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RECORD OF REVISIONS

Rev.	Date	Description	POC	RM
0	06/23/2016	Initial issue as provisional document.	Tobin Oruch, <i>ES-DO</i>	Mel Burnett, <i>CENG-OFF</i>
1	05/25/2017	Made mandatory. Added acquisition document review and an example request package checklist; clarifications	Tobin Oruch, <i>ES-DO</i>	Lawrence Goen, <i>ES-DO</i>
2	02/11/2026	Merged/streamlined requirements for designed SSC and Non-SSC software. Clarified requirements for toolbox code V&V and Simple and Easily Understood software.	Tobin Oruch, <i>ES-FE</i>	Michael Richardson, <i>ES-DO</i>

As with all Los Alamos National Laboratory (LANL) Engineering Standards, please contact the chapter point of contact ([POC](#)) (LANL only) with comments, issues, etc. For LANL, suggestions and questions may be entered in the Engineering Standards Manual (ESM) tool [here](#).

SOFT-V&V: SOFTWARE VERIFICATION AND VALIDATION

1.0 INTRODUCTION

1.1 Purpose

SOFT-V&V addresses software verification and validation (V&V) and software approval for use (SWAU).

For non-SSC (structure, system, and component) software, it also includes such requirements of both safety basis toolbox codes used for analysis and “simple and easily understood” software used in the design of the SSCs.

1.2 Applicability

See Sections 1.0–2.0 of SOFT-INTRO for a description of the overall applicability of Chapter 21 requirements.

For SSC software, use SOFT-V&V in conjunction with ESM Chapter 15, *Commissioning*; AP-341-801, *Post Modification/Post Maintenance (PMT)*; or both.

Note: Throughout this chapter, the terms commission, commissioning, commissioning documents, Cx, etc., refer to either of the above test-related documents, based on applicability.

When making software changes during V&V see SOFT-GEN for additional requirements.

1.3 Summary Tables

The following tables provide an overview of the requirements and deliverables of this Section. **They also address who performs tasks, and when.**

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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 ¹			Implementation Detail			Reference ESM Ch. 21 Ref. ⁵
		1, 2	3	4	How	When ²	Who ^{3, 4}	
1.0 For Designed SSC Software								
1	Review design (input) requirements	R	Gr	Gr	<ul style="list-style-type: none"> Review design input documents (“docs”) to SOFT-DESIGN design (input) requirement criteria As applicable to ML-1 and ML-2 software, ensure commercial grade dedication (CGD) requirements are addressed 	<ul style="list-style-type: none"> Before software design as much as practical 	<ul style="list-style-type: none"> SD (R) SRLM (R) LCxA (R) FDAR (R) 	SOFT-V&V, 4; SOFT-DESIGN, 3
2	Develop/review test plan (SWTP)	R	Gr	Gr	<ul style="list-style-type: none"> Develop software test plan (SWTP) and submit 60%, 90%, and 100% test plan submittals Review test plan according to SOFT-V&V test plan criteria Integrate into/with SSC commissioning (Cx) docs 	<ul style="list-style-type: none"> After requirements and concurrent with design Before interim testing, acceptance testing, or both 	<ul style="list-style-type: none"> SD (D, R, A) LCxA (R) SRLM (R, A) 	SOFT-V&V, 4
3	Review software design	R	Gr	Gr	<ul style="list-style-type: none"> Review according to SOFT-DESIGN and SOFT-V&V criteria Review 60%, 90%, and 100% software design documents/submittals 	<ul style="list-style-type: none"> Per software design schedule Before acceptance testing 	<ul style="list-style-type: none"> SD (R) SRLM (R) IR (R) 	SOFT-V&V, 4; SOFT-DESIGN, 3, 4
4	Review computer program code	R	-	-	<ul style="list-style-type: none"> Review computer program code where feasible 	<ul style="list-style-type: none"> Before acceptance testing 	<ul style="list-style-type: none"> SD (R) SRLM (R) IR (R) 	SOFT-V&V, 4
5	Test/commission and review	R	Gr	Gr	<ul style="list-style-type: none"> Test (including interim tests) per SSC design, software test plan, and Cx docs Perform acceptance test in simulated test environment (i.e., test bed) Perform acceptance test in operating environment Provide, review, and approve test (qualification) report (SWTR) 	<ul style="list-style-type: none"> Per software test plan, Cx docs, and SSC design Before approval for use 	<ul style="list-style-type: none"> T (D, R, A) SD (R, A) SO (R, A) LCxA (R, A) SRLM (R, A) 	SOFT-V&V, 4

