Fabrication of ASME Code Items Prior to the Identification of an Owner/Licensee

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Executive Summary

Historically, the fabrication of large safety-related components for nuclear reactors began after a licensee submitted a construction permit (CP) or combined license (COL) application to the Nuclear Regulatory Commission (NRC). In this traditional model, the licensee would delegate authority for the fabrication to a supplier and pass down applicable NRC requirements. The NRC would then have inspection and enforcement authority over the supplier and fabrication activities of the safety-related component.

The nuclear industry is developing an alternative model to the fabrication of safety-related components that better aligns with the emerging new business models of advanced reactor designs. In the alternative model, the design authority (also known as the Nuclear Steam Supply System – NSSS – supplier, or the reactor designer) would begin fabrication before a licensee or applicant has been identified as the Owner. In doing so, the design authority would fabricate – and pass down to any sub-suppliers – the NRC requirements that are expected to be applicable to a future licensee. Sometime after fabrication has begun, which could be after fabrication has been completed, a licensee or applicant would be identified as the Owner, and the NRC would then have inspection and enforcement authority over the supplier and fabrication activities of the safety-related component.

The Statutes permit, and there are no NRC requirements that fundamentally preclude, the fabrication of safety-related components before they are under contract by an NRC licensee. However, currently this is restricted for certain ASME Code items. Specifically, the current ASME Code limits fabrication without an Owner to only small ASME code items. ASME is not aware of any technical rationale to limit fabrication without an Owner to small components, and established ASME Code Case N-883 to provide a process for the fabrication of any ASME code component without an identified owner. The Code Case imposes certain requirements, some of which apply to the future owner once they are identified.

This guidance provides the regulatory basis for the NRC acceptance of ASME Code Case N-883 and a future licensee's acceptance of ASME Code Items that were fabricated prior to being under contract by an NRC licensee. ASME Code Case N-883 and this guidance provide reasonable assurance that the applicable NRC requirements in Appendix B and Part 21, and ASME Code Requirements will be satisfied, and provides a pathway for NRC inspection and enforcement once those components are accepted by the licensee.

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1 INTRODUCTION

The purpose of this document is to establish an alternative model to fabricate safety-related components prior to the identification of an Owner (i.e., NRC applicant or licensee), that ensures an 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.

Historically, the fabrication of safety-related components for nuclear reactors began after an applicant has submitted a construction permit (CP), operating license (OL), or combined license (COL) application to the Nuclear Regulatory Commission (NRC) or a licensee is identified as the Owner. In this traditional model, the licensee would delegate authority for the fabrication to a supplier and pass down applicable NRC requirements. The NRC would then have inspection and enforcement authority over the supplier and fabrication activities of the safety-related component.

The nuclear industry is developing an alternative model to the fabrication of safety-related components that better aligns with the emerging new business models and the practical implications of advanced reactor designs that are smaller than traditional large light-water reactors (LLWRs). In the alternative model, the design authority (also known as the Nuclear Steam Supply System – NSSS – supplier, the reactor designer, or technology developer) would fabricate components before contracting with a licensee or applicant. In doing so, the design authority would fabricate – and pass down to any sub-suppliers – the NRC requirements that would be applicable to a future licensee. Sometime after fabrication has begun, which could be after fabrication has been completed, the Owner would be identified, and would accept the component, and the NRC would then have inspection and enforcement authority over the licensee and the compliance of the safety-related component to the NRC applicable requirements, and, if the component is still in fabrication, to the supplier and fabrication activities.

In this manner, the licensee is responsible for compliance with the Atomic Energy Act and NRC regulations and is subject to NRC inspection and enforcement actions. It is important to note that licensees are permitted to delegate their responsibilities to suppliers, and by extension the NRC would have jurisdiction over those suppliers to the extent that they are fulfilling the requirements of the Act and NRC regulations. In the traditional model, the delegation could be made prior to beginning fabrication of safety-related components, whereas in the alternative fabrication model proposed in this document the delegation could occur after the safety-related component has been fully fabricated. While the NRC would have inspection and enforcement authority over the supplier after a licensee is identified, the scope of the NRC activities could be limited to retrospective review of the completed component and may preclude the ability to have real time in-process review. This is not expected to adversely impact the NRC's ability to provide reasonable assurance that the products provided by unlicensed organizations for use in licensed activities meet NRC requirements.

The desired business model is currently permissible for safety-related components, except for certain ASME Code items. The components of specific interest in this guidance document are those that would be designed and fabricated following the requirements in the ASME Boiler and Pressure Vessel Code, Section III. The traditional business model for nuclear power reactors focuses on an Owner, who is the licensee or applicant for the facility, that will finance the project, have a contract with the engineering, procurement, and construction companies to perform their scope of the work, and will be the license holder for the construction and operation of the plant. In this model, the owner is responsible for the procurement of all components, including the long-lead time components. The existing language in the ASME Code emphasizes the role of the owner in the procurement process. In some cases, once an

owner has been identified, the design authority can procure long-lead time components on the owner's behalf. This has been the traditional approach for procuring reactor pressure vessels for large light-water reactors.

Figure 1 depicts the major features of the traditional and alternative models for fabricating safety-related components as it relates to the NRC licensing, inspections and enforcement, and the application of NRC and Code requirements.

Figure 1: Key Differences in Traditional and Alternative Models for the Fabrication of Safety-Related Components

There are numerous aspects of the advanced reactor technologies and emerging new business models that are driving the need for fabrication without an identified licensee or applicant as the Owner; however, the regulatory approach to enable the alternative model for fabricating safety-related components would be the same. To provide greater clarity, the following are the major factors currently driving the need for an ability to perform fabrication without an identified licensee:

1. **Reduced Critical Path**: Small modular reactors (SMRs) can incorporate much more factory construction, resulting in significant reductions in the amount of on-site construction, which itself is more representative of assembly rather than traditional site construction activities. As the site construction schedule is reduced, expected to be less than 3 years or potentially significantly shorter, the schedule of fabrication needs to begin earlier in the project, as it becomes a larger critical path driver of the overall project schedule. In this manner, the start of fabrication for some long lead components may need to begin prior to the licensee or CP or COL applicant becoming the Owner.

