

**THIS PRELIMINARY PROPOSED RULE LANGUAGE AND ACCOMPANYING DISCUSSION IS BEING RELEASED TO SUPPORT INTERACTIONS WITH STAKEHOLDERS AND THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS). THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS DOCUMENT AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.**

**THE STAFF IS PRIMARILY SEEKING INSIGHTS REGARDING THE CONCEPTS IN THIS PRELIMINARY LANGUAGE AND SECONDARILY SEEKING INSIGHTS RELATED TO DETAILS SUCH AS NUMERICAL VALUES FOR VARIOUS CRITERIA.**

**STAFF DISCUSSION OF SUBPART E (CONSTRUCTION/MANUFACTURING) – PRELIMINARY RULE LANGUAGE (02/2021)**

Preliminary Language	Discussion
<p><b>Subpart E – CONSTRUCTION AND MANUFACTURING</b></p>	<p>This subpart addresses requirements for the construction of advanced nuclear plant and the possible factory fabrication of reactors using a manufacturing license. The preliminary language for construction-related activities reflects current requirements without any fundamental changes. The preliminary language for manufacturing activities largely mirrors the construction-related activities and the discussion table includes areas for needed public discussions, such as possible loading of fuel at a manufacturing facility and the transport of fueled reactors.</p> <p><b>Note</b> - The text below reflects a renumbering of sections §§ 53.210 – 53.230 in Subpart B based on stakeholder comments. The new numbering is as follows:            § 52.210 First Tier Safety Criteria            § 53.220 Second Tier Safety Criteria            § 53.230 Safety Functions</p>

<p><b>§ 53.600 Construction and Manufacturing. Scope and Purpose</b></p> <p>This subpart applies to those construction and manufacturing activities authorized by a Construction Permit (CP), Combined License (COL), Manufacturing License (ML) or a Limited Work Authorization (LWA) under subpart H of this regulation. The term construction, as defined in § 53.xyz, refers to those activities contributing to meeting the first and second tier safety criteria defined in §§ 53.210 and 53.220, respectively, that are conducted on-site to build the nuclear facility in support of subsequent operations. [Note - Definition of construction to exclude items currently excluded by 50.10(a)(2)]. The term manufacturing, as defined in § 53.xyz, refers to those activities conducted at one or more facilities under a ML for transport to a licensed location for installation and operation.</p> <p>These requirements are intended to provide assurance that construction and manufacturing activities are managed and conducted such that when combined with associated design features and programmatic controls, the plant will satisfy the first and second tier safety criteria required in §§ 53.210 and 53.220 throughout the plant's lifecycle.</p>	<p>This section establishes the overall construction and manufacturing requirements in relation to the safety criteria in subpart B and interfaces with other areas such as design in subpart C.</p>
<p><b>§ 53.610 Construction (a) Management and Control</b></p> <p>Before starting construction activities, the licensee or permit holder must ensure that the following plans, programs, and organizational units are in place to manage and control the construction activities:</p> <ul style="list-style-type: none"> <li>(1) Design and analyses that are sufficiently complete to provide assurance that construction will conform with associated requirements in subpart C of this part.</li> </ul>	<p>This subsection establishes the requirement to have in place a well-defined command and control structure to manage construction activities. The requirements generally reflect current requirements, with an emphasis on the quality assurance program (taken from Appendix B to 10 CFR part 50).</p> <p>Specific requirements are also provided to address the introduction of special nuclear material and byproduct material to the construction site. These</p>

