

NEI 25-05:
Fabrication of ASME
Code Items Prior to the
Identification of an
Owner/Licensee
NRC Public Meeting

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New Business Model – Description and Motivation

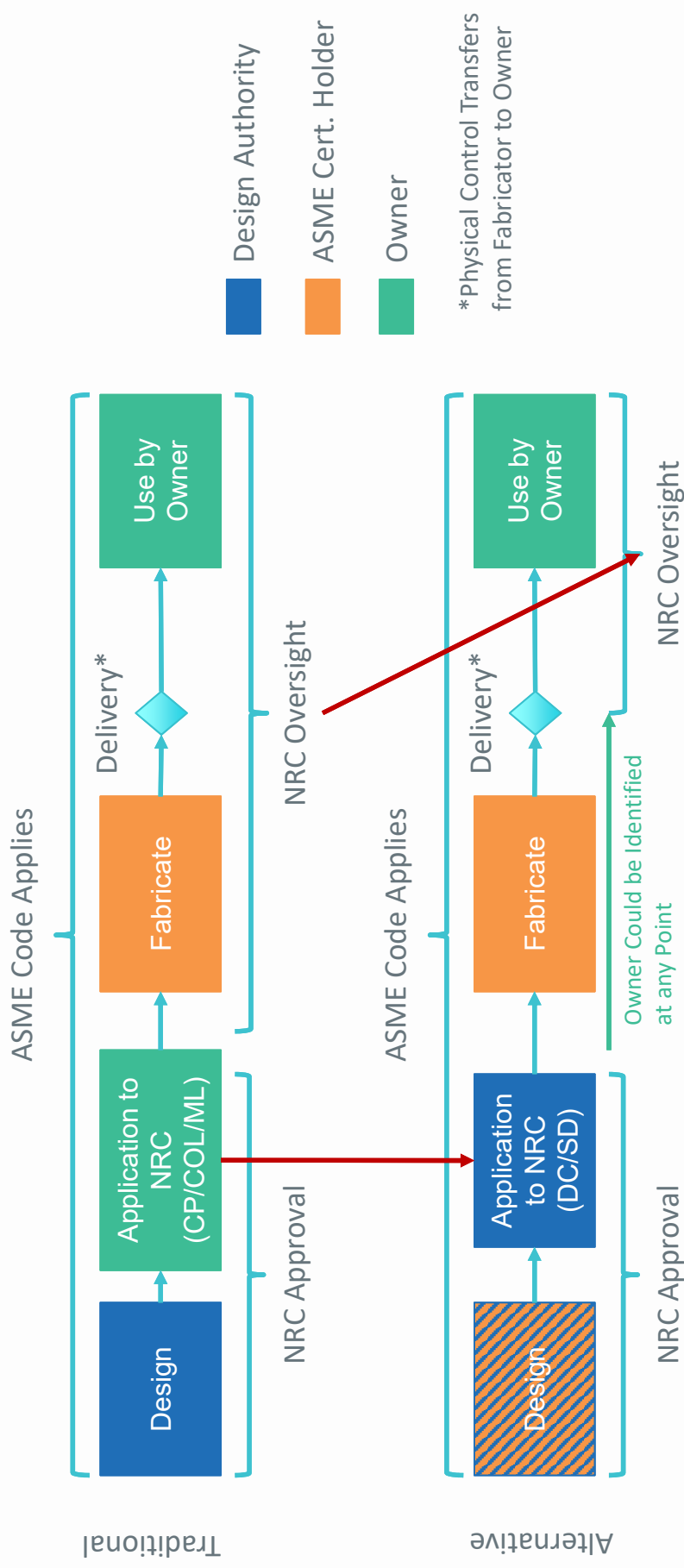
Fabrication of Safety-Related Components before an Owner (NRC Licensee) is Identified



- 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
 - Prospective manufacturing – NEI Paper 2021 and SECY 24-0008
- Currently permissible by NRC for safety-related components
 - Not currently allowable for certain ASME Code Items
 - Restriction is in the ASME Code cited in NRC Regulations – 10 CFR 50.55a

Key Differences in Traditional and Alternative Model

All practices are the same, but without Owner, NRC's Oversight and Enforcement may not begin until after component is fabricated



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



- Current risk of NRC acceptance imposes undue regulatory burden
 - Unknown 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
 - Focus on future Owner's acceptance and use of components fabricated prior to Owner identification
 - Reconciliation of Owner's requirements with design requirements
 - ASME Certificate Holder's compliance with requirements, including QA and Part 21

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

NEI 25-05 Guidance



- **Purpose:** Establish an alternative model to fabricate safety-related components prior to the identification of a licensee, that ensures a consistent, efficient and predictable approach to provide reasonable assurance that products and services provided by unlicensed organizations for use in licensed activities meet applicable NRC requirements.
- **Use By:** Future Licensee – including future applicant or Holder of a Construction Permit or Combined License
- **Regulatory Status of Design prior to start of fabrication:** Does not require any regulatory status (i.e., includes design authorities that have not submitted the design to the NRC for review), includes Applicant or Holder of a Standard Design Approval (SDA) or Design Certification (DC)

