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Rev	Date	Description	POC	RM
0	06/23/16	Initial issue	Tobin Oruch, <i>ES-DO</i>	Mel Burnett, <i>CENG-OFF</i>
1	05/25/17	Added acquisition document review and an example Request Package Checklist; clarifications.	Tobin Oruch, <i>ES-DO</i>	Lawrence Goen, <i>ES-DO</i>

## 1.0 PURPOSE AND APPLICABILITY

Purpose: This section describes the “how, when, and who” for:

- verifying and validating (V&V) software, and
- approving software for use (SWAU)

See Tables 21.4-1 and 21.4-2 below for a summary of SOFT-V&V for SSC software and Non-SSC software respectively.

Applicability: See Chapter 21 applicability in SOFT-GEN. In addition:

1. Apply the V&V and SWAU subsections that are applicable to your software. For example, for acquired Non-SSC software, Subsections 1.0–3.0 and 7.0 apply.
2. For software changes during V&V, see SOFT-GEN.
3. Use this section for V&V and SWAU of software that is acquired and for software that is designed.
4. Read-Only: This section includes V&V for Read-Only SSC software. This is SSC software where the computer program cannot be modified other than through replacement of the computer program or the associated SSC. It is sometimes referred to as embedded software or firmware; however, for this section, the term Read-Only SSC software is used.
5. For SSC software, use this section in conjunction with [ESM](#) Chapter 15, *Commissioning* or [AP-341-801](#), *Post Modification/Post Maintenance Testing*.  
**Note:** Throughout this chapter, the terms commission, commissioning, Cx documents, etc. refer to either of the above test documents, based on applicability.
6. For Non-SSC software, this section includes V&V and SWAU for: (a) toolbox codes and (b) software used in SSC design that is Simple and Easily Understood. See SOFT-GEN for definitions.
7. For computer programs that are commercially dedicated, the applicable V&V requirements of this section are required for critical characteristics specified in the CGD technical evaluation. SWAU requirements of this chapter also apply.

**Table 21.4-1 Software SOFT-V&V Summary for SSC Software**  
 (This table is a summary only and does not include all requirement details. See text for details.)

Activity No.	SQM Activity	ML <sup>1</sup>			Implementation Detail			ESM Ch. 21 Ref. <sup>5</sup>
		1, 2	3	4	How	When <sup>2</sup>	Who <sup>3, 4</sup>	
<b>1.0 For <u>Designed</u> SSC Software</b>								
1	Review design (input) requirements	R	Gr	Gr	<ul style="list-style-type: none"> <li>Review design input documents (docs.) to SOFT-DESIGN design (input) requirement criteria</li> <li>As applicable to ML-1 and ML-2 software, ensure Commercial Grade Dedication (CGD) requirements are addressed</li> </ul>	<ul style="list-style-type: none"> <li>Prior to software design as much as practical</li> </ul>	<ul style="list-style-type: none"> <li>SD ( R)</li> <li>SRLM (R)</li> <li>LCxA (R)</li> <li>FDAR (R)</li> </ul>	SOFT-V&V, 4; SOFT-DESIGN, 3
2	Develop/ review test plan (SWTP)	R	Gr	Gr	<ul style="list-style-type: none"> <li>Develop software test plan (SWTP) and submit 60%, 90% and 100% test plan submittals</li> <li>Review test plan to SOFT-V&amp;V test plan criteria</li> <li>Integrate into/with SSC Commissioning (Cx) docs.</li> </ul>	<ul style="list-style-type: none"> <li>After requirements and concurrent with design</li> <li>Prior to interim testing and/or acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (D, R, A)</li> <li>LCxA (R)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 4
3	Review software design (SWDD)	R	Gr	Gr	<ul style="list-style-type: none"> <li>Review to SOFT-DESIGN and SOFT-V&amp;V criteria</li> <li>Review 60%, 90% and 100% software design documents/submittals</li> </ul>	<ul style="list-style-type: none"> <li>Per software design schedule</li> <li>Prior to acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (R)</li> <li>SRLM (R)</li> <li>IR (R)</li> </ul>	SOFT-V&V, 4; SOFT-DESIGN, 3,4
4	Review computer program code	R	-	-	<ul style="list-style-type: none"> <li>Review computer program code where feasible</li> </ul>	<ul style="list-style-type: none"> <li>Prior to acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (R)</li> <li>SRLM (R)</li> <li>IR (R)</li> </ul>	SOFT-V&V, 4
5	Testing/ Commissioning (Cx) & review	R	Gr	Gr	<ul style="list-style-type: none"> <li>Test (including interim tests) per SSC design, software test plan, and Cx docs.</li> <li>Perform acceptance test in simulated test environment (i.e., test bed)</li> <li>Perform acceptance test in operating environment</li> <li>Provide, review &amp; approve test (qualification) report (SWTR)</li> </ul>	<ul style="list-style-type: none"> <li>Per software test plan, Cx docs, and SSC design</li> <li>Prior to approval for use</li> </ul>	<ul style="list-style-type: none"> <li>T (D, R, A)</li> <li>SD (R, A)</li> <li>SO (R, A)</li> <li>LCxA, (R, A)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 4
6	Review/ SWAU	R	Gr	-	<ul style="list-style-type: none"> <li>Prepare software approval for use (SWAU) request package</li> <li>Review to SOFT-MAINT SWAU criteria</li> <li>Approve and document SWAU</li> </ul>	<ul style="list-style-type: none"> <li>Prior to intended use</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 4; SOFT-MAINT, 3

**Table 21.4-1 Software SOFT-V&V Summary for SSC Software**  
 (This table is a summary only and does not include all requirement details. See text for details.)

Activity No.	SQM Activity	ML <sup>1</sup>			Implementation Detail			ESM Ch. 21 Ref. <sup>5</sup>
		1, 2	3	4	How	When <sup>2</sup>	Who <sup>3, 4</sup>	
<b>2.0 For Read Only SSC Software</b>								
1	Review (Input) requirements	R	Gr	Gr	<ul style="list-style-type: none"> <li>Review SSC design/acquisition requirement (input) docs. (e.g. Statement of Work, [SOW]) per governing doc. control process</li> <li>As applicable to ML-1 and ML-2 software, ensure CGD requirements are addressed</li> </ul>	<ul style="list-style-type: none"> <li>Prior to acquisition</li> </ul>	<ul style="list-style-type: none"> <li>Per governing doc. control process</li> </ul>	SOFT-V&V, 5; SOFT-DESIGN, 3; SOFT-ACQUIRE, 3
2	Develop and review test plan	R	Gr	Gr	<ul style="list-style-type: none"> <li>Use SSC Cx documents per <a href="#">ESM</a> Chapter 15 as software test plan documents</li> </ul>	<ul style="list-style-type: none"> <li>Per <a href="#">ESM</a> Chapter 15</li> <li>Prior to Cx</li> </ul>	<ul style="list-style-type: none"> <li>Per <a href="#">ESM</a> Chapter 15</li> </ul>	SOFT-V&V, 5
3	Review the design	R	Gr	Gr	<ul style="list-style-type: none"> <li>Review software as part of the SSC design deliverables (<a href="#">ESM</a> Chapter 1)</li> </ul>	<ul style="list-style-type: none"> <li>Per SSC design schedule</li> </ul>	<ul style="list-style-type: none"> <li>Per governing SSC review process</li> </ul>	SOFT-V&V, 5
4	Commissioning and Review	R	Gr	Gr	<ul style="list-style-type: none"> <li>Test per SSC design and Cx docs.</li> <li>Provide, review, and approve Cx report per <a href="#">ESM</a> Chapter 15</li> </ul>	<ul style="list-style-type: none"> <li>Per Cx docs. and SSC design</li> <li>Prior to approval for use</li> </ul>	<ul style="list-style-type: none"> <li>Per <a href="#">ESM</a> Chapter 15</li> </ul>	SOFT-V&V, 5;
5	Review and approve for use	R	Gr	-	<ul style="list-style-type: none"> <li>Prepare SWAU request package</li> <li>Review to SOFT-MAINT SWAU criteria</li> <li>Approve and document SWAU</li> </ul>	<ul style="list-style-type: none"> <li>Prior to intended use</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 5; SOFT-MAINT, 3
<p><sup>1</sup> ML = Management Level; R = Required; Gr = Required but graded. “-“ = Not required</p> <p><sup>2</sup> “When” constitutes the V&amp;V control points (points in the process where reviews are performed)</p> <p><sup>3</sup> D = Develop or Execute; R = Review; A = Approve</p> <p><sup>4</sup> SD = Software Designer; SO = Software Owner. SRLM = Software Responsible Line Manager. FDAR = Facility Design Authority Representative; T = Testers; IR = Independent Reviewer. LCxA = LANL Commissioning Authority. See associated <a href="#">ESM</a> Chapter 21, SOFT-GEN for more information</p> <p><sup>5</sup> Ref. = <a href="#">ESM</a> Chapter 21 section name and subsection number (e.g., section SOFT-GEN, Subsection 3, Software Identification and Determination)</p>								

