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ATTACHMENT 1: CHAPTER 21 SUMMARY TABLE

FORMS:

- SOFT-GEN-FM01: SOFTWARE BASELINE FORM (SWBL)
- SOFT-GEN-FM02: NON-SSC SOFTWARE CHANGE PACKAGE FORM (SWNCP)
- SOFT-GEN-FM03: SOFTWARE DATA SHEET FORM (SWDS)

Rev	Date	Description	POC	RM
0	06/23/16	Initial issue	Tobin Oruch, ES-DO	Mel Burnett, CENG-OFF

**Note:** This entire chapter is currently a provisionally issued document. In this case, that means chapter use is optional until SOFT-GEN is revised to remove provisional markings (expected in approximately 4-8 months from date of Rev. 0 of this section). Managers may invoke chapter sooner (also, training for software managers and owners is being developed). In other words, assuming no intermediate provisional revisions of SOFT-GEN, Rev. 1 of SOFT-GEN will not have this note and, thus, the entire chapter will become mandatory.

As with all LANL Engineering Standards, but especially with this all-new chapter, please contact the Chapter [POC](#) with comments, issues, etc.

## 1 Section SOFT-GEN: General Software Requirements

Rev. 0, 06/23/16  
PROVISIONAL CHAPTER

## 1.0 PURPOSE, SCOPE, APPLICABILITY AND ORGANIZATION

## 1.1 Chapter 21 Purpose, Scope, and Applicability

A. Chapter 21 is the software plan for the Facility Conduct of Engineering program (FAC-COE)<sup>1</sup>, including safety basis activities. It provides reasonable assurance that in-scope software will consistently, compliantly, and efficiently satisfy its intended use. It describes the “how, when, and who” for implementing the software requirements of:

1. DOE Order [414.1D](#), *Quality Assurance*, (hereafter O 414.1D) and
2. [ASME NQA-1-2008/NQA-1A-2009](#), *Quality Assurance Requirements for Nuclear Facility Applications, Part I and Part II* (hereafter NQA-1<sup>2</sup>).

B. For new and modified software, this chapter applies only when software is either:

1. Within the scope of [PD340](#), *Conduct of Engineering for Facility Work*, or
2. Within the scope of [PD110](#), *Safety Basis*.

Note: Modified software includes Major computer program changes (see Definitions). Both major computer program changes (including upgrades from non-safety to safety software) and software plans considered non-compliant<sup>3</sup> are subject to this chapter. LANL: Once the need to adopt this chapter for a given software is identified, initiate a PFITS action to resolve deficiencies versus the chapter with a due date agreed to by both SRLM and Chapter POC.<sup>4</sup>

C. Exclusions: This chapter does not apply to:

1. Software covered by existing, compliant software quality management plans/processes. The issuance of this chapter does not necessitate immediate replacement of those controls (grandfathering applies) unless/until a Major change;
2. Programmatic R&D engineering that does not affect the safety basis or technical baseline configuration of a LANL facility (nor is described in the Hazard Analysis (HA) or [is] adjacent [to nuclear safety] structures, systems, and components (SSCs)<sup>5</sup>. (Such work is conducted pursuant to the provisions of [PD370](#), *Conduct of Engineering for Research and Development [R&D]*);
3. Uncomplicated software tools, including productivity aids that are adequately controlled through the design process. Examples include unit conversion software, spike computer programs, equipment selection software, diagnostic software, or interpolation calculators; and/or,
4. Personal productivity and collaboration software that does not provide calculation output.

<sup>1</sup> FAC-COE defined by [PD340](#), *Conduct of Engineering for Facility Work*, and clarified by ES-DO: 15-006 (EMRef-74) to also include the first parenthetical in 1.1.C.2.

<sup>2</sup> [NQA-1](#) requirements are clarified for LANL application in [SD330](#), *LANL Quality Assurance Program*, and [P1040](#), *Software Quality Management (SQM)*.

<sup>3</sup> Compliant means meeting applicable DOE O 414.1D and NQA-1 SQA requirements. Compliance with LANL P1040 is also acceptable. When in doubt about compliance of a given plan, assess against relevant requirements (QPA may be able to assist).

<sup>4</sup> Six months is believed appropriate for most software while some may justify longer.

<sup>5</sup> Criteria from PD340 and ES-DO: 15-006. Excluded unless electively invoked by the Responsible Line Manager (RLM).

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- D. The chapter defines and applies to two major types of software:
1. System, structure, and component (SSC) software; and,
  2. Non-SSC software (see definitions), including “simple and easily understood” software used in the design of SSCs.<sup>6</sup>
- E. Subcontractors (architect-engineers, consultants, etc.): For software within the applicability statements above, including both SSC and Non-SSC software, Chapter 21 provides minimum expectations for software quality assurance (SQA).
1. For software used for safety design or analysis, it includes program expectations and basic reporting requirements to facilitate oversight.
  2. For SSCs with software being specified or designed, and for any software being delivered for LANL ownership and use, Chapter 21 requires the same documentation deliverables that LANL personnel provide to the extent the information is known in the design and construction phases.<sup>7</sup> When not known, insert TBDs and deliver as “Draft.”
  3. Subcontractor quality assurance programs must meet the expectations of this chapter, comply with [O 414.1D](#), and -- where required by subcontract -- [NQA-1](#), including Part I and Part II, Subparts 2.7 and 2.14.

## 1.2 Chapter 21 Organization and Use

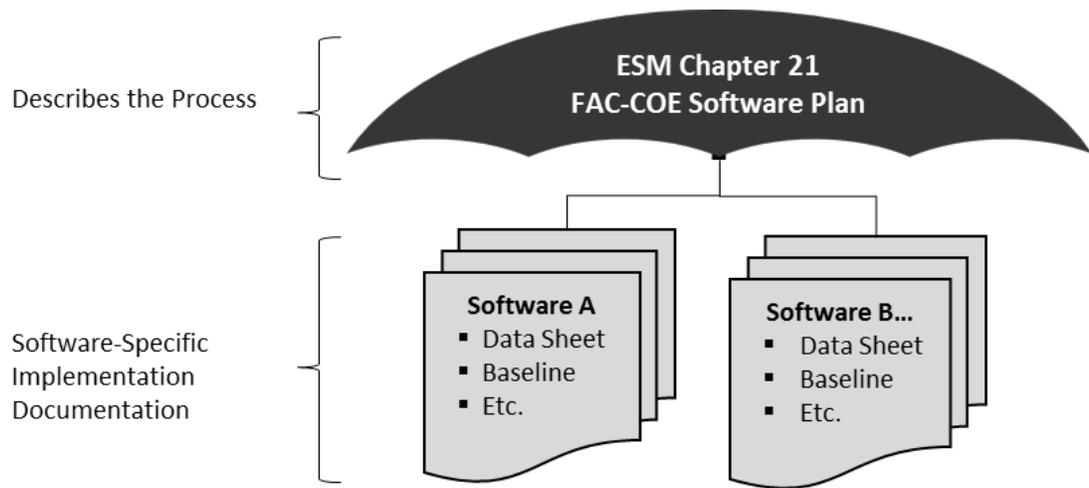
- A. Concept: As shown in Figure 21.1-1, *Chapter 21 Software Plan Concept*, this chapter uses an umbrella concept for SQA. That is, Chapter 21 serves as the software plan for software within its scope. Implementation of this chapter/plan will produce software-specific SQA implementation documentation (e.g., software baseline, software data sheet) for multiple software items. The software-specific documentation includes information that is unique<sup>8</sup> to each software program. Examples of software-specific information include the software technical requirements, software ownership, and software test plans.
- B. Organization: Chapter 21 is divided into six (6) sections that span the software lifecycle. These sections and a summary of deliverables are depicted in Figure 21.1-2, *Chapter 21 Sections and Deliverables*.<sup>9</sup>

<sup>6</sup> See definitions in SOFT-GEN Appendix A, *Chapter 21 Definitions and Acronyms*. Includes safety and non-safety software. Also, see applicability of quality assurance controls summarized in SOFT-GEN Attachment 1, *Chapter 21 Summary Table* and further details in Chapter 21 sections.

<sup>7</sup> For SSC software: Use of chapter forms/doc numbers provides standardization and retrievability of documents that LANL must maintain going forward. As necessary, documentation will be updated or produced by construction subcontractors and verified by LANL in the start-up/commissioning process in conjunction with the system engineer function.

<sup>8</sup> Unique in that it cannot otherwise readily be addressed on a higher level (in this chapter proper). This centralized+distributed model ensures consistency of approach/rigor within user organizations while eliminating the production of standalone SQA plans that repeat boilerplate; it also utilizes a living, stand-alone documentation approach for those documents that are subject to change, easing revision of same without necessitating revision of an entire plan. Also, revision of Chapter 21 does not invalidate the approach or documentation associated with a previous chapter revision unless the revised chapter material specifically states this.

<sup>9</sup> The 6 phases encompass all life cycle phases described by other industry documents in a simplified approach.



