# Implementation of Quality Assurance Criteria and 10 CFR 50.59 for Nuclear Power Plant Components Produced Using Advanced Manufacturing Technologies

## Draft for Public Comment

## AMT Regulatory Basis Document
## AMT Action Plan, Revision 1, Subtask 2A

ENCLOSURE

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# Table of Contents

# Executive Summary

Advanced Manufacturing Technologies (AMTs) of interest to the NRC are those material processing and component fabrication methods that have not been traditionally used in the U.S. nuclear industry and have not yet received NRC approval through NRC-endorsed industry codes and standards or the approval of an industry submittal. This paper documents the NRC staff's generic review of quality assurance (QA) criteria in Title 10 of the *Code of Federal Regulations,* Part 50 (10 CFR Part 50), Appendix B and the process in 10 CFR 50.59 for AMT components. A summary of important considerations for implementation of QA and 10 CFR 50.59 for AMT components is provided below:

- Prior to performing the 10 CFR 50.59 process, the licensee should perform a *technical evaluation* (Section 3.2) to address the suitability of a proposed AMT component for its intended design function. The results of the technical evaluation will determine how the change to use an AMT item is processed in accordance with 10 CFR 50.59. For safety-related applications, the technical evaluation should meet the design control requirements in Criterion III of Appendix B to 10 CFR Part 50. Procurement specification and acceptance of AMT products for safety-related use should be in accordance with Appendix B, Criteria IV and VII, and 10 CFR Part 21. These processes may include commercial grade dedication of AMT products for safety-related use.

- Technical evaluation and procurement of AMT components for safety-related applications may follow established NRC and industry guidance for technical evaluation and commercial grade dedication of *non-identical* (i.e., *alternate*) replacements. Technical evaluation per NRC and industry guidance should be performed for safety-related items (basic components and commercial grade items), augmented quality items, and/or safety significant items categorized under 10 CFR 50.69.

- Since AMT fabrication involves a significant change to the material and manufacturing process when compared to traditional fabrication methods, an AMT item is not *identical* to the original and therefore should not be considered a *like-for-like* replacement (Section 3.2). However, the licensee's technical evaluation process might include an *equivalency evaluation* (Section 3.2.4) to address the impact of the change in design, material, and manufacturing process on the ability of the AMT item to perform its intended design function. If there is no adverse impact on design function, the AMT item may be considered "equivalent" to the original in its ability to perform its intended design function.

- If the design of the original item includes fabrication requirements specified in an *industry consensus code or standard* (Section 3.2.1), the use of an AMT item would likely require that an equivalent code or standard be available covering the AMT fabrication technique for the intended application. Until the AMTs of interest have been formally standardized by the U.S. nuclear industry, an equivalency evaluation may not be the appropriate technical process for a change to use an AMT for such components – an *engineering design modification* (Sections 3.1 and 3.2.4) might be required to address potential adverse impacts of the non-standardized AMT fabrication method on functional performance.

- *Critical characteristics*, as defined in 10 CFR 21.3 (Section 3.1), are identified and verified as part of the commercial grade dedication process for safety-related applications. 10 CFR 21.3 critical characteristics are a subset of the *design characteristics* (Section 3.2.4) that need to be identified and evaluated as part of the equivalency evaluation process for a proposed AMT item. Equivalency evaluation based on comparison of the design characteristics of proposed AMT items with the design characteristics of the original should include a *failure modes and effects analysis* (Section 3.2.3). An equivalency evaluation might also involve an analysis of *bounded technical requirements* (Section 3.2.4) to ensure that applicable component and system design bases are not adversely impacted by the change to use an AMT item.