4 Section SOFT-V&V: Software Verification and Validation

Rev. 1, 05/25/17

Table 21.4-2 SOFT-V&V Summary for <u>Non-SSC</u> Software								
(This table is a summary only and does not include all requirement details. See text for details.)								
Activity No.	SQM Activity	ML <sup>1</sup>			Implementation Detail			ESM Ch. 21 Ref. <sup>6</sup>
		1, 2	3	4	How	When <sup>2</sup>	Who <sup>3, 4</sup>	
<b>1.0 For <u>Designed</u> Non-SSC Software</b>								
1	Review design (input) requirements	R	R	R	<ul style="list-style-type: none"> <li>Review design input docs. to SOFT-DESIGN design (input) requirement criteria</li> <li>As applicable to ML-1 and ML-2 software, ensure Commercial Grade Dedication (CGD) requirements are addressed</li> </ul>	<ul style="list-style-type: none"> <li>Prior to software design as much as practical</li> <li>Prior to software acquisition</li> </ul>	<ul style="list-style-type: none"> <li>SD ( R)</li> <li>SRLM (R)</li> </ul>	SOFT-V&V, 6; SOFT-DESIGN, 6
2	Model V&V	R	Gr	Gr	<ul style="list-style-type: none"> <li>As applicable, V&amp;V the appropriateness of the model in addition to the computer code</li> <li>Document in design and testing reviews</li> </ul>	<ul style="list-style-type: none"> <li>After requirements and concurrent with design</li> </ul>	<ul style="list-style-type: none"> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 6; SOFT-DESIGN, 6
3	Develop/ review test plan	R	Gr	-	<ul style="list-style-type: none"> <li>Develop software test plan (SWTP) (e.g., Form <a href="#">3055</a> (future)) and submit 60%, 90% and 100% test plan submittals</li> <li>Review test plan to SOFT-V&amp;V test plan criteria</li> </ul>	<ul style="list-style-type: none"> <li>After requirements and concurrent with design</li> <li>Prior to formal interim testing and/or acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (D, R, A)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 6
4	Review software design	R	Gr	Gr	<ul style="list-style-type: none"> <li>Review to SOFT-DESIGN design and SOFT-V&amp;V criteria</li> <li>Review 60%, 90% and 100% software design documents/submittals</li> </ul>	<ul style="list-style-type: none"> <li>Per software design schedule</li> <li>Prior to acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (R)</li> <li>SRLM (R)</li> <li>IR (R)</li> </ul>	SOFT-V&V, 6; SOFT-DESIGN, 6, 7
5	Review computer program code	R	-	-	<ul style="list-style-type: none"> <li>Review computer program code where feasible</li> </ul>	<ul style="list-style-type: none"> <li>Prior to acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (R)</li> <li>SRLM (R)</li> <li>IR (R)</li> </ul>	SOFT-V&V, 6, 8
6	Testing and review	R	Gr	Gr	<ul style="list-style-type: none"> <li>Test per software test plan</li> <li>Provide, review and approve test report (SWTR)</li> </ul>	<ul style="list-style-type: none"> <li>Per software test plan,</li> <li>Prior to approval for use</li> </ul>	<ul style="list-style-type: none"> <li>T (D, R, A)</li> <li>SD (R, A)</li> <li>SO (R, A)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 6

Table 21.4-2 SOFT-V&V Summary for <u>Non-SSC</u> Software								
(This table is a summary only and does not include all requirement details. See text for details.)								
Activity No.	SQM Activity	ML <sup>1</sup>			Implementation Detail			ESM Ch. 21 Ref. <sup>6</sup>
		1, 2	3	4	How	When <sup>2</sup>	Who <sup>3, 4</sup>	
7	Review/ SWAU	R	Gr	-	<ul style="list-style-type: none"> <li>Prepare SWAU request package</li> <li>Review to SOFT-MAINT SWAU criteria</li> <li>Approve and document SWAU</li> </ul>	<ul style="list-style-type: none"> <li>Prior to intended use</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 6; SOFT-MAINT, 4
<b>2.0 For <u>Acquired</u> Non-SSC Software</b>								
1	Model V&V	R	Gr	Gr	<ul style="list-style-type: none"> <li>As applicable, V&amp;V the appropriateness of the model in addition to the computer code</li> <li>Document in acquisition and testing reviews</li> </ul>	<ul style="list-style-type: none"> <li>Should be completed prior to acquisition; must be completed prior to SWAU</li> </ul>	<ul style="list-style-type: none"> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 7; SOFT-DESIGN, 7 SOFT-ACQUIRE, 4
2	Review acquisition (input) requirements	R	R	R	<ul style="list-style-type: none"> <li>Review acquisition input docs. (e.g., SOW) to SOFT-ACQUIRE acquisition (input) requirement criteria</li> <li>As applicable to ML-1 and ML-2 software, ensure CGD requirements are addressed</li> </ul>	<ul style="list-style-type: none"> <li>Prior to software acquisition</li> </ul>	<ul style="list-style-type: none"> <li>SO (R)</li> <li>SRLM (R)</li> </ul>	SOFT-V&V, 7; SOFT-ACQUIRE, 4
3	Develop/ review test plan	R	Gr	-	<ul style="list-style-type: none"> <li>Develop software test plan (SWTP) (e.g., Form <a href="#">3055</a> (future))</li> <li>Review test plan to SOFT-V&amp;V test plan criteria</li> </ul>	<ul style="list-style-type: none"> <li>After requirements and concurrent with acquisition</li> <li>Prior to acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SD (D, R, A)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 7
4	Review acquisition	R	Gr	-	<ul style="list-style-type: none"> <li>Review and document conformance with acquisition documents</li> </ul>	<ul style="list-style-type: none"> <li>Prior to acceptance testing</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> </ul>	SOFT-V&V, 7
5	Testing and review	R	Gr	Gr	<ul style="list-style-type: none"> <li>Test per software test plan</li> <li>Provide, review and approve test report (SWTR)</li> </ul>	<ul style="list-style-type: none"> <li>Per software test plan,</li> <li>Prior to approval for use</li> </ul>	<ul style="list-style-type: none"> <li>T (D, R, A)</li> <li>SD (R, A)</li> <li>SO (R, A)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 7