**Figure 21.1-1 Chapter 21 Software Plan Concept**

- C. Refer to SOFT-GEN, SOFT-V&V, SOFT-INV, and SOFT-MAINT for all software within the chapter scope. Also follow SOFT-ACQUIRE for software that is acquired, and SOFT-DESIGN for software that is designed (term used interchangeable with developed).
- D. Definitions and Acronyms: See SOFT-GEN Appendix A, *Chapter 21 Definitions and Acronyms* for key definitions and acronyms. Defined terms are often capitalized, set in quotes, or both in this chapter.
- E. Refer to SOFT-GEN Attachment 1, *Chapter 21 Summary Table*, for a summary of this entire chapter. Refer to the table(s) at the beginning of each section for a summary of that section. These tables address both SSC software and Non-SSC software.
- F. Italics: Throughout the ESM, italics are one method used to indicate guidance. Exception: When italics are used to highlight document titles.
- G. Graded Approach: Management levels (MLs) -- rather than software type, category, or Software Risk Level (SRL) terms -- are used throughout.<sup>10</sup> See Form [2033](#) for an *ML crosswalk (guidance table) to software types, categories and software risk levels (SRLs)*. This may necessitate performance of an *ML determination using AP-341-502 when the software may be a lower ML level than the system it supports*.<sup>11</sup>
- H. Roles, Responsibilities, Authorities, and Accountabilities: See SOFT-GEN Appendix B, *SO and SRLM Decision Diagram for FAC-COE*, for guidance on determining these key positions.

<sup>10</sup> Promotes a common vernacular for users.

<sup>11</sup> Current AP-341-502 excludes software but revision is planned; proceed with determination in the meantime.

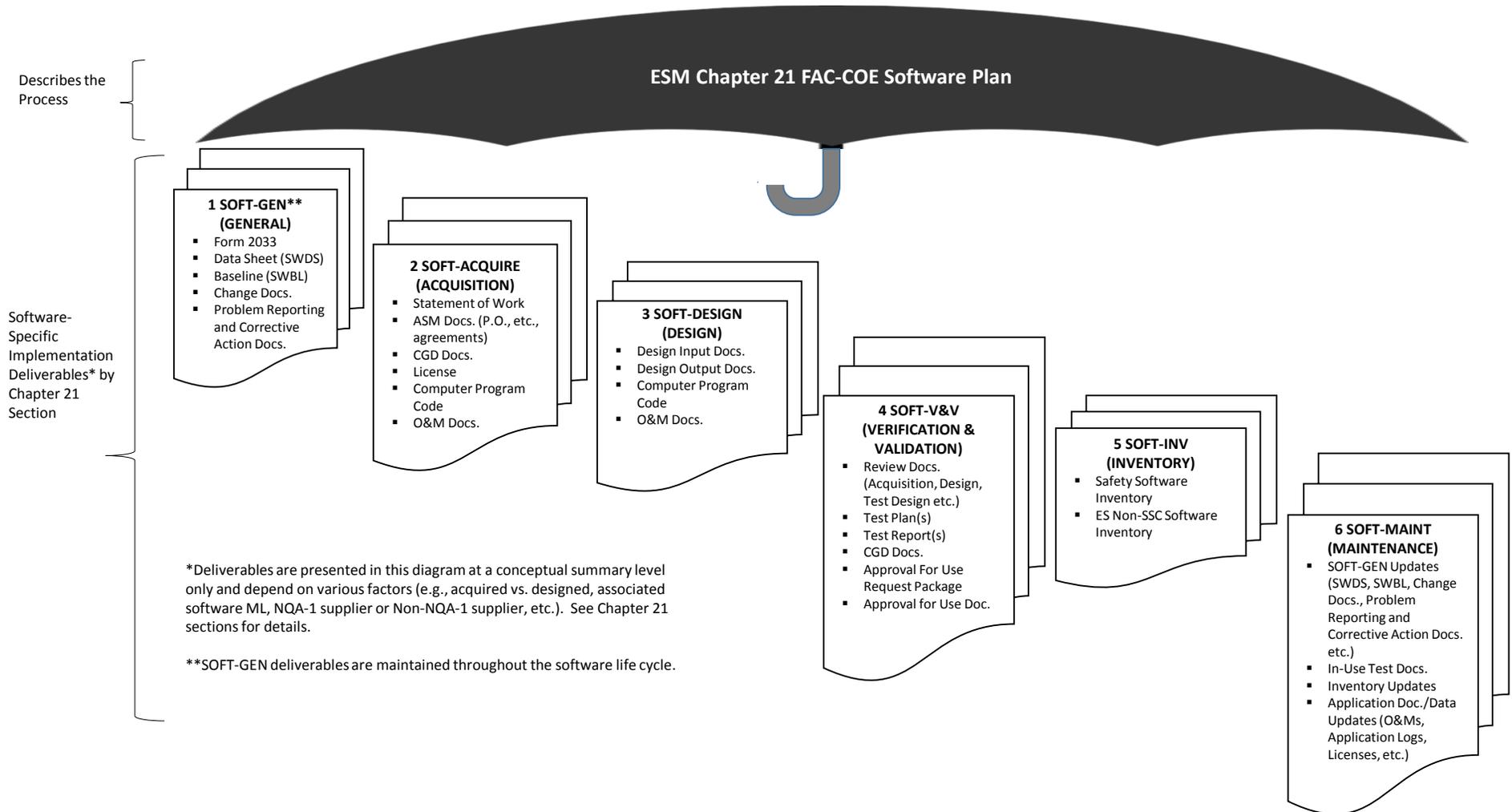


Figure 21.1-2 Chapter 21 Sections and Deliverables

- I. Or Equivalent: When this term is used, the Software Responsible Line Manager (SRLM) determines equivalency. If questions arise regarding equivalency, the Chapter 21 Point of Contact (POC) will resolve.
- J. References: See SOFT-GEN, Appendix C, *Chapter 21 Reference Listing* for hyperlinked references. Additional hyperlinks are provided in key locations throughout the chapter for convenience.
- K. Forms:
  - 1. LANL personnel: Endeavor to use Chapter forms as-is and report issues and improvement ideas to the Chapter 21 POC.<sup>12</sup> POC may authorize other methods equivalent to chapter forms in writing.
  - 2. LANL subcontractors must use Chapter forms to satisfy Chapter requirements for SSC software. For Non-SSC software, subs may either use their own forms or integrate, adapt, and reformat the forms; either approach is acceptable so long as key functions, data, and approvals are retained.
  - 3. LANL Form 2033 must be used as-is.
- L. Upkeep: So long as NQA-1 compliance is maintained, the POC is authorized to resolve conflicts within the Chapter in a manner that may not be most stringent; similarly, the Standards Manager is authorized to approve and issue revised forms, references, and GEN Att. 1 summary independently of associated Sections.

### 1.3 Section SOFT-GEN Purpose, Scope, and Applicability

- A. SOFT-GEN provides general software information and requirements to implement Chapter 21. These general requirements include how to: (a) identify software and make software determinations (e.g., Form [2033](#)), (b) implement configuration management (e.g., baselines and software changes), (c) report problems/take corrective actions, and (d) perform software risk management.
- B. See Table 21.1-1 for a summary of SOFT-GEN. For SOFT-GEN applicability, see the Chapter 21 applicability subsection above and the following:
  - 1. Other than for software identification and determination, SOFT-GEN does not apply to “Simple and Easily Understood” software used in the design of SSCs if the software is individually verified as described in SOFT-V&V.
  - 2. SOFT-GEN applies to Subcontractors providing design agency or analysis services to LANL<sup>13</sup>.

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<sup>12</sup> Forms are designated as samples which means minor aspects may be modified so long as all functions, key data, and approvals are retained. Alternatively, LANL user organizations may direct that other, comparable forms be used (with prior permission of the Chapter POC). Forms may be revised administratively and reposted without revision of associated section (and with only POC and Standards Manager approval).

<sup>13</sup> SSC and Non-SSC software resulting from and/or used in the SSC design must be identified and software determinations completed as stated herein.

1 Section SOFT-GEN: General Software Requirements

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Table 21.1-1 Section SOFT-GEN Summary for SSC Software and Non-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			Reference	
		1	2	3	4	How	When	Who <sup>2,3</sup>	P1040 R9 Ref. Section	ESM Ch. 21 Ref. <sup>4</sup>
1	Identify software and complete software determinations	R	R	R	G	<ul style="list-style-type: none"> <li>Identify SO and SRLM</li> <li>Develop software list</li> <li>Determine reasonable probability</li> <li>Complete and retain Form <a href="#">2033</a></li> </ul>	<ul style="list-style-type: none"> <li>Earliest practical time</li> <li>Before software design, acquisition</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> <li>FDAR (R, A)</li> </ul>	3.2	SOFT-GEN, 2
2	Prepare Software Data Sheet (SWDS)	R	R	R	-	<ul style="list-style-type: none"> <li>Develop Software Data Sheet (SWDS), SOFT-GEN-FM03</li> </ul>	<ul style="list-style-type: none"> <li>Earliest practical time</li> <li>Before design, acquisition</li> <li>Maintain throughout software lifecycle</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	3.3.3	SOFT-GEN, 3.0
3	Develop and maintain software baseline	R	R	R	-	<ul style="list-style-type: none"> <li>Develop software baseline (SWBL) using SOFT-GEN-FM01</li> <li>Maintain baseline accuracy</li> <li>Document baseline information in the computer program code (where possible)</li> </ul>	<ul style="list-style-type: none"> <li>Earliest practical time</li> <li>Before/after acceptance testing</li> <li>Before software approval for use (SWAU)</li> <li>After approved changes</li> <li>For ML-1/ML-2 designed software, at major design activity</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	3.3.3	SOFT-GEN, 4.0

