Enabling New Business Models – Rapid Deployment through Early Manufacturing

NRC Meeting

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NUCLEAR ENERGY INSTITUTE

Goal and Need

Need for Early Manufacturing

- Business Models
  - Prospective Manufacturing (e.g., prior approved design)
  - Reduce critical path (e.g., rapid high-volume deployment, short licensing and construction timelines, but long lead manufacturing times)
- License/Permit
  - Limited Work Authorization
  - Construction Permit / Combined License
  - Design Certification or Standard Design Approval
  - Manufacturing License
- Regulatory Status
  - Not Applicant
  - Applicant
  - Holder

Need: Technical basis to enable business models for early manufacturing for combinations of license/permit and regulatory status to enable the business models.

New Business Model – Description and Motivation

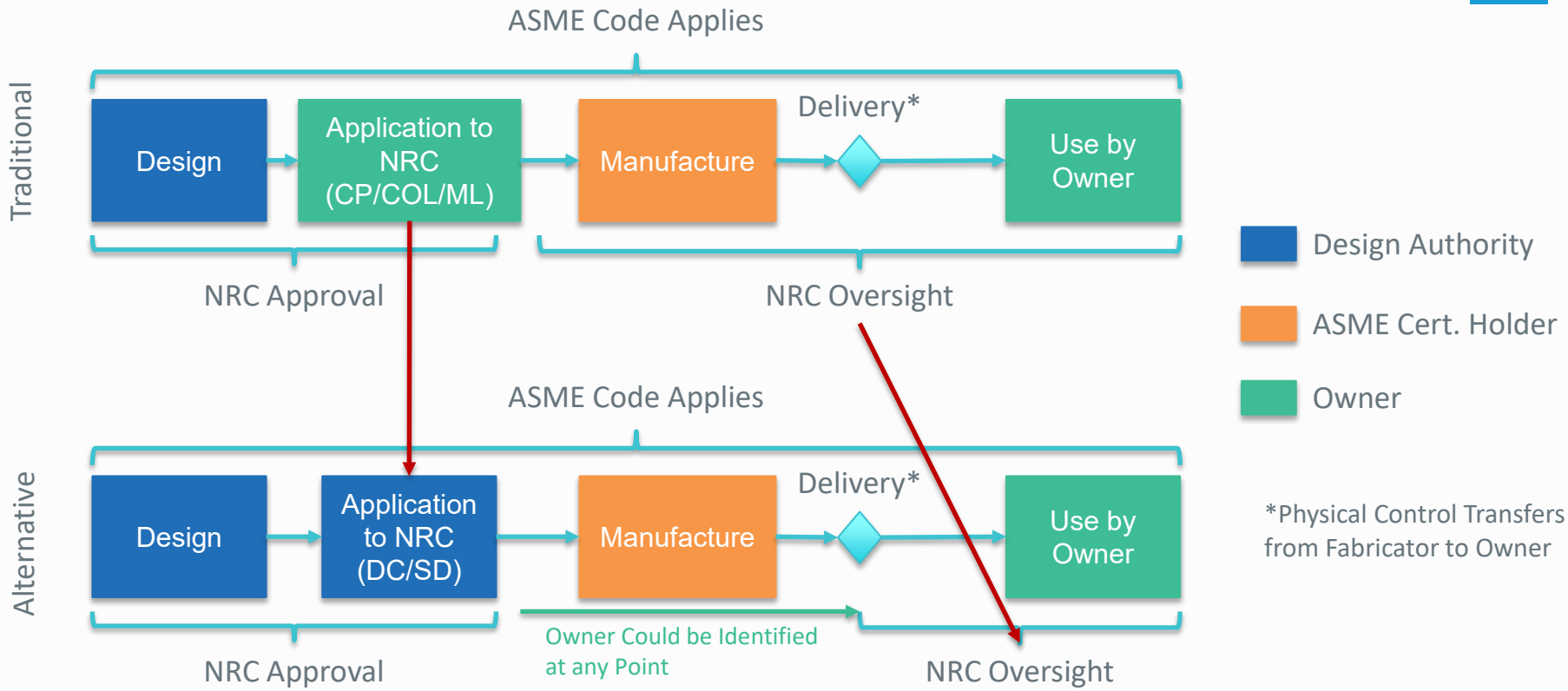
Manufacturing of Components using DC or SDA before owner is identified