2. **Continuity of Fabrication**: There may be some situations in which a licensee has been identified, and fabrication has begun or is in process to begin, and then the licensee's business plans change such that they no longer plan to construct a reactor on the original schedule. In this situation, the design authority may wish to continue the fabrication schedule as they work with other potential licensees or applicants to take ownership of the components. As such, there

would be a period during which there is no licensee or applicant as the Owner during fabrication. This situation is consistent with the conditions discussed in the NuScale letter to the NRC on June 21, 2024 (ML24177A233).

3. **Rapid-High Volume Deployment**: Meeting the emergent need for new nuclear energy is expected to require hundreds to thousands of new reactors of various power levels. Deployment of this large number of reactors by 2050 will necessitate reductions in the time to license, fabricate, and construct reactors compared to the traditional timelines for the existing fleet of large light-water reactors. The NEI proposal submitted to the NRC on July 31, 2024 (ML24213A337) discusses the business models for Rapid High-Volume Deployable reactors and the need for fabrication without an identified licensee or applicant as the Owner.

4. **Prospective Manufacturing**: In the past, some SMR developers have discussed manufacturing reactors prospectively and storing the reactors until a specific customer (and hence a host site) is identified. The NRC's current Part 50/52 regulations permit such an approach under a Manufacturing License (ML), although prospectively manufacturing may be pursued by design authorities without an ML. The NEI paper discusses prospective manufacturing as a consideration in Part 53 in the July 16, 2021, paper (ML21197A103).

To enable these advanced reactor technologies and the emerging new business models, the regulatory approach for fabrication without an Owner is being developed for use by **Future Licensees,** including a future applicant, or a Holder of a Construction Permit or Combined License.[1] Nevertheless, the guidance is also useful to inform design authorities and ASME Certificate Holders regardless of the regulatory status of the design (i.e., includes design authorities that have not submitted the design to the NRC for review, applicant or holder of a Standard Design Approval (SDA) or Design Certification (DC)).

Supporting this deployment will require changes in approaches for licensing, fabrication of critical components, and overall construction of the facilities. Simply following traditional approaches will not meet this increasing demand. While there have been and continue to be efforts to improve key aspects of the traditional approach, there are other aspects that warrant change to support timely fabrication of key components and the deployment of reactors.

Design Standardization enables the fabrication of components and identifying the Owner later. This aligns with the NRC Advanced Reactor Policy Statement that encourages Design Standardization. Flexibility in delivery and potential change in the sequencing of projects is important to future business models. Markets and customers need a pathway to manufacture components prior to identifying an Owner. This would shorten time to deployment and open up markets for time sensitive uses and customers. This is also discussed in NRC SECY 24-0008, which addresses the need for fabrication prior to identifying Owners.

This guidance provides a pathway to a very important aspect of improving timely deployment, namely beginning fabrication of long-lead time components in advance, and a regulatory process that reduces uncertainty and financial risk to design authorities and potential Owners.

[1] This guidance is not developed in anticipation that it would be used by a Manufacturing License (ML) Applicant or Holder, since the NRC has regulatory authority over the ML Holder who can fabricate safety-related components using the traditional model.

2 DEFINITIONS

Construction: In this document, the term construction is used to mean the definition in 10 CFR 50.10. Specifically, §50.10(a)(1) defines "Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:

(i) Safety-related structures, systems, or components (SSCs) of a facility, as defined in 10 CFR 50.2;

(ii) SSCs relied upon to mitigate accidents or transients or used in plant emergency operating procedures;

(iii) SSCs whose failure could prevent safety-related SSCs from fulfilling their safety-related function;

(iv) SSCs whose failure could cause a reactor scram or actuation of a safety-related system;

(v) SSCs necessary to comply with 10 CFR part 73;

(vi) SSCs necessary to comply with 10 CFR 50.48 and criterion 3 of 10 CFR part 50, appendix A; and

(vii) Onsite emergency facilities necessary to comply with either § 50.160 or § 50.47 and appendix E, as applicable."

§50.10(a)(2) identifies activities that are not construction.

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." This definition includes all activities performed under Section III from procurement of material to applying the ASME Certification Mark on a completed system. Where specific instances of the term Construction is intended to have the ASME Section III meaning it is identified as *"construction"*.

Certificate Holder: ASME Section III defines Certificate Holder as an organization holding a Certificate of Authorization with a scope of work that certificate holder is permitted to perform. Each Certificate type (N, NPT, NA, NV, NS) has its own definition. When this guide refers to a Certificate Holder, it refers to the N Certificate Holder who assumes responsibility for Code compliance with respect to material, design, fabrication, installation, examination, testing, inspection, certification, and stamping of items. In Code Case N-883, The Certificate Holder assumes responsibility until an Owner is identified.

Design Authority: Neither the NRC nor ASME define "Design Authority." The term in this guidance is used to mean the, the reactor designer or the technology developer.

Fabrication: The ASME Code defines "fabrication" to mean "those actions required to manufacture components, parts, supports, and appurtenances. These actions may include forming, machining, assembling, welding, brazing, heat treating, examination, testing, inspection, and certification." The NRC does not define "fabrication."

Licensee: NRC defines "licensee" as a company, organization, institution, or other entity to which the NRC or an Agreement State has granted a general license or specific license to construct or operate a nuclear facility, or to receive, possess, use, transfer, or dispose of source material, byproduct material, or special nuclear material. As used in this document the term "licensee" includes an applicant for or Holder of a construction permit, combined license or manufacturing license.