1 Section SOFT-GEN: General Software Requirements

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		1	2	3	4	How	When	Who <sup>2,3</sup>	P1040 R9 Ref. Section	ESM Ch. 21 Ref. <sup>4</sup>
4	Control software changes (change control)	R	R	R	G	<ul style="list-style-type: none"> <li>Document changes in computer program code (where possible)</li> <li>For SSC software, prepare changes per Table 21.1-4;</li> <li>For Non-SSC software, prepare SWNCP per SOFT-GEN-FM02</li> <li>Make doc. changes per governing document control process</li> <li>Revise software baseline</li> </ul>	<ul style="list-style-type: none"> <li>In a timely manner</li> <li>When required to ensure proper performance</li> <li>Per Table 21.1-4</li> </ul>	<ul style="list-style-type: none"> <li>Per Table 21.1-4 or equivalent</li> </ul>	3.3.3	SOFT-GEN, 4
5	Perform problem reporting and corrective action	R	R	R	G	<ul style="list-style-type: none"> <li>Before approval for use (SWAU), use <a href="#">P330-6</a>, <a href="#">P322-4</a>, less formal methods (e.g., bug lists, comments in program) Or Equivalent</li> <li>After SWAU, use <a href="#">P330-6</a>, <a href="#">P322-4</a> Or Equivalent</li> </ul>	<ul style="list-style-type: none"> <li>Throughout software lifecycle</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	3.3.3	SOFT-GEN, 5
6	Perform software risk management	R	R	R	G	<ul style="list-style-type: none"> <li>Implement Chapter 21</li> <li>Develop and maintain risk list as part of SWDS</li> </ul>	<ul style="list-style-type: none"> <li>Throughout software lifecycle</li> </ul>	<ul style="list-style-type: none"> <li>SO (D)</li> <li>SRLM (R, A)</li> </ul>	3.3.3	SOFT-GEN, 6

Notes:

<sup>1</sup> ML = Associated Management Level as per Form 2033. R = Required. G = Required but graded. "-" = Not required.

<sup>2</sup> D = Develop; R = Review; A = Approve.

<sup>3</sup> SO = Software Owner. SRLM = Software Responsible Line Manager. FDAR = Facility Design Authority Representative.

<sup>4</sup> Ref. = ESM Chapter 21 section name and subsection number (e.g., Section SOFT-GEN, Subsection 3, Software Identification and Determination).

## 2.0 SOFTWARE IDENTIFICATION AND DETERMINATION

### 2.1 Software Identification

#### A. How

1. For Non-SSC ML-1 through ML-4 software that is planned to be acquired or designed, identify and summarize the software.<sup>14</sup>

Develop a list of the software. Include the following on the list: (a) software name, (b) software functional description (what it does), (c) software application (where/how used), (d) whether the computer program can be changed other than through replacement of the software (replacement includes software upgrades).

2. For SSC ML-1 through ML-3 software that is planned to be acquired or designed, identify and summarize software as described above with the following clarification (Note: For ML-4 SSCs, this chapter does not require software identification; however, it may be invoked by the SRLM):

- a. Analyze the SSC to determine whether the SSC has software. Visually inspect and/or review vendor information (product specifications, catalog data, operations and maintenance manuals, etc.). Identify to a practical extent and to a level that the software can be controlled. *For example, for a control system module that has multiple pieces of software on a single module and the software cannot be modified other than through replacement of the entire module, then identifying the software to the module part number is appropriate.* Do not introduce a potential for: adversely affecting manufacturer warranties, SSC damage, or unintended software changes.

3. Provide the list to the LANL Software Responsible Line Manager (SRLM). See Appendix B for guidance in determining the SRLM.<sup>15</sup>

B. When. For Non-SSC software, provide the software list to the LANL SRLM prior to software acquisition or design. For SSC software, provide draft lists with 60% and final with 90% detail design deliverables (Ref. ESM [Chapter 1](#), Section Z10, *General*). For deferred SSC design, include in deferred design submittals.

C. Who. The Software Owner (SO) is responsible for software identification. See Appendix B for guidance on determining the SO.

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<sup>14</sup> The software list is not a controlled document or quality record. The responsible LANL SRLM uses this information to ensure that software determinations and subsequent required actions in this chapter are completed.

<sup>15</sup> For Subcontractors, listing to be provided per 30-60-90% deliverable schedule; LANL project engineer function will ensure review by appropriate SMEs and/or FDAR.

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## 2.2 Software Determination

A. How. Use Table 21.1-2, and the following text, to complete software determinations.

1. Ask the following question as shown in Table 21.1-2:

<b>Table 21.1-2 The Reasonable Probability Software Question</b>
<p>Excluding personal productivity and collaboration software that does not provide calculation output (e.g., e-mail software, presentation software)<sup>1</sup>, is or will the software be used in connection with<sup>3</sup> the design, analysis, and/or operation of:</p> <ul style="list-style-type: none"> <li>▪ a nuclear (including radiological) facility (Ref. <a href="#">LANL Nuclear Facility List</a> and <a href="#">Conduct Of Operations Resources</a> websites);</li> <li>▪ an accelerator, live-firing range, biological hazard facility, high explosive facility, or moderate- or high- chemical hazard facility<sup>2</sup> as determined using Safety Basis Procedure (<a href="#">SBP111-1</a>, Facility Hazard Categorization and Documentation; or</li> <li>▪ LANL's Essential Functions (EFs) as described in <a href="#">EPP-COOP-006</a>, <i>LANL COOP [Continuity of Operations] Plan</i> ?</li> </ul>
<p>Notes:</p> <p><sup>1</sup>Personal productivity and collaboration software that does not provide calculation output is non-safety, commercially controlled software.</p> <p><sup>2</sup>From <a href="#">SBP111-1</a>, a facility is defined as equipment, structure, system, process, or activity that fulfills a specific purpose except for utility distribution structures.</p> <p><sup>3</sup>Use must be associated with ML-1, ML-2 or ML-3 items. The term “in connection with” captures software that directly or indirectly is used in relation to design, analysis or operation. Operation includes SSC operation (e.g., valve actuation) and administrative operation (e.g., combustible load tracking software).</p>

If the answer to the question is “yes” or “not sure” and the associated SSC ML is ML-1 through ML-3 or unknown, then complete Form [2033](#). If the associated SSC is ML-4, then do not complete Form [2033](#) unless required by the SRLM or Subcontract.

By default, all software is non-safety and commercially controlled (analogous to ML-4) unless there is a reasonable probability that the software could be safety software or risk significant software.

*Guidance: Examples of commercially controlled, non-safety software include: Microsoft PowerPoint® presentation graphics program, Microsoft Outlook® messaging software.*

2. Complete Form [2033](#) using the instructions on the form. See form instructions for which revisions of the form may be used. If the software is planned to be used as “simple and easily understood software” used in the design of SSCs (see definitions), then note it on the form.

*Guidance: Form 2033 allows multiple software items to be included (often it is the support software), and SOFT-INV allows SSC software to be inventoried as a software collection (bundled); see 3.0, A. 5. Bundling may work better if all software is the same ML level relative to 2033 form and subsequent Ch. 21 requirements (may cause confusion if not). Example of where bundling might be considered: A control panel that has a PLC and a*

## 1 Section SOFT-GEN: General Software Requirements

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*touchscreen and separate programs for these components, those separate programs, both ML-2, could be given a single SWID (and 2033, etc.)*

3. Obtain a software identification number (SWID) in accordance with [AP-341-402](#), *Engineering Document Management in Operating Facilities*. Ensure the SWID is part of the Form [2033](#) record number and subsequent software documentation. Retain the completed Form [2033](#) as a record in accordance with the SRLM's governing records management process.

B. When.

1. Complete at the earliest practical time before software design or acquisition<sup>16</sup>.
2. If the application of the software significantly changes, review the original determination and complete a new Form [2033](#) as required. *Guidance: It is recommended that Form [2033](#)s are reviewed at least every three years or other time period that is commensurate with the associated risk of the software.*

**Note:** Changes made to the software (i.e., software version) do not require a new Form [2033](#) to be completed unless the change significantly affects the application. The software inventory must be reviewed and updated as required. See SOFT-INV.

C. Who. The SRLM is responsible for software determinations.

### 3.0 SOFTWARE DATA SHEET (SWDS)

- A. How. For ML-1 through ML-3 software, prepare a Software Data Sheet (SWDS). See SOFT-GEN-FM03, *Software Data Sheet Form (SWDS)*. One SWDS can be used for multiple installations. Process and retain the data sheet in accordance with the SRLM's governing document control/records management processes (e.g., *EDMS*, and for *ES-Div*, *associated Desktop Instruction*).

Ensure the correct SWID (obtained when completing Form [2033](#)) is part of the SWDS record number and subsequent software documentation.

**ML-4 Note:** Software data sheets are not required for ML-4 software however may be used at the SRLM's discretion.

- B. When. Complete a SWDS at the earliest practical time and before design and/or acquisition as applicable (e.g., at end of planning).<sup>17</sup> Revise the SWDS as required to maintain accuracy.

**Note:** *It is recommended that the SRLM review the data sheet at least every two years.*

- C. Who. At a minimum, the SO develops and the SRLM reviews and approves the SWDS.

<sup>16</sup> For SSC software, submit draft 2033 forms with the 60% detail design submittals and finals with the 90% submittal. Indicate "To be determined (TBD)" where information is not available.

<sup>17</sup> Ref. IEEE 12207. At the end of the planning phase, SWDS is proof of a plan and management commitment to the project.

#### 4.0 CONFIGURATION MANAGEMENT (CM)

- A. Maintain software configuration management (CM) in accordance with this Subsection<sup>18</sup>.

#### 4.1. Develop and Maintain a Software Baseline (SWBL)

- A. How.

