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Software Quality Assurance Criteria and Review Approach Document

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1.0   PURPOSE

The mission of the U.S. Department of Energy (DOE) Office of Environment, Safety and Health Assessments (EA-30) is to assess the effectiveness of safety and emergency management systems and practices used by line management and contractor organizations and to provide clear, concise, rigorous, and independent evaluation reports of performance in protecting workers, the public, and the environment from the hazards associated with DOE activities.

In addition to the general independent oversight requirements and responsibilities specified in DOE Order 227.1A, *Independent Oversight Program*, this criteria and review approach document (CRAD), in part, fulfills the responsibility assigned to the Office of Enterprise Assessments (EA) in DOE Order (O) 226.1B, *Implementation of Department of Energy Oversight Policy*, to conduct independent oversight and appraisals of high consequence activities. This CRAD specifically provides objectives, criteria, and review approaches to assess the effectiveness of software quality assurance (SQA) programs and processes at DOE sites.

The CRADs are available to DOE line and contractor assessment personnel to aid them in developing effective DOE oversight, contractor self-assessment, and corrective action processes. The current revisions of EA's CRADs are available at https://www.energy.gov/ea/criteria-and-review-approach-documents.

2.0   APPLICABILITY

The following CRAD is approved for use by the Office of Environment, Safety and Health Assessments (EA-30) and sub-tier offices.

3.0   FEEDBACK

Comments and suggestions for improvements on this CRAD can be directed to the Director, Office of Environment, Safety and Health Assessments.

4.0   CRITERIA AND REVIEW APPROACH

This CRAD guides an evaluation of the effectiveness of contractor quality assurance programs for software used at, or in support of DOE nuclear facilities in compliance with 10 Code of Federal Regulations (CFR) 830, *Nuclear Safety Management*, subpart A, *Quality Assurance Requirements*, and DOE O 414.1E, *Quality Assurance*. The CRAD also addresses the adequacy of the Federal review and approval of contractor quality assurance programs for software and adherence to software quality implementing procedures and processes. American Society of Mechanical Engineers (ASME) consensus standard NQA-1-2017, *Quality Assurance Requirements for Nuclear Facility Applications*, part I and part II, subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications*, is the preferred standard for use as the basis of Hazard Category 1, 2, and 3 nuclear facility quality assurance programs, and it is cited herein as a normative reference. The following objectives, criteria, and lines of inquiry are designed as stand-alone sections to be used in any combination based on the assessment scope. Questions that can be answered with a "yes" or "no" should be followed with an open-ended question to obtain insight and details supporting the one-word response.

OBJECTIVES

SQA.1: The contractor Quality Assurance Program (QAP) has been reviewed and approved by DOE line management and adequately incorporates applicable software quality assurance requirements from 10 CFR 830, *Nuclear Safety Management*, subpart A, *Quality Assurance Requirements*; DOE O 414.1E, *Quality Assurance*; and appropriate consensus standards approved by DOE (e.g., ASME NQA-1-2017, *Quality Assurance Requirements for Nuclear Facility Applications*).

Criteria:

1. The contractor establishes and maintains a DOE-approved QAP to incorporate applicable requirements from 10 CFR 830, DOE O 414.1E, and approved consensus standards.
2. The contractor submits QAP modifications to DOE for approval when needed and before implementation of the changes.
3. The contractor QAP describes a graded approach to be used for all software which ensures that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with:
    - The relative importance to safety, safeguards, and security.
    - The magnitude of any hazard involved.
    - The life-cycle stage of a facility or software.
    - The programmatic mission of the facility for which the software is implemented or supports.
    - The particular characteristics of a facility or software.
    - The relative importance of the software to radiological and non-radiological hazards.
    - Any other relevant factors.
4. The contractor QAP includes applicable requirements for <u>all</u> software that are also incorporated and referenced in implementing procedures.