<p>(2) An organization, headed by qualified personnel, responsible for managing, controlling and evaluating the adequacy of the construction activities.</p> <p>(3) Approved procedures describing the qualifications for personnel in key positions in the licensee's or permit holder's management and control organization and the organizational responsibilities, authority and interfaces with other parts of the licensee's or permit holder's organization.</p> <p>(4) Procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant.</p> <p>(5) A preliminary plan for coping with emergencies that includes an on-site emergency organization capable of providing first aid, transporting individuals to off-site treatment facilities, decontaminating any radiological hazard and establishing and maintaining arrangements with local off-site organizations that can provide support services, if needed.</p> <p>(6) A fitness-for-duty program, in accordance with 10 CFR part 26, applicable to the licensee's or permit holder's construction management and control personnel and to the construction work force.</p> <p>(7) A Quality Assurance (QA) Program conforming with generally accepted consensus codes and standards, applicable to construction activities, describing the policies, procedures and instructions to be used to ensure the facility is constructed in accordance with the design. The QA Program must provide control over the activities affecting quality and performance of the safety-related (SR) SSCs and the special treatment of SSCs determined to be safety-significant (SS). As a minimum, the QA Program must include the following:</p> <p>I. <u>Organization</u>: A description of the personnel and organizational units within the licensee's or permit holder's organization responsible for QA, including their qualifications, authority and duties. The personnel and</p>	<p>requirements also generally reflect current requirements.</p> <p>(2) From 10 CFR 50.34(a)(6) and 10 CFR 52.79(a)(26)</p> <p>(3) From 10 CFR part 50, App. B, Criterion I,</p> <p>(4) From 10 CFR 50.34(f)(3)(i)</p> <p>(5) From 10 CFR 50.34(a)(10) and part 50 App. E</p> <p>(6) From 10 CFR 52.79(a)(44)</p> <p>(7) From 10 CFR 50.34(a)(7) and 10 CFR 50.55(f)(1)</p> <p>I. From 10 CFR part 50, App. B, Criterion I and 10 CFR 50.34(f)</p>
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<p>organizational units responsible for QA must have sufficient authority and freedom to identify quality problems, initiate or recommend corrective actions and verify satisfactory resolution. The personnel and organizational units performing the QA functions must report to the construction management and control organization at a high enough level to be independent from other competing interests.</p> <p>II. <u>Scope:</u> The licensee or permit holder must identify the SR and SS SSCs and other activities covered by the QA program. The planned QA to be performed should be identified in consideration of (1) the requirements contained in the codes and standards used in the design and construction, (2) the specifications and instructions from the design organization, and (3) the potential for other activities to affect the quality or performance of the SR and SS SSCs.</p> <p>III. <u>Use of Procedures:</u> Construction, fabrication and test activities that could affect the quality or performance of SR and SS SSCs must be conducted using approved procedures, instructions or drawings, where appropriate. The procedures, instructions and drawings must contain qualitative or quantitative acceptance criteria that can be used to determine if the work is satisfactorily completed.</p> <p>IV. <u>Use of Qualified Personnel:</u> The SR and SS construction activities must be conducted by personnel qualified for the work assigned. The required qualification and associated training must be documented along with records that show the personnel performing the work have been appropriately qualified.</p> <p>V. <u>Document Control:</u> Measures must be in place to control the issuance of documents such as procedures, instructions and drawings, including any subsequent changes. These measures must assure that the documents, including any subsequent changes, are reviewed and approved for use by authorized and qualified</p>	<p>II. From 10 CFR part 50, App. B, Criterion II</p> <p>III. From 10 CFR part 50, App. B, Criterion V</p> <p>IV. From 10 CFR part 50, App. B, Criterion II</p> <p>V. From 10 CFR part 50, App. B, Criterion VI</p>
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personnel. Any document changes must be reviewed and approved by the same organization that approved the original document, unless there is a justified reason for changing the approval process. The measures must also assure that the documents are distributed to and used at the place where the construction activity takes place.

VI. Quality of Purchased Items: Purchase documents for materials, components and services must contain information on quality, such as regulatory requirements, applicable codes and standards, cleanliness requirements and other relevant controls. When appropriate, suppliers should be required to submit to the licensee or permit holder a copy of their QA program that will be used to ensure quality. Measures must be established to assure that purchased material, components and services for SR and SS SSCs conform to the purchase documents. This applies to material, components and services purchased directly by the licensee or permit holder or indirectly through contractors or subcontractors. These measures must consider objective evidence of quality, such as previous satisfactory performance by the supplier, relevant information submitted by the supplier demonstrating quality, inspections of the supplier carried out by the licensee or permit holder and receipt inspection of the finished product. Documentation that the products conform to the purchase specifications must be maintained by the licensee or permit holder. Periodic assessments of contractor and subcontractor performance in controlling quality must be conducted by the licensee or permit holder to determine if a degradation in quality has occurred over time and what corrective action is appropriate.