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6	Review/SWAU	R	Gr	-	<ul style="list-style-type: none"> Prepare software approval for use (SWAU) request package Review according to SWAU criteria Approve and document SWAU 	<ul style="list-style-type: none"> Before intended use 	<ul style="list-style-type: none"> SO (D) SRLM (R, A) FDAR 	SOFT-V&V, 4; SOFT-MAINT, 3
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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 ¹			Implementation Detail			Reference ESM Ch. 21 Ref. ⁵
		1, 2	3	4	How	When ²	Who ^{3, 4}	
2.0 For Read-Only SSC Software								
1	Review (input) requirements	R	Gr	Gr	<ul style="list-style-type: none"> Review SSC design/acquisition requirement (input) docs. (e.g., statement of work [SOW]) per governing doc control process As applicable to ML-1 and ML-2 software, ensure CGD requirements are addressed 	<ul style="list-style-type: none"> Before acquisition 	<ul style="list-style-type: none"> Per governing doc control process 	SOFT-V&V, 6; SOFT-DESIGN, 3; SOFT-ACQUIRE, 2
2	Develop and review test plan	R	Gr	Gr	<ul style="list-style-type: none"> Use SSC Cx documents as software test plan documents 	<ul style="list-style-type: none"> Per ESM Chapter 15 or AP-341-801, Post Modification/Post Maintenance Before Cx 	<ul style="list-style-type: none"> Per ESM Chapter 15 or AP-341-801, Post Modification/Post Maintenance 	SOFT-V&V, 6
3	Review design	R	Gr	Gr	<ul style="list-style-type: none"> Review software as part of the SSC design deliverables (ESM Chapter 1) 	<ul style="list-style-type: none"> Per SSC design schedule 	<ul style="list-style-type: none"> Per governing SSC review process 	SOFT-V&V, 6
4	Commission and review	R	Gr	Gr	<ul style="list-style-type: none"> Test per SSC design and Cx docs Provide, review, and approve Cx report 	<ul style="list-style-type: none"> Per Cx docs and SSC design Before approval for use 	<ul style="list-style-type: none"> Per ESM Chapter 15 or AP-341-801, Post Modification/Post Maintenance 	SOFT-V&V, 6
5	Review and approve for use	R	Gr	-	<ul style="list-style-type: none"> Prepare SWAU request package Review according to SWAU criteria Approve and document SWAU 	<ul style="list-style-type: none"> Before intended use 	<ul style="list-style-type: none"> SO (D) SRLM (R, A) 	SOFT-V&V, 6; SOFT-MAINT, 3

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- ¹ ML = management level; R = required; Gr = required but graded; “-” = not required
- ² “When” constitutes the V&V control points (points in the process when reviews are performed)
- ³ D = develop or execute; R = review; A = approve
- ⁴ 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 [ESM](#) Chapter 21, SOFT-GEN, for more information
- ⁵ Ref. = [ESM](#) Chapter 21 section name and subsection number (e.g., Section SOFT-GEN, Subsection 2, *Software Identification and Determination*)

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 ¹			Implementation Detail			Reference ESM Ch. 21 Ref. ⁵
		1, 2	3	4	How	When ²	Who ^{3,4}	
1.0 For <u>Designed</u> Non-SSC Software								
1	Review design (input) requirements	R	R	R	<ul style="list-style-type: none"> ▪ Review design input docs according to SOFT-DESIGN design (input) requirement criteria ▪ As applicable to ML-1 and ML-2 software, ensure commercial grade dedication (CGD) requirements are addressed 	<ul style="list-style-type: none"> ▪ Before software design as much as practical ▪ Before software acquisition 	<ul style="list-style-type: none"> ▪ SD (R) ▪ SRLM (R) 	SOFT-V&V, 4; SOFT-DESIGN, 3
2	Model V&V	R	Gr	Gr	<ul style="list-style-type: none"> ▪ As applicable, V&V the appropriateness of the model in addition to the computer code ▪ Document the model V&V in design and testing reviews 	<ul style="list-style-type: none"> ▪ After requirements and concurrent with design 	SRLM (R, A)	SOFT-V&V, 4; SOFT-DESIGN, 4
3	Develop/ review test plan	R	Gr	-	<ul style="list-style-type: none"> ▪ Develop SWTP (e.g., Form 2329 and Form 2328, or Form 3055 if preferred/available) and submit 60%, 90%, and 100% test plan submittals ▪ Review test plan according to SOFT-V&V test plan criteria 	<ul style="list-style-type: none"> ▪ After requirements and concurrent with design ▪ Before formal interim testing, acceptance testing, or both 	<ul style="list-style-type: none"> ▪ SD (D, R, A) ▪ SRLM (R, A) 	SOFT-V&V, 4
4	Review software design	R	Gr	Gr	<ul style="list-style-type: none"> ▪ Review according to SOFT-DESIGN design and SOFT- 	<ul style="list-style-type: none"> ▪ Per software design schedule 	<ul style="list-style-type: none"> ▪ SD (R) ▪ SRLM (R) 	SOFT-V&V, 4; SOFT-DESIGN, 4

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					V&V criteria <ul style="list-style-type: none"> Review 60%, 90%, and 100% software design documents/submittals 	<ul style="list-style-type: none"> Before acceptance testing 	IR (R)	
5	Review computer program code	R	-	-	<ul style="list-style-type: none"> Review computer program code where feasible 	<ul style="list-style-type: none"> Before acceptance testing 	<ul style="list-style-type: none"> SD (R) SRLM (R) IR (R) 	SOFT-V&V, 4, 8 SOFT-DESIGN, 5
6	Test and review	R	Gr	Gr	<ul style="list-style-type: none"> Test per software test plan Provide, review, and approve test report 	<ul style="list-style-type: none"> Per software test plan Before approval for use 	<ul style="list-style-type: none"> T (D, R, A) SD (R, A) SO (R, A) SRLM (R, A) 	SOFT-V&V, 4
7	Review/SWAU	R	Gr	-	<ul style="list-style-type: none"> Prepare SWAU request package Review according to SOFT-MAINT SWAU criteria Approve and document SWAU 	<ul style="list-style-type: none"> Before intended use 	<ul style="list-style-type: none"> SO (D) SRLM (R, A) 	SOFT-V&V, 4; SOFT-MAINT, 4