5. The contractor QAP and implementing procedures define processes for all work with software items to address management, performance, and assessment quality assurance criteria presented in 10 CFR 830.122 and DOE O 414.1E, attachment 2, part A.
6. The contractor QAP and implementing procedures define processes to identify, establish, and implement suspect/counterfeit item (S/CI) prevention for software.
7. The contractor QAP and implementing procedures identify and establish processes to be implemented for software quality assurance, consistent with DOE O 414.1E, attachment 2, part C.
8. The contractor QAP and implementing procedures identify and establish processes to be implemented for software quality assurance.
9. The contractor applies all requirements applicable to software with the graded approach that is defined and described in the QAP including additional requirements for tracking/inventory beyond typical software practices for, as a minimum, software important to mission accomplishment, and software related to nuclear safety.
10. The contractor employs trained and qualified SQA subject matter experts to establish, maintain, and ensure an effective SQA program.
11. The contractor QAP and implementing procedures document the processes and results for assigning grading levels to all software commensurate with relative importance to safety, safeguards, and security.
12. If software on the Software Central Registry is used, controls for its use are addressed in the contractor QAP and implementing procedures including justification for use for known software quality issues.
13. The contractor ensures implementation of SQA requirements through management and independent assessments and the issues management process.
14. The contractor QAP and implementing procedures document the processes and results for control of acquired software, including no-cost software, per the consensus standard.
15. The contractor QAP and implementing procedures document the processes and results for control of pre-verified software used for design analysis per the consensus standard.
16. For developed software, the contractor QAP and implementing procedures document the processes and results for software design control per the consensus standard.
17. The contractor QAP and implementing procedures document the processes and results for control of testing of software, including embedded software, per the consensus standard.

Lines of inquiry:
- How does the contractor ensure an annual review and update (if needed) of the QAP, and timely submission to the DOE approval authority, when necessary?
- How does the contractor QAP identify all the criteria listed in DOE O 414.1E, attachment 2, part A, *Quality Assurance Criteria,* for all software*?*
- Does the contractor QAP address all processes identified in DOE O 414.1E, attachment 2, part B, *Suspect/Counterfeit Item (S/CI Prevention),* and part C*, Software Quality Assurance Processes*, for all software?
- Does the contractor QAP identify implementing processes for all requirements that are applicable to software?
- How does the approved graded approach incorporate relevant factors from DOE O 414.1E, attachment 1, sections 2.a.(4)(a) and (b), to ensure the levels of analyses, documentation, and actions used to comply with requirements are commensurate with risks associated with the software?
- How does the approved graded approach address requirements in DOE O 414.1E, attachment 2, part C, section 1?
- How does the approved SQA program identify and implement the selected consensus standard(s) for the software lifecycle?
- Has the contractor assigned an individual(s) responsible for SQA who is adequately trained and qualified and how is that documented?

- How is the flow down of software requirements into the contractor QAP and implementing procedures from 10 CFR 830, subpart A and DOE O 414.1E documented?
- How are the software classification and grading processes described and documented?
- How does the contractor ensure that all software has been evaluated to determine whether it requires additional tracking/inventory?
- How does the contractor ensure that all software has been assigned a grading level?
- If the site uses software from the Software Central Registry, how is documentation of its use addressed in the contractor QAP and implementing procedures including justification of use when known software quality issues exist?
- How does the contractor control QAP and implementing procedure updates as changes are made?
- How does the contractor ensure that management and independent assessments are performed to ensure implementation of SQA requirements and that resulting issues are addressed?
- How does the contractor incorporate consensus standard requirements for control of acquired and no-cost software?
- How does the contractor incorporate consensus standard requirements for control of pre-verified software used for design analysis?
- How does the contractor incorporate consensus standard requirements for control of contractor developed software?
- How does the contractor incorporate consensus standard requirements for control of testing of all software, including embedded software?

SQA.2: QA and SQA program requirements are adequately implemented for software graded at all established levels. (10 CFR 830, subpart A, and DOE O 414.1E)

Criteria:

1. The reviewed software adequately implements established requirements in the applicable SQA implementing procedures for DOE O 414.1E, attachment 2, part A, *Quality Assurance Criteria*.
    a) Management/Program
        - Those managing, performing, and assessing the reviewed software follow established organizational structure, functional responsibilities, levels of authority, and interfaces.
        - Established management processes, including planning, scheduling, and providing resources for the work are followed.
    b) Management/Personnel Training and Qualification
        - Personnel associated with the reviewed software:
            – Are trained and qualified to be capable of performing their assigned work.
            – Are provided continuing training to maintain their proficiency.
    c) Management/Quality Improvement:
        - Established processes to detect and prevent quality problems are implemented.
        - Software and associated services and processes that do not meet established requirements are identified, controlled, and corrected.
        - Identification of causes of problems with software and associated services and processes and prevention of recurrence are part of corrective action planning.
        - Software characteristics, process implementation, and other quality related information are reviewed to identify software and associated services and processes needing improvement.
    d) Management/Documents and Records
        - Documents to prescribe processes, specify requirements, or establish design are prepared, reviewed, approved, issued, used and revised.
        - Records are specified, prepared, reviewed, approved, and maintained.