The ASME definition of "Owner" is focused on the entity that will own and operate the facility after its construction and therefore constitutes the same scope of organizations as the NRC's definition of licensee.

In this paper, Licensee and Owner are both used within the context of such use, but otherwise can be considered equivalent.

Supplier – A supplier of products or services to be used in an NRC-licensed facility or activity. (50 FR 47716). ASME Section III includes the term *supplier,* which is generic to any organization that provides materials or services in accordance with a procurement document.

3 REGULATORY BASIS

The following discusses the existing regulatory framework that relates to the fabrication of safety-related components, and the ability to perform fabrication without an identified licensee.

3.1 Statutory Requirements

The NRC derives its principal authority to license and regulate the civilian use of nuclear materials from two statutes: (1) the Atomic Energy Act (AEA) of 1954, as amended, which provides broad authority to license and regulate the civilian use of nuclear materials, and (2) the Energy Reorganization Act (ERA) of 1974, as amended, which established the Agency and its major offices. The Administrative Dispute Resolution Act of 1996 (ADRA), 5 U.S.C. §§ 571-584, provides the statutory framework for the Federal Government to use alternative dispute resolution (ADR).

The Atomic Energy Act, Section 206, applies to (among others) individual directors or responsible officers of a firm supplying components of any facility licensed pursuant to the AEA, as it relates to defects in basic components. This section specifically addresses the NRC's authority to conduct inspections and other enforcement activities to ensure compliance with the Section. As discussed below in the section discussing 10 CFR Part 21 (which is the NRC regulation to implement AEA Section 206), the NRC has concluded that a component does not become a basic component until it is accepted by the licensee. Therefore, this section could not be applicable to a fabrication of a safety-related component if no licensee has been identified.

From the NRC letter to NuScale (ML24204A242), "*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.*

The Act focuses on regulating licensees. The NRC has jurisdiction over unlicensed entities in certain limited circumstances not present here—if, for example, they possess regulated material or a facility that requires a license. Beyond that, the structure of the Act plainly indicates that Congress limited the Commission's authority to holding licensees and their agents responsible for assuring adequate protection of the public health and safety and the common defense and security. Further, 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. Absent such status, the NRC has no regulatory authority over such an entity."

Therefore, there is nothing in the Statutory requirements that precludes a future licensee (e.g., CP or COL) from using safety-related components, including large ASME Section III Components, that began or completed fabrication prior to them becoming a licensee. In other words, the Statutes permit the fabrication of safety-related components, including large ASME Code Items, in cases where there is no licensee and for a future licensee to use those previously fabricated components, provided they meet applicable NRC requirements.

3.2 NRC Requirements

10 CFR 50.10 "Construction"

NRC's regulations relative to the beginning of construction, and need for a licensee, are addressed in §50.10

- 50.10(c) *Requirement for construction permit, early site permit authorizing limited work authorization activities, combined license, or limited work authorization*. No person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a construction permit under this part, a combined license under part 52 of this chapter, an early site permit authorizing the activities under paragraph (d) of this section, or a limited work authorization under paragraph (d) of this section.

- 50.10(a) *Definitions*. As used in this section, *construction* means the activities in paragraph (a)(1) of this section, and does not mean the activities in paragraph (a)(2) of this section.

- 50.10(a)(2) Construction does not include:

    - (viii) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility;

From the NRC's definition of construction activities, the NRC does not require a construction permit, early site permit, combined license or limited work authorization in order to procure or fabricate components occurring at other than the final in-place location of the facility. Therefore, procurement and fabrication of these items could proceed without requiring the licenses discussed in §50.10(c).

50.55(a) ASME Code

The requirement in §50.55a(b) states "Systems and components of boiling and pressurized water-cooled nuclear power reactors must meet the requirements of the ASME BPV Code…" The language in the

ASME Code emphasizes the role of the Owner (e.g. an NRC licensee or an applicant for a license). The emphasis on the role of the Owner is not consistent with fabrication without an identified licensee. ASME NCA-3211 addresses the timing to begin *"construction"* of ASME Code Items.

ASME Section III NCA-3211.19 requires the Owner to provide a Design Specification upon which all other construction activities are based. NCA3211.3 requires the N Certificate Holder to use the Design Specification as a basis for complying with Section III. Following these rules, a component cannot be constructed until there is an Owner to prepare and certify a design specification. An exception was made in NCA-3211.19(e)(2) for pumps and valves 4 inch and under and standard supports. Design Specifications for these items can be prepared by the Certificate Holder constructing them. ASME Code experts with historical insights into the development of NCA-3211 (and NCA-3256 that preceded it) have indicated that the limitation was established in the 1970s based on commercial considerations and was not based on any technical concerns. The commercial considerations focused on the fact that small pumps and valves were typically mass produced and stocked, because these were more standardized across various plants and designs. Thus there was a business need to permit these components to be fabricated without an owner, and there was a tolerance for the business risk of having to later reconcile that the components met the plant design (The Code requires a Certificate Holder to prepare a Design Specification and then the Owner to reconcile the Certificate Holder's Design Specification with the Owner's Design Specification). In contrast, larger ASME components, which were much more expensive, were specialty built with expected variation across plants, even with the same type of design, and was not a reasonable business risk. For advanced reactors, the business conditions that existed in the 1970s for smaller components are now also applicable for much larger ASME components.

While this limitation is not an explicit NRC requirement in regulations, it becomes a requirement in that the regulations require that the ASME code be met.

However, the cognizant Code Committee has developed Code Case N-883-2 "Construction of Items Prior to the Establishment of a Section III, Division 1 Owner" which 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. This Code Case is 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. The Code Case N-883 is being updated to address the NRC concerns that resulted in an exception to its endorsement.