Table 21.4-2 SOFT-V&V Summary for <u>Non-SSC</u> Software (This table is a summary only and does not include all requirement details. See text for details.)								
Activity No.	SQM Activity	ML <sup>1</sup>			Implementation Detail			ESM Ch. 21 Ref. <sup>6</sup>
		1, 2	3	4	How	When <sup>2</sup>	Who <sup>3, 4</sup>	
6	Review/ SWAU	R	Gr	-	<ul style="list-style-type: none"> <li>Prepare SWAU request package</li> <li>Review to SOFT-MAINT SWAU criteria</li> <li>Approve and document SWAU</li> </ul>	<ul style="list-style-type: none"> <li>Prior to intended use</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 7; SOFT-MAINT, 4
<b>3.0 For Acquired Non-SSC (OTS) – <u>Toolbox Codes</u></b>								
1	V&V and SWAU	R	R	R	<ul style="list-style-type: none"> <li>V&amp;V per the Registry instructions for the toolbox code</li> <li>Prepare SWAU request package</li> <li>Review to SOFT-MAINT SWAU criteria</li> <li>Approve and document SWAU</li> </ul>	<ul style="list-style-type: none"> <li>For each toolbox code installation</li> <li>Prior to intended use</li> </ul>	<ul style="list-style-type: none"> <li>SO (D, R, A)</li> <li>SRLM (R, A)</li> </ul>	SOFT-V&V, 8; SOFT-MAINT, 4
<b>4.0 For <u>Simple &amp; Easily Understood</u> Non-SSC Software Used in Design of SSCs</b>								
1	V&V as part SSC design V&V	R	Gr	Gr	<ul style="list-style-type: none"> <li>V&amp;V using the methods previously described for Non-SSC software, or, V&amp;V the software each time it is used for SSC design in accordance with the SSC design process</li> <li>Provide and review minimum software information (e.g., computer-generated evidence of the programmed algorithms or equations)</li> <li>Apply appropriate SSC design review rigor to ensure the computer program produces satisfactory results.</li> </ul>	<ul style="list-style-type: none"> <li>Each time the software is used for an SSC design and when required by the SSC design V&amp;V process</li> <li>Prior to intended use</li> </ul>	<ul style="list-style-type: none"> <li>As per the applicable SSC design V&amp;V process</li> </ul>	SOFT-V&V, 9; SOFT-MAINT, 4
<p><sup>1</sup> ML = Management Level; R = Required; Gr = Required but graded</p> <p><sup>2</sup> “When” constitutes the V&amp;V control points (points in the process where V&amp;V activities are performed)</p> <p><sup>3</sup> D = Develop or Execute; R = Review or Inspect; A = Approve</p> <p><sup>4</sup> SD = Software Designer; SO = Software Owner. SRLM = Software Responsible Line Manager. FDAR = Facility Design Authority Representative; T = Testers; IR = Independent Reviewer</p> <p><sup>5</sup> A SD subject matter expert (SME) other than the SD that developed the code shall be used to perform the code review</p> <p><sup>6</sup> Ref. = <a href="#">ESM</a> Chapter 21 section name and subsection number (e.g., Section SOFT-GEN, Subsection 3, Software Identification and Determination)</p>								

## 2.0 KEY DEFINITIONS AND ACROYNMS

See SOFT-GEN for definitions and acronyms and note the following: Often the terms verification and validation are confused with each other. In simplified layman's terms: verification indicates whether "you built the item correctly" whereas validation indicates whether "you built the right item."

## 3.0 V&V AND SOFTWARE APPROVAL FOR USE (SWAU) - GENERAL

The following requirements apply to both SSC and Non-SSC software:

- A. Base the extent of V&V on the complexity of the software, the degree of standardization, the similarity with previously approved software, and the importance to safety.

**Note:** For the following Paragraphs B–E, the documentation details are specified in subsequent subsections.

- B. For ML-1 and ML-2 software, trace, document, and V&V the software from requirements development through design, acquisition, testing and SWAU. Refer to [ESM Chapter 20, Systems Engineering](#) (future). See *SOFT-V&V References: V&V Examples* for an example software requirements matrix (SWTM).
- C. For ML-1 through ML-3 software, document the V&V results, including the identification of the verifier/validator.
- D. For ML-1 and ML-2 reviews, document the reviewers, reviewer responsibilities, comments, and dispositions; retain reviewer comments and dispositions as records per the record retention schedule but at least until the software is approved for use.
- E. For ML-3 and ML-4 reviews, at a minimum, document the reviewers (names) and their comments, and retain the comments as records.
- F. Ensure the limits of use associated with the V&V are clearly defined. If the software is intended to be used outside the original limits of use, evaluate and, as appropriate, perform additional V&V to determine if the software can be used for outside the original limits.
- G. For other than acceptance testing reviews, if the review alone is inadequate to determine if requirements are satisfied, use alternate calculations and/or develop and integrate (interim) tests (may include demonstrations) to support the review.
- H. Suppliers that design SSC and Non-SSC software for LANL must V&V software based on Subsection 4 and Subsection 6, respectively. The V&V must be performed as part of the supplier's software product development. For ML-1 and ML-2 software, suppliers must provide V&V processes and objective evidence of the supplier's V&V for LANL review and retention.
- I. LANL workers must complete and document reviews and retain review comments and dispositions as per this section and the governing document control and records management process. For ES-Div Non-SSC software and SSC software, ensure the correct SWID (obtained when completing Form [2033](#)) is part of the documentation record number. See [AP-341-402, Engineering Document Management in Operating Facilities](#) for details.
- J. Protect against suspect/counterfeit items (S/CI) items. As applicable, review and ensure valid software licenses. See [P330-9, Suspect Counterfeit Items \(S/CI\)](#) for additional information on identifying and processing an S/CI item.



## 4 Section SOFT-V&amp;V: Software Verification and Validation

Rev. 1, 05/25/17

- K. Software design verification shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design, but who may be from the same organization. cursory supervisory reviews do not satisfy the intent of this chapter. Verification may be performed by the originator's supervisor, provided (a) the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design, or (b) the supervisor is the only individual in the organization competent to perform the verification.
- L. Verification must include any one or a combination of design reviews, alternate calculations, and tests performed during computer program development. Although multiple reviews are specified herein, the reviews may be performed and documented separately or combined, as appropriate.
- M. Software tools must be evaluated, reviewed, tested, accepted for use, and placed under configuration control; software tools that do not affect the performance of the software need not be placed under configuration control.
- N. When commercial grade dedication (CGD or dedication) is used to V&V software, satisfy NQA-1, Part II, Subpart 2.14, *Quality Assurance Requirements for Commercial Grade Items and Services* and the following:
1. The dedication process shall be documented and include:
    - a. Identification of the capabilities and limitations for intended use as critical characteristics,
    - b. Utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations, and
    - c. Instructions for use (e.g., user manual) within the limits of the dedicated capabilities.
  2. The performance of the actions necessary to accept the software shall be reviewed and approved. The resulting documentation and associated computer program(s) shall establish the current baseline.
  3. For guidance in dedicating computer programs, see [ASME NQA-1-2015 Part III, Subpart 3.2-214](#), *Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services* and the references therein.
  4. Subsequent revisions of ML-1 and ML-2 software from non-NQA-1 qualified suppliers that do not follow NQA-1 Subpart 2.7 to V&V the software for acceptance (as described in SOFT-V&V) shall be dedicated. See SOFT-GEN for details. Unless a more conservative approach is required by the LANL SRLM, use the following graded approach for dedicating MI-1 and ML-2 software revisions (changes):
    - a. Dedicate major changes (see Definitions).
    - b. Dedicate minor changes (see Definitions) if the changes affect the critical characteristic(s) that pertain to the functionality of the computer program or the associated SSC.
  5. Incorporate the following guidance as applicable, when dedicating computer programs (Ref. NQA-1-2015, Part III, Subpart 3.2-2.14):
    - a. *Guidance: Acceptable data for historical performance should evaluate the industry-monitored performance of the commercial*

*grade computer program, industry product tests, certification to national codes and standards (nonnuclear-specific), and other industry records or databases. When a computer program has been demonstrated to be reliable based on its historical performance, it should be credited during dedication. Historical performance should be supported by the use of one of the other verification methods listed above.*

- b. This acceptance method [Method 4: Acceptable Supplier Item or Service Performance Record] should have a greater application for the dedication of computer programs used in design or analysis. Computer programs that are commercially available and that have industrywide application may be used successfully hundreds or even hundreds of thousands of times daily. The results of these uses and engineering judgment associated with the acceptance of the computer program should be considered when dedicating the computer program.*
- c. Errors reported by the users to the supplier and failures associated with structures, systems, and components may be evaluated as part of the failure analysis investigation. This method is most effective when the supplier provides error reports to the purchaser for applicability and significance evaluation and when the users contact the supplier when computer program errors are suspected. A technical support agreement in the procurement documents provides assurance that there is adequate communication between the supplier and users.*

#### 4.0 DESIGNED SSC SOFTWARE V&V AND SWAU

**Note:** To minimize text duplication, many of the Non-SSC software subsections that appear later (e.g., 5-7) refer back to this SSC-related subsection with instructions that the SSC-related requirements do not apply. Therefore, to facilitate comprehension, Subsection 4.0 SSC-only requirements are followed by a red “\*” at the end of the text and these should be modified or ignored in accordance with direction in those later Subsections. If additional clarification is needed, contact the Chapter POC.

Table 21.4-3 summarizes the minimum V&V and SWAU activities for designed SSC software. The text that follows it provides additional detail.