e) Performance/Work Processes
  - Work is performed using approved instructions, procedures, or other appropriate means.
  - Software and associated hardware are identified and controlled to ensure proper use.
  - Software and associated hardware are maintained to prevent damage, loss, or deterioration.
  - Software for process monitoring or data collection equipment is maintained.
f) Performance/Design
  - Software and processes are designed using sound engineering/scientific principles and appropriate standards.
  - Applicable requirements and design bases are incorporated in software design work and design changes.
  - Software design interfaces are identified and controlled.
  - Adequacy of software design products is verified or validated using individuals or groups other than those who performed the work.
  - Design work is verified or validated before approval and implementation of the software.
g) Performance/Procurement
  - Procured software and services meet established requirements and perform as specified.
  - Prospective software suppliers are evaluated and selected based on specified criteria.
  - Established processes to ensure that approved software suppliers continue to provide acceptable software and services are implemented.
h) Performance/Inspection and Acceptance Testing
  - Software is inspected and tested using established acceptance and performance criteria.
  - Software for inspection and testing equipment is maintained.
i) Assessment/Management Assessment
  - Managers assess their software processes and identify and correct problems that hinder the organization from achieving its objectives.
j) Assessment/Independent Assessment
  - Independent assessments to measure software quality, to measure adequacy of software work process performance, and to promote improvement, are planned and conducted.
  - Independent assessment teams have sufficient authority and freedom from line management.
  - Independent assessments are performed by persons who are technically qualified and knowledgeable in the areas to be assessed.
2. The reviewed software adequately implements established requirements in the applicable SQA implementing procedures for DOE O 414.1E, attachment 2, part C, *Software Quality Assurance*, including selection of the software engineering consensus standard, and, when appropriate, additional tracking/inventory controls.
   a) The DOE-approved graded approach is applied to the selection, management, control, documentation, and implementation of the software, including software systems and subsystems.
   b) Software is documented, managed, and controlled throughout the software's lifecycle using appropriate national or international software engineering consensus standards.
   c) Software important to mission accomplishment is included in the defined tracking/inventory system.
   d) Software related to nuclear safety (e.g., safety basis analysis software used for control selection, software used to determine limits for emergency management, and software used in TSR implementation) is included in the defined tracking/inventory system.
   e) Other types of software identified in the contractor QAP are included in the tracking/inventory system.

3. The reviewed software adequately implements DOE O 414.1E, attachment 2, part B, *S/CI Prevention*, and other applicable security requirements.
    a) Established S/CI prevention processes are implemented:
        • To prevent the entry of suspect software into the DOE supply chain.
        • To determine during maintenance and/or inspections whether suspect software is installed.
    b) Personnel associated with the reviewed software are trained on S/CI processes and controls.
4. Other documentation, reviews, and approvals required by the DOE-approved SQA program and associated implementing procedures have been completed for the reviewed software for all applicable phases of the software life cycle.

Lines of inquiry:
• How were established organizational structure, functional responsibilities, levels of authority, and interfaces followed by those managing, performing, and assessing the reviewed software?
• How were established management processes for planning, scheduling, and providing resources followed for the reviewed software?
• How were personnel associated with the reviewed software trained and qualified to be capable of performing their assigned work for the reviewed software?
• How was continuing training provided for personnel associated with the reviewed software to maintain proficiency?
• How were established processes implemented to detect and prevent quality problems associated with the reviewed software?
• How were software and associated services that do not meet the established requirements identified, controlled, and corrected?
• How did the corrective action planning process identify causes of problems with reviewed software and associated services to prevent recurrence?
• How were software characteristics, process implementation, and other quality related information reviewed to identify needed improvements?
• How were documents prescribing processes, specifying requirements, or establishing design prepared, reviewed, approved, issued, implemented, and revised for the reviewed software?
• How were records for the reviewed software and associated services specified, prepared, reviewed, approved, and maintained?
• How was the work associated with the reviewed software performed using approved instructions, procedures, or other appropriate means?
• How was the reviewed software and associated hardware identified and controlled to ensure proper use?
• How was the reviewed software and associated hardware maintained to prevent damage, loss, or deterioration?
• How was software for process monitoring or data collection equipment maintained?
• How were sound engineering/scientific principles and appropriate standards used in the design of the reviewed software?
• How were applicable requirements and design bases incorporated into the reviewed software design and design changes?
• How were design interfaces identified and controlled for the reviewed software?
• How was the adequacy of software design products independently verified or validated by individuals or groups who did not perform the work for the reviewed software?
• Was the reviewed software design verified or validated before approval and implementation?
• How were procured software and services determined to meet the established requirements and to perform as specified?

