
	<i>Criterion 6 – Design.</i> Do designs include methods to mitigate the consequences of software failures? <b>(CD-4.21)</b>	
	<b><i>Verification and Validation</i></b>	
	<i>Criterion 4 – Inspection and Acceptance Testing.</i> Were validation activities performed at the end of the software development or acquisition processes to ensure the software meets the intended requirements? <b>(CD-4.22)</b>	
	<i>Criterion 2 – Personnel Training and Qualification.</i> Were V&V activities performed by competent staff other than those who developed the item being verified or validated? <b>(CD-4.23)</b>	
	<i>Criterion 5 – Work Processes.</i> Were reviews and inspections performed on software deliverables, requirement specifications, procurement documents, software design, code modules, test results, training materials, user documentation, and processes that guide the software development activities? <b>(CD-4.24)</b>	
	<i>Criterion 5 – Work Processes.</i> Has verification of software design been completed prior to approval of the software for use? <b>(CD-4.25)</b>	
	<i>Criterion 5 – Work Processes.</i> Did V&V activities include supplier assessments where appropriate? <b>(CD-4.26)</b>	
	<i>Criterion 5 – Work Processes.</i> Did the software tests documents include objective acceptance criteria, expected results, actual results and evidence that the acceptance criteria were met? <b>(CD-4.27)</b>	
	<i>Criterion 8 – Inspection and Acceptance Testing.</i> Does acceptance testing include functional testing, performance testing, security testing, stress testing, and load testing? <b>(CD-4.28)</b>	

ID #	Performance Objectives and Criteria	Met?
<b><i>Approval of Start of Operations and Project Completion</i></b>		
	<i>Criterion 5 – Work Processes.</i> Has test activity documents (e.g., test plans, cases, procedures, and test results) placed under configuration management? <b>(CD-4.29)</b>	
	<i>Criterion 8 – Inspection and Acceptance Testing.</i> When new versions of software tools are obtained, are predetermined and ad-hoc test cases and procedures executed to ensure the software tool does not impact the proper operation of the application software? <b>(CD-4.30)</b>	
	<i>Criterion 8 – Inspection and Acceptance Testing.</i> Are plans developed to continually monitor each software system to estimate its continuing reliability and safety? <b>(CD-4.31)</b>	
	<i>Criterion 8 – Inspection and Acceptance Testing.</i> Will periodic testing of each operational software system be performed to detect any degradation? <b>(CD-4.32)</b>	
<b><i>Problem Reporting and Corrective Action<sup>14</sup></i></b>		
	<i>Criterion 3 - Quality Improvement.</i> Are software problem reporting and corrective action part of the overall quality system problem reporting and corrective action system? <b>(CD-4.33)</b>	
	<p><i>Criterion 3 – Quality Improvement.</i> Does the software problem reporting and corrective action system: <b>(CD-4.34)</b></p> <ul style="list-style-type: none"> <li>• Include methods for documenting, evaluating and correcting software problems;</li> <li>• Include an evaluation process for determining whether a reported problem is indeed a defect or an error;</li> <li>• Include the roles and responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation;</li> <li>• correlate the error with the appropriate software engineering elements;</li> <li>• identify the potential impacts and risks to past, present, and future developmental and operational activities;</li> <li>• support the development of mitigation strategies; and</li> <li>• apprise all users of errors to ascertain any impacts upon safety basis decisions?</li> </ul>	

<sup>14</sup> This activity should be fully implemented for all Level A and B software types (custom developed, acquired, configurable, and commercial design and analysis) and for Level C custom developed. A graded approach that reduces the formality of documenting problem reports and approving corrective actions taken may be applied for Level A and B utility calculation safety software and all Level C software applications except custom developed.

ID #	Performance Objectives and Criteria	Met?
<b>Approval of Start of Operations and Project Completion</b>		
	<b>Training of Personnel in Safety Software<sup>15</sup></b>	
	<i>Criterion 2 - Personnel Training and Qualification.</i> Are training needs for the development and test teams, and application users identified? <b>(CD-4.35)</b>	
	<i>Criterion 2 - Personnel Training and Qualification.</i> Are training plans commensurate with the scope, complexity, and importance of the tasks and the education, experience, and proficiency of the individual? <b>(CD-4.36)</b>	
<b>Software Identification &amp; Registry</b>		
	<i>General Requirements.</i> Is all software to be used during the project operations phase identified? Does this identification contain the following: unique identifier, software name, version identifier, safety software designation, any grade level description, and responsible individual? <b>(CD-4.37)</b> <ul style="list-style-type: none"><li>• Safety software is the only software required to be included in an inventory with the above attributes. However, best practices necessitate the identification of software to perform the proper level of quality assurance.</li></ul>	
	<i>General Requirements.</i> Is this inventory maintained? <b>(CD-4.38)</b> <ul style="list-style-type: none"><li>• Safety software is the only software required to be included in an inventory with the above attributes. However, best practices necessitate the identification of software to perform the proper level of quality assurance.</li></ul>	
<b>Consensus Standard and Guidance Use</b>		
	<i>General Requirement.</i> What consensus standard(s) are being applied to software that will be developed, maintained, or procured and used during the project operations phase? <b>(CD-4.39)</b> <ul style="list-style-type: none"><li>• For safety software, the consensus standard must be either ASME NQA-1-2000, ASME NQA-1-2008, or other DOE approved consensus standard.</li></ul>	
	<i>General Requirement.</i> Have DOE guides for quality assurance and software quality assurance been considered for use? <b>(CD-4.40)</b>	

<sup>15</sup> For Level B and C software applications, this work activity can be graded to include periodic evaluation