2.0 For Acquired Software

1	Model V&V	R	Gr	Gr	<ul style="list-style-type: none"> As applicable, V&V the appropriateness of the model in addition to the computer code Document the model V&V in acquisition and testing reviews 	<ul style="list-style-type: none"> Should be completed before acquisition; must be completed before SWAU 	<ul style="list-style-type: none"> SRLM (R, A) 	SOFT-V&V, 5; SOFT-DESIGN, 7; SOFT-ACQUIRE (ALL)
2	Review acquisition (input) requirements	R	R	R	<ul style="list-style-type: none"> Review acquisition input docs (e.g., SOW) according to SOFT-ACQUIRE acquisition (input) requirement criteria As applicable to ML-1 and ML-2 software, ensure CGD requirements are addressed 	<ul style="list-style-type: none"> Before software acquisition 	<ul style="list-style-type: none"> SO (R) SRLM (R) 	SOFT-V&V, 5; SOFT-ACQUIRE (ALL)
3	Develop/review test plan	R	Gr	-	<ul style="list-style-type: none"> Develop SWTP (e.g., Form 2329 and Form 2328, or Form 3055 if preferred/available) Review test plan according to SOFT-V&V test plan criteria 	<ul style="list-style-type: none"> After requirements and concurrent with acquisition Before acceptance testing 	<ul style="list-style-type: none"> SD (D, R, A) SRLM (R, A) 	SOFT-V&V, 5
4	Review acquisition	R	Gr	-	<ul style="list-style-type: none"> Review and document conformance with acquisition documents 	<ul style="list-style-type: none"> Before acceptance testing 	<ul style="list-style-type: none"> SO (D) 	SOFT-V&V, 5
5	Test and review	R	Gr	Gr	<ul style="list-style-type: none"> Test per software test plan Provide, review, and approve test report 	<ul style="list-style-type: none"> Per software test plan Before approval for use 	<ul style="list-style-type: none"> T (D, R, A) SD (R, A) SO (R, A) SRLM (R, A) 	SOFT-V&V, 5

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6	Review/ SWAU	R	Gr	-	<ul style="list-style-type: none"> Prepare SWAU request package Review according to SOFT-MAINT SWAU criteria Approve and document SWAU 	<ul style="list-style-type: none"> Before intended use 	<ul style="list-style-type: none"> SO (D) SRLM (R, A) 	SOFT-V&V, 5; SOFT-MAINT, 4
3.0 For Acquired Non-SSC (OTS)—Toolbox Codes								
1	V&V and SWAU	R	R	R	<ul style="list-style-type: none"> V&V per the registry instructions for the toolbox code Prepare SWAU request package Review according to SOFT-MAINT SWAU criteria Approve and document SWAU 	<ul style="list-style-type: none"> For each toolbox code installation Before intended use 	<ul style="list-style-type: none"> SO (D, R, A) SRLM (R, A) 	SOFT-V&V, 7; SOFT-MAINT, 4
4.0 For Simple and Easily Understood Non-SSC Software Used in Design of SSCs								
1	V&V as part of SSC design V&V	R	Gr	Gr	<ul style="list-style-type: none"> Pre-verify using the methods previously described for non-SSC software, or V&V the software each time it is used for SSC design in accordance with the SSC design process Provide and review minimum software information (e.g., computer-generated evidence of the programmed algorithms or equations) Apply appropriate SSC design review rigor to ensure the computer program produces satisfactory results 	<ul style="list-style-type: none"> Each time the software is used for an SSC design and when required by the SSC design V&V process Before intended use 	<ul style="list-style-type: none"> As per the applicable SSC design V&V process 	SOFT-V&V, 8; SOFT-MAINT, 4
<p>¹ ML = management level; R = required; Gr = required but graded</p> <p>² “When” constitutes the V&V control points (points in the process when V&V activities are performed)</p> <p>³ D = develop or execute; R = review or inspect; A = approve</p> <p>⁴ SD = software designer; SO = software owner; SRLM = software responsible line manager; FDAR = facility design authority representative; T = testers; IR = independent reviewer</p> <p>⁵ An SD subject matter expert (SME) other than the SD who developed the code shall perform the code review</p> <p>⁶ Ref. = ESM Chapter 21 section name and subsection number (e.g., Section SOFT-GEN, Subsection 2, <i>Software Identification, Ownership, and Determination</i>)</p>								

2.0 DEFINITIONS AND ABBREVIATIONS

Selected definitions specific to SOFT-V&V follow.

Other Chapter 21 terms are in Appendix A of SOFT-INTRO. Beyond that, many definitions are contained in [GLOS-COE-1](#), the *Conduct of Engineering Glossary*, and those definitions supersede should they conflict with Chapter 21.