Table 21.4-3 Minimum Required V&V Activities - Designed SSC Software					
No	V&V Activity Description	Apply by ML <sup>1</sup>			
		1	2	3	4
1	Design Requirement (Input) Review	R	R	R	Gr
2	Software Test Plan (SWTP) Development & Review <sup>2</sup>	R	R	Gr	Gr
3	Software Design Review <sup>3</sup>	R	R	Gr	Gr
4	Software Code Review <sup>4</sup>	R	R	-	-
5	Testing/Cx & Review <sup>*2</sup>	R	R	Gr	Gr
6	Software Review and Approval for Use (SWAU)	R	R	Gr	-

<sup>1</sup> R = Required; Gr = Required but graded; "-" = Not required

<sup>2</sup> See [ESM](#) Chapter 15, *Commissioning* for minimum test/commissioning (Cx) requirements based on ML

<sup>3</sup> See SOFT-DESIGN for design deliverables

<sup>4</sup> Where feasible as determined by the LANL SRLM

#### 4.1 Design Requirement (Input) Review

- A. How. In accordance with the governing document control process<sup>1</sup>, review and document the review of design (input) requirements to ensure they satisfy the design requirement criteria in SOFT-DESIGN. As guidance for ML-1 through ML-3 software, use the requirement review criteria from [IEEE Std 1012-2012](#), *IEEE Standard for System and Software Verification and Validation*<sup>2</sup>. For CGD of ML-1 and ML-2 software in accordance with [AP-341-703](#), Commercial Grade Dedication or equivalent, ensure that CGD requirements are addressed.
- B. When. As much as practical, review prior to software design.
- C. Who. The Software Designer (SD), SRLM, LANL Commissioning Authority (LCxA) and FDAR review ML-1 through ML-3 software. \* The FDAR review is not required for ML-4 software.

#### 4.2 Test Plan Development and Review

Tests to verify conformance of a computer program to requirements must be planned and executed. The software test plan (SWTP) may include interim testing to support software design, acceptance testing to support commissioning (Cx) and/or in-use testing to support operations after the software is approved for use (SWAU). \* Therefore, because the test plan may be broader than acceptance testing, it is not used synonymously with Cx test planning documents. The acceptance testing portion of the test plan however, must be integrated into or with Cx documentation. \*

For testing that requires changes to the approved configuration management SSCs of an operating facility, see [AP-341-504](#), *Temporary Modification Control*.\*

<sup>1</sup> See [AP-341-620](#), *Review of LANL Produced Design Documents*; [AP-341-621](#), *Design Authority Technical Review*, [AP-341-622](#), *LANL Review of Designs Produced by External Agencies*, and [AP-321-624](#), *Independent External Design Review*, or approved equivalent.

<sup>2</sup> The V&V tasks/criteria in this standard uses system integrity levels (SILs) for grading instead of MLs; use the following approximate correlation: ML-1 = SIL 4; ML-2 = SIL 3; ML-3 = SIL 2; ML-4 = SIL 1.

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- A. How. Plan tests as required by the SSC design, [ESM](#) Chapter 15, *Commissioning (Cx)*<sup>3</sup> and this Subsection. Document in a test plan. \* Review and disposition comments in accordance with the governing document control process.

Address the following in the test plan:

1. Perform at least one acceptance test in a simulated environment (i.e., test bed or bench testing) for ML-1 software. \* For ML-2 software, perform at least one acceptance testing in a simulated environment when specified by the FDAR. \* Perform simulated environment acceptance tests prior to acceptance testing in the actual operating environment. \*
2. As determined by the FDAR for ML-1 and/or ML-2 software, where the simulated environment without hardware cannot adequately test the software, test in an environment with hardware. \*
3. Perform a comprehensive, end-of-development acceptance test in the operating environment<sup>4</sup> prior to use. Include support software tests as appropriate.
4. As a recommendation and/or as required by other [ESM](#) chapters, plan for tests during various points in the software design (interim tests) in addition to the acceptance test. Interim tests may be informal tests or formal tests to support reviews. Test plan documentation for informal testing is recommended, but not required.
5. Test plan documentation for formal interim tests used to support reviews is required and must satisfy the same applicable criteria as the acceptance test<sup>5</sup>. Include the tests and test results in the acceptance testing documentation.
6. Coordinate and integrate the software test plan and testing with Cx and the governing (SSC) work control requirements. \*
7. For ML-1 through ML-3 software, include software testing required after approval for use (in-use tests) that confirms continued acceptable performance in the operating system. Include either directly in the test plan or through reference to other documents. Perform in-use tests after the computer program is installed on a different computer, or when there are significant changes in the operating system.  
**Note:** The in-use test frequency for ML-3 software is typically less frequent than for ML-1 or ML-2 software. ML-3 in-use tests may be simplified tests that address only the key required software functions. Testing of all functional requirements is not required for ML-3 in-use testing.
8. Create a test record form or template that contains, at a minimum, the following:
  - a. SSC(s)/item tested, \*
  - b. date of test,

<sup>3</sup> See [AP-350-406](#), *Start-up and Commissioning* or equivalent for details.

<sup>4</sup> As determined by the LANL SRLM, where testing in the operating environment introduces unacceptable risk or loss, an exception to performing testing in the operating environment may be pursued in accordance with [ESM](#), Chapter 1, General, Z10, *General Requirements for All Disciplines/Chapters*.

<sup>5</sup> From NQA-1. Note that "same criteria" allows one to employ a subset of the full suite of acceptance test criteria for unit testing (i.e., white box testing); program, subsystem, or system testing (i.e., gray-box testing).

- c. characteristics tested,
  - d. tester (name) and/or data recorder,
  - e. type of observation (i.e., type of test),
  - f. results, applicability and acceptability (of the test),
  - g. action taken in connection with any deviations,
  - h. reference to the test methodology/test plan used with associated revision,
  - i. person evaluating and accepting test results,
  - j. a unique test record identifier to allow traceability to the specific item tested (if not subsequently assigned as part of the records management protocols),
  - k. computer program tested including system software, as applicable<sup>6</sup>,
  - l. computer hardware, as applicable
  - m. test equipment and calibrations, as applicable, (Include equipment identification, calibration date, and calibration expiration date for M&TE, Ref. [P330-2](#))
  - n. simulation models used, as applicable, and
  - o. test problems/cases.
9. Incorporate Appendix A, *Software Test Plan Requirements Table*.
  10. See [ISO/IEC/IEEE 29119](#), *Software and systems engineering—Software testing*, for guidance.
  11. Provide 60%, 90% and 100% test plan submittals for review and approval. See References, *V&V Examples* for an example test plan.
  12. When dedicating software in accordance with [AP-341-703](#), *Commercial Grade Dedication* or equivalent, the acceptance test plan may be a separate test plan or combined with the CGD Technical Evaluation and Acceptance (TEA) Plan. If combined, ensure CGD requirements such as critical characteristics are specified.
  13. Identify and coordinate with associated SSC tests (e.g., qualification tests for seismic qualification of electrical equipment, Ref. [IEEE Std 344](#), *Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations.*) \*
  14. Review, approve and control the test plan (including test record form) in accordance with the governing document control process (e.g., controlled and accessible in EDMS). Review for adequacy and conformance to this chapter.
  15. Maintain test plan accuracy through approval for use.
  16. As required, identify hold and/or witness points and associated responsibilities.
  17. For ML-1 and ML-2 software, design tests to demonstrate performance requirements are satisfied and relevant unintended defects are detected. In

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<sup>6</sup> For read-only software, identify computer program name to the extent possible (See SOFT-GEN).

layman's terms, design tests to try to "break the software"<sup>7</sup>. Incorporate the following:

- a. Incorporate hazards analysis and industry accepted test strategies and techniques.<sup>8</sup>
  - b. Ensure the integrated software/SSC system can handle and recover from errors. \* *Ensure testing addresses latent run-time errors that may occur (e.g., an error that causes a program to continually use up Random Access Memory (RAM) while the program is running that results in a system "crash" after the system is in operation for a time.)*
  - c. Demonstrate that loss of operational control (i.e., the computer program crashes) does not occur in normal and abnormal conditions and/or that software errors do not damage or otherwise cause SSC failures or unsafe conditions. \*
18. For final acceptance tests in the operating environment that are used to verify the quality of ML-1 and ML-2 SSCs in Hazard Category II or II nuclear facilities, include the requirement for testers to satisfy the tester certification requirements of [P330-8](#), *Inspection and Test*. See ESM Ch. 15, and/or [AP-341-801](#), *Post Modification/Post Maintenance Testing* for certification details.
- B. When. Develop after software requirements have been established, and concurrent with the software design. Submit draft test plans with draft software design deliverables. Submit final test plan with the final software design and prior to acceptance testing.
- C. Who. A SD develops, reviews and approves the test plan (including test record form); the LCxA reviews; \* the SRLM reviews and approves. *Review by a quality assurance subject matter expert (QA SME) is recommended for ML-1 and ML-2.*

**Note:** Where possible, the SD should be a subject matter expert (SME) other than the SD that designed the software.

#### 4.3 Software Design Review

- A. How. In accordance with the governing document control process<sup>9</sup>, review and document the review to ensure the software design satisfies the software design criteria specified in SOFT-DESIGN. Perform the following as part of the design review:
1. Review for acceptability of the design requirements, the design and conformance to the design process.
  2. Evaluate the technical adequacy of the approach;
  3. Ensure internal completeness, consistency, clarity, and correctness of the software design.