1. For ML-1 through ML-3 software, develop and maintain a software baseline. ML-4 software does not require a software baseline unless it is required by the LANL SRLM. Use SOFT-GEN-FM01, *Software Baseline Form (SWBL)*. The software baseline may be a standalone document, or it may be part of other documents.
2. Integrate the software baseline, as applicable with SSC technical baseline documents. See *Engineering Standards Manual Chapter 1, Section Z10, General*; [AP-341-616](#), *Technical Baseline Change During Design*; and [AP-341-405](#), *Identification and Control of Technical Baseline, Variances, Alternate Methods, and Clarifications in Operating Facilities*.
3. As applicable for SSC software, ensure configurations (e.g., set points) are established in accordance with [AP-341-613](#), *Instrumentation Set Point Control*.
4. Document the baseline configuration items needed to run the program. Include, as applicable<sup>19</sup>:
  - a. **Documentation** - software design requirements; instructions for computer program use including installation and test requirements; system description; test plans and results; characteristics derived from regulatory requirements and commitments; calculations and analyses; support software documentation.
  - b. **Computer program(s)** - source, object, back-up, data,<sup>20</sup> configuration, and support software files needed to run the program. Configuration files include limits, settings, set points, etc.
5. Develop and control the software baseline in accordance with the SRLM's document control process (e.g., *EDMS*). Ensure only authorized changes are made to software baselines.

Ensure the correct SWID (obtained when completing Form 2033) is part of the SWBL record number and subsequent software documentation. See [AP-341-402](#) for details.
6. Update the software baseline after software changes. Ensure that the baseline defines the most recent approved software configuration.<sup>21</sup>

<sup>18</sup> See [ANSI/IEEE Std. 828](#), *IEEE Standard for Configuration Management in Systems and Software Engineering* for guidance.

<sup>19</sup> Applicability is the determination that the activities and processes are actually used. For example, if the work scope does not include or contribute to design, then design requirements do not apply and the related design procedures are not used [Ref. [SD330](#), *LANL Quality Assurance Program*].

<sup>20</sup> This is the data needed to run the program. This can include data such as limits, set points, and databases.

<sup>21</sup> In the event the in-use computer program fails, becomes corrupted, or other problems occur, the baseline may be used to re-establish operation

7. Identify the associated hardware needed to run the computer program indirectly in the system design description document(s) or directly in the baseline.
8. When “Support Software” (including software tools) is used for new or modified software, one must evaluate, review, accept for use and place it under configuration control as well. Note however, that software tools that do not affect the performance of the software need not be placed under configuration control. Identify the software/tool in the baseline and manage the configuration. Changes to software tools must be evaluated for impact on the software product to determine the level of reviews and retesting that will be required. Vendor-supplied software used with hardware to configure control systems is an example of support software.
9. Implement a baseline labeling system in accordance with the following:
  - a. Uniquely identify each configuration item (documentation or computer program).
  - b. Identify changes to configuration items by revision.
  - c. Provide the ability to uniquely identify each configuration of the revised software available for use.
  - d. For baseline document labeling, use the SRLM’s approved document numbering system (e.g., [AP-341-402](#), *Engineering Document Management in Operating Facilities*).
  - e. Include baseline label information within the computer source code where possible. For each logical block or class, include a brief description of its function, the name of the person writing the description and the date the description was added.. For code changes following SWAU, update the header comments with the revision number (e.g. 1.01, 1.02...) and the SCP number driving the change. Guidance: *Include a brief description of the block function, the name of the person providing the description and the date the description was provided.*
  - f. For off the shelf software (OTS) or other (existing) software with a compliant labeling configuration, use the OTS or existing software labeling configuration.
  - g. For other software not described in (f), use Table 21.1-3, *Computer Program File Labeling System*, or as approved by the Chapter 21 POC.
  - h. Ensure the correct SWID (obtained when completing Form 2033) is integrated into the baseline labeling where possible.

Table 21.1-3 Computer Program File Labeling System			
Prior to Approval for Use <sup>1</sup>		After Approval for Use	
Major Change <sup>2</sup>	Minor Change <sup>2</sup>	Major Change	Minor Change
A, B, C...	A.01, A.02, A.03...	1, 2, 3...	1.01, 1.02, 1.03...
<sup>1</sup> Software approval for use (SWAU) constitutes that the software requirements have been satisfied (including testing, user's manuals, etc.) and the software is ready to be used in its intended operating environment. <sup>2</sup> See definitions of major change and minor change in the definitions section.			

B. When.

1. For ML-1 and ML-2 designed software, establish software baselines at the completion of each major software design activity.
2. Establish software baselines as soon as practical. At a minimum, establish before formal acceptance testing/commissioning. Pre-acceptance testing may be performed to support verification of the baseline prior to (final) acceptance testing. Maintain baselines (configuration items) under configuration management until software retirement.

C. Who. The SO prepares the baseline. The SRLM and others as required in the governing document control process, review and approve the software baseline.

## 4.2. Control Software Changes

A. How.

1. Safety Software: For computer program changes (revisions) to software, use SOFT-V&V to V&V the software change and/or commercial grade dedication (CGD), e.g., per AP-341-703, to dedicate the change. Unless a more conservative approach is required by the LANL SRLM, use the following graded approach for dedicating software 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 and as applicable, the associated SSC.
2. For all ML levels, see Table 21.1-4 and apply the following to Major and Minor software changes:
  - a. For designed software, institute design control measures commensurate with those applied to the original design.
  - b. Document changes and include the following in the change documentation:
    - 1) a description of the change;
    - 2) rationale for the change;
    - 3) identification of affected software baselines; and
    - 4) evaluation and approval of the change (see SOFT-V&V for evaluation methods/criteria).

Table 21.1-4 SOFT-GEN Software Change Summary by Software Management Level (ML) (This is a summary only and does not include all requirement details. See text for details.)									
For the following types of software changes	Provide the following deliverable	SSC Software ML <sup>1</sup>				Non-SSC Software ML <sup>1</sup>			
		1	2	3	4	1	2	3	4
Less than minor change, minor and major changes made <u>before or after</u> approval for use (SWAU)	Documented comment in the computer program code where feasible	R	R	R	R	R	R	R	R
Minor or major changes made during design implementation and <u>before</u> SWAU	<a href="#">AP-341-519</a> change documents <sup>2</sup>	R	R	G	G	-	-	-	-
Minor or major changes made once software is baselined	Revised baseline <sup>3</sup>	R	R	R	-	R	R	R	-
Minor or major changes made <u>after</u> SWAU	SSC Software Change Package (SCP) Form <a href="#">AP-341-507-FM01</a> <sup>4</sup>	R	R	G	-	-	-	-	-
	Non-SSC SWNCP Form, SOFT-GEN-FM02	-	-	-	-	R	R	G	-

<sup>1</sup> See Form 2033 for a crosswalk between MLs and software type, category and software risk levels. R = Required. G = Required but graded. "-" = Not required.

<sup>2</sup> Includes Field Change Notices (FCNs), Field Change Requests (FCRs), Design Revision Notices (DRNs), Design Change Forms (DCFs) as described in [AP-341-519](#) unless explicitly superseded by another administrative procedure.

<sup>3</sup> Use SOFT-GEN-FM01, *Software Baseline Form (SWBL)*. Include documents and computer program files.

<sup>4</sup> See ESM Chapter 15, *Commissioning and AP-341-801, Post Modification/Post Maintenance Testing* for related testing requirements of software changes.

- c. Perform appropriate verification activities and validation (V&V) of changes (see SOFT-V&V). Perform appropriate acceptance testing for the change.
- d. Incorporate the changes in documentation, and maintain traceability of the change to the software design requirements.
  - 1) Include the (1) initiation, evaluation, and disposition of a change request, (2) control and approval of changes prior to implementation, and (3) requirements for retesting (e.g., regression testing) and acceptance of the test results.
- e. Perform the following:
  - 1) maintain a current status of configuration items and control configuration changes until they are incorporated into the approved product baseline;

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- 2) maintain the status of changes that are proposed and approved, but not implemented; and
  - 3) provide notification of this information to affected organizations.
  - f. For changes to documentation only, use the governing document control process.
  - g. Implement the processes described and/or referenced in this chapter to ensure that interfaces are controlled/managed such that unintended consequences do not occur.
  - h. As applicable, ensure configurations changes are established (Ref. [AP-341-613](#), *Instrumentation Set Point Control*).
  - i. Update the software baseline.
- B. When. Control changes per Table 21.1-4, in a timely manner and when required to ensure proper performance.
- C. Who.
1. See [AP-341-507](#), [AP-341-519](#) unless explicitly superseded by another procedure and SOFT-GEN-FM02, Non-SSC Software Change Package Form (SWNCP).
  2. The organization responsible for the original software design and others as deemed necessary by the SRLM must evaluate, and approve software changes unless an alternate organization has been given the authority by the SRLM to approve the changes.
  3. As determined by the SRLM, only those that are knowledgeable in the computer program code may make changes to the computer program code.

**5.0 PERFORM PROBLEM REPORTING & CORRECTIVE ACTION**

- A. How.
1. For ML-1 through ML-4 software, perform software problem reporting and corrective action throughout the software life cycle.
  2. For ML-4 software, less formal methods (e.g., bug lists, use of comment fields within the computer program, software-tailored tools such as [TeamForge](#) and [trac](#)), or formal methods (see below) may be used throughout the software lifecycle.
  3. For ML-1 through ML-3 software, less formal methods may be used through development and testing; however, formal methods must be used after software approval for use (SWAU).<sup>22</sup> Individually or in combination, [P330-6](#), *Nonconformance Reporting*, [P322-4](#), *Laboratory Performance Feedback and Improvement Process*, or equivalent as determined by the SRLM, must address the following:
    - a. Describe the evaluation process for determining whether a reported problem is an error (see definitions) or other type of problem (e.g., user mistake).
    - b. Define the responsibilities for disposition of problem reports, including notification to the originator of the results of the evaluation.