- *Verification* is the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements (Ref. NQA-1). In the context of software, verification means providing objective evidence that the software and its associated products conform to requirements (e.g., for correctness, completeness, consistency, accuracy) for all life cycle activities during each life cycle process (e.g., acquisition, supply, development, operation, maintenance); satisfy standards, practices, and conventions during life cycle processes; successfully complete each life cycle activity; and satisfy all the criteria for initiating succeeding life cycle activities (e.g., building the software correctly).
- *Software design verification* is the process of determining if the product of the software design activity fulfills the software design requirements (NQA-1-2008/1a-2009).
- *Validation* is 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 an operating environment (Ref. NQA-1). In the context of software, validation means providing evidence that the software and its associated products satisfy system requirements allocated to software at the end of each life cycle activity, solve the right problem (e.g., correctly model physical laws, implement business rules, use the proper system assumptions), and satisfy the intended use and user needs.
- *Software approval for use (SWAU)* is an approval that confirms that the software requirements have been satisfied (including installation and operating instructions) and that the software is ready to be used in the intended operating environment.
- *Simple and Easily Understood (Non-SSC) software* is that which that satisfies the following criteria:
 - The software is used in the design of SSCs;
 - The results of the computer program can be easily confirmed through hand calculations;
 - A person technically qualified in the subject can review and understand the program and the supporting calculations; and,
 - The software is individually verified with each use (e.g., calculation). (Based on [NQA-1](#)).

Note: When such is present, and the “Each-Time” V&V method is chosen, users should follow that subsection herein in lieu of other V&V requirements herein.

3.0 GENERAL REQUIREMENTS

The following requirements apply to all software (Requirements 21-0501 – 0508):

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

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

- B. Trace, document, and V&V the software from requirements development through design (as applicable), acquisition (as applicable), testing, and SWAU.
- C. Document the V&V results, including the identification of the verifiers and validators.

- D. For the review of V&V activities for ML-1 and ML-2 software, 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 the review of V&V activities for ML-3 and ML-4 software, document the reviewers and their comments and retain reviewer comments as records per the record retention schedule.
- F. Ensure the limits of use associated with the V&V are clearly defined.
- G. For other than acceptance testing reviews, if the review alone is inadequate to determine whether requirements are satisfied, use alternate calculations or develop and integrate (interim) tests to support the review.
- H. Suppliers that design software specifically for LANL must V&V software based on subsection 4.0 on designed software. 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 (ref. SOFT-INTRO, §2.3).
- I. Ensure the software identification number (SWID) is part of the V&V documentation record number.
- J. Perform software design verification in accordance with the requirements of this document and of AP-341-620, *Review and Verification of Design Documents*. For SSC software, document software design verification [e.g., using [Form 2329](#), Software Test Plan and Report (SWTPR) attached to (when new) form SOFT-V&V-FM01 or, for approved/operating software modifications, SOFT-GEN-FM04].
- K. Software design verification shall be performed by competent individual(s) or group(s) other than those who developed and documented the original design.
 - 1. Verification may be performed by the originator’s supervisor, if (a) the supervisor did not specify a design approach, rule out design considerations, or establish the design inputs or (b) the supervisor is the only individual in the organization competent to perform the verification.
- L. Verification must include one or a combination of design reviews, alternate calculations, and tests performed during computer program development.
- 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.

A form that may be used for documenting test cases: [2328 - Software Test Case \(SWTC\)](#)

In addition, examples are on the website under SOFT-V&V (useful content while perhaps not using above forms).

4.0 DESIGNED SOFTWARE V&V AND SWAU

This subsection is for software designed by or for LANL. When “simple and easily understood” software such as a spreadsheet, read Subsection 8.0 first.

Table 21.4-3 Minimum Required V&V Activities— <u>Designed Software</u>	
4.0 § No.	V&V Activity Description
4.1	Design requirement (input) review
4.2	Software test plan development and review

Table 21.4-3 Minimum Required V&V Activities—Designed Software

4.0 § No.	V&V Activity Description
4.3	Software design review
4.4	Software code review
4.5	Testing/commissioning and review
4.6	Software review and approval for use

4.1 Design Requirement (Input) Review

Table 21.4-3 above lists the minimum V&V and SWAU activities that must be performed for developed software. Additional details on these activities is provided later in this subsection.

Review design requirement inputs to ensure they satisfy the design requirement criteria in SOFT-DESIGN and maintain a record of the review per the governing document control process. The SWAU (or, for changes, SWCP or SWNCP) is used to document the completion of this review.

- Perform the review before software design where possible.
- For ML-1 through ML-3 SSC software, the SD, SRLM, LCxA rep (optional), and FDAR must perform the review. FDAR review is not required for ML-4 software.
- For non-SSC software, the SD and SRLM must perform the review.

Note: SOFT-DESIGN steps must be followed in the design phase and considered throughout the V&V phase. See also SOFT-DESIGN Appendix A when designing test cases.

4.2 Software Test Plan Development and Review

Plan and execute tests to verify conformance of the computer program(s) to requirements. The SWTP may include interim testing to support software design activities, acceptance testing to support commissioning (SSC only), in-use testing to support operations after SWAU, or a combination of these. For SSC software, the acceptance testing portion of the SWTP must be integrated into or with commissioning documentation.

NOTE: SOFT-V&V Appendix A, Computer Program Test Plan Requirements (Table), contains detailed test plan expectations in addition to those in this subsection.

Form [2329 - Software Test Plan and Report \(SWTPR\)](#) may be used to produce the plan; also, one may produce a combined Plan and test cases using [3055 - Software Test Plan \(SWTP\) Template](#) if preferred and available (internal links).