VII. Identification: Measures must be established for the identification and control of materials, parts and components used in the construction of SR SSCs. This must include identification of each item by part number,

VI. From 10 CFR part 50, App. B, Criteria IV and VII

VII. From 10 CFR part 50, App. B, Criterion VIII

<p>serial number or other means of identification such that the origin and acceptability of the item can be determined. Appropriate special treatment associated with construction must be defined and implemented to ensure SSCs determined to be SS satisfy the requirements of § 53.460.</p> <p>VIII. <u>Handling, Shipping and Storage</u>: Measures must be established for the handling, cleaning, storage and shipping of purchased materials and components. These measures must address protection of purchased material and components from damage or contamination during shipping, protection from damage, deterioration, theft or tampering during storage and, if required, providing a special protective environment (e. g. inert atmosphere) for certain items, as specified in the purchase documents.</p> <p>IX. <u>Control of Items Released for Use in Construction</u>: Measures must be established to control the release of materials, components and other items used in construction (e.g. weld rod, NDE materials) to ensure the released items are consistent with the procedures, instructions or drawings used for construction.</p> <p>X. <u>Special Conditions and Processes</u>: Measures must be established to ensure that the construction activities and processes (e.g. welding, NDE, testing) are conducted under controlled conditions. These measures include using qualified personnel and procedures in accordance with applicable codes, standards, specifications or other special requirements and establishing a controlled environment, when necessary.</p> <p>XI. <u>Inspection</u>: An inspection program to verify construction activities are conducted in conformance with approved procedures, instructions or drawings must be established. An inspection plan and schedule must be developed and maintained up to date, in coordination with the construction schedule, identifying the planned inspections. Risk insights should be used to focus the inspection program on the</p>	<p>VIII. From 10 CFR part 50, App. B, Criterion XIII</p> <p>IX. From 10 CFR part 50, App. B, Criterion VIII</p> <p>X. From 10 CFR part 50, App. B, Criterion IX</p> <p>XI. From 10 CFR part 50, App. B, Criterion III</p>
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most risk significant components, subcomponents, construction activities and processes. The inspections must be conducted by personnel independent from those who performed the work. Hold points must be established where there is a critical activity or milestone requiring witnessing or inspection by the licensee's or permit holder's designated representative. The hold points must be included in the inspection plan and described in the procedures or instructions for conducting the construction activity. Where field changes are proposed or made to the design, the inspection must confirm that the design organization has approved the change, that the change was made using approved procedures, instructions or drawings, including acceptance criteria, and that the change is acceptable.

XII. Testing: All testing required to demonstrate that the SR and SS SSCs perform satisfactorily must be identified in the inspection plan and in the construction procedures and instructions. The testing must be performed using approved written procedures which also contain the acceptance criteria and identify any prerequisites, special test instrumentation, and environmental conditions needed for the test. The test program may include proof tests conducted prior to installation and proof of performance tests conducted after installation to demonstrate satisfactory completion of construction. All instrumentation, tools or other devices used to verify the acceptance criteria have been met must be properly calibrated and controlled to maintain accuracy.

XIII. Inspection and Test Status: Measures must be established to indicate the status of each SR and SS SSC with respect to inspection, testing and acceptance. In addition, the operating status of equipment such as valves, switches, pumps, etc. should be clearly indicated to prevent inadvertent operation or a change in power status.