Statutory Requirements

Nothing in the Statutes preclude these activities

- **Atomic Energy Act Section 206 (Implemented in 10 CFR Part 21)**
 - NRC's authority to conduct inspections and other enforcement
 - Not applicable to fabrication if no licensee identified
 - *"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. As explained below, 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."*
(ML24204A242)
- **Other Statutes in AEA, Energy Reorganization Act**
 - The Statutes permit the fabrication of safety-related components, including large ASME Code Items, in cases where there is no licensee.
 - The Statutes permit a future licensee to use those previously fabricated safety-related components, provided they meet applicable NRC requirements



Applicable NRC Requirements (1/2)

ASME Code – Not NRC Regulations – Require an Owner prior to and during Fabrication (for certain Code Items)



- **10 CFR 50.10 “Construction”**

- (c) Requires CP, COL, ESP, or LWA prior to beginning construction activities
- (a) Definition of construction does not include procurement or fabrication of components or portions of facility occurring at other than final in-place location

- **10 CFR 50.55(a) “ASME Code”**

- (b) Systems and components of LWRs must meet requirements of ASME BPV Code
- ASME NCA-3211 – Requires an Owner for “construction”
 - “Construction” includes fabrication and other activities not included in NRC definition
 - NCA-3211.19 requires Owner to provide Design Specifications upon which all other construction activities are based
 - NCA-3211.3 requires N Certificate Holder to use the Design Specifications to comply with Section III
 - NCA-3211.19(e)(2) provide exception for pumps and valves ≤4” and standard supports
 - Exception based on business considerations and not on safety/quality concerns

Applicable NRC Requirements (2/2)

NRC's Oversight and Enforcement requirements permit these activities

- **10 CFR Part 50, Appendix B “Quality Assurance”**
 - Applicable to “safety-related” components
 - Applicable to Applicants and Holders of CP, COL, ESP, SDA, DC, ML
 - Permit delegation to comply to others (e.g., contractors, agents, consultants) – Applicant/Holder retains responsibility
 - Cover design, purchasing, fabricating, etc.
 - None preclude a future applicant/licensee (i.e., Owner) from purchasing safety-related components previously fabricated under a QA program compliant with Appendix B requirements
 - Licensee acceptance of prior fabricated components already exists, NRC requirements:
 1. Appropriate QA program established and effectively implemented
 2. Verified, e.g., through checks, audits, inspections, that activities affecting safety-related functions have been correctly performed
- **10 CFR Part 21 “Reporting of Defects and Non-Compliance”**
 - Applicable to “basic components” with similar definition as “safety-related”
 - Reporting and Enforcement not applicable until component is “delivered” to purchaser
 - NRC endorsed Guidance: NEI 24-09

NRC Enforcement and Inspections

NRC: “Vendor inspection are elective, additional, and not the foundation for ensuring compliance”



- 10 CFR Part 2 – Subpart B – “Procedure for Imposing Requirements”
- NRC Enforcement Policy – Implementation of enforcement and inspection requirements
 - Ensure adequate protection of public health and safety – presumed by compliance with NRC requirements
 - Applicable to non-licensees, including applicants/licensees, their contractors and suppliers of safety-related components to NRC licensees
 - Policy and not a requirement - *“The Commission may deviate from this statement of policy as appropriate under the circumstances of a particular case.”*
- Vendor Inspections
 - 1985 NRC decision (50 FR 47716): increase focus on vendor activities (i.e., suppliers)
 - Objective: Provide *“increased assurance that products and services provided by unlicensed organization for use in licensed activities meet NRC requirements.”*
 - Performed at vendor shops to examine whether vendor has been complying with Part 50 Appendix B and Part 21 requirements as required by procurement contracts with licensees
- NRC SECY 07-0150 broadened scope of NRC Vendor Inspections for new reactors
 - Broaden scope, increase oversight, additional inspections, training and guidance

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Assessment of NRC Vendor Inspection Experience



- From 2014 to 2025 (to-date)

	ASME Certification (N, NPT)	No ASME Certification
Total Inspections	49	166
Inspections with Findings	22	85
Total Nonconformances	37	154
Total Violations	3	18

- Insights

- Inspections focus on programs to meet requirements and not on compliance of specific components
- ASME Certificate Holders generally had fewer findings of lower significance than non-ASME
- Violations were Severity Level IV or lower: generally not considered to pose a significant risk to safety
- Nonconformances: did not meet contractual requirement, but did not violate NRC requirements
- Findings were predominately Process-Oriented Deficiencies and very few were related to end-state quality
- The procedural issues generally were not directly related to defects in components.
- Majority of findings related to small set of topics, e.g., design control, nonconforming materials, corrective actions, Commercial-Grade Dedication (CGD), and Part 21