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<sup>7</sup> If testing of the completed integrated software/hardware unit adequately tests the software, then software-only testing is not required.

<sup>8</sup> See *Certified Software Quality Engineer Handbook*, L. Westfall, American Society of Quality Press.

<sup>9</sup> See [AP-341-620](#), *Review of LANL Produced Design Documents*; [AP-341-621](#), *Design Authority Technical Review*, [AP-341-622](#), *LANL Review of Designs Produced by External Agencies*, and [AP-321-624](#), *Independent External Design Review* or equivalent.

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4. Verify that the software design is compliant with and traceable to the approved software design requirements.
5. Review test results.

As guidance for ML-1 through ML-3 software, use design review criteria from [IEEE Std 1012](#), *IEEE Standard for System and Software Verification and Validation*<sup>10</sup> and [IEEE STD 1028](#), *IEEE Standard for Software Reviews and Audits*.

- B. When. Review in accordance with the software design deliverable submittal schedule and prior to acceptance testing.
- C. Who. The SD and SRLM review. In addition, for ML-1 and ML-2 software, one or more individuals other than those who designed the software must review (Independent Reviewers, or IRs). IRs may be from the same organization.

#### 4.4 Computer Program Code (Code) Review

- A. How. In accordance with the governing document control process, review and document the review to ensure the code satisfies the criteria in SOFT-DESIGN. *Guidance: Use the code review criteria from [IEEE Std 1012](#), IEEE Standard for System and Software Verification and Validation.*<sup>11</sup>
- B. When. Review the code prior to acceptance testing.
- C. Who. The Software Designer (SD) and SRLM review. In addition, an independent reviewer (IR) SME other than the SD that developed the code shall review.

#### 4.5 Testing/Cx, Review, and Report

- A. How. For SSC software (as well as Non-SSC software) test, review and provide test (also commonly referred to as qualification) reports in accordance with the design, software test plan, and as applicable, Cx documents. These reports are referred to as SWTRs. Ensure the following:
  1. Complete activities to prepare for testing in accordance with the governing (SSC) work control documents and: \*
    - a. Ensure required software backups are accessible in the event that a need to “rollback” to original files arises.
    - b. Ensure that documentation required prior to testing has been received.
    - c. Review results and resolution of nonconformances identified by prior tests (e.g., Nonconformance reports (NCRs), bug/error reports, etc.). Ensure that issues have been sufficiently resolved to proceed with the test.
    - d. Ensure suitable environmental conditions exist throughout the testing process.
    - e. As required for integrated software/hardware testing, ensure M&TE such as calipers, thermometers, etc. are in calibration, ready for use, and that proper M&TE maintenance, storage and handling is in place

<sup>10</sup> To apply the V&V tasks/criteria in this standard that uses system integrity levels (SILs) for grading instead of MLs, use the following correlation: ML-1 = SIL 4; ML-2 = SIL 3; ML-3 = SIL 2; ML-4 = SIL 1.

<sup>11</sup> As determined by the LANL SRLM, when it is not feasible for LANL to obtain source code (e.g., for proprietary reasons), review the supplier's code review V&V process and objective evidence.

in accordance with [P330-2](#), *Control and Calibration of Measuring and Test Equipment (M&TE)*, or equivalent. \*

- f. Ensure readiness of temporal test requirements (e.g., ensuring witnesses are present and ready when required etc.).
- g. Verify that those performing and/or supporting testing have the minimum training, qualification, authorization, and as appropriate, certifications. NQA-1 certified testers are required for ML-1 and ML-2 SSC testing in the operating environment in Hazard Category II or III nuclear facilities (Ref. [P330-8](#)).
- h. Ensure a clear understanding of the roles and responsibilities for those performing the test(s), as well as those that may be affected by the test(s).
- i. Perform other activities as may be required by the test plan.
- j. Conduct tests under controlled conditions using established acceptance and performance criteria.
- k. Ensure specified calibration, environmental conditions, and storage requirements are maintained throughout the test process. \*
- l. Ensure configuration requirements are satisfied throughout the duration of the test.
- m. Indicate the status of the test (i.e. tested, not tested, testing in process). Indicate on the SSC or in documents traceable to the SSC to ensure that required tests are performed and to ensure SSCs that have not passed tests are not inadvertently used or operated. For ML-1 and ML-2 software, use physical location, tags, markings, shop travelers, stamps, inspection records, or other suitable means to indicate test status. For Non-SSC software, requiring software to be maintained in a test environment until acceptance testing is complete is an acceptable method to control the test status. Specify the authority for application and removal of tags, markings, or removal from the test environment etc.
- n. Retest, (e.g., regression test) as appropriate, modified and/or replaced software.
- o. Ensure the required post-test configuration is in place after completing the test. \*
- p. Document the test results on a test record form to indicate the ability of the software to satisfactorily perform its intended function/performance criteria. Include the minimum test record information on the form or template (see Section 4.2).
- q. As applicable, ensure that CGD requirements are addressed.
- r. Review and evaluate the test results to requirements and ensure requirements have been satisfied. Assure that the software produces correct results. Determine and document the acceptability of the test in a test (qualification) report (SWTR). Review in accordance with the test plan. Address the following:
  - 1) Perform preliminary evaluations to determine the validity of the test results and the appropriateness of further testing.



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- Identify additional test requirements and required changes to the test plan. Retest as required.
- 2) Analyze and evaluate the data to verify completeness of results, conformance to design (input) requirements, achievement of test objectives, and conformance to the test plan. See References: *V&V Examples* for an example report.
2. Retain test documentation per the governing document control/records management processes. Ensure test records have a unique identifier and are traceable to the software.
- B. When. Conduct tests when specified in the SSC design, test plan, and/or Cx documents and prior to approval for use. \*
- C. Who.
1. For ML-1 – ML-3 software, authorized testers (Ts), as identified in the software plan and/or Cx documents perform tests. \* For ML-4 software, Ts as identified in the SSC design and/or Cx documents perform tests. \*
  2. For ML-1 – ML-3 software, those responsible for review and approval are as indicated in the test plan however must include the following: Lead Tester (T), SD or other SD SME individual familiar with the design detail and intended use of the computer program, SO, LCxA and SRLM. \*
  3. For ML4, authorized Ts shall be facility operations and/or Cx personnel authorized by facility management. The SO, LCxA and SRLM review and approve acceptance tests. \*

#### 4.6 Review and Approval for Use

- A. How. For suppliers, perform software product review and release in accordance with the supplier's quality assurance program. For LANL workers that are approving ML-1 through ML-3 software for use at LANL, review and approve for use (SWAU) in accordance with this Subsection. SWAU is not required for ML-4 software unless invoked by the LANL SLRM.
1. Prepare a SWAU request package that demonstrates: (a) satisfactory completion of V&V, (b) the applicable operational and maintenance (O&M) controls in SOFT-MAINT are in place, and (c) the software is ready to be used in its intended environment.
  2. Perform a review of the SWAU request package using the criteria from SOFT-V&V and SOFT-MAINT and document the review and SWAU<sup>12</sup>. For ML-1 and ML-2 software, include (either directly or through reference) the intended use and any associated limitations, access controls, etc. for using the software. See SOFT-V&V-FM01, *Software Approval for Use Form (SWAU, Sample) With Example*.
  3. For changes to software in LANL facilities, [AP-341-507](#), *SSC Software Change Package* and [AP-341-801](#), *Post Modification/Post Maintenance Testing* may be used to document SWAU. \*

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<sup>12</sup> In cases where the acquisition predated mandatory use of Chapter 21, use the above and/or criteria from the approved QAP and implementing procedures used to deliver the item. Same logic applies to Read-only and Non-SSC software.

