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United States Government | Department of Energy

memorandum

DATE: JUL 2 8 1992

REPLY TO ATTN OF: RW-3

SUBJECT: Review of Supplement I of the Quality Assurance Requirements and Description Document Draft OB

TO: Distribution

I am forwarding the rewritten Supplement I of Draft OB of the Quality Assurance Requirements and Description (QARD) Document for review and comment. The Supplement was completely rewritten by the Software Advisory Group (SAG) and is intended to replace the earlier version included in the QARD review package dated May 22, 1992. Review is to be performed in accordance with the May 22, 1992 instructions.

As the QARD Draft OB has been reviewed and comment resolution is in process, please forward your comments to the OCRWM Office of Quality Assurance no later than August 7, 1992.

If you have any questions please contact Bob Clark at (202) 586-5969 or Dick Spence at (702) 794-7504.

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I.1 GENERAL

This Supplement establishes requirements for the development, acquisition, control and use of scientific and engineering and radiological environmental software applications as related to items on the Q-List. The qualification of software that is an integral part of M&TE or DA equipment is controlled by Section 12.

I.2 REQUIREMENTS

I.2.1 Qualification Life Cycle

A. Acquired, developed and modified software shall be qualified prior to release for use.

B. Each affected organization shall document and approve a qualification life cycle for each software item prior to development and modification of the 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. The requirements for each software baseline element shall be established when the life cycle is defined. The requirements for acquired software are described in Section I.2.2. The requirements for modified and developed software are described in Section I.2.3.

C. The qualification life cycle shall be comprised of the following elements:

1. Performance of software verification and software validation.
2. Software configuration management control.
3. Software defect reporting and resolution.
4. Software media control.
5. The release and use of software.
6. Baseline element reviews.

D. Qualification of acquired software that was developed or modified in accordance with this Supplement shall include the following:

1. Performing installation testing to ensure that software performs as required in the operational environment.

2. Developing test cases as necessary to ensure that the software meets the requirements for its intended use.

3. Placing the software under configuration controls.

E. Qualification of acquired software not developed or modified in accordance with this Supplement shall include the following:

1. Ensuring that the software meets the documentation requirements of this supplement.

2. Performing validation to an approved plan, to ensure that software meets the requirements for its intended use.

3. Placing the software under configuration controls of I.2.5.

I.2.2 Requirements for Acquired Software

Acquired Software 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. Requirements information:

1. A description of the overall nature and purpose of the software.

2. Requirements for its intended use.

3. A description of models and numerical methods as applicable to scientific and engineering software.

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.
   c. Anticipated errors and how the user can respond.
   d. The hardware and software environments.
   e. A description of the allowable and tolerable ranges for inputs and outputs.

2. Available sample problems.

3. Changes since the last release that affect the user.

4. Installation procedures.

C. Validation information:

1. A description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software validation.

2. A record of the results of the execution of planned software validations including the approved plan and the extent to which the results agree with the specified acceptance criteria.

I.2.3 Requirements for Software Developed or Modified in accordance with this Supplement

Developed or modified software shall be documented according to the following requirements.

A. Requirements and design information:

1. Functional requirements.

2. Performance requirements and design constraints.

3. A description of models and numerical methods as applicable to scientific and engineering software.

4. Interfaces with external data, hardware, or other software.

5. Applicable software and hardware operation issues to include programming languages and versions, portability, maintainability, reliability, and efficiency.

6. A description of the major software items as they relate to the functional requirements.

7. A description of the software structure including software internal interfaces, control logic, and data structure and flow.

8. A copy of developed software items and modifications to software items.

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.
   c. Anticipated errors and how the user can respond.
   d. The hardware and software environments.
   e. A description of the allowable and tolerable ranges for inputs and outputs.

2. Available sample problems.

3. Changes since the last release that affect the user.

4. Installation procedures.

C. Verification and Validation:

1. The software verification and software validation plan shall include a description of the tasks, methods, implementing documents, and acceptance criteria for accomplishing the software verification and software validation.

2. A record of the results of the execution of planned software verification and software validations including the extent to which the results agree with the specified acceptance criteria.

I.2.4 Software Verification and Software Validation

A. Software verification and software validation (software validation as used in this Supplement does not include model validation) shall be performed as part of qualification prior to release.

B. Software verification and software validation plans shall employ methods such as review, inspection, analysis, demonstration and test.

C. Software verification and software validation activities shall be accomplished by an independent individual or organization, who did not work on the original software development. The person who directed the work may perform these activities with a higher level of management approval.

D. In those cases where qualification cannot be met prior to the release of the software, the following requirements shall apply:

1. The portions of software that have not been qualified shall be identified and controlled.
2. Justification of the reason shall be documented.