10 CFR Part 50, Appendix B – QA

NRC established quality assurance (QA) requirements for safety-related components in 10 CFR Part 50, Appendix B. The NRC requires a description of the QA program for construction permits (50.34), combined licensed (52.79), early site permit (52.17), design approval or design certification (52.137 and 52.47), manufacturing license (52.157). The requirements are applicable to (i.e., are requirements that must be met for) applicants of these NRC permits, licenses and approval, where the term "applicant" includes "holders" after the NRC has approved the applications. The regulations permit the delegation to others, such as contractors, agents or consultants, to comply with any part of the requirements, but the applicant shall retain the responsibility for the QA program.

The NRC requirements cover, among other things, the design, purchasing, fabricating and quality control of safety-related components. 10 CFR Part 50 Appendix B establishes 18 basic requirements, none of which preclude a future owner (i.e., applicant or holder of a CP or COL) from purchasing a safety-related

component that was previously fabricated (i.e., fabrication was completed before the licensee contracted for the component) under a QA program compliant with 10 CFR Part 50 Appendix B. In fact, such procurements of already fabricated safety-related components are routine. The NRC QA requirements establishes that the future owner, when they procure the safety-related component, ensure that 1) the appropriate QA program was established and effectively implemented for the component, and 2) has been verified, such as by having been checked, audited and inspected that activities affecting the safety-related functions have been correctly performed. This is consistent with the ability of the licensees to delegate QA responsibilities, as permitted by NRC requirements. The permissibility of this under NRC regulations is further clarified when considering that Appendix B pertains to the design of the components, and clearly the NRC has not required or expected that there first be an licensee before the design of the component can begin, only that the design has been performed under an Appendix B compliant program.

The NRC reviews and approved QA programs for applicants of the licenses, permits and approvals discussed above. In particular, the NRC reviews and approves the QA programs of design authorities to confirm compliance with 10 CFR Part 50 Appendix B.

10 CFR Part 21, Reporting of Defects and Non-Compliance

NRC establishes requirements to implement AEA Section 206 for reporting defects and non-compliance of basic components in 10 CFR Part 21. Basic components in Part 21 are equivalent to safety-related components designed and manufactured under a QA program complying with 10 CFR Part 50, Appendix B. Like Appendix B requirements, the Part 21 requirements are passed down to suppliers. A basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

While Part 21 is applicable over the range of the lifecycle of design and fabrication, the requirements related to reporting and enforcement are not applicable until the component has been delivered to the purchaser. Part 21 requirements and guidance in NEI 14-09 *Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance* (endorsed in RG 1.234), clarify that the reporting and enforcement requirements are not applicable until a basic component has been delivered to the purchaser. In relation to Part 21, “Delivered means that the purchaser has taken control of the basic component after completing an acceptance process.” An acceptance process is typically the receipt inspection, and in some cases can be the acceptance/functional testing. “At that point, the control and ownership of the component transfers to the purchaser, and 10 CFR Part 21 responsibilities for reporting of defects and non-compliances come into effect. In some specific situations, such as for certified designs, delivery is based upon whether it has been offered for use, instead of being established by an acceptance process. See Section 7.4 for more guidance.” For ASME Code Items that must be accepted by the Owner, they could not be delivered and thus reporting and enforcement requirements would not be applicable, until a CP or COL licensee or applicant receives the components. As the guidance discusses, the reason for this is that a basic component cannot result in a substantial safety hazard if it has not been received by the owner.

3.3 NRC Enforcement and Inspections

The NRC's enforcement program is governed by its regulations. Title 10 of the Code of Federal Regulations (10 CFR) Part 2, "Agency Rules of Practice and Procedure," Subpart B, "Procedure for Imposing Requirements by Order, or for Modification, Suspension, or Revocation of a License, or for Imposing Civil Penalties," describes the formal procedures that the NRC uses to implement its enforcement authority.

The NRC enforcement and inspection requirements are implemented through the "NRC Enforcement Policy": https://www.nrc.gov/docs/ML2420/ML24205A249.pdf, and https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html

The NRC Enforcement Policy supports the NRC's mission. Adequate protection is presumptively assured by compliance with NRC requirements. Compliance with NRC requirements, including regulations, technical specifications, license conditions, and Orders, provides reasonable assurance to the NRC and the public that safety and security are being maintained.

The NRC Enforcement Policy is applicable to non-licensees, including contractors and subcontractors, applicants or holders of NRC approvals (e.g., certificates of compliance, early site permits, standard design certificates), QA program approvals, and employees of any of the foregoing, who knowingly provide components, equipment, or other goods or services that relate to a licensee's activities subject to NRC regulation.

The Enforcement Policy applies to all NRC licensees and applicants, to various categories of non-licensees, and to individual employees of licensed and non-licensed entities involved in NRC-regulated activities. These include, but are not limited to the following:

a) organizations and individuals holding NRC licenses

b) license applicants

c) contractors and subcontractors to NRC licensees

d) holders of and applicants for various NRC approvals, including, but not limited to:

    1. NRC certificates of compliance

    2. early site permits

    3. standard design certifications

    4. QA program approvals

    5. certifications

    6. limited work authorizations (LWA)

    7. construction authorizations

8. other permits and forms of NRC approval

e) suppliers supplying safety-related components to NRC licensees

f) employees of any of the above

Not all NRC requirements apply to all of the categories listed above; however, the Agency uses the Enforcement Policy, as appropriate, to address violations of NRC requirements.