XII. From 10 CFR part 50, App. B, Criterion XI

XIII. From 10 CFR part 50, App. B, Criterion XIV

<p>XIV. <u>Corrective Action:</u> Measures must be established to ensure that defective material, components or other non-conforming items are identified and corrected. The cause of the non-conformance must be identified and, along with the corrective action, reported to management. Where repetitive non-conformances are identified, management should be notified and action taken to correct any systemic cause.</p> <p>XV. <u>Record Keeping:</u> Measures must be established for the retention of records related to procurement, receipt inspection, inspections, tests and test logs, procedures, instructions, and drawings used for construction, personnel qualification, corrective actions, and audits. The licensee or permit holder is responsible for determining the duration, location, and responsibility for the record keeping.</p> <p>XVI. <u>Audits of the QA Program:</u> Planned and periodic audits shall be carried out to verify compliance with all aspects of the QA Program and to determine the effectiveness of the program. Audits shall be conducted using written procedures or checklists using trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the areas audited.</p> <p>(8) A radiation protection program, that includes measures for monitoring the dose to individuals working with radioactive materials brought onto the site, must be established in accordance with 10 CFR part 20.</p> <p>(9) An information security program must be established in accordance with 10 CFR 73.21, 73.22 and 73.23, as applicable.</p> <p>(10) Construction activities must conform to a cyber security program established in accordance with 10 CFR 73.54, as applicable.</p> <p>(11) Posting of Requirements</p>	<p>XIV. From 10 CFR part 50, App. B, Criteria XV and XVI</p> <p>XV. From 10 CFR part 50, App. B, Criterion XVII</p> <p>XVI. From 10 CFR part 50, App. B, Criterion XVIII. (Note that activities such as audits in the QA Program that might span the lifecycle might be moved to another subpart.)</p> <p>(8) Applicable requirements from 10 CFR parts 20, 30, 40, and 70</p> <p>(9) From 10 CFR 50.34(e) and 50.54(v) - need to have this for the construction of some SSCs and development of a plan prior to fuel arrival</p> <p>(10) Note - RG 1.152 covers CDA security prior to physical security plan implementation (RG addresses § 50.55a(h) and GDC 21 for computers used with</p>
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<p>(i) Signs and labels, in accordance with subpart J of 10 CFR part 20, must be posted where there is a potential radiation hazard.</p> <p>(ii) Each individual, licensee, permit holder, partnership, corporation, dedicating entity, or other entity subject to the regulations in this subpart must post current copies of the regulations in this subpart; Section 206 of the Energy Reorganization Act of 1974 (ERA); and procedures adopted under the regulations in this subpart.</p> <p>(iii) If posting of the regulations in this subpart or the procedures adopted under the regulations in this subpart is not practical, the licensee, permit holder or firm subject to the regulations in this subpart must, in addition to posting Section 206 of the ERA, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where the regulation, procedures, and reports may be examined.</p>	<p>safety systems). Cyber security plan starts at fuel inside protected area or fuel load.</p> <p>(11) From 10 CFR 50.55(e)(2)</p>
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**§ 53.610 Construction**  
**(b) Construction Activities**

- (1) Licensees or permit holders must meet the following requirements:
- I. As appropriate, considering the types and quantities of radioactive materials being brought onto the site.
    - i. The licensee or permit holder must maintain and follow a special nuclear material (SNM) Material Control and Accounting (MC&A) Program, a measurement control program, and other material control procedures that include corresponding record management requirements as required by the provisions of 10 CFR 70.32. Prior to initial receipt of SNM onsite, the permit holder (or licensee) shall implement a SNM MC&A Program in accordance with 10 CFR part 74.
    - ii. Procedures must be in place to receive, possess, and use source, byproduct, and SNM in accordance with applicable portions of 10 CFR parts 30, 40, and 70.
    - iii. A plant staff training program associated with the receipt of radioactive material must be approved and implemented prior to initial receipt of byproduct, source or SNM (excluding exempt quantities as described in 10 CFR 30.18).
  - II. For construction of nuclear power plants to be operated on multi-unit sites, plans and procedures must be in place prior to the start of construction activities to prevent and/or mitigate potential hazards to the SSCs of operating units resulting from construction activities, including the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation of the operating units are not exceeded as a result of construction activities at the multi-unit sites. [The term "site" refers to the contiguous real estate on which nuclear units are located and for which one or more licensees has the legal right to control access by individuals and to restrict and use for purposes of limiting the potential

This subsection establishes the requirements for proceeding with the construction activities. As with paragraph (a), the requirements generally reflect current requirements.

(I) General requirements from parts 30, 40, and 70

(II) From 10 CFR 50.34(a)(11)

<p>doses from radiation or radioactive material during normal operation of the units.]</p> <p>III. Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction and seepage.</p> <p>IV. A plan must be developed for redress of activities performed under the CP or LWA should one of the following situations arise:</p> <ul style="list-style-type: none"> <li>(a) CP or LWA work activities are terminated by the holder of the CP or LWA</li> <li>(b) the CP or LWA is revoked by the NRC</li> <li>(c) the Commission denies the associated operating license application.</li> </ul> <p>(2) On-site fresh fuel storage must be in compliance with 10 CFR 73.67 or within a protected area in compliance with 10 CFR 73.55. Before fuel is brought within a protected area, a cyber security program that meets the requirements of 10 CFR 73.54, a physical security program that meets the requirements of 10 CFR 73.55 and an access authorization program that meets the requirements of 10 CFR 73.56 must be established.</p> <p>(3) Fire protection measures for work and storage areas (including adjacent fire areas that could affect the work or storage area) must be implemented before initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in 10 CFR 30.18). The fire protection measures for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) must be implemented before receipt of fuel. Prior to the receipt of fuel, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.</p>	<p>(III) Clinch River ESP52.79(a)(40); COL license conditions</p>
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**§ 53.610 Construction**

**(c) Inspection and Acceptance**

- (1) The licensee or permit holder must have a process for accepting individual or groups of SSCs upon completion of construction and protecting them from damage or tampering as other construction activities continue.
- (2) The post construction acceptance process must consider the results of the inspections, pre-operational tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that there is reasonable assurance the facility has been constructed and will be operated in conformity with the operating license, the provisions of the Atomic Energy Act, and the Commission's rules and regulations.