I.2.4.1 Software Verification

The software verification shall be performed and documented in accordance with the approved plans to ensure that the products of a life cycle control point meet the requirements established for that control point.

I.2.4.2 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. The test plans and test cases shall be documented and performed in accordance with the software validation plan.

I.2.5 Software Configuration Management

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

A. Configuration identification shall include:

1. Definition of the baseline elements of each software baseline.

2. Unique identification of the software items 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 items shall be maintained.

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 changes, the rationale for the changes, and the identification of affected baseline elements.

   a. The changes 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 and information concerning approved changes shall be transmitted to all organizations affected by the changes.

   c. Software verification shall be performed for the changes as necessary to ensure that changes are appropriately reflected in software documentation and to ensure that document traceability is maintained.

   d. Software validation shall be performed as necessary for the changes.

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.2.6 Defect Reporting and Resolution

A software defect reporting and resolution system shall be developed and 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. Affected organizations shall be appropriately notified.

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.

I.2.7 Media Control

Media containing a copy of the completed/released software items shall be controlled to prevent inadvertent damage or degradation.

I.2.8 Use of Qualified Software

A. Affected organizations shall establish procedures for controlling and documenting the use of qualified software in accordance with this Supplement. These procedures shall allow an independent repetition of the use of qualified software.

B. Software uses shall be approved and independently reviewed to ensure that the software selected is applicable to the problem being solved and that inputs and assumptions are valid and traceable.

C. If use of a software item falls outside the range of validation, further validation shall be performed prior to use in a quality affecting activity.

GLOSSARY

Acquired Software - All software developed outside the affected organizations implementation of the requirements of this document.

Baseline Element - An individual component of a software baseline.

Model - A representation of a physical system or process.

Model Validation - The process that demonstrates that the model is an acceptable representation of the process or system for which it is intended.

Qualified Software - Software that has successfully completed software verification and software validation and meets the requirements of Supplement I.

Regression Testing - Selective retesting of a system or component to verify that modifications have not caused unintended effects and that the system or component still complies with its specified requirements.

Release - The formal notification and distribution of qualified software.

Software - Software item and associated documentation.

Software Baseline - (1) A specification or product that has been formally reviewed and agreed upon, that thereafter is the basis for further development, and that can be changed only through formal change procedures. (2) A document, a set of documents, or a product formally designated and controlled at a specific time during software life cycle.

Software Control Point - A specified point in the software life cycle when controls are applied to the software baseline elements with prescribed requirements and products.

Software Item - Source code, object code, job control code, control data, or a collection of these items that function as a single unit.

Software Life Cycle - A series of activities that begins when a software product is conceived and ends when the software is no longer available for use.

Software Validation - The process of evaluating a system or component during or at the end of the development process to dete e whether it satisfies specified requirements.

Software Verification - The process of determining whether the products of a given software life cycle phase satisfy the conditions imposed at the start of that phase.

SHEET 1 OF
QA

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.

DOCUMENT REVIEW RECORD

DOCUMENT NAME	Quality Assurance Requirements and Description Supplement I
REVISION	Draft 0B Replacement
DATE	July 27, 1992

REVIEW INSTRUCTIONS/ACCEPTANCE CRITERIA

All Reviewers: Review only those sections of the document that apply to your scope of work. Review the document against:

1. commitments to external organizations, including the NRC.
2. response to open CARs, DRs, SDRs, and responses to the 1991 Management Assessment recommendations.
3. organizational charts, interfaces, and responsibilities to ensure this document agrees with existing organization structures and accurately reflects the current methods of doing business.
4. the regulatory, commitment, and guidance documents incorporated into this document for compliance with the intent of those documents.

REVIEW INSTRUCTIONS/CRITERIA PREPARED BY	REVIEW INSTRUCTIONS/CRITERIA APPROVED BY
JAMES GEORGE James George 7/27/92	R.W. Clark 7/27/92
Signature / Date	Signature / Date

FORWARD RESULTS TO

R. Clark, RW-3.1 by 8/7/92

COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTION.

SECT./ PARA.	COMMENT	RESPONSE	INITIALS DATE

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Signature / Date	Signature / Date

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RADIOACTIVE WASTE MANAGEMENT
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WASHINGTON, D.C.

DOCUMENT REVIEW RECORD (continuation sheet)

DOCUMENT NAME	Quality Assurance Requirements and Description Supplement I
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COMMENTS THAT ARE ANNOTATED WITH AN (*) ARE MANDATORY AND REQUIRE RESPONSE AND RESOLUTION.

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Signature	Date	Signature	Date

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