- How were prospective software and service suppliers evaluated and selected based on specified criteria?
- How were processes to ensure approved suppliers continue to provide acceptable software and services implemented?
- How was the reviewed software inspected and tested using established acceptance and performance criteria?
- How was software for inspection and testing equipment maintained?
- How did management assess their software processes and identify and correct problems that affect achievement of organizational objectives?
- How were independent assessments planned and conducted to measure software quality, to ensure adequacy of software work process performance, and to promote improvement?
- How was sufficient authority and freedom from line management ensured for independent assessment personnel?
- How were independent assessment personnel determined to be technically qualified and knowledgeable in the areas to be assessed?
- How was the DOE-approved graded approach applied to the selection, management, control, documentation, and implementation of the reviewed software, including software systems and subsystems?
- How was the reviewed software documented, managed, and controlled throughout the software lifecycle using appropriate and approved national or international software engineering consensus standards?
- How was the defined tracking/inventory system implemented for reviewed software important to mission accomplishment?
- How was the defined tracking/inventory system implemented for reviewed software related to nuclear safety (e.g., safety basis analysis software used for control selection, software used to determine limits for emergency management, software used in TSR implementation, etc.)?
- How were other types of reviewed software identified in the contractor QAP, if any, included in the defined tracking/inventory system?
- How were S/CI prevention processes and other security requirements for the reviewed software implemented and documented during procurement, maintenance, and/or inspections?
- How were personnel associated with the software and services trained on S/CI processes and controls?
- How were other documentation, reviews, and approvals required by the DOE approved SQA program and associated implementing procedures completed for the reviewed software for all applicable phases of the software life cycle?

SQA.3: The Federal program for oversight of SQA is established and effective in ensuring contractor SQA programs satisfy DOE requirements. (DOE O 226.1B and DOE O 414.1E)

Criteria:

1. DOE line management reviews and approves contractor QAPs and submitted modifications.
2. DOE line management assigns trained and qualified SQA subject matter experts (SMEs) to oversee the contractor SQA program.
3. DOE line management includes SQA in documented oversight processes and procedures.
4. SQA SMEs evaluate contractor implementation of SQA requirements.
5. DOE line management oversees contractor corrective actions and improvement efforts.

Lines of inquiry:
- How does DOE line management perform and document timely review and approval of contractors' QAP and updates to ensure appropriate flow down of requirements?
- How does DOE line management assign resources for oversight of the contractor SQA program?
- Have assigned SQA SMEs been trained and qualified to DOE-STD-1172, *Safety Software Quality Assurance Functional Area Qualification Standard*?
- How do SQA SMEs plan, perform, and document assessments of contractor SQA implementation across all software categories and grade levels?
- How does DOE line management follow up on identified issues and corrective actions?

REVIEW APPROACH

Record Reviews:
- List of site software applications identified by category, grade level, and owning organization
- Documentation of site QAP review and approval
- Effective site QAP documents and applicable implementing procedures and records
- Applicable IT and cyber security procedures and records if not integrated within the SQA program
- DOE oversight documentation and records
- Documentation of contractor assurance of activities relevant to software quality assurance (e.g., contractor management assessment and independent assessment documentation and records)
- Software Life Cycle documentation and records for selected software
- Issues management records associated with software quality and/or performance within the last 3 years
- Training and qualification documentation and records for selected DOE and contractor personnel

Interviews:
- DOE QA Manager
- DOE SQA SMEs
- Software Owners
- Software Users
- Contractor QA Manager
- Contractor SQA Independent Reviewers
- IT and/or Cyber Security Manager and SMEs

Observations:
- DOE and/or contractor oversight activities
- Meetings associated with software grading
- Configuration Management Review Board and Change Board meetings
- Meetings associated with software important to mission accomplishment or related to nuclear safety determinations
- Meetings associated with software grading activities
- Software field use; input/output
- Training demonstrations
- Digital workflow demonstrations