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- 4. For startup and restart of ML-1 through ML-3 software in LANL nuclear facilities, the operational readiness processes may be used to document SWAU. See [PD115](#), *LANL Readiness Program*.
- B. When. Review and SWAU prior to intended use (operation).
- C. Who. The SO prepares the SWAU request package. The SRLM reviews and approves ML-1 through ML-3 software for use. If [AP-341-507](#), [PD115](#), or other processes are used for approval for use, the reviews and approvers are as specified in the respective process. \*

5.0 READ-ONLY SSC SOFTWARE V&V AND SWAU

This Subsection applies to LANL workers that acquire Read-Only SSC software. Read-Only software is software where the computer program cannot be changed other than through replacement of the computer program and/or the associated SSC.<sup>13</sup>

Table 21.4-4 presents the minimum V&V and SWAU activities that must be performed for Read-Only SSC software. The following text provides additional detail.

Table 21.4-4 Minimum Required V&V Activities - Read Only SSC Software				
No	V&V Activity Description	Apply by ML <sup>1</sup>		
		-1, -2	3	4
1	Requirement (Input) Review	R	Gr	Gr
2	Test Plan Development and Review <sup>2</sup>	R	Gr	Gr
3	Design Review	R	Gr	Gr
4	Testing/Cx and Review <sup>2</sup>	R	Gr	Gr
5	Review and Approval for Use (SWAU)	R	Gr	-

<sup>1</sup> R = Required; Gr = Required but graded; "-" = Not required.  
<sup>2</sup> See [ESM](#) Chapter 15, *Commissioning* for minimum test/commissioning (Cx) requirements based on ML.

5.1 Requirement (Input) Review

Read Only SSC software input requirements are specified in the SSC design and/or acquisition requirement (input) documents. Examples include a Requirements Criteria Document (RCD) and Statement of Work (SOW). Prior to acquisition, review the SSC requirement to the requirement criteria of the respective document in accordance with the governing document control process. As applicable, ensure CGD requirements are addressed.

5.2 Test Plan Development and Review

Use the SSC Cx documents and SSC design as the software test plan documents. Apply the General Test Plan Requirements in Table 21.4-A1 to Cx as shown in the table. Use the remaining Subsection 4.2 requirements as Cx guidance. Review and approve the Cx documents per [ESM Chapter 15](#) prior to testing.

<sup>13</sup> Facility/system control software is considered designed SSC software for the purposes of this chapter.

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5.3 Design Review

Review the Read-Only software as part of the review of the associated SSC design in accordance with the SSC design deliverable schedule in ESM [Chapter 1](#), Z10. Perform the review in accordance with the governing SSC design review process.<sup>14</sup>

For ML-1 and ML-2 software, review the supplier’s V&V documentation of the software product (e.g., as specified in the Scope of Work such as Exhibit D or H). Review based on Subsection 4 criteria and as applicable, commercial grade dedication (CGD) requirements.

5.4 Testing/Cx and Review

Test per the SSC Cx and SSC design documents. Provide, review and approve Cx report per ESM [Chapter 15](#) prior to approval for use.

5.5 Review and Approval for Use

See Subsection 4.6 and apply to Read-Only SSC software.

6.0 DESIGNED NON-SSC SOFTWARE V&V AND SWAU

Table 21.4-5 summarizes the minimum V&V and SWAU activities for designed Non-SSC software.

The following text provides additional detail.

Table 21.4-5 Minimum Required V&V Activities –Designed Non-SSC Software				
No	V&V Activity Description	Apply by ML <sup>1</sup>		
		-1, -2	3	4
1	Model V&V <sup>2</sup>	R	Gr	Gr
2	Design Requirement Review	R	R	R
3	Test Plan (SWTP) Development and Review	R	Gr	-
4	Design Review <sup>2</sup>	R	Gr	Gr
5	Code Review <sup>4</sup>	R	-	-
6	Testing & Review	R	Gr	Gr
7	Review and Approval for Use (SWAU)	R	Gr	-
<sup>1</sup> R = Required; Gr = Required but graded; “-“ = Not required. <sup>2</sup> Required for software that includes models. <sup>3</sup> See SOFT-DESIGN for design deliverables. <sup>4</sup> Where feasible as determined by the LANL SRLM.				

6.1 Model V&V

A. How. For software that includes models (see SOFT-DESIGN), verify and validate the appropriateness of the model in addition to the appropriateness of the computer code used to provide the outcome of the model. In addition to the requirements of this subsection, use industry accepted model V&V methods to quantify confidence and

<sup>14</sup> See [AP-341-620](#), Review of LANL Produced Design Documents; [AP-341-621](#), Design Authority Technical Review, and [AP-341-622](#), LANL Review of Designs Produced by External Agencies.

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build credibility in a numerical model for the purpose of making a prediction.<sup>15,16</sup> Example methods include alternate calculations, references to previously established standards and practices, and specialized peer reviews. Document the model V&V in addition to the computer code V&V as part of the software design and testing reviews.

- B. When. After requirements and concurrent with design.
- C. Who. The SRLM reviews and approves.

**6.2 Design Requirement (Input) Review**

See Subsection 4.1 and apply the following clarifications:

- Requirements associated with SSCs do not apply.
- FDAR and LCxA review are not required.

**6.3 Test Plan Development and Review**

See Subsection 4.2 and apply the following clarifications:

- Requirements associated with SSCs, including commissioning (Cx) and governing SSC work controls do not apply.
- Acceptance testing in a simulated environment (i.e., test bed) does not apply.
- See Form [3055](#), Software Test Plan (future) for an example test plan template

**6.4 Software Design Review**

See Subsection 4.3.

**6.5 Designed Non-SSC Computer Program Code Review**

See Subsection 4.4.

**6.6 Testing and Review**

See Subsection 4.5 and apply the following clarification:

- Requirements associated with SSCs, including testing in simulated environment, commissioning (Cx), governing SSC work controls and M&TE do not apply.

**6.7 Review and Approval for Use**

See Subsection 4.6 and apply the following clarifications:

- Requirements associated with SSCs, including [AP-341-507](#), do not apply.
- For changes of ML-1 through ML-3 software in LANL facilities, use SOFT-GEN-FM03, *Non-SSC Software Change Package Form (SWNCP)* or equivalent.

**7.0 ACQUIRED NON-SSC SOFTWARE V&V AND SWAU**

Table 21.4-5 presents the minimum V&V and SWAU activities that must be performed for acquired Non-SSC software. The following text provides additional detail.

<sup>15</sup> LA-14167-MS, Los Alamos National Laboratory, *Concepts of Model Verification and Validation*, Thacker et al., 2004.

<sup>16</sup> ANSI/ANS 10.7-2013, *Non-Real-Time, High-Integrity Software for the Nuclear Industry – Developer Requirements*.

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Table 21.4-5 Minimum Required V&V Activities – Acquired Non-SSC Software				
No	V&V Activity Description	Apply by ML <sup>1</sup>		
		1, 2	3	4
1	Model V&V <sup>2</sup>	R	Gr	Gr
2	Acquisition Requirement (Input) Review	R	R	R
3	Test Plan (SWTP) Development and Review <sup>3</sup>	R	Gr	-
4	Acquisition Review	R	Gr	-
5	Testing & Review <sup>3</sup>	R	Gr	Gr
6	Review and Approval for Use (SWAU)	R	Gr	-

<sup>1</sup> R = Required; Gr = Required but graded; \* = Not Required.  
<sup>2</sup> Required for software that includes models.  
<sup>3</sup> For software acquired from an NQA-1 qualified supplier, most of the V&V requirements are satisfied by the supplier.

**7.1 Model V&V**

See Subsection 6.1. Model V&V should be completed prior to acquisition and must be completed prior to SWAU.

**7.2 Acquisition Requirement (Input) Review**A. How.

1. In accordance with the governing acquisition and associated document control processes<sup>17</sup>, review the acquisition documents (e.g., Statement of Work, Exhibit H etc.) to ensure they satisfy the acquisition criteria in the SOFT-ACQUIRE. As applicable, ensure CGD requirements are addressed.