**(d) Communication**

Procedures for communication among elements of the construction program must be established that require:

- (1) Interfacing among construction activities, inspections and other ongoing work.
- (2) Coordination with operating units on the site.
- (3) Coordination with site preparation activities for other units being built on the site to ensure site characteristics (e.g. drainage) remain acceptable.
- (4) Coordination with NRC on planned inspections.

Subsection (c) provides the requirements for inspection and accepting items used in the construction.

(1) Extension of 10 CFR part 50, App. B, Criterion XIV.

(2) Addressing turnover from construction to operations; Consistent with 10 CFR part 52 ITAAC requirements; SRP 14.3; and Section 50.57 finding.

Subsection (d) provides the requirements for coordinating activities within the licensees' organizations and with the NRC regarding planned inspections.

## § 53.620 Manufacturing

### (a) Management and Control

Before starting manufacturing activities, the licensee must ensure that the following plans, programs and organizational units are in place to manage and control the manufacturing activities:

- (1) Design and analysis performed in accordance with subpart C.
- (2) An organizational and management structure responsible for the managing, controlling and evaluating the adequacy of the reactor design and manufacturing activities.
- (3) Approved procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.
- (4) A program to evaluate the applicability of other national and international design and manufacturing experience to the planned and ongoing manufacturing activities.
- (5) A fitness for duty program, in accordance with 10 CFR part 26, applicable to the licensee's management and control organization personnel and the manufacturing work force.
- (6) A QA program conforming with generally accepted consensus codes and standards, applicable to design and manufacturing activities, describing the policies, procedures and instructions to be used to ensure that the reactor is designed and manufactured must be established. The QA Program must provide control over the activities affecting quality and performance of the SR SSCs and the special treatment of SSCs determined to be SS consistent with their risk significance. As a minimum, the QA Program must include the following:
  - I. Organization: A description of the personnel and organizational units within the licensee's organization responsible for QA, including their qualifications, authority and duties. The personnel and organizational units responsible for QA must have sufficient authority

Subsection (a) establishes the requirements to have in place a well-defined command and control structure to manage manufacturing-related activities. This preliminary language generally mirrors the requirements of § 53.610 (Construction) with an emphasis on the quality assurance program (taken from Appendix B to 10 CFR part 50).

The further development of this section will need to be coordinated with the manufacturing license (ML) provisions planned for subpart H, "Licensing."

- (1) Coordination of design and manufacturing elements of the ML
- (2) From 10 CFR 52.157(f)(26)(i)
- (3) From 10 CFR 52.157(f)(26)(ii), (iii) and (v)
- (4) From 10 CFR 52.157(f)(12)
- (5) From 10 CFR parts 70 and 26
- (6) From 10 CFR 52.157(f)(17)

and freedom to identify quality problems, initiate or recommend corrective actions and verify satisfactory resolution. The personnel and organizational units performing the QA functions must report to the design and manufacturing management and control organization at a high enough level to be independent from other competing interests.

- II. Scope: The licensee must identify the SR and SS SSCs and activities covered by the QA program. The planned QA activities to be performed should be identified in consideration of (1) the requirements contained in the codes and standards used in the design and manufacturing, (2) the specifications and instructions from the design organization, (3) best industry practices and (4) the potential for other activities to affect the quality or performance of the SR and SS SSCs.
- III. Use of Procedures: Design, manufacturing, fabrication and test activities that could affect the quality or performance of SR and SS SSCs must be conducted using approved procedures, instructions or drawings, where appropriate. The procedures, instructions and drawings must contain qualitative or quantitative acceptance criteria that can be used to determine if the work is satisfactory.
- IV. Use of Qualified Personnel: The SR and SS design and manufacturing activities must be conducted using personnel qualified for the work assigned. The required qualification and associated training must be documented along with records that show the personnel performing the work have been appropriately qualified.
- V. Document Control: Measures must be in place to control the issuance of documents such as procedures, instructions and drawings, including any subsequent changes. These measures must assure that the documents, including any subsequent changes, are

reviewed and approved for use by authorized and qualified personnel. Any document changes must be reviewed and approved by the same organization that approved the original document, unless there is a justified reason for changing the approval process. The measures must also assure that the documents are distributed to and used at the place where the manufacturing activity takes place.