The NRC Enforcement Policy notes: "*this is a policy statement and not a regulation. The Commission may deviate from this statement of policy as appropriate under the circumstances of a particular case.*"

Vendor Inspections

In a *Federal Register* notice (50 FR 47716)[2] issued on November 20, 1985, the NRC announced a minor revision to its Enforcement Policy to describe how the policy applies to vendors that supply products or services to the nuclear industry for ultimate use in NRC-licensed facilities or activities. That revision reflected a Commission decision to support increased focus on NRC inspection and oversight of industry vendor activities. In addition, the NRC expanded various sections of its Enforcement Policy, including the purpose section and supplements, to encompass vendor activities and add references to the Notice of Nonconformance to vendors.[3]

Vendor inspections are conducted at vendor shops principally to examine whether the vendor has been complying with Appendix B to Title 10, Part 50, of the Code of Federal Regulations (10 CFR Part 50), as required by procurement contracts with licensees. Notices of Nonconformances or Notices of Violations are issued to vendors for failures to meet quality commitments or the requirements of 10 CFR Part 21, "Reporting of Defects and Noncompliance," respectively. 10 CFR Part 21 was last updated on July 6, 2012. Specifically, the objective for vendor inspections (50 FR 47716) is to provide "increased assurance that the products and services provided by unlicensed organizations for use in licensed activities meet NRC requirements." This recognizes that the NRC regulates licensees and relies on licensees to pass down and ensure compliance with applicable requirements. Therefore, the NRC vendor inspection provides additional assurances and is not itself the foundation for ensuring compliance with requirements, but rather an additional layer that is elective and applied in a manner appropriate to the safety significance. The NRC states, "The program is based, however, on the premise that licensees have the primary responsibility for the procurement of quality products and services for use in licensed activities." This also recognizes that the NRC has limited direct control over vendor activities, except in the cases such as Appendix M of Part 50, or Part 52 standard design and design certification holders, where vendors are subject to a licensing-type review by the NRC. "The NRC inspection program for licensees and vendors was designed to determine whether licensees and vendors were conducting their activities so as to promote safety and compliance with the requirements….The vendor inspection program is being directed to determine if reactor licensees are adequately monitoring the activities of their vendors….However, the philosophy that the licensee should be held primarily responsible for the procurement of high quality products that are to be used in nuclear activities has remained unchanged. In furtherance of this philosophy, reactor licensees have been held primarily accountable from an enforcement standpoint if violations of Appendix B to 10 CFR Part 50 are identified…. The NRC has issued Notices of Nonconformance to vendors of reactor licensees when deviations from contracts, QA

[2] https://www.govinfo.gov/content/pkg/FR-1985-11-20/pdf/FR-1985-11-20.pdf
[3] https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance/vendor-insp.html

programs or internal procedures were discovered or identified during the inspection process. A nonconformance involves a failure to satisfy a commitment or obligation that has or could cause a vendor product or service to be unacceptable. The NRC expects vendors to respond in writing to Notices of Nonconformance describing their corrective action to remedy the problem and the measures to be taken to prevent recurrence. The NRC also issues Notices of Violation to vendors when the NRC has direct statutory authority over them. See 10 CFR 2.201."

NRC SECY 07-0150 implemented specific enhancements to the vendor inspection program, including broadening its scope, increasing oversight of supplier audit activities, and developing additional inspection, as well as training and qualification guidance. Historically, the agency has conducted inspections at vendor facilities principally to examine whether vendors have complied with requirements under Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10, Part 50, "Domestic Licensing of Production and Utilization Facilities," of the Code of Federal Regulations (10 CFR Part 50), hereafter referred to as Appendix B, and 10 CFR Part 21, "Reporting of Defects and Noncompliance," (10 CFR Part 21) as required under vendor procurement contracts with licensees. The staff performs routine supplier inspections to verify effective implementation of a supplier's QA program used to furnish safety-related components and/or services to the nuclear industry, as required by Appendix B. The agency performs focused, reactive inspections of nuclear component suppliers when needed for allegation support and under special circumstances to address operational events or allegations.

In NRC SECY 09-0182, The Office of the General Council (OGC) and the technical staff have not identified any legal constraints on leveraging foreign authority inspection results and gaining insight from them to help inform the prioritization of NRC vendor inspection resources, as described above. This practice is acceptable because the foreign authority inspection results are merely one source of information, and the NRC retains the ultimate authority to decide whether any particular vendor satisfies NRC requirements.

For additional information, see the following related pages:

- NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants," May 1984
- NRO SECY Paper on Enhancements to the Vendor Inspection Program for New Reactors
- NRO SECY Paper on Legal Constraints of Relying on Vendor Inspection Results of Foreign Regulators and the Need for Additional Resources to Achieve the Appropriate Number of NRC Vendor
- Inspection Procedures
- Generic Letters
- Information Notices
- Regulatory Information Summaries
- Commercial-Grade Dedication
- NUREG-0302, Revision 1 (10 CFR Part 21)
- Inspection Reports
- ITAAC Related Vendor Inspection Findings
- Vendor Inspection Program Plan
- Vendor Newsletters
- Link to Regulations.gov for Part 21 Rulemaking Documents – Search for Docket – NRC–2012–0012

- 10 CFR Part 21 Clarification and Rulemaking
- Regulatory Issue Summary 2014-07 Enhancements to the Vendor Inspection Program - Vendor Information Request

4 PROCUREMENT PRACTICES

Historically the fabrication of large ASME Code Items began after a licensee submitted a CP or COL application to the NRC. While the licensee retains ultimate responsibility for the quality, they typically delegate authority for quality inspections and oversight to the design authority. In this manner, the Certificate Holders qualify their sub-contractors through audits, so that the licensee does not need to perform inspections of the fabricator (e.g., ASME Certificate Holder) of the safety-related component to verify compliance with NRC QA and Part 21 requirements (though they may inspect the supplier to manage business risk). Rather, the licensee relies on the design authority's inspection and oversight of the fabricator as part of their delegation of authority and then inspects the design authority to ensure the integrity of the QA program, either directly or through third party inspections (e.g., Authorized Inspection Agency, Nuclear Procurement Issues Corporation).