B. When. Review prior to software acquisition.C. Who. The SO and SRLM review.**7.3 Test Plan Development and Review**

See Subsection 4.2 and apply the following clarifications:

- Subsection 4.2 does not apply to ML-4 software unless invoked by the LANL SLRM. Install and test per the supplier instructions.
- For software obtained from an NQA-1 qualified supplier, most of the V&V requirements, including acceptance test plan and testing activities, have been performed by the supplier. Prepare a simplified test plan that uses the applicable supplier-provided test cases (and/or other test cases) to demonstrate the software is adequately installed, suitable for the intended application, and properly working in the intended operating environment. See Form [3055](#), Software Test Plan (future).
- For ML-1 and ML-2 **safety** software acquired from a non-NQA-1 qualified supplier, apply chapter test plan and testing requirements for the software critical characteristics specified in the CGD technical evaluation.
- For ML-3 safety software and ML-1 through ML-3 non-safety software, CGD is not required; however, prepare a test plan and perform testing in accordance with this

<sup>17</sup> See P840-1, *Quality Assurance for Procurements* or equivalent.

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chapter for the key software functional requirements required for the intended application.

- Requirements associated with SSCs, including commissioning (Cx) and governing SSC work controls do not apply
- Acceptance testing in a simulated environment (i.e., test bed) does not apply
- Testing associated with software design (e.g., interim tests) do not apply
- Preparation or incorporation of a hazard analysis is not required
- The test plan is prepared, reviewed and approved in accordance with the governing document control process
- Supplier-provided test cases, documentation and comparative alternate calculations/published data may be used to demonstrate the software meets requirements for its intended use.
- Perform test plan development and review after establishing requirements, concurrent with the acquisition, and prior to acceptance testing.
- The SO or a SD may develop the test plan.

**7.4 Acquisition Review**

- A. How. For ML-1 through ML-3 software, review the acquired software for conformance to the acquisition documents (see SOFT-ACQUIRE). Evaluate the technical adequacy and completeness and verify that the software is traceable to the acquisition requirements. As applicable, review in accordance with CGD requirements. As applicable, ensure valid software licenses and markings that indicate original manufacture's product to help prevent acquisition of suspect/counterfeit software. Document the review (checklist recommended) and retain a record of the review in accordance with the governing document control/records management processes. *Guidance: An example checklist is posted below this section on the website (Note: At time of writing, the example was for MACCS2, a safety basis toolbox code, so the checklist does not contain all the tasks/documents that would be appropriate for a non-toolbox program; these would need to be added by the checklist preparer).*
- B. When. Review prior to acceptance testing.
- C. Who. The SO performs the acquisition review.

**7.5 Testing and Review**

See Subsection 6.6 with the following clarifications:

- Requirements associated with software design (e.g., interim testing) do not apply.
- Subsection 6.6 does not apply to ML-4 software unless invoked by the LANL SLRM. Install and test per the supplier instructions.

**7.6 Review and Approval for Use**

See Subsection 6.7.

**8.0 TOOLBOX CODE V&V AND SWAU**

- A. How. V&V toolbox codes (see SOFT-ACQUIRE for definition and information) in accordance with the Registry instructions for the specific toolbox code. Review and SWAU per Subsection 6.7.

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- B. When. Complete for each installation of a toolbox code.
- C. Who. The SO performs and the SO and SRLM review and approve.

**9.0 SIMPLE & EASILY UNDERSTOOD NON-SSC SOFTWARE V&V/SWAU**

- A. How. Perform V&V/SWAU on “Simple and Easily Understood” Non-SSC software used in the design of the SSCs per Subsections 6 or 7 (pre-verify), or V&V/SWAU as part of the SSC design V&V for each time it is used (individually verify).
  - 1. To individually verify:
    - a. Follow the SSC design process. Document the design analysis (e.g., [AP 341-605](#), *Calculations*, for LANL). Include the following in the calculation:
      - 1) Whether the software is pre-verified or individually verified
      - 2) the objective of the analyses
      - 3) design inputs and their sources
      - 4) results of literature searches or other applicable background data
      - 5) assumptions and indication of those assumptions that must be verified as the design proceeds.
      - 6) identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence or reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.
      - 7) review and approval.
    - b. The following software information should be included in the SSC design verification documentation and retained as a record: (e.g., calculation documentation): (a) design inputs, (b) the computer-program-generated results, (c) computer-generated evidence of the programmed algorithms or equations (e.g., computer program listings, spreadsheet cell contents).
    - c. Those performing individual software verifications must be cognizant that software may not have undergone CGD and/or may not have been purchased from an NQA-1 supplier. Accordingly, they must apply the appropriate rigor in the SSC design review to ensure the computer program produces satisfactory results. Show that the software produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. As applicable, show that the encoded mathematical model produces a valid solution to the physical problem associated with the particular application.
  - 2. To SWAU, see Subsection 6.7.
- B. When. V&V/SWAU the software each time the software is used for a SSC design, when required by the SSC design V&V process, and prior approval of the associated SSC design.

- C. Who. As per the applicable SSC design V&V process.

## APPENDICES, FORMS, AND REFERENCES

### APPENDICES:

APPENDIX A: SOFTWARE TEST PLAN REQUIREMENTS TABLE

### FORMS:

SOFT-V&V-FM01: SOFTWARE APPROVAL FOR USE FORM (SWAU)

### REFERENCES:

V&V EXAMPLES

The reference collection associated with SOFT-V&V contains example V&V documentation. Examples initially provided are for informational purposes only and have not been reviewed for compliance to the requirements of this chapter. Better examples will be posted as they are shared with chapter POC. At time of writing, they included:

Example Requirements Traceability Matrix (Source Tracker)

Example No. 1 Test Plan (Source Tracker)

Example No. 1 Test Plan/Report (Source Tracker)

Example No. 2 Test Report

Example No. 3 Test Report

Example SWAU Request Package Checklist (MACCS2)



## APPENDIX A: COMPUTER PROGRAM TEST PLAN REQUIREMENTS

Table 21.4-A1 provides computer program test plan requirements. The text in *italicized print* should be used as guidance for all items marked as “Gr”.

Table 21.4-A1 Computer Program Test Plan Requirements					
No	Requirement	Apply by ML <sup>1</sup>			
		1	2	3	4
<b>1.0 General Test Plan Requirements<sup>6</sup></b>					
1.01	Include or reference the test name, objective(s) and date.	R	R	R	*
1.02	Include or reference the test configuration ( <i>including pre-test, during testing, and post-test configurations where appropriate</i> ).	R	R	Gr <sup>2</sup>	*
1.03	Satisfy test prerequisites. Prerequisites include the following as applicable: calibrated instrumentation, appropriate and/or special equipment, trained personnel, condition of test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. Ensure suitability and readiness of equipment and/or algorithms used for simulated computer program test inputs/fault seeding.	R	R	R	*
1.04	Assure that suitable environmental conditions are satisfied during testing	R	R	R	*
1.05	Assure adequate instrumentation is available and used.	R	R	R	*
1.06	Assure appropriate tests and equipment are used (e.g., performance of a pneumatic leak test may be required because a hydrostatic leak test could damage the item). Select measuring and test equipment based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.	R	R	R	*
1.07	Provide for traceability of measuring and test equipment to the test.	R	R	R	*
1.08	Assure necessary monitoring is performed.	R	R	R	*
1.09	Specify characteristics to be tested.	R	R	R	*
1.10	Obtain test requirements and acceptance criteria <i>from, or approved by, the responsible design organization</i> .	R	R	Gr	*
1.11	Control the test. (This includes controlling changes during testing; includes as appropriate, software design verification, factory acceptance, site acceptance, and in-use tests.)	R	R	R	*
1.12	Control tests under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.	R	R	R	*
1.13	Develop/specify test methods to obtain necessary data with sufficient accuracy for evaluation and acceptance.	R	R	R	*
1.14	Base test requirements and acceptance criteria upon specified requirements contained in the applicable design documents, or other pertinent technical documents that provide approved requirements. Ensure acceptance criteria are specific, unambiguous, measurable, and attainable.	R	R	R	*
1.15	Document and maintain test results.	R	R	R	*
1.16	When changes to an approved configuration management SSC of an operating facility are required for testing purposes, obtain approval by the Facility Design Authority (DA) or FDAR, and others as required in the governing work control process (e.g., <a href="#">AP-341-504</a> , <i>Temporary Modification Control</i> ), prior to performing the test.	R	R	R	*