- Design Standardization enables the manufacturing of components and identifying the specific owner/licensee later
  - NRC Adv. Rx. Policy Statement encourages Design Standardization
  - Flexibility in delivery and potential change in the sequencing of projects
- Markets and Customers need a pathway to manufacture components prior to identifying owner/licensee
  - Shortens time to deployment and opens up market for time sensitive uses and customers
  - NEI Proposal on Rapid High Volume Deployable Reactors (July 31, 2024) is dependent upon manufacturing components prior to identifying Owner/Licensee
  - Need to have ability for DC and SDA, not only for ML
- Manufacturing of Components and Modules Prior to Identifying an Owner
  - NEI Paper (2021), SECY 24-0008 – address need for manufacturing prior to identifying owner

Goal: Clarity on Process for an Alternative Approach (Using a Design Certification or Standard Design Approval)

*Unless otherwise stated, italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

Key Differences in Traditional and Alternative Model



Current Situation
Seeking Common Understanding

NRC: Only has regulatory authority over Licensees

- *"the structure of the Act {Atomic Energy Act} plainly indicates that Congress limited the Commission's authority to holding licensees and their agents responsible"*
- *"neither an SDA nor a Design Certification rule (DCR) is a license, and neither one confers specific rights or obligations on the entity who applied for it, unless that entity serves as a contractor or subcontractor for an NRC licensee or applicant for a license"*
- *"the NRC does not have regulatory authority over ASME Certificate Holders who are unlicensed, except to the extent they are acting as contractors to or suppliers of an NRC licensee or license applicant."*
- *"the NRC does not have any regulatory authority with respect to these items {procured under a commercial contract, and not by an NRC licensee or applicant for an NRC license}."*
- *"Nevertheless…could take actions within the existing regulatory framework…involve some risk"*
  - We understand that NRC could create a process to provide regulatory clarity and predictability for the business model (manufacturing components before identifying the owner)

Desired Outcome: Clarity on how to provide reasonable assurance that component can perform its safety functions

*Italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

NRC Is Seeking Dialogue to Enable Alternative Model

- NRC: two options for enabling manufacturing of ASME components prior to identifying an Owner
  1. *"a manufacturing license for the component(s) that meet Part 52 requirements … designer would be considered an owner"* (traditional approach)
  2. "*applicant or licensee {future owner} demonstrate that component meets NRC requirements, ASME code, and capable of performing safety function demonstrated by a process meeting QA requirements*" (alternative approach)
- NRC "*is working diligently to identify a long-term solution to the question of how a component fabricator can qualify components as nuclear-grade in the absence of an Owner",* "Longer term solutions involve rulemaking…raise technical, policy and legal issues for Commission"
  - *"revise the definition of utilization facility to include major components and to create a regulatory scheme that would allow vendors to obtain licenses to fabricate components"* (traditional approach)
  - *"specific conditions to be met, such that NRC Appendix B to 10 CFR Part 50 and 10 CFR Part 21 requirements can be satisfied"* (alternative approach)

Objective: Establish Regulatory Basis for alternative approach that can be used for long-term solution and immediate use.
(Traditional – ML or Utilization Definition – Not current focus)

*Italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

NRC: ASME N-883 Cannot be Used as Intended (1/4)

- NRC RG 1.84 – Rev. 39 *"ASME N-883 Construction of Items Prior to the Establishment of a Section III, Division 1 Owner, Section III, Division 1"* (Ref. 2)
  - *NRC Exception: "This Code Case may only be used for the construction of items by a holder of a construction permit, operating license, or combined license {Owner} under 10 CFR Part 50 or Part 52. This Code Case may not be used by a holder of a manufacturing license or standard design approval or by a design certification applicant."*
- NRC Appears to have Four (4) Reasons (details in subsequent slides)
  1. ASME N-883 itself restricts use to NRC licensees or applicants
  2. ASME technical basis limited to components of 4 inches or less (nominal pipe size)
  3. NRC QA Requirements in Part 50 Appendix B only apply to NRC Licensees and Applicants
  4. NRC does not have jurisdiction over ASME Holders not in contract with NRC Licensee/Applicant
- *"NRC worked with ASME to revise N-883 so that if revision is endorsed by NRC it could be applied to ML Holder"* (Ref. 1)
  - Why is this needed? Wouldn't an ML Holder comply with 50.55(a) without need for CC N-883?
  - NRC letter clarifies that NRC has Regulatory Authority over ML Applicant/Holder