4.1 Historical Practices

Historically, the ASME Section III components have been "*constructed*" as follows:

- ASME Code has always permitted Certificate Holders to purchase material (NX-2000), without a Design Specification and/or without an Owner

- However, the Code has always *prohibited fabrication* activities (NX-4000, NX-5000, and NX-6000) prior to the filing of a (certified) Design Specification (NCA-3211.19(e)(1)). Fabrication activities are those activities covered by Articles NX-4000, NX-5000 and NX-6000, and generally cover, welding, forming and bending, special processes, heat treatments, NDE and hydrostatic testing. The reason the Code prohibits fabrication without a Design Specification is because the Authorized Inspection Agency (AIA) (third party oversight) is required for fabrication and the AIA must have the Design Specification to conduct the required inspection (third party oversight). *The Code has never permitted fabrication without third party oversight.*

- The preparation and certification of a Design Specification is the responsibility of the Owner (NCA-3211.19(a)). Therefore, by extension, the Code prohibits fabrication prior to the establishment of an Owner, because the Owner must prepared and certify the Design Specification.

- There is an exception for small pumps and valves (NPS 4 and smaller) that permits the Certificate holder to prepare and certify a Design Specification (NCA-3211.19(e)(2)), which may then be used to control fabrication activities. Once an Owner's Design Specification is available, reconciliation is required. This exception was based on economics, as small pumps and valves are mass produced and stocked, while larger components were not.

- The Code process uses third party oversight (using an Authorized Inspection Agency)

Authorized Nuclear Inspectors have specific responsibilities and duties under the ASME Code to:

- Verify the work scope
- Monitor the Certificate Holder's QA program
- Review Certificate Holder's qualification records
- Verify materials
- Witness or verify in-process fabrication (e.g., must witness some RT, PT, fit-ups)
- Witness or verify nondestructive examination and test
- Witness final pressure tests
- Certify Data Reports
- Review drawings and inspect in accordance with the drawings
- Assure that design reports are available
- Assure that capacity tests are certified with National Board before signing NV-1 Data Report
- Monitor the Code activities of the Owner
- Perform all other duties as required by QAI-1 latest Code approved edition
- Verify all preservice examinations have been completed to Section XI edition specified [NCA-3252(c)]

4.2 ASME Code Case N-883

Code Case N-883 extends the process to permit a Certificate Holder to prepare and certify a Design Specification, use that for fabrication, and perform a reconciliation once an Owner Design Specification is available. This was requested to meet the economic needs of reactor suppliers and does not alter any third-party oversight requirements in the Code. While this may create some business risk of fabricating large components prior to establishing an owner, this can be done without introducing any risk to quality or safety and indeed is currently done for other safety related components including for smaller Section III pumps and valves. A redline strikeout of Revision 2 to Code Case N-883 that is in the process of receiving Code Committee approval is the basis for and integral to the guidance in this document.

Recent work to enable the alternative model for fabrication without an identified licensee has centered around the ASME Code Case N-883, which ASME established to address the limitation of fabrication without an owner to only certain components and to make it available for larger components. Specifically, N-883 states, "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..." Those conditions establish the process for which it is acceptable to fabricate any ASME code component, including large components, without an identified

owner. Code Case N-883 does not provide exceptions or alternatives to any design, fabrication, inspection, examination, or testing requirements. Certificate Holders using N-883 are required to comply with all requirements including inspection by the Authorized Inspection Agency (AIA), e.g., Authorized Nuclear Inspector (ANI), and Authorized Nuclear Inspector Supervisor (ANIS) provided by the Authorized Inspection Agency (AIA). These independent inspections provide assurance the Section III requirements are being met for items.

The NRC provides their approval for use, or conditions on the use of ASME Section III Code Cases in Regulatory Guide 1.84. Code Case N-883 was addressed in Revision 39 of RG 1.84. The NRC imposed a condition on the use of Code Case N-883 which states "This Code Case may only be used for the construction of items by a holder of a construction permit, operating license, or combined license 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." This condition on the use of N-883 effectively prevents the prospective procurement of long-lead time components by design authorities such as organizations which hold or have applied for a Standard Design Certification or Standard Design Approval under Part 52.

The NRC's rationale for imposing this condition was addressed in the Federal Register addressing the publication of RG 1.84, Rev. 39. Specifically, "The NRC's main concern is that without the designation of an Owner, the NRC would not be able to provide regulatory oversight of the ASME certificate holder fabrication the items, which is not consistent with Appendix B to 10 CFR Part 50 and the requirements in § 50.55(a) for a basic component." Further, it is stated that the applied condition ''This Code Case may only be used for the construction of items by a holder of a construction permit, operating license, or combined license under 10 CFR Part 50 or Part 52,'' provides this specific regulatory authorization thereby ensuring the appropriate regulatory oversight."

In taking the exception, the NRC precluded the use of the code case by ASME certificate holders without an identified owner, defeating the purpose of the code case.

In response to recent discussions, and the establishment of this guidance, ASME is revising Code Case N-883 to address concerns that the code case itself precludes applicability to fabrication without a licensee, as that was not the intention. The draft code case N-883 is the basis for this guidance.

There is a clear implication that the NRC's oversight through the Vendor Inspection Program is fundamental to ensuring the quality of manufactured components. As stated in the FRN, the NRC does not have the authority to implement this regulatory oversight of non-licensed entities, e.g., ASME Certificate Holders. However, this would depart from the NRC's prior assertions that the vendor inspection is not fundamental to ensuring quality and that responsibility resides primarily with the owner (which could be identified after the component is fabricated), and that the vendor inspection program is being directed to determine if reactor licensees are adequately monitoring the activities of their suppliers.

5 ACCEPTANCE OF LARGE ASME COMPONENTS FABRICATED BEFORE AN OWNER IS IDENTIFIED

This guidance establishes an approach for a CP or COL licensee, including applicants for a CP or COL license, to accept the use of large ASME Code Items that were fabricated without an owner.

The approach is designed to provide confidence in the quality of the manufactured components absent NRC jurisdiction and authority during their fabrication. This will eliminate regulatory risks that the licensee would not be able to accept the component because it does not meet applicable NRC requirements, or that NRC would issue a non-conformance or violation of the component after it was accepted by the licensee because the licensee was not identified prior to beginning fabrication. This process follows current practices for the procurement of other safety-related components, including certain ASME Code Items, that are fabricated before a licensee contracts for the component.