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No	Requirement	Apply by ML <sup>1</sup>			
		1	2	3	4
1.17	When identification and traceability requirements are specified in requirements documents, design the test to satisfy the requirements.	R	R	R	*
1.18	When post-installation testing is planned, mutually establish post-installation test requirements and acceptance documentation with the item purchaser and supplier.	R	R	R	*
1.19	When special process examinations/tests are performed (e.g., Nondestructive Examination (NDE) such as radiographic testing, magnetic particle testing, ultrasonic testing, liquid penetrant testing, electromagnetic testing, neutron radiographic testing, leak testing, acoustic emission testing, and visual testing), address the applicable requirements of <a href="#">STD-342-100, Engineering Standards Manual</a> , Chapter 13, <i>Welding, Joining &amp; NDE</i> , and <a href="#">P330-5, Special Processes</a> .	R	R	R	*
1.20	Perform testing in accordance with the governing work control process and the test plan; address applicable health, safety, environmental and security requirements associated with the testing. Ensure post-configuration conditions meet post-configuration test plan requirements, including approvals as required.	R	R	R	*
1.21	Evaluate conformance of test results with test requirements and acceptance criteria.	R	R	R	*
1.22	Identify those responsible for accepting the test(s).	R	R	R	*
1.23	The process for obtaining a consent to waive specified hold points (testing, inspection and/or witness holds) or, make changes to the test plan, must be as described in applicable work control documents (e.g., field change, design change process, etc.) that govern configuration management for the item. If the waiver and/or change process is not addressed in the governing work control process, then address the waiver process, including obtaining consent from authorized personnel, in the test plan.	R	R	R	*
1.24	Obtain consent to waive hold points prior to continuation of work beyond the designated hold point and ensure documentation of the consent.	R	R	R	*
1.25	As applicable, develop and prepare an approach to sampling. <i>When used, base sampling on standard statistical methods with approval from the responsible engineer for the item. Obtain support from the responsible engineer and/or quality assurance representative in development of the plan as required. When used for accepting commercial grade items and services, base sampling upon standard statistical methods with supporting engineering justification. Consider lot/batch/traceability, homogeneity, and the complexity of the item.</i> If sampling is performed, document the sampling method <i>and the approval of the method by the responsible engineer.</i> When less than 100% sampling is used, draw samples at random.	R	R	Gr	*
1.26	<i>Demonstrate adequacy of performance under conditions that simulate the most adverse design conditions with operating modes and environmental conditions considered in determining the most adverse conditions.</i> <sup>4</sup>	R	R	Gr	*
1.27	<i>Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. Establish and verify scaling laws when tests are being performed on models or mockups.</i> <sup>4</sup>	R	Gr	Gr	*
1.28	<i>Perform error analysis, where applicable, on the results of model test work prior to the use of the final design.</i> <sup>4</sup>	R	Gr	Gr	*
<b>2.0 Additional Test Plan Requirements for General Computer Program Testing<sup>6</sup></b>					
2.01	<i>Involve engineering, in accordance with the governing work control process, as applicable, in safety software inspection, including obtaining concurrence to the acceptability of safety software verification results.</i>	R	R	Gr	*

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No	Requirement	Apply by ML <sup>1</sup>			
		1	2	3	4
2.02	<i>Obtain test requirements and acceptance criteria by the organization responsible for the use of the computer program.</i>	R	R	Gr	*
2.03	Include required tests, test sequence and frequency.	R	R	R	*
2.04	Include required ranges of input parameters.	R	R	R	*
2.05	Identify the stages at which testing is required.	R	R	R	*
2.06	<i>Include criteria for establishing test cases.</i>	R	R	Gr	*
2.07	<i>Include requirements for testing logic branches.</i>	R	R	Gr	*
2.08	Include requirements for hardware integration.	R	R	R	*
2.09	Include anticipated output values.	R	R	R	*
2.10	Include acceptance criteria, reports, records, standard formatting, and conventions.	R	R	R	*
2.11	Demonstrate the adherence of the computer program to documented requirements.	R	R	R	*
2.12	<i>Evaluate technical adequacy through comparison of test results from alternative methods such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.<sup>3</sup></i>	R	R	Gr	*
2.13	<i>For software design verification testing, demonstrate the capability of the computer program(s) to provide valid results for test problems encompassing a range of documented permitted usage.<sup>4</sup></i>	R	R	Gr	*
2.14	For those computer programs used for operational control, demonstrate required performance over the range of operation of the controlled function or process.	R	R	R	*
2.15	<i>For computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance, prescribe and perform periodic in-use manual or automatic self-check tests.<sup>5</sup></i>	R	R	Gr	*
2.16	Provide for system software testing. <i>For new or revised software, evaluate, review, test, and accept for use. Place system software under configuration change control. Evaluate system software changes for impact on the software product to determine the required level of retesting.</i>	R	R	Gr	*
<b>3.0 Additional Test Plan Requirements for Computer Program Acceptance Testing<sup>7</sup></b>					
3.01	Include the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.	R	R	R	*
3.02	Demonstrate that the computer program adequately and correctly performs all intended functions (i.e., specified software design and operating requirements). <sup>8</sup>	R	R	R	*
3.03	Demonstrate that the computer program properly handles abnormal conditions and events <i>as well as credible failures. As applicable include cybersecurity vulnerability testing.</i>	R	R	Gr	*
3.04	Demonstrate that the computer program does not perform adverse unintended functions.	R	R	R	*
3.05	<i>Demonstrate that the computer program does not degrade the system either by itself, or in combination with other functions or configuration items.</i>	R	R	Gr	*
3.06	Ensure that acceptance testing is performed and passed prior to approval of the computer program for use.	R	R	R	*

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No	Requirement	Apply by ML <sup>1</sup>			
		1	2	3	4
3.07	Ensure that configuration items are identified and are under configuration change control prior to starting acceptance testing.	R	R	R	*
3.08	Ensure that acceptance testing is planned, performed, and passed <i>for all software design requirements</i> .	R	R	Gr	*
3.09	Ensure that acceptance testing ranges from a single test of all software design requirements to a series of tests performed during computer program development. (Performance of a series of tests provides assurance of correct translation between activities and proper function of individual modules).	R	R	R	*
3.10	Include a comprehensive acceptance test that is performed in the operating environment prior to use.	R	R	R	*
3.11	<i>Provide for documentation and disposition of observations of unexpected or unintended results prior to test approval.</i>	R	R	Gr	*
3.12	For acceptance testing of changes to a computer program, provide for selective retesting to detect unintended adverse effects introduced during changes to the computer program. Provide assurance that the changes have not caused unintended adverse effects in the computer program, and to verify that a modified system (s) or system component (s) still meets specified software design requirements.	R	R	R	*

## Notes:

<sup>1</sup> R = Required; Gr = Graded by using *italicized text* as guidance and non-italicized text as required; \* = As required by [ESM](#) Chapter 15, *Commissioning* and the SRLM.

<sup>2</sup> Not used.

<sup>3</sup> Applies to Non-SSC software only.

<sup>4</sup> Applies to design verification testing only, reference NQA-1, Part I, Requirement 3, *Design Control*.

<sup>5</sup> Apply as required during testing to ensure that test results are valid.

<sup>6</sup> From NQA-1, Part I, Requirement 11, *Test Control*. As applicable, General Test Plan Requirements apply to testing of items as graded (items that include computer programs or do not include computer programs). Additional Test Plan Requirements for General Computer Program Testing apply to formal interim computer program tests and computer program acceptance tests as graded.

<sup>7</sup> From NQA-1, Part II, Subpart 2.7, *Quality Assurance Requirements for Computer Software for Nuclear Facility Applications* and associated guidance. As applicable, additional Test Plan Requirements for Computer Program Acceptance Testing apply to acceptance testing of computer programs in addition to requirements under Headings 1 and 2 in this table as graded in the table.

<sup>8</sup> If the software is required to perform a Technical Safety Requirement (TSR) surveillance, demonstrate satisfactory execution of the surveillance as part of the acceptance test.