Procurement Practices for Safety-Related Components

Confirmation of compliance with requirements for specific services or products is not performed by the licensee, but rather is assured through passing down requirements, for which each purchaser ensures their supplier's programs are properly implementing the requirements



- Licensee retains ultimate responsibility for compliance with NRC requirements (e.g., QA)
 - Licensee performs oversight of their contractor, and contractors do so for sub-contractors
 - Licensee oversight of contractor is to ensure contractor's QA program compliance – not a verification of every component or service (since the contractors QA program does that)
 - Licensee not required to perform inspections of the sub-contracted fabricator (e.g., ASME Certificate Holder) to verify compliance with NRC requirements
 - Licensee may inspect the supplier/sub-contractor to manage business risk
 - Licensee typically delegates authority for inspections and oversight to the design authority
 - Licensee relies on the design authority's inspection and oversight of the fabricator as part of their delegation of authority,
 - Licensee inspects the design authority to ensure the integrity of the quality assurance program, either directly or through third-party inspections

Procurement Practices for ASME Code Items

Confirmation of compliance with NRC requirements for components is provided by third party inspectors, not by Owner, and can be accomplished without an Owner

- **ASME Section III Components**
 - Permits purchase of material without a design specification and/or an Owner
 - Prohibits “*construction*” without third-party oversight (ANI – Authorized Nuclear Inspector)
 - Prohibits “*construction*” without a design specification
 - Preparation and certification of design specification responsibility of Owner
 - Exception provided for small pumps and valves (NPS 4 and smaller) that permit Certificate holder to prepare and certify a design specification, and a reconciliation by future Owner
- **ANI responsibilities under the ASME Code (not all inclusive)**
 - Monitor the Certificate Holder’s QA program
 - Review Certificate Holder’s qualification records
 - Witness or verify in-process fabrication (e.g., must witness some RT, PT, fit-ups)
 - Witness final pressure tests
 - Certify Data Reports
 - Review drawings and inspect in accordance with the drawings
 - Monitor the Code activities of the Owner
 - Perform all other duties as required by QAI-1 latest Code approved edition

Here “*construction*” is the ASME definition which includes fabrication, design, manufacturing.

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ASME Code Case N-883

Developed to remove ASME Code requirements for an Owner in order to perform fabrication

- The ASME BPV III has developed Code Case N-883-1 “Construction of Items Prior to the Establishment of a Section III, Division 1 Owner”
 - Establishes the conditions under which a Certificate Holder may construct items prior to the establishment of an Owner, and the conditions under which an Owner may utilize those components in their facility.
 - Intended to resolve the discrepancy between the language in § 50.10(a)(2)(viii) and the ASME Code emphasis on the role of an Owner.
- Regulatory Guide 1.84 Revision 39 endorsed CC N-883-1
 - Exception limited use to Holder of a CP, OL or COL (effectively invalidated use)
- CC N-883-2 revision to address the NRC concerns that resulted in an exception
 - Removed condition for Certificate Holders to be NRC licensee
 - Additional changes to include Section III Division 5, other minor clarifications
- Process in CC N-883-2
 - Items are “constructed” by Certificate Holder, with ANI Oversight
 - Holder prepares Design Specifications and performs Owner’s duties
 - When Owner is established, Owner performs reconciliation process



Future Licensee Acceptance Process

Minimizes regulatory risk and achieves manageable business risk

- Follows current practices for procurement of other safety-related components, including some ASME Code Items, that are fabricated before a licensee contract
- Owner's Acceptance Process
 - Perform a supplier audit to confirm supplier's programs comply with procurement requirements, including applicable NRC requirements that are passed down (e.g., Appendix B and Part 21)
 - Verify design requirements for component meet licensee's requirements
 - Confirm component was fabricated by ASME Certificate holder in compliance with ASME Code Case N-883
 - Review Cert. Holders records for component to ensure all requirements met, including third-party inspection by ANI (Design, Procurement, Fabrication, Oversight, Turnover)
 - Perform receipt inspection of component to verify as-fabricated component complies with applicable NRC requirements (disposition deviations as appropriate)
- Upon receipt, licensee accepts ownership and subject to 10 CFR Part 21 enforcement
- **Residual business risk:** component does not meet Owner's design requirements, in which case the component would not be accepted by Owner and Owner would need to find a different component that does meet their Design Specifications

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 of Component	ANI	ANI
Part 21 Reporting and Enforcement	Begins after Delivery - Owner Acceptance/Receipt	Begins after Delivery - Owner Acceptance/Receipt
Reasonable Assurance that Component can perform Safety Function(s)	Yes	Yes

Path Forward

1. June - Submittal of NEI 25-05
 - Guidance described today
 - Includes Appendix with draft CC N-883-2 (track changes)
2. July (requested) – NRC endorsement
 - NEI 25-05 Guidance
3. August (expected) – ASME approval
 - Finalize Code Case N-883-2
4. Address in the Comprehensive Regulatory Review
 - Alternatively Update R.G. 1.84 to endorse without exception ASME CC N-883-2



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?