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<sup>22</sup> P330-6 r10 has little on software but r11 is expected to include more direction.

- c. When a problem is determined to be an error (see definitions), provide, as appropriate, for
    - 1) how the error relates to appropriate software engineering elements;
    - 2) how the error impacts past and present use of the computer program;
    - 3) how the corrective action impacts previous development activities; and
    - 4) how the users are notified of the identified error, its impact, and how to avoid the error, pending implementation of corrective actions.
  - d. Problem reporting and corrective action must include methods for documenting, evaluating, and correcting software problems.
  - e. Conditions adverse to quality shall be identified promptly and corrected as soon as practicable.
  - f. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence.
  - g. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.
  - h. The verification of completed corrective actions.
- B. When. Perform throughout the software life cycle.
- C. Who. The SO performs software problem reporting and corrective action on behalf of the SRLM. The SRLM is responsible to ensure it is performed as required by the associated procedure (e.g., [P330-6](#) on NCRs).

## 6.0 PERFORM SOFTWARE (PROJECT) RISK MANAGEMENT

- A. How.
1. *Software risk management as required by O414.1D focuses on the risks to successfully complete the software project; it does not focus on the risks of potential failure of the software.<sup>23</sup> Software risk management applies to all phases of the software project life cycle. Overall software risk management is achieved through implementation of the NQA-1 based, systematic processes of this chapter and the supporting quality assurance program. That is, successful implementation of this chapter should result in successful completion of a software project. The SRLM should determine if project-level software Risk Management is needed (e.g., large and important projects).*
  2. For ML-1 through ML-3 software, also address software-specific risks (risks specific or unique to the software implementation). Manage software-specific risks by (a) assessing and (b) controlling the risks.
    - a. With a graded approach approved by the SRLM and Chapter POC, implement risk management based on industry accepted methods such as those

<sup>23</sup> Based on [DOE G 414.1-4](#), *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and [DOE O 414.1C](#), *Quality Assurance*.

described in [DOE SQAS21.01.00-1999](#), *Software Risk Management a Practical Guide*; [DOE G413.3-7](#), *Risk Management Guide*; and/or [DOE G 414.1-4](#), *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements*, and *DOE O 414.1C, Quality Assurance*.

3. *Risk assessment includes risk identification, analysis, and prioritization to ensure that the necessary resources are available to mitigate them.*
  4. *Risk control includes risk resolution and tracking. Resolve risks using risk avoidance, mitigation and/or transference.*
  5. Document and maintain software-specific risks on a risk list (also referred to as risk register) in the SWDS.
- B. When. Perform throughout the software life cycle.
- C. Who. The SO performs software risk management on behalf of the SRLM. The SRLM is responsible to ensure it is performed, and reviews and approves the risk list as part of the SWDS.

## 7.0 APPENDICES, ATTACHMENTS AND FORMS

### Appendices:

- APPENDIX A: Chapter 21 Definitions and Acronyms
- APPENDIX B: SO and SRLM Decision Diagram for FAC-COE
- APPENDIX C: Chapter 21 Reference Listing

### Attachments:

- ATTACHMENT 1: Chapter 21 Summary Table

### Forms:

- SOFT-GEN-FM01: Software Baseline Form (SWBL)
- SOFT-GEN-FM02: Non-SSC Software Change Package Form (SWNCP)
- SOFT-GEN-FM03: Software Datasheet Form (SWDS)

APPENDIX A: CHAPTER 21 DEFINITIONS AND ACRONYMS

Only key definitions are listed. See [PD340](#), *Conduct of Engineering for Facility Work*, [SD330](#), *Los Alamos National Laboratory Quality Assurance Program*, and documents referenced therein for additional definitions.

Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
acceptance testing, also known as software validation	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. (Ref. <a href="#">NQA-1</a> ).
acquired software	Software that is generally supplied through basic procurements, two-party agreements, or other contractual arrangements. Acquired software includes off-the-shelf (OTS) software such as operating systems, database management systems, compilers, software development tools, and commercial calculational software and spreadsheet tools. Downloadable software that is available at no cost to the user (referred to as freeware) is also considered acquired software. (Based on <a href="#">DOE G 414.1-4</a> ).
Acquired Non-SSC software	Non-SSC software that is acquired software where the code cannot be changed other than through replacement. This may also be referred to as Read-Only Non-SSC software. Replacement includes replacement with a subsequent software version or upgrade. (Definition developed for this chapter).
baseline	A specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for use and further development, and that can be changed only by using an approved change control process. (Ref. <a href="#">NQA-1</a> ). <b>Note:</b> See SOFT-GEN-FM01, <i>Software Baseline Form (SWBL)</i> . A software baseline includes the computer program (code and [configuration] data) and the computer program documentation. In layman’s terms, one may think of this as the information and computer program files that are needed to run the software for a specific application.
Change - Major computer program change	A change or bug fix that: <ul style="list-style-type: none"> <li>▪ the Software Responsible Line Manager (SRLM) or computer program supplier designates as a major change,</li> <li>▪ adds or deletes an ML-1, ML-2 or ML-3 SSC performance function (including set point changes),</li> <li>▪ modifies ML-1 or ML-2 SSC performance function code, excluding clarifying notes,</li> <li>▪ adds, deletes or modifies design and/or analysis output values of ML-1, ML-2 or ML-3 calculations,</li> <li>▪ recodes to another language, or</li> <li>▪ modifies a significant number of lines of code.</li> </ul> <b>Note:</b> A Major OTS computer program change is often indicated with increment increase in version number (e.g., change from version 1 to 2). An evaluation of the software however, is required to determine whether the version release is a major change. <b>Examples:</b> A change from Delta V control system software from version 7.0 to version 8.0. A change that adds code to implement an interlock functional performance requirement that an ML-3 laser system cannot be activated until area doors are locked. A change that modifies code on ML-2 ventilation system backdraft damper so that damper closure does not slam shut and potentially damage the damper assembly. A change in the algorithm or databased used for calculating the water flow rate in an ML-3 fire protection piping system design. A change in coding language from C to C++. A version change where 40% of the lines of code were modified. (Definition developed for this chapter).

Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
Change - Minor computer program change	<p>A change or bug fix that is not a major computer program change but:</p> <ul style="list-style-type: none"> <li>▪ adds or deletes an ML-4 SSC performance function (including setpoint changes),</li> <li>▪ modifies ML-3 SSC performance function code, excluding clarifying notes, or</li> <li>▪ adds, deletes or modifies design and/or analysis output values of ML-4 calculations</li> </ul> <p><b>Note:</b> A minor OTS software change is often indicated with a fractional increase in version number (e.g., 1.1 or 1.01). An evaluation of the software however, is required to determine whether the version release is a minor change.</p> <p><b>Examples:</b> Add code to implement automatic pump shut-off performance requirement on ML-4 sump low-level alarm. Modify code to fix a coding error on an ML-3 heating/cooling system so that cooling, rather than heating activates at high temperatures. Change the algorithm for calculating the current that flows in an ML-4 electric power system under abnormal conditions. (Definition developed for this chapter).</p>
Change - Less than minor computer program change	<p>A change or bug fix that is not a major or minor computer program change but:</p> <ul style="list-style-type: none"> <li>▪ adds, deleted and/or modifies ML-4 performance function code,</li> <li>▪ adds, deletes and/or modifies code that does <u>not</u> modify ML-1, ML-2, ML-3 performance function, or</li> <li>▪ imparts changes without adding, deleting or modifying design and/or analysis output values (all MLs).</li> </ul> <p><b>Examples:</b> Modify code to increase the ramp time on an ML-4 softstart pump. Install security patch/service pack updates. An OTS software patch that includes a code change to prevent a screen from “freezing” or loading slowly (all MLs). Add/modify code clarifying notes (all MLs). Modify code to produce multiple reporting formats (all MLs). (Definition developed for this chapter).</p>
commercially controlled software	<p>As determined using <a href="#">Form 2033, Safety/Non-Safety Software Determination, Categorization, and Software Risk Level (SRL)</a>, software that is not, or will not be safety software or risk significant software. Such software may be acquired (including off the shelf (OTS) software, freeware, or designed software.</p> <p><b>Examples:</b> Personal productivity software (e.g., Microsoft PowerPoint, Oracle Project Primavera, MS Outlook, etc.); typical business accounting systems, facility personnel comfort temperature control systems. (Based on <a href="#">P1040</a>).</p>
computer program	<p>A combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions. (Ref. <a href="#">NQA-1</a>).</p>
computer program listings	<p>A printout or other human readable display of the source and, sometimes, object statements that make up a computer program. (Ref. <a href="#">ISO/IEC/IEEE 24765</a>).</p>
configuration management	<p>The process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system’s life cycle, and recording and reporting the status of configuration items and change requests. (Ref. <a href="#">NQA-1</a>).</p>
Designed (or developed) software	<p>Software that is designed or developed rather than acquired.</p> <p><b>Note:</b> Includes the following from <a href="#">DOE G 414.1-4</a>. (a) custom developed software, (b) configurable software, and (c) utility calculation software. (Definition developed for this chapter).</p>
Designed Non-SSC Software	<p>Non-SSC software where the computer program can be changed other than through replacement. Replacement includes replacement with a subsequent software version or upgrade. (Definition developed for this chapter).</p>
Designed SSC Software	<p>SSC software where the computer program can be changed other than through replacement of the computer program and/or the associated SSC. (Definition developed for this chapter).</p>