While this process eliminates regulatory risks, it is recognized that there may be residual business risks inherent in this process, for example if the licensees' design requirements do not meet the requirements used for fabrication of the components. This would not be related to NRC Appendix B quality or Part 21 requirements, or to ASME code requirements, as these are well known and consistently applicable to components but would relate more to the overall design and whether the owner would want to take exceptions to the standard design offered by the design authority. In such cases, it is more likely that those components would not be applicable to that owner in the first place, and the owner would need to find a different design and set of related components. Code Case N-883 requires the Owner accept the Certificate Holder's Design Specification and Design Report as meeting the Owner's design and site construction requirements. N-883 also requires the Owner to notify the regulatory authority with jurisdiction at the installation site. This notification would begin the process of verifying the activities performed by the Certificate Holder meet the applicable regulatory requirements.

This process is focused on the acceptance of the components by the licensee. The licensee in accepting the components would perform the following:

1. Perform a supplier audit to confirm that the design authority complied with NRC requirements for 10 CFR Part 50 Appendix B and Part 21, including passing down these requirements to sub-suppliers of safety-related/basic components. The supplier audit may be delegated to and performed by a qualified third-part organization (e.g., NUPIC).

2. Verify that the design requirements for the component meets the licensee's design requirements.

3. Confirm that the fabrication was performed by an ASME Certificate Holder in compliance with the provisions of ASME Section III and Code Case N-883.

4. Review the Certificate Holder's records for the component to ensure all ASME Section III and NRC requirements were met, including third party inspection by the Authorized Nuclear Inspector.

5. Perform a receipt inspection of the ASME code component to verify that the as-fabricated component complies with applicable NRC requirements. Disposition any deviations between the records of "*construction"* and the applicable NRC requirements, to determine if the component can be accepted for use. Upon receipt of the component, the licensee accepts ownership and responsibility of the component and the component becomes subject to NRC inspection and enforcement under Appendix B and Part 21.

In assuring the quality of the as-fabricated components the licensee should verify the quality program includes:

- Design –
    - Component design is governed by the NRC regulations and by the requirements of the ASME Code. There are specific requirements addressing QA for both Standard Design Certifications and Standard Design Approvals. For a Standard Design Certification, §52.47(a)(19) requires a description of the QA program applied to the design of structures, systems, and components of the facility. Appendix B to 10 CFR 50…sets forth the requirements for QA programs for nuclear power plants. For a Standard Design Approval, §52.137(a)(19) includes the same language as §52.47(a)(19) requiring discussion of the QA program that conforms to Appendix B.
    - While design authorities would not traditionally procure equipment for an eventual facility, if the designer was to prospectively procure equipment, it is anticipated that they would invoke provisions of their Appendix B program addressing procurement.
- Procurement –
    - Procurement of long-lead time components cannot proceed until the design has reached a stage of maturity where all aspects of the component design are essentially complete. This does not imply that the applications for standard design approval or design certification have been completed and submitted for NRC review. However, the design must be sufficiently complete to prepare the procurement documents and provide confidence that the manufactured component will meet the final design requirements.
    - For fabrication of long-lead time components, the design authority would prepare the detailed procurement documents which would include a Design Specification. The Design Specification outlines the design requirements for a specific piece of equipment or system. It is crucial for ensuring that the equipment meets the user's needs and complies with ASME standards. The Design Specification is typically certified by a registered Professional Engineer (PE) experienced in component design, who ensures that the document meets the requirements outlined in ASME standards.
    - When Code Case N-883 is followed, the Certificate Holder “prepares or causes to be prepared” the Design Specification. This would necessarily involve the design authority, who may or may not be an ASME Certificate Holder.
    - It is anticipated that the design authority would inform NRC of the procurement activities, not to seek approval but to provide the NRC awareness of the developer’s activities.
- Fabrication –
    - Fabrication is governed by the ASME Code used in the design. This addresses materials and fabrication methods (e.g., welding and heat treatment), and non-destructive examination requirements and methods, and any testing requirements (such as pressure-testing requirements). If the fabricated component is to be stored until such time as an Owner is identified, the fabrication requirements would address requirements for the long-term

storage of the component. Code Case N-883 addresses this in paragraph (b) stating that the Design Specifications include shelf-life requirements which, if not addressed, could have an adverse effect on the design life of the component. Additionally, the Code Case requires "the Certificate Holder's QA program to define the requirements for long-term storage, cleaning, periodic maintenance, and preservation of completed items."

- ASME Certificate Holder QA -- ASME Certificate Holders are required to maintain a QA program that meets the standards set by ASME. This program ensures that products and services comply with the highest standards for safety, quality, and reliability. Certificate Holders must also undergo regular audits to verify that their QA program is effectively implemented and complies with ASME standards. For companies holding ASME certificates, an audit of their shop facility is periodically performed by an Authorized Inspection Agency (AIA) or ASME designated organization to confirm that the QA program is still in place and that the company can fabricate Code Items in compliance with the applicable ASME Boiler and Pressure Vessel Code requirements.

- ASME Authorized Inspection Agency (AIA) – Certificate Holders are required to make use of an ASME Authorized Inspection Agency (AIA) which is an organization that meets the criteria of the ASME Section III NCA-5000 and ASME QAI-1 standard, "Qualifications for Authorized Inspection". An organization must meet the qualification requirements and perform the duties specified in QAI-1, Chapter 2. To perform authorized inspections under an ASME standard, an Authorized Inspection Agency is accredited by the Society pursuant to the provisions set forth in QAI-1, Chapter 3. The Certificate of Accreditation will specify the ASME standard(s) for which authorized inspections will be provided by the AIA.

