



Office of Civilian Radioactive Waste Management

Quality Assurance Requirements and Description

Title: SOFTWARE

Effective Date: 06/05/98

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I.1 GENERAL

This supplement establishes requirements for the development, modification, control, and use of software. Software that is acquired as an integral part of measuring and test equipment, and has not been developed or modified by the Affected Organization, is controlled by Section 12.0, Control of Measuring and Test Equipment, and is exempt from the requirements of this supplement. Requirements for electronic management of data are addressed in Supplement V, Control of the Electronic Management of Data.

The following types of software are not required to be qualified using this supplement: operating systems; administrative and management systems; system utilities and compilers and their associated libraries; and word processing programs. Industry standard software such as database managers, graphing and visual display software, spreadsheets, and statistical software are also excluded. However, software routines and macros written for use within these types of industry standard software need to meet the requirements of Paragraph I.2.1.C.

I.2 REQUIREMENTS

I.2.1 Software Life Cycles, Baselines, and Controls

- A. For developed or modified software, each Affected Organization shall document and approve a specific software life cycle for each software item prior to development or modification of software.
1. Software life cycles shall be defined by control points at which software baseline elements shall be documented. Software life cycle activities may be performed in an iterative or sequential manner.
 2. When the software life cycle is defined for software development or modification within an Affected Organization, the documentation requirements of Subsections I.2.3, Software Verification, B and C, I.2.4, Software Validation, F and G, and I.2.5, Documentation, A, B, and C shall be established. All other requirements apply subsequent to establishment of the software life cycle.

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3. Reviews of software baselines shall be performed and documented at the software control points.
- B. For acquired software the following requirements shall be met:
1. Perform installation tests to ensure that software performs as required in the operational environment.
 2. Perform validation in accordance with Subsection I.2.4, Software Validation, D, E, F, and G using test cases developed independently of the software developer. Additional test cases provided by the developer may be used to supplement this process with justification for their use.
 3. Document in accordance with the requirements of Subsection I.2.5, Documentation, A, B, C.2, and C.6 as applicable.
 4. Perform and document reviews of software baselines.
 5. Place under the configuration controls in accordance with Subsection I.2.6, Software Configuration Management.
 6. Implement a defect reporting and resolution system in accordance with Subsection I.2.7, Defect Reporting and Resolution.
 7. Control the use of software in accordance with Subsection I.2.8, Control of the Use of Software.
- C. Software, including macros, that can be verified by visual inspection and/or hand calculations shall have limited requirements applied as follows:
1. Listing of the version and any subsequent changes to the software.
 2. Documentation that the software provides correct results for a specified range of input parameters.

I.2.2 Software Verification and Software Validation

- A. Software verification and software validation shall be performed prior to release. In those cases where this requirement cannot be met prior to the release of the software, the portions of software that have not been verified and validated shall be identified and controlled, and written justification of the reason documented.
- B. Software verification and software validation activities shall be performed or reviewed by independent individuals or organizations who did not work on the original software development or modification. The person who directed the work may perform these activities with a higher level of management approval and documented justification.

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I.2.3 Software Verification

- A. The software verification shall be performed and documented to ensure that baseline elements meet the established requirements.
- B. The verification documentation shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software verification.
- C. A record of the results of the execution of planned software verification shall be generated including the extent to which the results agree with the specified acceptance criteria.

I.2.4 Software Validation

- A. Software validation activities (such as the development of test plans and test cases) shall be integrated into the software life cycle.
- B. Testing shall be the primary method of software validation.
- C. Software validation of modifications to released software items shall include regression testing.
- D. Software validation shall be performed to an approved plan or process.
- E. The test methods and test cases shall be documented to ensure that software meets the Affected Organization's requirements for its intended use.
- F. The validation documentation shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software validation.
- G. A record of the results of the execution of planned software validation shall be generated including the extent to which the results agree with the specified acceptance criteria.

I.2.5 Documentation

Software activities shall be documented sufficiently to demonstrate the ability of the software to meet the needs of the Affected Organization and shall include the following:

- A. **Functional Requirements Information:**
 - 1. A description of the overall nature and purpose of the software.
 - 2. Requirements for its intended use.
- B. **User Information:**
 - 1. A description of how to use the software item including:
 - a. Input and output options.
 - b. Data files, input and output data, defaults, and file formats.

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- c. A description of the allowable and tolerable ranges for inputs and outputs.
 - d. Anticipated errors and how the user can respond.
 - e. The hardware and software environments.
2. Available sample problems.
 3. Installation procedures.
- C. Requirements and Design Information:
1. Performance requirements and design constraints.
 2. Interfaces with external data, hardware, or other software.
 3. Applicable software and hardware operation issues including programming languages and versions, portability, maintainability, reliability, and efficiency.
 4. A description of each software item as it relates to the functional requirements.
 5. A description of the software structure including software internal interfaces, control logic, and data structure and flow.
 6. A description of models and numerical methods.
 7. Source code for developed software or software modification.

I.2.6 Software Configuration Management

A software configuration management system shall be established to include configuration identification and configuration control and status accounting. Software shall be placed under configuration management control as each baseline element is approved.

- A. Configuration identification shall include:
1. A definition of the baseline elements of each software baseline.
 2. A unique identification of each software item to be placed under software configuration management.
 - a. Each version or revision of a software item shall be uniquely identified and labeled.
 - b. The software version or revision identifier shall be included with the generated output, when feasible.
 3. Assignment of unique identifiers that relate baseline documents to their associated software items. Cross-references between baseline documents and associated software shall be maintained.

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B. Configuration control shall include:

1. A release and control process for baseline elements.
2. Changes to baseline elements, including retirement and withdrawal, shall be formally controlled and documented. This documentation shall contain a description of the change, the rationale for the change, and the identification of affected baseline elements.
 - a. The change shall be formally evaluated and approved by the organization responsible for approving the baseline element.
 - b. Only approved changes shall be made to software baselines.
 - c. Information concerning approved changes shall be transmitted to all organizations affected by the changes.
 - d. Software verifications shall be performed for the changes as necessary to ensure the changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.
 - e. Software validation shall be performed as necessary for the change.

C. Configuration status accounting shall include:

1. A listing of the approved baseline elements and unique identifiers.
2. The status of proposed and approved changes to the baseline elements.
3. A brief chronology of the software items, including descriptions of the changes made between versions of software items.

I.2.7 Defect Reporting and Resolution

A software defect reporting and resolution system shall be implemented.

- A. The defect reporting and resolution system shall be integrated with the software configuration management system to ensure formal processing of defect resolutions.
- B. Software defect reporting and resolution systems shall include the following controls:
 1. Defects shall be documented and resolved.
 2. Defects shall be assessed for their impact on previous applications.
 3. Resolutions shall be reviewed and approved before changes are made to baseline elements.
 4. Notification of identified user organizations.

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- C. If a defect is identified in software that adversely impacts previous applications, then the condition adverse to quality shall be documented and controlled in accordance with Section 16.0, Corrective Action.

I.2.8 Control of the Use of Software

- A. Affected Organizations shall control and document the use of released software items such that comparable results can be obtained, with any differences explained, through independent replication of the process.
- B. Use of software shall be independently reviewed and approved to ensure that the software selected is suitable to the problem being solved.
- C. If use of a software item falls outside the range of validation, further validation shall be performed prior to use.