NRC's Position to Restrict Use of N-883 is not Clear to Industry
(Allowing it for use by DC or SDA Holder could enable new business models)

NRC: ASME N-883 Cannot be Used as Intended (2/4)

1. NRC: ASME N-883 itself restricts use to NRC licensees or applicant
   - *"NRC's condition for approving use of CC N-883 simply reflects the restriction that the code case already includes."*
   - *"The NRC staff cannot expand the applicability of CC N-883 to persons who are not NRC licensees or applicants for an NRC license without a Commission-approved rulemaking"*
   - *"The Code Case includes the provision "…in jurisdictions having no specific provisions for the use of this Case, this requirement does not apply[.]" It is the NRC staff's understanding that this provision was developed and included by ASME staff to address international stakeholders' processes, and to identify ASME as a global standards development organization, because CC N-883 can be used in any country. Nonetheless, the NRC cannot authorize use of CC N-883 by NRC licensees or license applicants without specific provisions to approve it."*

- However, N-883 specifically states the following intended applicability without those restrictions (Ref. 3)
  - *"It is the opinion of the Committee that Certificate Holders may construct items prior to the establishment of an Owner, and that Owners may utilize items constructed under these provisions, under the following conditions:"*
  - The key statement in reference to NRC's position is: *"Owners may utilize items constructed under the provisions of this Case only when the items have been constructed by Certificate Holders who are specifically authorized by the regulatory authority having jurisdiction at the nuclear facility to construct items using this Case."*
  - *Another statement is similar: "…Code endorsed by the regulatory authority having jurisdiction over the facility where the items will be installed."*
- The "jurisdiction" noted by NRC is referring to the regulatory authority for the facility where the component will be installed (i.e., facility to construct items using this code case). Here ASME uses "construct" to mean "fabricate" or "manufacture".**

*Italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

**ASME Section III defines "construction" as "an all-inclusive term comprising materials, design, fabrication, examination, testing, inspection, and certification required in the manufacture and installation of an item."

NRC: ASME N-883 Cannot be Used as Intended (3/4)

2. NRC: ASME N-883 is restricted to components of 4 inches or less
   - *"As noted on the slides for the public meetings on CC N-883 and in the NRC staff's meeting summary (ML24164A200), the NRC staff acknowledged that*
   - *NCA-3211.19(e) limits the construction of items without an Owner to pumps, valves, and some supports to 4 inches nominal pipe size (NPS) or less and that the technical basis for NCA-3211.19(e) continues to be applicable for advanced and small modular reactors.*
   - *The technical basis has not been developed for ASME code items greater than 4 inches NPS.*

- NCA-3211.19 has this limit. However, our understanding is that Code Case N-883 intended to remove it, and one purpose of issuing CC N-883 was to not limit manufacturing to only 4" and under.
  - We understand this was a commercial decision back in the 70s, and not based on technical concerns.
  - The reason is that small pumps and valves are typically mass produced and stocked
  - The Code requires a Certificate Holder to prepare a Design Specification and then a reconciliation process against the owners Design Specification.
  - Certificate Holders constructed and stamped small valves and pumps at risk.
  - The new business models want to do essentially the same thing for larger components
  - Code Case N-883, uses essentially the same process, we believe it was not intended to be limited to smaller pumps and valves.
  - Would the NRC need N-883 updated to explicitly permit larger components and document the basis?

*Italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

NRC: ASME N-883 Cannot be Used as Intended (4/4)

3. NRC: *"Further, the requirements of Appendix B to 10 CFR Part 50 are only applicable to NRC license applicants and licensees."*
   - Does "applicable" mean "able to be used" or "required to be used"?
   - DC/SDA Holder (Design Authority) and ASME Certificate Holders (Manufacturer) are able to use NRC Approved QA Programs (e.g., Use of ASME NQA-1)
   - Is the NRC concern that if Appendix B is not required, then it will not be used, or used incorrectly? In lieu of a current requirement, can there be a process to later confirm manufacturing under an Appendix B QA program once the Owner is identified or takes receipt of the component and Appendix B becomes "required"?
4. NRC: *"As ASME Certificate Holders not acting under a procurement contract with an NRC licensee or license applicant are neither an NRC license applicant nor a licensee, those entities remain outside of the NRC's regulatory jurisdiction. The NRC staff would only have regulatory jurisdiction if an NRC license applicant or licensee were part of the procurement."*
   - Does the NRC need to have jurisdiction during the manufacturing if later, when an Owner is identified or takes receipt of component, the NRC has jurisdiction and is able to confirm that the component is in compliance with NRC requirements, including Appendix B QA, and ASME Code Requirements prior to the component being put into service?

*Italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

It is unclear what challenge(s) need to be solved to enable an alternative approach

- *"NRC licensee's ability to use these components would be subject to an acceptance process to be proposed … and discussed in future public meetings with the staff"*
  - *"The Atomic Energy Act of 1954, as amended (the Act), does not require a license to fabricate such components and ASME Certificate Holders currently do not need to obtain NRC licenses to fabricate components under the ASME Code for use in NRC-licensed facilities"*
  - *"the NRC does not currently have the regulatory authority in accordance with the Act to carry out this request {enable fabrication of ASME Code items by Certificate Holer in accordance with ASME Code without the establishment of an Owner} as written (i.e., without rulemaking)"*
- NRC's position is not clear: AEA does not require a license, but NRC cannot allow without a licensee?
  - Is the central/sole issue the lack of NRC jurisdiction to provide oversight and enforcement during the manufacturing before an Owner is identified or accepts (takes receipt) of the component?
  - We understand that the Code currently allows a Certificate Holder to fabricate items, welded with filler metal, stamped, with ANI involvement, and does not require an Owner in order to be able to do so. This is limited to tubular products welded with filler metal fabricated to a material specification to any Section III Edition/Addenda, and does not require a design specification. There is no size restriction on this.
  - What existing NRC requirements preclude the Alternative Approach?
    - Is it only 50.55(a), Part 50 Appendix B and Part 21, or other requirements? How do they preclude use (please reference specific rule language)?
  - What NRC requirements are missing that would enable the Alternative Approach?
    - Why does the absence of a requirement preclude the manufacturing without an owner for designs approved by DC/SDA?

*Italicized quotes are taken from NRC Letter dated 11/1/24 (Ref. 1)

Lack of a clear process for manufacturing components without an owner imposes undue regulatory risks

- Current risk of NRC acceptance imposes undue regulatory burden
  - Unknow what NRC will or will not accept
  - Potential for NRC to not accept component even if it meets all requirements
  - Components are expensive, take a long time to manufacture and are critical path for owners
  - Financial risk is much more than the cost of the component
  - Regulatory risk is threat to viability of new business models
- Regulatory Risk can be minimized and even eliminated
  - A clear process that, if followed, NRC will accept component
  - Within the control of the Design Authority and Manufacturer
  - Includes the Future Licensee as the ultimate Owner / Responsibility to NRC
- Commercial Risk is manageable with a clear regulatory process
  - ASME Certificate Holder's compliance with requirements, including QA and Part 21
  - Reconciliation of Owner's requirements with design requirements
  - Owner's acceptance/receipt process

Request: Eliminate undue Regulatory Risk.
(Industry is willing to accept commercial risk)

Proposed Solution and Path Forward

Proposed Process to Enable Alternative Approach and Provide Regulatory Clarity and Predictability