VI. Quality of Purchased Items: Purchase documents for materials, components and services must contain information on quality, such as regulatory requirements, applicable codes and standards, cleanliness requirements and other relevant controls. When appropriate, suppliers should be required to submit to the licensee a copy of their QA program that will be used to ensure quality. Measures must be established to assure that purchased material, components and services for SR and SS SSCs conform to the purchase documents. This applies to material, components and services purchased directly by the licensee or indirectly through contractors or subcontractors. These measures must consider objective evidence of quality, such as previous satisfactory performance by the supplier, relevant information submitted by the supplier demonstrating quality, inspections of the supplier carried out by the licensee and receipt inspection of the finished product. Documentation that the products conform to the purchase specifications must be maintained by the licensee. Periodic assessments of contractor and subcontractor performance in controlling quality must be conducted by the licensee to determine if a degradation in quality has occurred over time and what corrective action is appropriate.

VII. Identification: Measures must be established for the identification and control of materials, parts and

components used in the manufacturing of SR SSCs. This must include identification of each item by part number, serial number or other means of identification such that the origin and acceptability of the item can be determined. Appropriate special treatment must be defined and implemented to ensure SSCs determined to be SS satisfy the requirements of § 53.460

- VIII. Handling, Shipping and Storage: Measures must be established for the handling, cleaning, storage and shipping of purchased materials and components. These measures must address protection of purchased material and components from damage or contamination during shipping, protection from damage, deterioration, theft or tampering during storage and, if required, providing a special protective environment (e. g. inert atmosphere) for certain items, as specified in the purchase documents.
- IX. Control of Items Released for Use in Manufacturing: Measures must be established to control the release of materials, components and other items used in manufacturing (e. g. weld rod, NDE materials) to ensure the released items are consistent with the manufacturing license.
- X. Special Conditions and Processes: Measures must be established to ensure that the manufacturing activities and processes (e.g. welding, NDE and testing) are conducted under controlled conditions. These measures include using qualified personnel and procedures in accordance with applicable codes, standards, specifications, manufacturing license, or other special requirements and establishing a controlled environment, when necessary.
- XI. Inspection: An inspection program to verify manufacturing activities are conducted in conformance with approved procedures, instructions or drawings



must be established. An inspection plan and schedule must be developed and maintained up to date, in coordination with the manufacturing schedule, identifying the planned inspections. Risk insights should be used to focus the inspection program on the most risk significant components, subcomponents, manufacturing activities and processes. The inspections must be conducted by personnel independent from those who performed the work. Hold points must be established where there is a critical activity or milestone requiring witnessing or inspection by the licensee's designated representative. The hold points must be described in the inspection plan and included in the procedures or instructions for conducting the manufacturing activity. Where field changes are proposed or made to the design, the inspection must confirm that the design organization has approved the change, that the change was made using approved procedures, instructions or drawings, including acceptance criteria, and that the change was satisfactorily made.

- XII. Testing: All testing required to demonstrate that the SR and SS SSCs will perform satisfactorily must be identified in the inspection plan and in the manufacturing procedures or instructions. The testing must be performed using approved written procedures which also contain the acceptance criteria and identify any prerequisites, special test instrumentation and environmental conditions needed for the test. The test program may include proof tests conducted prior to installation and proof of performance tests conducted after installation to demonstrate satisfactory completion of manufacturing. All instrumentation, tools or other devices used in the testing must be properly calibrated and controlled to maintain accuracy.