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Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
Engineering Services Software Coordinator	Individual assigned to maintain the software inventory for ES Division, and to perform other duties as assigned (e.g., per desktop instruction [future]).
error	An error is a condition deviating from an established baseline including deviations from the current approved computer program and its baseline requirements. (Ref. <a href="#">NQA-1</a> ). An error is something which requires a software change (major or minor). Examples of errors include (a) if a computer program used for design of a structural member provides incorrect design output, and (b) if a computer program turns on heating instead of cooling at high temperature settings.
freeware	Software that is available for use at no cost or for a nominal, usually voluntary fee. (Ref. <a href="#">Merriam-Webster Dictionary</a> ).
major document change	A document change that is not a minor document change. A major document change includes revisions, changes, or modifications to a document (e.g., procedure, work instruction, drawing, etc.) which impact the effective implementation of the requirement(s). (Based on <a href="#">P1020-2</a> ).
minor document change	A document change, as defined by the governing document control program, that includes but is not limited to inconsequential editorial corrections, grammatical and spelling changes, organizational name and acronym changes, and similar type changes. (Based on <a href="#">P1020-2</a> ).
model	Simplifications of the real world constructed to gain insights into select attributes of a particular physical, biological, economic, engineered, or social system. (Ref. EPA/100K-09/003, <i>Guidance on the Development, Evaluation, and Application of Environmental Models</i> .)
Non-safety software	As determined using <a href="#">Form 2033</a> , software that is not otherwise determined to be safety software. Non-safety software includes risk significant and commercially controlled software. (Ref. <a href="#">P1040</a> ).
Non-SSC software	Software used in design, analysis and/or for administrative control. This software does not physically monitor and/or control SSCs. <b>Examples:</b> Piping system design/analysis software (CAESAR II®), fire protection system design software (SprinkCAD), area lighting calculation software, spreadsheets used to perform structural load calculations, safety analysis software used to perform dispersion modeling, software used to track facility combustible loading, and software used to track Technical Safety Requirement (TSR) implementation. (Definition developed for this chapter).
operating environment	A collection of software, firmware, and hardware elements that provide for the execution of computer programs. (Ref. <a href="#">NQA-1</a> ). It is also the location and conditions (environment) where the software will be used or operated to meet its intended function. (Based on P330-8).
Read-Only SSC Software	SSC software where the computer program cannot be changed other than through replacement of the computer program and/or the associated SSC. (It is sometimes referred to as embedded software or firmware; however, for this Chapter, the term Read-Only SSC software is used.) <b>Note:</b> Read-only software includes software where limits and/or set points can be configured (e.g., via keypad entries) without modifying the computer program (code). (Definition developed for this chapter).

Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
Risk Significant software	Software that is, or will be, used for any of the purposes for which safety software is used (see <a href="#">Form 2033</a> ), only such purposes are in or for an accelerator, live-fire range, biological hazard facility, explosive hazard facility, or a moderate- or high- hazard chemical facility; or failure of the software would prevent LANL from performing Essential Functions as described in <a href="#">EPP-COOP-006</a> , <i>LANL COOP [Continuity of Operations] Plan</i> . Commercially controlled software is not risk significant software. (Ref. <a href="#">P1040</a> ).
Safety and Hazard Analysis and Design Software (SHADS)	Safety software that is used, or will be used, to classify, design, or analyze nuclear (including radiological) facilities. This software is not part of an SSC, but helps to ensure the proper accident or hazards analysis of nuclear (including radiological) facilities or an SSC that performs a safety function. This is Non-SSC software, safety software, and is categorized as SHADS. (Ref. <a href="#">P1040</a> ).
Safety Management and Administrative Controls Software (SMACS)	Safety software that performs, or will perform, a hazard control function in support of nuclear (including radiological) facility radiological Safety Management Programs (SMPs) or TSRs; and/or this is software that performs, or will perform, a control function in support of a nuclear (including radiological) facility necessary to provide adequate protection from nuclear (including radiological) facility radiological hazards. It supports eliminating, limiting, or mitigating nuclear hazards to workers, the public, or the environment as addressed in <a href="#">10 CFR 830</a> , <a href="#">10 CFR 835</a> , <i>Occupational Radiation Protection</i> , and the Department of Energy Acquisition Regulation (DEAR) Integrated Safety Management System (ISMS) clause <a href="#">48 CFR 970.5223-1</a> , <i>Integration of Environment, Safety, and Health into Work Planning and Execution</i> . This is safety software and is categorized as SMACS. (this is a clarification of definition in <a href="#">P1040</a> r9; r10 expected to include same).
Safety Software	Software that includes any of the following: SSS, SHADS, or SMACS. Both SSC software and Non-SSC software can be safety software. (Ref. <a href="#">P1040</a> ).
Safety System Software (SSS)	Safety software for a nuclear (including radiological) facility that performs, or will perform, a safety function as part of an SSC and is cited in either (a) a DOE-approved documented safety analysis, or (b) an approved hazard analysis per <a href="#">DOE P 450.4A</a> , <i>Integrated Safety Management Policy</i> and <a href="#">48 CFR 970-5223-1</a> , <i>Integration of Environment, Safety, and Health into Work Planning and Execution</i> . This is SSC software, safety software and is categorized as SSS.  <b>Note:</b> References implemented at LANL as described in PD110, <i>Safety Basis</i> . See DOE-approved documented safety analyses at <a href="#">LANL Safety Basis Document Lists (SBDLs)</a> . Analyses include Documented Safety Analyses (DSAs), Preliminary Documented Safety Analyses (PDSAs), Bases for Interim Operations (BIOs) etc. (Based on <a href="#">P1040</a> ).
simple and easily understood (Non-SSC) software used in the design of SSCs	Software that satisfies the following criteria: <ul style="list-style-type: none"> <li>a. The software is used in the design of SSCs;</li> <li>b. The results of the computer program can be easily confirmed through hand calculations;</li> <li>c. A person technically qualified in the subject can review and understand the program and the supporting calculations; and,</li> <li>d. The software can be individually verified with each use (e.g., calculation). (Based on <a href="#">NQA-1</a>).</li> </ul>
software	Computer programs and associated documentation and data pertaining to [needed for] the operation of a computer system. (Ref. <a href="#">NQA-1</a> ).
software approve/approval /approved for use (SWAU)	An approval that constitutes that the software requirements have been satisfied (including installation and operating instructions), and the software is ready to be used in the intended operating environment. (Ref. <a href="#">P1040</a> ).

Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
Software Coordinator	Individual(s), designated by division management, providing coordinating and/or administrative functions in support of chapter compliance (e.g., inventory and associated reporting). <i>ES Division has an ES-Div Software Coordinator.</i>
software design requirement	A requirement that impacts or constrains the design of a software system or software system component. (Based on <a href="#">ISO/IEC/IEEE 24765</a> ).
software engineering elements	(a) software acquisition method(s) for controlling the acquisition process for software and software services; (b) software engineering method(s) used to manage the software life-cycle activities; (c) application of standards, conventions, and other work practices that support the software life cycle; (d) controls for support software used to develop, operate, and maintain computer programs. (Ref. <a href="#">NQA-1</a> ).
Software Owner (SO)	Selected responsibilities from P1040 Rev 9 follow; see others in Ch 21: <ul style="list-style-type: none"> <li>• Provides the software information and <a href="#">Form 2033, Safety/Non-Safety Software Determination, Categorization, and Software Risk Level (SRL)</a> and obtains review and concurrence of the form in accordance with this document.</li> <li>• Reviews and approves the software project planning documentation.</li> <li>• Owns the software and supports the SRLM in complying with the requirements of this document.</li> <li>• Prepares the approval for use documentation that describes the intended use and any associated limitations, access controls, etc., for using the software.</li> </ul>
Software Point of Contact (SPOC)	That individual selected by division management to act as software owner for specific software or multiple Non-SCC software programs. Ideally it's the main or super-user of each program, but can be another user or even a single individual for a group or division.

Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
Software Responsible Line Manager (SLRM)	<p>Responsibilities (performs or causes to be performed, from P1040 Rev 9 for Software Owner RLM follow; see others in Ch 21:</p> <ul style="list-style-type: none"> <li>• Manages and maintains software in accordance with this document to ensure it operates as intended.</li> <li>• Determines reasonable probability, software type, software category, and as applicable SRL.</li> <li>• Reviews Form 2033, Safety/Non-Safety Software Determination, Categorization, and Software Risk Level (SRL) for completeness, accuracy and adequacy, and signs Form 2033 indicating concurrence with the software determination, categorization, and as applicable, SRL.</li> <li>• Retains the completed Form 2033 as a record in accordance with the SRLM's records management system.</li> <li>• Identifies, documents, approves, controls, and maintains safety and risk significant software owned by the SRLM that is new software or in-use software at LANL nuclear (including radiological) facilities.</li> <li>• Provides SRLM safety software inventory information and any changes thereto to QPA-IQ.</li> <li>• Transmits the SRLM inventory information to QPA-IQ in accordance with applicable document control protocols, including as required, derivative classification review and marking for sensitive information; retains information as a record.</li> <li>• Applies the appropriate amount of SQA rigor in software planning and implementation.</li> <li>• Reviews and approves the software project planning documentation.</li> <li>• As applicable, acquires software and/or software services.</li> <li>• Except for SQA associated with using the software, is responsible for the SQA of the software.</li> <li>• V&amp;Vs the software.</li> <li>• Identifies and ensures reviews are performed by competent individuals or groups other than those who developed and documented in the original software design (but who may be from the same organization).</li> <li>• Ensures software owning organization personnel managing or working to this document are adequately trained and as required, qualified.</li> <li>• Approves software for use.</li> <li>• Completes in-use tests in the operating environment.</li> <li>• Retires software, including removal of safety software from software inventory.</li> </ul>
software tool	<p>A computer program used in the development, testing, analysis or maintenance of a program or its documentation. Examples include vendor-supplier configuration tools, conversion tables, comparators, cross-reference generators, compilers, CASE (Computer-Aided Design Software Engineering) tools, configuration and code management software, decompilers, disassemblers, editors, flowcharters, monitor test case generators, and timing analyzers. (Based on <a href="#">NQA-1</a>).</p>
Software User (SU)	<p>Responsibilities from P1040 Rev 9; see others in Ch 21.</p> <ul style="list-style-type: none"> <li>• Reviews and approves the software project planning documentation.</li> <li>• Applies the appropriate amount of SQA rigor in software planning and implementation.</li> <li>• Reports software errors and problems.</li> <li>• Uses software within software limitations and in accordance with this document.</li> </ul> <p>[Note, for SSC software, choose as the SU the individual that best adds value when considering the above role. <i>It may depend on and change whether in design or an operating facility. It may be the responsible engineer (or technician or maintenance in some cases) rather than facility ops personnel.</i>]</p>

