

**U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

**NUCLEAR WASTE TECHNICAL REVIEW BOARD
FULL BOARD MEETING**

SUBJECT: QUALIFICATION OF SOFTWARE

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Definitions

Model: Some representation of a physical process or system

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

Definitions

(Continued)

Software: Source code, object code, job control code, control data, or a collection of these items that function as a single unit, and associated documentation

Software Verification: The process of determining whether the products of a given software lifecycle phase satisfy the conditions imposed at the start of that phase

Software Validation: The process of evaluating a system or component either during or at the end of the development process to determine whether it satisfies specified requirements

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”

Two Types of Acquired Software

- **Software developed wholly outside OCRWM QA (pre-QA, commercial, other agencies, etc.)**
- **Software developed under one participant's QA program and transferred to another participant (models, etc.)**

For Software Developed Wholly Outside the QA Program

The user must

- **Validate software to an approved plan to ensure that the software meets the requirements for its intended use**
- **Place the software under the controls of software configuration management**
- **Provide or develop documentation of**
 - **Requirements**
 - **User information**
 - **Validation information**
 - **Information on reviews**