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| <p>XIII. <u>Inspection and Test Status</u>: Measures must be established to indicate the status of each SR and SS SSC with respect to inspection, testing and acceptance. In addition, the operating status of equipment such as valves, switches, pumps, etc. should be clearly indicated to prevent inadvertent operation or a change in power status.</p> <p>XIV. <u>Corrective Action</u>: Measures must be established to ensure that defective material, components or other non-conforming items are identified and corrected. The cause of the non-conformance must be identified and, along with the corrective action, reported to management. Where repetitive non-conformances are identified, management should be notified and action taken to correct any systemic cause. If the non-conformance could represent a substantial safety hazard, reporting in compliance with 10 CFR part 21 should also made.</p> <p>XV. <u>Record Keeping</u>: Measures must be established for the retention of records related to design, procurement, receipt inspection, inspections and inspection records, tests and test logs, procedures, instructions and drawings used in manufacturing, personnel qualification, corrective actions and audits. The licensee is responsible for determining the duration, location and responsibility for the record keeping.</p> <p>XVI. <u>Audits of the QA Program</u>: Planned and Periodic audits shall be carried out to verify compliance with all aspects of the QA Program and to determine the effectiveness of the program. Audits shall be conducted using written procedures or checklists using trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the areas audited</p> |  |
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<p>(7) A Radiation Protection Program that includes measures for monitoring the dose to individuals working with radioactive materials must be established in accordance with 10 CFR part 20.</p> <p>(8) An information security program must be established in accordance with 10 CFR 73.21, 73.22 and 73.23, as applicable.</p> <p>(9) A cyber security program must be established in accordance with 10 CFR 73.54, as applicable.</p> <p>(10) Posting of Requirements</p> <p>(i) Signs and labels, in accordance with subpart J of 10 CFR part 20, must be posted where there is a potential radiation hazard.</p> <p>(ii) Each individual, licensee, partnership, corporation, dedicating entity, or other entity subject to the regulations in this subpart must post current copies of the regulations in this part, Section 206 of the Energy Reorganization Act of 1974 (ERA) and procedures adopted under the regulations in this subpart.</p> <p>(iii) If the posting of the regulations in this subpart or the procedures adopted under the regulations in this subpart is not practical, the licensee or firm subject to the regulations in this subpart must, in addition to posting Section 206 of the ERA, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where the regulation, procedures and reports may be examined.</p>	
<p><b>§ 53.620 Manufacturing.</b></p> <p><b>(b) Manufacturing Activities</b></p> <p>(1) Licensees must meet the following requirements:</p> <p>I. The manufacturing process must be conducted within facilities that are controlled by the manufacturing license holder. This licensee must establish access controls to the</p>	<p>Subsection (b) establishes the requirements for proceeding with the manufacturing activities. As with paragraph (a), the requirements generally reflect current requirements related to quality assurance.</p>

<p>portions of each facility involved in the manufacturing processes governed by the ML</p> <p>II. Manufacturing processes must be performed in accordance with the ML and the referenced generally accepted consensus codes and standards</p> <p>III. Quality control of the manufacturing process and key steps within the process must be ensured by appropriate verifications, inspections, and tests as required by paragraph (a) of this section.</p> <p>IV. As appropriate considering the types and quantities of radioactive materials being brought into the manufacturing facility;</p> <p>i. Procedures must be in place to receive, possess and use source, byproduct and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70.</p> <p>ii. A fire protection program must be approved and implemented before the initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in 10 CFR 30.18). The fire protection measures for areas associated with fresh fuel (including all fuel handling, fuel storage and adjacent areas where a fire could affect the fresh fuel) must be implemented before receipt of fresh fuel at the manufacturer's facility. Prior to the receipt of fuel at the manufacturer's facility, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.</p> <p>iii. An emergency plan for responding to the radiological hazards of an accidental release of special nuclear material and to any associated chemical hazards directly incident thereto must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in 10 CFR 30.18).</p>	<p>(ii) From 10 CFR 52.79(a)(40) and DC/COL-ISG-22</p> <p>(iii) From 10 CFR 30.32(i)(1)(ii)</p>
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<ul style="list-style-type: none"> <li>iv. A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source or SNM (excluding exempt quantities as described in 10 CFR 30.18).</li> <li>v. Prior to the receipt of fresh fuel at the manufacturer's facility, the following measures must be in place: <ul style="list-style-type: none"> <li>a. A physical security program for the storage of fresh fuel in accordance with 10 CFR 73.67 or 10 CFR 73.54, 10 CFR 73.55, and 10 CFR 73.56.</li> <li>b. An access authorization program in accordance with 10 CFR 73.56.</li> <li>c. A Material Control and Accounting Program in accordance with 10 CFR part 74.</li> <li>d. Measures to prevent criticality accidents in accordance with 10 CFR 70.24.</li> </ul> </li> <li>vi. Procedures shall be in place to describe how the facility design and manufacturing process will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Manufacturing licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the facility site, including the subsurface, in accordance with the approved radiation protection program.</li> <li>vii. A post manufacturing inspection and acceptance process must be established and implemented prior to fuel loading or shipping. The process must consider the results of inspections, pre-operational tests and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that there is reasonable assurance the reactor has been manufactured in accordance with the ML.</li> </ul>	<ul style="list-style-type: none"> <li>(iv) From 10 CFR 30.33(a)(3)</li> <li>(v) Based on 10 CFR part 73</li> <li>(vi) Based on 10 CFR 30.36(g) and 10 CFR 40.42(g)</li> <li>(vii) Consistent with 10 CFR part 52 ITAAC requirements; SRP 14.3</li> </ul>
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**§ 53.620 Manufacturing**