Develop the SWTP after software requirements have been established and concurrently with the software design. Submit the final test plan with the final software design and before acceptance testing.

The SD develops (and reviews and approves along with others) the SWTP. (Where possible, the SD should be a subject matter expert other than the SD who designed the software.)

- For ML-1 and ML-2 software, SWTP review by an SQA SME is recommended.

Address the following in the test plan:

- A. For SSC software, plan tests as required by the SSC design; ESM Chapter 15, *Commissioning* (as applicable); and this chapter. Document the plan in an SWTP. Review and disposition comments on the SWTP in accordance with the governing document control process.

For ML-1 software, perform at least one acceptance test in a simulated environment (i.e., test bed or bench testing). For ML-2 software, perform at least one acceptance test in a

simulated environment when required by the FDAR. When performing acceptance tests in the simulated environment, do so before performing acceptance tests in the actual operating environment.

When the simulated environment without hardware cannot adequately test the software, as determined by the FDAR, test in a simulated environment with hardware, or without associated hardware if possible.

- B. Perform a comprehensive acceptance test in the operating environment before use.¹ Include support software tests as appropriate. Refer to SOFT-INTRO for tester qualifications (e.g., for ML -1 or 2).

As required by other ESM chapters, plan for interim testing during planned stop points in the software design process (in addition to the final acceptance test). Interim tests may be formal or informal to support reviews.

Test plan documentation is required for formal interim tests used to support reviews, and this documentation must satisfy the same criteria as the acceptance test. Include the tests and test results in the acceptance testing documentation.

- C. For ML-1 through ML-3 software, include in-use tests to be performed after SWAU to verify continued acceptable performance in the operating environment. Perform in-use tests whenever the computer program is installed on a different computer or when there are significant changes in the operating system.

- D. Create an SWTP record form or template that records the following (as applicable).

1. SSC(s), software tested, or both
2. Date of test
3. Characteristics tested
4. Tester, data recorder, or both
5. Type of observation (i.e., type of test)
6. Test results, applicability, and acceptability
7. Action taken in connection with any deviations
8. Reference to the test methodology/test plan used with associated revision
9. Test result evaluator/acceptor
10. A unique test record identifier to allow traceability to the specific item tested (if not subsequently assigned as part of the records management protocols)
11. Test environment (e.g., computer hardware, operating system)
12. Measuring and test equipment used (include equipment identification, calibration date, and calibration expiration date)
13. Simulation models used
14. Test problems/cases [[2328 - Software Test Case \(SWTC\)](#) may be used]

- E. Provide 60%, 90%, and 100% test plan submittals for review and approval. Review, approve, and control the test plan in accordance with the governing document control process.

¹ Also meet NQA-1 Req 11, 200 Test Reqs, (c): "If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test. Note, when testing in the operating environment introduces unacceptable risks, testing in an identical beta environment is acceptable, with FDAR approval.

- F. Identify any required SWTP hold or witness points, and associated responsibilities, or both.
- G. For ML-1 and ML-2 software, design tests to demonstrate that performance requirements are satisfied and unintended results are detected (to the extent possible). Consider negative testing in addition to positive (see Definitions).
- H. Identify authorized software testers. Note: Testers and reviewers should normally be identified by role rather than by name.
- I. Identify individuals responsible for reviewing and approving the completed software test. As a minimum, the LANL SO and SRLM review and approve the SWTP.
- J. Produce Software Test Report (SWTR).
 - For ML-1 through ML-3 software, SWTR reviewers/approvers must include the lead tester (SD or SME familiar with the design detail and intended use of the computer program), LANL SO, LCxA (SSC only, optional), and LANL SRLM.
 - For ML-4 software, SWTR reviewers/approvers must include the LANL SO, LCxA (SSC only, optional), and LANL SRLM.

4.3 Software Design Review

Review the software design to ensure that it satisfies the software design criteria specified in SOFT-DESIGN and maintain a record of the review per the governing document control process. Perform the following as part of the design review (Requirements 21-0509 – 0519):

- Verify the acceptability of the design requirements.
- Evaluate the technical adequacy of the software design approach.
- Ensure internal completeness, consistency, clarity, and correctness of the software design.
- Verify that the software design is compliant with and traceable to the approved software design requirements.
- Review any interim test results.

Review the design in accordance with the software design deliverable submittal schedule and before acceptance testing.

The SD and SRLM review the software design. In addition, for ML-1 and ML-2 software, one or more individuals other than those who designed the software must review the design. Independent reviewers may be from the same organization.

4.4 Computer Program Code Review

Review the computer program code to ensure that it satisfies the criteria specified in SOFT-DESIGN and maintain a record of the review per the governing document control process. Review the code before acceptance testing.

The SD and SRLM review the code. In addition, an independent SME other than the SD who developed the code performs a review.