## 1 Section SOFT-GEN: General Software Requirements

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Table 21.1-A1 Chapter 21 Definitions	
Item	Definition
Software User Responsible Line Manager (SU RLM)	<p>Selected responsibilities from P1040 Rev 9; see others in Ch 21.</p> <ul style="list-style-type: none"> <li>Reviews and approves the software project planning documentation.</li> <li>Approves software for use.</li> <li>Supports completion of in-use tests in the operating environment.</li> <li>Ensures software users and software user organization personnel managing or working to this document are adequately trained, and as required, qualified.</li> </ul>
SSC software	<p>Software that controls and/or monitors system, structures and components (SSCs) and is running and interacting with its environment in real time. SSC software may be safety or non-safety software.</p> <p><u>Examples:</u> Building Automation Control System (BAS) software, process gas monitoring and control system software, fire alarm control panel (FACP) software, continuous air monitor (CAM) software, seismic switch software, and uninterrupted power supply (UPS) software. (Based on TR. No. 397, <i>Quality Assurance for Software Important to Safety</i>, IAEA, 2000).</p>
support software	<p>Software or a program that aides in the development, maintenance, or use of other software or provides general application-independent capability (Ref. <a href="#">ISO/IEC/IEEE 24765</a>). Support software includes software tools and system software (Ref. <a href="#">NQA-1</a>).</p> <p><b>Note:</b> SSC and Non-SSC software may have support software.</p>
system software	<p>An element of support software, the computer programs used to provide basic or general functionality and facilitate the operation and maintenance of the application computer program. Examples include lower level software layers, assemblers, interpreters, diagnostics, and utilities. (Based on <a href="#">NQA-1</a>).</p>
test case	<p>A set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement. (Ref. <a href="#">NQA-1</a>).</p>
test plan (Procedure)	<p>A document that describes the approach to be followed for testing a system or component. Typical contents identify the items to be tested, tasks to be performed, and responsibilities for the testing activities. (Ref. <a href="#">NQA-1</a>).</p>
toolbox code	<p>Software that is listed on the <a href="#">DOE Safety Software Quality Assurance Central Registry</a> (Registry). (Ref. <a href="#">P1040</a>).</p>
validation (software)	<p>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. <a href="#">NQA-1</a>); and providing evidence that the software, and its associated products, satisfies system requirements allocated to software at the end of each life cycle activity, solves the right problem (e.g., correctly models physical laws, implements business rules, uses the proper system assumptions), and satisfies the intended use and user needs (Ref. <a href="#">DOE O 414.1D</a>).</p>
verification	<p>The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements (Ref. <a href="#">NQA-1</a>); and providing objective evidence that the software and its associated products conform to requirements (e.g., for correctness, completeness, consistency, and accuracy) for all life cycle activities during each life cycle process (e.g., acquisition, supply, development, operation, and 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) (Ref. <a href="#">O 414.1D</a>).</p>

## 1 Section SOFT-GEN: General Software Requirements

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Table 21.1-A2 Chapter 21 Acronyms	
Acroynm <sup>1</sup>	Definition
A	Approve
AFU	Approval for Use
ASCE	American Society of Civil Engineers
AP	Administrative Procedure
ASM	Acquisition Services Management
ASME	American Society of Mechanical Engineers
BAS	Building Automation System
BIO	Basis for Interim Operations
CAM	Continuous Air Monitor
CGD	Commercial Grade Dedication (Dedicated)
CM	Configuration Management
COOP	Continuity of Operations Plan
Cx	Commissioning
D	Develop
DA	Design Authority
DAG	Design Agency
DCF	Design Change Form
DOE	(United States) Department of Energy
DRN	Design Revision Notice
DSA	Documented Safety Analysis
EF	Essential Function
ES	Engineering Services
ES-Div	Engineering Services Division
ESM	Engineering Standards Manual
ESSC	Engineering Services Software Coordinator
FAC-COE	Facility Conduct of Engineering
FACP	Fire Alarm Control Panel
FCR	Field Change Request
FDAR	Facility Design Authority Representative
FDD	Facility Design Description
G	Grade (or Guide)
IEEE	Institute of Electrical and Electronics Engineers
IESL	LANL Institutional Evaluated Supplier List
IWR	Interim Work Request
LANL	Los Alamos National Laboratory
LCxA	LANL Commissioning Authority
ML	Management Level
NA	Not Applicable
NQA-1	<a href="#">ASME NQA-1-2008/NQA-1A-2009</a> , Quality Assurance Requirements for Nuclear Facility Applications, Part I and Part II
OCIO	Office of Chief Information Officer
O&M	Operations and Maintenance

Table 21.1-A2 Chapter 21 Acronyms	
Acroynm <sup>1</sup>	Definition
OTS	Off the Shelf
PDSA	Preliminary Documented Safety Analysis
PFD	Process Flow Diagram
P&ID	Process and Instrumentation Diagram
POC	Point of Contact
R	Required or review (see context)
RE	Responsible Engineer
RLM	Responsible Line Manager
SB	Safety Basis Division
SBP	Safety Basis Procedure
S/CI	Suspect/Counterfeit Item
SDD	System Design Description
SHADS	Safety and Hazard Analysis Software
SMACS	Safety Management and Administrative Controls Software
SME	Subject Matter Expert
SO	Software Owner
SOO	Sequence of Operations
SOW	Statement of Work
SPOC	Software Point of Contact
SRLM	Software Responsible Line Manager
SSC	Structure, System Component
SSS	Safety System Software
SRL	Software Risk Level
SU	Software User
SWAU	Software Approve (Approval) for Use
SWDD	Software Design Documentation (or Document)
SWBL	Software Baseline
SWDS	Software Data Sheet
SWHA	Software Hazards Analysis
SWID	Software Identification Number
SWNCP	Non-SSC Software Change Package
SWRS	Software Requirements Specification
SWYRS	Software System Requirements Specification
SWTM	Software Traceability Matrix
SWTP	Software Test Plan
SWTR	Software Test Report
TA	Technical Area
UPS	Uninterrupted Power Supply
V&V	Verify and Validate (or verification and validation)

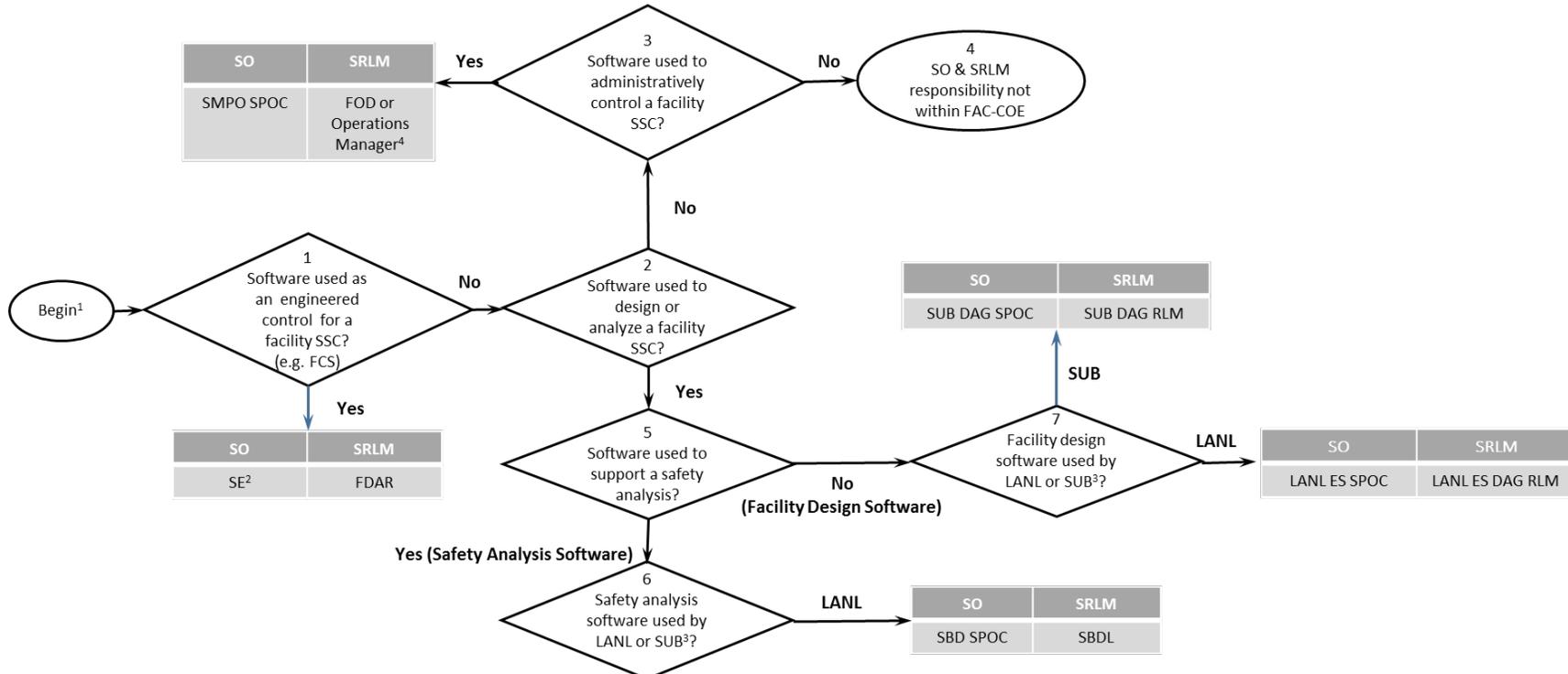
<sup>1</sup> Only key acronyms are listed. See [PD340](#), *Conduct of Engineering for Facility Work* and documents referenced therein for additional meanings.