**(c) Fuel Loading** [to be more fully developed if pursued]

- (1) If the ML authorizes fuel loading at the manufacturing facility, the following must be in place prior to the receipt of SNM:
- (I) Radiation monitoring instrumentation and alarms.
  - (II) Criticality monitoring instrumentation and alarms.
  - (III) Procedures, equipment and personnel qualified to handle fresh fuel, load it into the reactor, monitor the reactivity, conduct any low power physics tests necessary for acceptance and secure the fuel and reactor assembly for shipment.
  - (IV) A physical security program that meets the requirements of 10 CFR 73.55.
  - (V) An access control program that meets the requirements of 10 CFR 73.56.
  - (VI) A cyber security program must be established in accordance with 10 CFR 73.54, as applicable.
- (2) If the ML authorizes criticality testing or other nuclear-related testing at the manufacturing facility, design features and programmatic controls must be developed, implemented, and maintained to achieve the following:
- (I) Criticality Control
  - (II) Radiation Protection
  - (III) Safety Protocols
  - (IV) Other ?

**(d) Communication**

The applicant must coordinate with NRC on planned manufacturing activities, inspections, and nuclear-related testing.

Subsection (c) establishes possible requirements to address the loading of fuel within a facility controlled under the manufacturing license. The need for and appropriate controls to cover such an option is a topic of discussion.

Subsection (d) incorporates the requirements for coordinating activities within the licensee's organizations and with the NRC regarding planned inspections.

For discussion: If not a security program meeting 10 CFR 73.55, what would be appropriate?

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**(e) Transportation**

(1) A holder of a manufacturing license may not transport or allow to be removed from the places of manufacture the manufactured reactor or major portions thereof as defined in the ML except to the site of a licensee with either a construction permit or a combined license. The construction permit or combined license must authorize the construction of a nuclear power facility using the manufactured reactor(s).

(2) A holder of a manufacturing license shall include, in any contract governing the transport of a manufactured reactor or major portions thereof as defined in the ML from the places of manufacture to any other location, a provision requiring that the person or entity transporting the manufactured reactor to comply with all NRC-approved shipping requirements in the manufacturing license.

(3) Procedures governing the preparation of the manufactured reactor or major portions thereof as defined in the ML for transport and the conduct of the transport must be prepared and approved prior to transport. The procedures must implement the protective measures and restrictions described in the ML to protect the reactor from damage, contamination or accidental criticality, if containing fuel.

(4) If the reactor contains fuel, the packaging and shipping must be done in compliance with 10 CFR parts 71 and 73.

Subsection (e) establishes the interface between activities at facilities involved in the manufacturing process and the delivery of a reactor to a site with a construction permit or combined license. Paragraphs (e)(1) and (e)(2) reflect current requirements in subpart F of 10 CFR part 52.

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**(f) Acceptance and Installation at the Site**

(1) Installation at the site must follow the regulations in § 53.610 of this subpart.

(2) Upon arrival at the site, the manufactured reactor must be certified to be in compliance with the ML and inspected, using approved procedures, to verify it is in acceptable condition. These procedures must also include confirming appropriate interfaces between the manufactured reactor and the remaining portions of the nuclear power plant. Upon completion of the inspections, but prior to installation at the site, it must be concluded that:

(i) The reactor has arrived with no damage or contamination that could affect its safe operation.

(ii) The reactor has been manufactured in conformity with the manufacturing license; the provisions of the Act, and the Commission's rules and regulations; and

(iii) The manufactured reactor can be operated safely in conformity with the approved design.

Subsection (f) addresses the need for requirements for onsite inspection, acceptance, and installation.