4.5 Acceptance Testing/Commissioning, Software Test Report, Review

Perform acceptance testing in accordance with approved design documents, SWTPs, commissioning documents, or a combination of these. Following acceptance testing, prepare SWTRs and perform SWTR reviews before SWAU. Ensure the following items are addressed (Requirements 21-0520 – 0522):

- A. Complete activities to prepare for testing in accordance with any governing work control documents and address the following items.
 - 1. Ensure required software backups are accessible should a need to “roll back” to original files arises.
 - 2. Ensure that documentation required before testing has been received.
 - 3. Review the results of prior testing and resolution of any identified deficiencies (e.g., bug or error reports). Ensure that issues have been sufficiently resolved to proceed with the test.
 - 4. Ensure that those performing or supporting testing have all required training, qualifications, and authorization and include all individuals specified in the SWTP.
 - 5. Ensure that those performing or supporting testing have a clear understanding of their roles and responsibilities and the SSCs that may be impacted by the tests.
 - 6. For SSC software, ensure specified calibration, environmental conditions, and storage requirements are maintained throughout the test process.
 - 7. For SSC software, ensure any necessary measuring and test equipment (e.g., thermometers, manometers) is calibrated and on hand. (Requirement 21-0523)
 - 8. Control Testing: For SSC software, indicate status (e.g., tested, not tested, testing in process) on the SSC or in documents traceable to it to prevent inadvertently operational use (e.g., segregate the SSC or use tags, markings, shop travelers, stamps, and/or inspection records). List the authority for removal/change of status. For Non-SSC software, keeping in a test environment until SWAU is sufficient. (Requirement 21-0524)
 - 9. Conduct tests under controlled conditions using approved acceptance and performance criteria.
 - 10. Retest (e.g., regression test) modified or replaced software.
 - 11. For SSC software, ensure the required post-test configuration is in place after completing the test.
- B. Document the test results on the approved SWTP record forms, templates, or both.
- C. Review and evaluate the test results and verify that all requirements have been satisfied and that the software produces correct results. Perform the following as part of the test results review:
 - 1. Perform preliminary evaluations to determine the validity of the test results and the need for further testing. Identify any additional test requirements and required changes to the test plan and retest as needed.
 - 2. Analyze and evaluate the data to verify the completeness of results, conformance to design requirements, achievement of test objectives, and conformance to the SWTP.
- D. Document the acceptability of the test results in the SWTR.
- E. Ensure that the SWTR is reviewed by all individuals specified in the SWTP.
- F. Retain test documentation per the governing document control/records management processes. Ensure test records have a unique identifier and are traceable to the tested software.

4.6 Review and Approval for Use

Before using software for its intended purpose, obtain a formal software approval for use. For initial SWAU, prepare a SWAU request package and document approval via Chapter 21 form SOFT-V&V-FM01, *Software Approval for Use* (Requirement 21-0525).

- A. The SWAU request package shall include all documentation necessary to demonstrate that the software is ready for its intended use, including
 - satisfactory completion of V&V;
 - attestation that any applicable operational and maintenance controls from SOFT-MAINT are in place; and
 - for ML-1 through ML-3 software, documentation of any associated limitations, access controls, etc., for software use.
- B. SWAU following changes to existing and approved software shall be documented as follows:
 - For ML-1 through ML-3 software, use Chapter 21 forms SOFT-GEN-FM03, *Non-SSC Software Change Package Form (SWNCP)*, or SOFT-GEN-FM04, *SSC Software Change Package Form (SWCP)*.
 - For ML-4 SSC software, SWAU is implicitly granted following successful completion of commissioning or post-modification testing per AP-341-801, *Post Modification/Post Maintenance Testing*.
 - For ML-4, non-SSC software, when used by Facility Engineering divisions, SWAU is implicit when software is in the Graded Software Inventory/GSI as “Completed” and current on GSI review date, indicating SRLM concurs with its use.

5.0 ACQUIRED SOFTWARE V&V AND SWAU

Table 21.4-4 lists the minimum V&V and SWAU activities that must be performed for acquired software, both SSC and Non-SSC. Additional detail on these activities is provided later in this subsection.

Note: Read-only SSC (firmware) software requirements are contained in Subsection 6.0.

Table 21.4-4 Minimum Required V&V Activities—Acquired Software	
5.0 § No.	V&V Activity Description
5.1	Acquisition requirement (input) review
5.2	Test plan development and review (optional for ML-4)
5.3	Acquisition review (optional for ML-4)
5.4	Testing and review
5.5	Review and approval for use

5.1 Acquisition Requirement (Input) Review

Before software acquisition and in accordance with the governing acquisition/procurement and associated document control processes, the SO and SRLM shall review the acquisition/procurement documents (e.g., statement of work, Exhibit H) to ensure that they satisfy the acquisition criteria in SOFT-ACQUIRE and that the associated software requirements are correct and complete.

As applicable, ensure CGD requirements are addressed (Requirement 21-0526).

5.2 Test Plan Development and Review

For ML-1 through ML-3 software, follow the requirements of Subsection 4.2 with the following exceptions:

- A. For software obtained from an IESL-listed supplier, prepare a simplified test plan that uses the applicable supplier-provided test cases to demonstrate that the software is adequately installed, suitable for the intended application, and properly working in the intended operating environment.
 - Acceptance testing in a simulated environment (i.e., test bed) does not apply.
 - Testing associated with software design (e.g., interim tests) does not apply.
- B. Preparation or incorporation of a hazard analysis is not required. Supplier-provided test cases, documentation, and comparative alternate calculations/published data may be used to demonstrate that the software meets requirements for its intended use.
- C. The SO or an SD may develop the test plan.