**APPENDIX B: SO AND SRLM DECISION DIAGRAM FOR FAC-COE**

Use Figure 21.1-B1 to identify the SO and SRLM. For clarification, contact the Facility Design Authority Representative (FDAR).

- For software used within a single facility/application and/or under a single FDAR, the associated FDAR has the ultimate authority to determine the appropriate SO and SRLM.
- For software used among multiple facilities/applications where there may be multiple FDARs, the LANL Facility Design Authority (DA) has the ultimate authority to make the determination.

Figure 21.1-B1 SO and SRLM Determination for FAC-COE (Guidance)



**NOTES:**

- <sup>1</sup> Answer the questions to determine the SO and SRLM.
- <sup>2</sup> Once operating, normally the plant system engineer, process engineer, or cognizant system engineer. During larger projects, functions are often performed by Design Agency.
- <sup>3</sup> As flowed down in supplier/subcontractor agreement.
- <sup>4</sup> For software used across multiple FODs, the SMP Program Owner should be the SRLM.
- <sup>5</sup> For clarification, contact the FDAR who has the ultimate authority to determine the appropriate SO and SRLM.

**KEY:**

DAG	Design Agency	SBDL	Safety Basis Division Leader
ES	Engineering Services Division	SE	System Engineer
FAC-COE	Facility Conduct of Engineering	SMPO	Safety Management Program Owner
FCS	Facility Control System	SO	Software Owner
FDAR	Facility Design Authority Representative	SPOC	Software Point of Contact
FOD	Facility Operating Director	SRLM	Software Responsible Line Manager
MAR	Material at Risk	SSC	System, Structure, Component
RLM	Responsible Line Manager	SUB	Subcontractor
SBA	Safety Basis Analyst		

## APPENDIX C: CHAPTER 21 REFERENCE LISTING

Most recent document revision (including revised document numbering and/or titles) applies unless otherwise stated. *Most national standards are available to LANL personnel via links; others must purchase.*

[10 CFR 830](#), *Nuclear Safety Management*

[10 CFR 835](#), *Occupational Radiation Protection*

[48 CFR 970-5223-1](#), *Integration of Environment, Safety, and Health into Work Planning and Execution*

[ANSI/ANS-10.7](#), *Non-Real-Time, High-Integrity Software for the Nuclear Industry – Development Requirements*

[ASME NQA-1-2008/NQA-1A-2009](#), *Quality Assurance Requirements for Nuclear Facility Applications, Part I and Part II*

[ASME NQA-1-2015 Part III, Subpart 3.2-2.14](#), *Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services*

[Certified Software Quality Engineer Handbook](#), L. Westfall, American Society of Quality Pres.

## DOE

[DOE O 414.1D](#), *Quality Assurance*

[DOE Safety Software Quality Assurance Central Registry](#)

[DOE G 414.1-4](#), *Safety Software Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance (Revision A pending)*

[DOE P 450.4A](#), *Integrated Safety Management Policy*

[DOE SQAS21.01.00-1999](#), *Software Risk Management a Practical Guide*

[DOE-STD-1195](#), *Design of Safety Significant Safety Instrumented Systems Used at DOE Nonreactor Nuclear Facilities*

[EPA/100/K-09/003](#), *Guidance on the Development, Evaluation, and Application of Environmental Models*, [www.epa.gov/crem](http://www.epa.gov/crem)

IAEA TR. No. 397, *Quality Assurance for Software Important to Safety*, IAEA, 2000

## IEEE

[ANSI/IEEE Std 7-4.3.2-2010](#), *IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations*

[ANSI/IEEE Std 828](#), *IEEE Standard for Configuration Management in Systems and Software Engineering*

[ANSI/IEEE Std 26514](#), *Systems and Software Engineering—Requirements for Designers and Developers of User Documentation*

[ANSI/IEEE Std 29148](#), *Systems and Software Engineering – Life Cycle Processes – Requirements Engineering*

[IEEE Std 344](#), *Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations*

[IEEE Std 829](#), *IEEE Standard for Software and System Test Documentation*

[IEEE Std 830](#), *IEEE Recommended Practice for Software Specifications*

[IEEE Std 1012](#), *IEEE Standard for System and Software Verification*

[IEEE Std 1016](#), *IEEE Standard for Information Technology – System Design – Software Design Descriptions*

[IEEE Std 1016.1](#), *IEEE Guide to Software Design Descriptions*

[IEEE Std 1028](#), *IEEE Standard for Software Reviews and Audits*

[IEEE Std 1666](#), *IEEE Standard for Standard System C Language Reference Manual*

[IEEE Std 12207](#), *Systems and Software Engineering – Software Life Cycle Processes*

[ISO/IEC/IEEE 24765](#), *Systems and Software Engineering – Vocabulary*

[ISO/IEC/IEEE 29148](#), *Systems and Software Engineering-Life Cycle Processes-Requirements Engineering*

[ANSI/ISA S84.00.01](#), *Functional Safety: Safety Instrumented Systems for the Process Industry Sector*

LANL (internal-only unless noted). Contact the chapter POC for assistance in obtaining LANL documents.

[AP-341-402](#), *Engineering Document Management in Operating Facilities*

[AP-341-405](#), *Identification and Control of Technical Baseline, Variances, Alternate Methods, and Clarifications in Operating Facilities*

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[AP-341-502](#), Management Level Determination and Identification of Quality Assurance and Maintenance Requirements

[AP-341-504](#), Temporary Modification Control

[AP-341-507](#), SSC Control Software Change Package

[AP-341-510](#), Field Walk-down, Data Gathering, and Inspections

[AP-341-519](#), Design Revision Control

[AP-341-605](#), Calculations

[AP-341-601](#), Functions and Requirements Document

[AP-341-602](#), Requirements and Criteria Document (RCD)

[AP-341-611](#), System Design Descriptions

[AP-341-613](#), Instrumentation Set Point Control

[AP-341-616](#), Technical Baseline Change During Design

[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

[AP-341-703](#), Commercial Grade Dedication

[AP-341-801](#), Post Modification/Post Maintenance Testing

[AP-341-802](#), System Health Reporting

[AP-341-901](#), Performing Vital Safety System Assessments

[AP-350-406](#), Startup and Commissioning

[ASM 3400.00.041](#), Goods or Services Requiring Special Review/Approval

[ASM Website](#)

[Conduct of Operations Resources](#)

[EPP-COOP-006](#), LANL COOP [Continuity of Operations] Plan

[ES Division Office \(ES-Div\) Website](#)

[Information System Security Officer \(ISSO\)](#)

[LANL Institutional Supplier List \(IESL\)](#)

[LANL Nuclear Facility List](#)

[LANL Safety Basis Document List](#)

[LA-14167-MS](#), Los Alamos National Laboratory, Concepts of Model Verification and Validation, Thacker et al., 2004

[P204-1](#), Controlled Unclassified Information

[P218](#), Cyber Security Access Controls

[P322-4](#), Laboratory Performance Feedback and Improvement Process

[P330-2](#), Control and Calibration of Measuring and Test Equipment (M&TE)

[P330-3](#), Quality Audits

[P330-5](#), Special Processes

[P330-6](#), Nonconformance Reporting

[P330-8](#), Inspection and Test

[P330-9](#), Suspect/Counterfeit Items (S/CI)

[P341](#), Facility Engineering Processes Manual

[P342](#), Engineering Standards

[P343](#), Facility Engineering Training and Qualification Manual

[P805](#), Export Control

[P840-1](#), Quality Assurance for Procurements

[P1020-2](#), Laboratory Document Control

[P1040](#), Software Quality Management

[P1011](#), Computer Hardware, Software, and Services: Exceptions to Acquisition, Maintenance, and Support

[PD110](#), Safety Basis

[PD115](#), LANL Readiness Program

[PD210](#), Cyber Security Program

[PD328](#), LANL Assessment Program

[PD340](#), Conduct of Engineering for Facility Work

[PD370](#), Conduct of Engineering for Research and Development (R&D)

[QPA-DO-FSD-001](#), LANL Safety Software Inventory Procedure

[SBP-15-351](#), Design Basis or Safety Basis Change Review

[SBP111-1](#), Facility Hazard Categorization and Documentation

[SBP112-3](#), Unreviewed Safety Question (USQ) Process

[SBP113-3](#), Unreviewed Safety Issue (USI) Process

[SD210](#), Information Risk Management Framework

[SD330](#), Los Alamos National Laboratory Quality Assurance Program

[STD-342-100](#), Engineering Standards Manual (available externally)

[Merriam-Webster Dictionary](#)

[TeamForge \(LANL-internal\)](#)

[Trac](#)