- Oversight –

  - For situations where the design authority is prospectively procuring components, it is anticipated that it would implement aspects of its Appendix B program addressing inspection of activities affecting quality, and of test control for the manufactured components. This could involve in-process inspection by the design authority or their representative. If its Appendix B program does not address these activities, the program would have to be amended to provide adequate treatment of these activities.

  - ASME Section III NCA-4000 requires ASME Certificate Holders to perform inspection and internal oversight during "construction" with documented acceptance criteria and results.

  - NRC has expressed concern that deviating from the traditional approach would not allow for adequate 3rd party oversight. However, the AIA provides detailed, 3rd party oversight and its use by the Certificate Holder is required.

  - The potential for the identification of a non-conformance with applicable regulations or the identification of defects which could create a substantial safety hazard must be recognized as part of the overall oversight of component fabrication. When the fabrication is conducted on behalf of an Owner/licensee or license applicant, the requirements of Part 21 "Reporting of Defects and Noncompliance" apply. However, Part 21 does not apply for fabrication under a Standard Design Certification or Standard Design Approval. Consequently, provisions must be included as part of the procurement documentation that

would require reporting such non-conformance or defects to the design authority (or its representative other than the Certificate Holder) and to the Certificate Holder. Documentation of the report and of the actions taken to address the reported non-conformance or defect is to be maintained by the design authority and by the Certificate Holder. Once an Owner has been identified, this documentation would be provided as part of the overall documentation provided to the Owner. The Owner/licensee or license applicant would submit this documentation to the NRC as a Part 21 report for the NRC's subsequent review and action. The Certificate Holder that constructed the component would also retain future Part 21 reporting responsibility if a defect is found in future construction that could be present in previously constructed components.

  - Industry evaluation of suppliers through the Nuclear Procurement Issues Corporation (NUPIC) provides an element of oversight of the component supplier and is a form of 3rd party oversight. As stated on NRC's webpage addressing NUPIC, the "NRC periodically accompanies a NUPIC team to observe selected audits and ensure that the audit process remains an acceptable alternative to the NRC's vendor inspection/audit program." While not formal regulatory oversight, accompanying NUPIC teams can provide NRC with first-hand observations of component supplier processes.

- Turnover to an Owner –

  - The primary responsibility for the safety of a nuclear power plant rests with the Owner/licensee. Part of that responsibility involves assuring that components installed in the facility meet the various regulatory requirements, which would include the quality of the manufactured component.

  - An Owner/licensee or license applicant may be identified at any point during the fabrication process. The interface between the design authority, the Certificate Holder, and the identified Owner would be addressed through the contractual arrangement.

  - Code Case N-883 provides specific requirements addressing responsibilities for the Owner/licensee as well as for the Certificate Holder and AIA to ensure complete documentation is provided to the Owner.

  - Document turnover would include any reports of non-conformances or defects, and detailed description of how those reports were dispositioned.

- NRC inspection of the Owner/licensee documentation and acceptance inspections.

  - Delivery of the component to the Owner/licensee's site provides NRC an opportunity to conduct an inspection of the facilities and complete set of documentation provided to the Owner/licensee, including any reports of non-conformances or defects which would likely be handled as Part 21 reports by the Owner/licensee or license applicant.

  - If deficiencies are identified by the NRC. enforcement action can be taken to ensure the deficiencies are corrected prior to use by the Owner.

  - NRC routinely conducts retrospective inspections to ensure prior activities were conducted in accordance with NRC's regulations. Thus, inspecting the design, fabrication, and quality

documentation after delivery of the component would be consistent with current regulatory oversight practice.

The licensee acceptance process confirms that there is sufficient in-process oversight by a competent organization to provide NRC confidence in the quality of the component, and provides the NRC with a process under which they can inspect the fabrication records and provide appropriate retroactive regulatory oversight in reaching the determination that the installed components will support the adequate protection finding for the completed facility.

The proposed approach imposes certain conditions on the design authority and ASME Certificate Holder in order to enable Owners/licensees or license applicants, as they are identified, to install and make use of the components fabricated prior to identifying an owner, and which would be subject to retrospective inspection by the Owner and NRC once the owner is identified.

6 CONCLUSION

The Statutes permit, and there are no NRC requirements that fundamentally preclude, the fabrication of safety-related components before they are under contract by an NRC licensee. The current restriction to fabricate without a licensee certain ASME Code Items, which excludes large ASME Code Items, is imposed by the ASME Code. ASME is not aware of any technical rational to limit fabrication without an owner to small components, and established ASME Code Case N-883 to provide a process for the fabrication of any ASME code component without an identified owner. The Code Case imposes certain conditions, some of which apply to the future owner once they are identified. This guidance provides the regulatory basis for the NRC acceptance of ASME Code Case N-883 and a future licensee's acceptance of large ASME Code Items that were fabricated prior to being under contract by an NRC licensee or applicant. ASME Code Case N-883 and this guidance provide a high level of assurance that the applicable NRC requirements in Appendix B and Part 21, and ASME Code Requirements will be satisfied, and provide a pathway for NRC inspection and enforcement once those components are accepted by the licensee.

The proposed approach to fabrication of large ASME Code Items without an identified owner involves a significant emphasis on assuring the quality of the procured components so they would reliably perform their design function throughout the design life of the facility. The detailed documentation provided to the Owner/licensee or license applicant by the design authority would be reviewed and accepted by the Owner/licensee or license applicant and can be inspected by the NRC.

An applicant for a construction permit, operating license, or combined license would include or reference this information in its application. The detailed documentation would demonstrate that the proposed approach had been followed and that the manufactured component could be installed and used in the facility. NRC's oversight would be to ensure that the approach had been followed and that there were no deficiencies in the process. Disposition of Part 21 reports based on identified non-conformances or defects would follow the current Part 21 process but would not challenge the process for fabrication of large ASME Code Items without an identified owner.