5.3 Acquisition Review

For ML-1 through ML-3 software, before acceptance testing, the SO shall 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 the software in accordance with CGD requirements. As applicable, verify valid software licenses and markings that indicate an original manufacturer's product to prevent acquisition of suspect/counterfeit software. Document and retain a record of the review in accordance with the governing document control/records management processes.

5.4 Testing and Review

- A. For ML-1 through ML-3 software, follow the requirements of Subsection 4.3 except for those associated with software design (e.g., interim testing).
- B. For ML-4 software, install and test the software per the supplier instructions.

5.5 Review and Approval for Use

Follow the requirements of Subsection 4.6.

6.0 READ-ONLY SSC SOFTWARE V&V AND SWAU

Read-only SSC software is firmware/embedded software that cannot be changed except through replacement of the computer program, the associated SSC, or both (see SOFT-INTRO for further discussion of it).

- If such software meets all conditions for partial exclusion from Chapter 21 in SOFT-INTRO (§2.3), and the required actions are performed, neither this subsection nor the balance of the chapter are required.
- If, however, any partial exclusion entry condition for the applicable ML is not met, perform Subsections 6.1–3.

6.1 Design Review

When LANL can be involved in the design of the software, review the design as part of the review of the SSC (e.g., at the phases of SSC design deliverable schedule in ESM Chapter 1 Z10 Att. C) under the governing SSC design review process.

6.2 Testing/Commissioning and Review

Test the read-only SSC software per the SSC design and commissioning documents. Provide, review, and approve a commissioning report before approval for use.

6.3 Review and Approval for Use

Follow Subsection 4.6 as applicable to read-only SSC software.

7.0 TOOLBOX CODE V&V AND SWAU

Note: These are programs used by Safety Basis analysts.

- A. Verify and validate the toolbox codes (see SOFT-INTRO Appendix A for definition and information) in accordance with the registry instructions for the specific toolbox code. Review and complete SWAU per Subsection 4.6.
- B. Complete V&V and SWAU for each installation of a toolbox code. The SO performs these activities, and the SO and SRLM review and approve them.

8.0 “SIMPLE & EASILY UNDERSTOOD” NON-SSC SOFTWARE V&V/SWAU

For “simple and easily understood” non-SSC software used in the design of the SSCs, V&V/SWAU the software (all MLs):

- each time the software is used for an SSC design,
- when required by the SSC design V&V process, and
- before approval of the associated SSC design.

There are two options for doing this verification – either pre-verifying or verifying each time the software is used — as described below.

8.1 Pre-Verification²

- A. Perform V&V/SWAU per Subsections 4 or 5.

8.2 Each-Time Verification Process³

- A. To individually verify, do the following:
 1. Follow the SSC design process. Document the design analysis (e.g., AP-341-605, *Calculations*, for LANL). Include the following in the calculation:
 - a. The objective of the analysis

² This might be most appropriate for a spreadsheet tool such as one to inform the need for lighting protection, wherein it is V&V'd, formulas then locked and published for users to enter specifics and get results.

³ Here, the software is V&V'd by the calculation verifier each time, so likely more appropriate for software that won't be reused often, and/or has input values embedded in it by the developer/user (e.g., an unlocked spreadsheet).

- b. Design inputs and their sources
 - c. Results of literature searches or other applicable background data
 - d. Assumptions and indication of assumptions that must be verified as the design proceeds
 - e. Identification of any computer calculation, including identification of the computer type; computer program name; 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
 2. Review and approval. Include the following software information in the SSC design verification documentation and retain it as a record (e.g., calculation documentation):
 - a. Design inputs
 - b. The computer program-generated results
 - c. Computer-generated evidence of programmed algorithms or equations (e.g., computer program listings, spreadsheet cell contents)
 3. Ensure that those performing individual software verifications are cognizant that software may not have undergone CGD and 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. They must show that the software produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. As applicable, they need to show that the encoded mathematical model produces a valid solution to the physical problem associated with the application.
- B. Regarding SWAU, following usage controls in SOFT-MAINT (e.g., for ES, PFE, PIE) ensure software adequacy.

9.0 RESOURCES

The resource collection posted with SOFT-V&V contains example V&V documentation and templates. Examples provided are for informational purposes only and do not always use the latest form available. These examples may include the following:

- Form 3056, *Software Requirements Traceability Matrix (SWRTM or SWTM)*
- Form 3055, *Software Test Plan (SWTP)*
- Form 2328, *Software Test Case (SWTC)*
- Form 2329, *Software Test Plan and Report (SWTPR)*
 - 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)

10.0 APPENDICES AND FORMS

- SOFT-V&V Appendix A, Computer Program Test Plan Requirements (Table)
- SOFT-V&V-FM01: Software Approval for Use Form (SWAU); FM01(I) Instructions with Example

Posted with SOFT-GEN:

- SOFT-GEN-FM03: Non-SSC Software Change Package Form (SWNCP)
- SOFT-GEN-FM04: SSC Software Change Package Form (SWCP)

Institutional forms that may be used/adapted

- [2328 - Software Test Case \(SWTC\)](#)
- [2329 - Software Test Plan and Report \(SWTPR\)](#)

In addition, examples (not using above forms) are on the Chapter 21 webpage under SOFT-V&V.