1. **Design**: Components are designed to NRC requirements and meet ASME Code
2. **Procurement**: Design Authority contracts with Manufacturer that includes procurement specifications to meet applicable NRC requirements (e.g., design, Appendix B QA, Part 21, ASME Code, Code Case N-883)
3. **Manufacturing**: By ASME Certificate Holder under Appendix B QA Program (e.g., NQA-1)
4. **Owner**: (When Identified) Confirm/reconcile Owner's and Component's requirements
5. **Independent Oversight**: Performed at time Owner is identified or when Owner Accepts Component
    - ASME requires independent oversight, since the origin of the code, this is done by Authorized inspectors
    - Purpose: Confirm component manufactured in conformance to NRC requirements, ASME Code and Appendix B QA process; communicate issues to Design Authority or Manufacturer to address (e.g., in-process)
    - Eligible Entities to Perform Oversight
        - NRC: Perform review of QA and manufacturing paperwork to confirm conformance (e.g., when owner identified) then continue oversight through Vendor Inspection process
        - Owner: Perform review of QA and manufacturing paperwork to confirm conformance (e.g., when owner identified) then through NRC Oversight of Owner
        - 3rd Party (E.g., NUPIC, Current Licensee, ANI): Independent Oversight from the beginning of procurement/manufacturing to independently confirm conformance
6. **Owner Delivery –** Confirm compliance with procurement requirements during receipt inspection
    - Certificate Holder N3 Data report to comply with Code
7. **NRC Acceptance / Approval** – Confirm compliance with above process through review of paperwork – no need for additional testing or inspection of component

Comparison of Traditional and Alternative Approaches

Key Element	Traditional	Alternative
NRC Approval of Design	Yes	Yes
Manufactured by ASME Certificate Holder	Yes	Yes
Manufactured to NRC Requirements	Yes	Yes
Manufactured under Appendix B QA (NCA)	Yes	Yes
NRC Confirmation of Conformance	Independent Oversight	Independent Oversight
Independent Oversight Entity	NRC, Owner	NRC, Owner or Third Party
Independent Oversight Timing	During Entire Manufacturing	Depends on Entity
Independent Oversight Process	Vendor Inspection Process, Owner	Depends on Entity
Part 21 Enforcement	Begins after Delivery - Owner Acceptance/Receipt	
Reasonable Assurance that Component can perform Safety Function(s)	Yes	Yes

Path Forward

1. Alignment on the Technical Basis for an Alternative Approach (No Owner Identified)
   - Does the NRC see any showstoppers in approach proposed today? (Not asking for Regulatory Decision only if there are any concerns identified today)
   - What is needed in order for NRC to accept/endorse/issue a process for accepting an alternative approach? (either in today's proposal or in a modification to that process)
2. Near Term Use of Technical Basis/Process – Using "Alternative Approach"
   - Part 52 and Part 50 pathways
3. Long Term Regulatory Clarity and Durability – NRC endorsement of Technical Basis/Process

References

1. NRC Letter "*Request for NRC Actions to Promptly Enable Construction of ASME Code Items without an Owner*", dated November 1, 2024 (ML24204A242)
2. NRC Regulatory Guide 1.84 Version 39 "*Design, Fabrication, and Materials Code Case Acceptability, ASME Section III*" (ML21181A225)
3. ASME Code Case N-883, "*Construction of Items Prior to the Establishment of a Section III, Division 1 Owner Section III, Division 1"*

QUESTIONS?

By Third Way, GENSLER

Reference Slides

Alternatives Considered by NRC (Ref. 1)

- *"During this time, the NRC staff also held two public meetings (ML24164A200 and ML24218A197) Four ideas were discussed during these meetings:*
  1. *using the existing Vendor Inspection Program (VIP) to perform inspections at the ASME Certificate Holder's facility;*
  2. *using a voluntary ASME Code inspection program instead of the VIP;*
  3. *developing a regulatory framework to issue specific licenses for construction of items by ASME Certificate Holders; and*
  4. *taking no further action. NRC vendor inspections of ASME Certificate Holders facilities are conducted based on safety-related procurement contracts between the ASME Certificate Holders and NRC license applicants or licensees that impose the regulatory requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.*
- *Without a license applicant's or licensee's safety-related procurement contract with a vendor, the NRC does not currently have the regulatory authority to conduct vendor inspections at ASME Certificate Holders' facilities; and jurisdiction over a vendor cannot be established on a voluntary basis."*

None Appear To Address the Need for an Alternative Approach