Appendix A. Computer Program Test Plan Requirements

Appendix A provides computer program test plan requirements in addition to those above (e.g., in Subsection 4.2, which also addresses plan development role). The text in italicized print should be used as guidance for all items marked as “Gr.” (Requirements 21-0527 – 0545)

No.	Requirement	Apply by ML ¹			
		1	2	3	4
1.0 General Test Plan Requirements ²					
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 ³	*
1.03	Satisfy test prerequisites. Prerequisites include the following as applicable: calibrated instrumentation, appropriate and special equipment, trained personnel, the condition of the test equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition. Ensure the suitability and readiness of equipment and algorithms used for simulated computer program test inputs/fault seeding.	R	R	R	*
1.04	Ensure that suitable environmental conditions are satisfied during testing.	R	R	R	*
1.05	Ensure that adequate instrumentation is available and used.	R	R	R	*
1.06	Ensure that appropriate tests and equipment are used (e.g., 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 assess 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	Ensure that 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 requirement includes controlling changes during testing and, as appropriate, comprises 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 that fulfills 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 or FDAR and others as required in the governing work control process (e.g., AP-341-504 , <i>Temporary Modification Control</i>) before performing the test.	R	R	R	*
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	*

No.	Requirement	Apply by ML ¹			
		1	2	3	4
1.19	When special process examinations/tests are performed (e.g., nondestructive examination, 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 STD-342-100, Engineering Standards Manual, Chapter 13, Welding, Joining & NDE , and P330-5, Special Processes .	R	R	R	*
1.20	Perform testing in accordance with the governing work control process and the test plan and 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 the 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	Within applicable work control documents (e.g., field change, design change) that govern configuration management for the item, describe the process for obtaining consent to waive specified hold points (testing, inspection, witness holds, or a combination of these) or to make changes to the test plan. If the waiver and change processes are 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 before work continues beyond the designated hold point. Document the consent.	R	R	R	*
1.25	As applicable, develop and prepare an approach to sampling. <i>When sampling is used, base it on standard statistical methods with approval from the responsible engineer for the item. Obtain support from the responsible engineer, quality assurance representative, or both in development of the plan as required. When sampling is used for accepting commercial-grade items and services, base it 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 and the approval of the method by the responsible engineer. When less than 100% sampling is used, draw samples at random.	R	R	Gr	*
1.26	<i>Demonstrate the 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.⁴</i>	R	R	Gr	*
1.27	<i>Where the test is intended to verify only specific design features, verify the other features of the design by other means. Establish and verify scaling laws when tests are performed on models or mockups.⁴</i>	R	Gr	Gr	*
1.28	<i>Perform error analysis, where applicable, on the results of model test work before using the final design.⁴</i>	R	Gr	Gr	*
2.0 Additional Test Plan Requirements for General Computer Program Testing²					
2.01	<i>Involve engineering, in accordance with the governing work control process and as applicable, in safety software inspection, including obtaining concurrence with the acceptability of safety software verification results.</i>	R	R	Gr	*
2.02	<i>Obtain test requirements and acceptance criteria from the organization responsible for the computer program's use.</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	*

Section SOFT-V&V: Software Verification and Validation

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No.	Requirement	Apply by ML ¹			
		1	2	3	4
2.10	Include acceptance criteria, reports, records, standard formatting, and conventions.	R	R	R	*
2.11	Demonstrate the computer program's adherence to documented requirements.	R	R	R	*
2.12	<i>Evaluate technical adequacy through the comparison of test results against results from alternative methods, such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.</i> ⁵	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.</i> ⁴	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.</i> ⁶	R	R	Gr	*
2.16	For system software testing (new or revised software), evaluate, review, test, and accept the software 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.	R	R	Gr	*
3.0 Additional Test Plan Requirements for Computer Program Acceptance Testing⁷					
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). ⁸	R	R	R	*
3.03	Demonstrate that the computer program properly handles abnormal conditions and events, as well as credible failures. As applicable, include cybersecurity vulnerability testing.	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 before the computer program's approval for use.	R	R	R	*
3.07	Ensure that configuration items are identified and are under configuration change control before starting acceptance testing.	R	R	R	*
3.08	Ensure that acceptance testing is planned, performed, and passed for all software design requirements.	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 before use.	R	R	R	*
3.11	<i>Provide for the documentation and disposition of observations regarding unexpected or unintended results before 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 verify that a modified system(s) or system component(s) still meets specified software design requirements.	R	R	R	*

No.	Requirement	Apply by ML ¹			
		1	2	3	4
<p>Notes:</p> <p>¹ R = required; Gr = graded by using <i>italicized text</i> as guidance and non-italicized text as required; * = as required by ESM Chapter 15, <i>Commissioning</i>, the SRLM, or both</p> <p>² From NQA-1 Part I Requirement 11, <i>Test Control</i>. 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.</p> <p>³ Not used.</p> <p>⁴ Applies to design verification testing only; reference NQA-1 Part I Requirement 3, <i>Design Control</i>.</p> <p>⁵ Applies to non-SSC software only.</p> <p>⁶ Apply as required during testing to ensure that test results are valid.</p> <p>⁷ From NQA-1 Part II Subpart 2.7, <i>Quality Assurance Requirements for Computer Software for Nuclear Facility Applications</i>, 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.</p> <p>⁸ If the software is required to perform a technical safety requirement surveillance, demonstrate satisfactory execution of the surveillance as part of the acceptance test.</p>					