- The 10 CFR 50.59 applicability determination (Section 4.1) may consider whether the AMT item meets the regulatory definitions in 10 CFR 50.59, Paragraphs (a)(1) and (a)(3) of being a "[c]hange" to the "[f]acility as described in the final safety analysis report (as updated)." With respect to other requirements that may take precedence over 10 CFR 50.59, the ASME Code, Section XI, IWA-4200 requires that items for repair/replacement of ASME Code Class components meet the requirements of the original construction code, later editions of the applicable construction code, or the ASME Code Section III, provided that the later construction code requirements are reconciled with the original construction code. If the AMT fabrication method and product form is not approved for use in a construction code that is authorized for repair/replacement in accordance with ASME Section XI, IWA-4200, this reconciliation cannot occur. In this scenario, a proposed alternative to the ASME Code requirement to implement the AMT repair or replacement activity must be submitted for NRC authorization in accordance with 10 CFR 50.55a(z).

- The 10 CFR 50.59 screening step (Section 4.2) should address whether the use of the AMT item has an adverse impact on the FSAR-described structures, systems, and components (SSC) design function(s) and/or inputs into FSAR-described evaluation methods for demonstrating that design function(s) are accomplished. 10 CFR 50.59 screening should consider the degree of specificity for the material and/or fabrication method in the FSAR. If the FSAR describes an *industry consensus code or standard* for construction/fabrication of the item, and a corresponding consensus document is not available for the AMT component to establish equivalency, the use of the AMT item may need to receive a 10 CFR 50.59 evaluation per the eight criteria in 10 CFR 50.59(c)(2). If a valid equivalency evaluation determines that the AMT item has no adverse impact on FSAR-described SSC design function(s) and associated FSAR-described evaluation methods, the equivalency evaluation may be used as a basis for a 10 CFR 50.59 screening determination that a 10 CFR 50.59(c)(2) evaluation is not required.

- 10 CFR 50.59 screening should consider any changes to numerical material properties or other physical design parameters derived from the technical evaluation. Changes to such properties should be reviewed to determine whether they are changes to *input parameters* or *elements* (Section 4.2) of evaluation methods described in the FSAR for demonstrating the performance of SSC design function(s). The use of an AMT component should be evaluated against the eight criteria in 10 CFR 50.59(c)(2) if there is an adverse change to either an *input parameter* or an *element* of an FSAR-described evaluation method for demonstrating that SSC design function(s) are accomplished.

- 10 CFR 50.59(c)(2) evaluation of AMT components (Section 4.3) will be highly dependent on the specifics of the AMT application. The evaluation of criteria (c)(2)(i) through (c)(2)(vii) should emphasize potential adverse impacts of AMT fabrication on applicable SSC design function(s), including numerical inputs to FSAR-described evaluations for demonstrating that SSC design function(s) are accomplished. For criterion (c)(2)(viii), the evaluation should consider how an input parameter is obtained or derived so it can be determined if the change to the parameter is a change to an element of a methodology. If an input parameter is not an element of the methodology, the change to the input parameter should be evaluated against the first seven criteria in 10 CFR 50.59(c)(2).

**Implementation of Quality Assurance Criteria and 10 CFR 50.59**
**For Nuclear Power Plant Components**
**Produced using Advanced Manufacturing Technologies**
**(AMT Regulatory Basis Document)**
**- AMT Action Plan, Revision 1, Subtask 2A -**

## 1.0 Introduction

Subtask 2A of the U.S. Nuclear Regulatory Commission (NRC) Advanced Manufacturing Technologies (AMT) Action Plan, Revision 1 [1] directed the NRC staff to complete its review of the implementation of Title 10 of the *Code of Federal Regulations,* Part 50, Section 50.59 (10 CFR 50.59), "Changes, Tests and Experiments" [2] for changes in the facility that involve the use of AMT components. The completion of this review required the consideration of comments from NRC stakeholders[1] in the headquarters (HQ) program offices and in the regions. Based on the consideration of these comments, the staff identified that, in addition to 10 CFR 50.59, this review also needed to address quality assurance (QA) criteria and guidance that are applicable to the technical evaluation and procurement of AMT components. Therefore, the deliverable for this subtask is the following paper documenting the staff's review of QA criteria and 10 CFR 50.59 for AMT components. The staff's review is primarily focused on the following two topics.

The first topic is identification of any generic regulatory and technical challenges associated with implementation of QA criteria and 10 CFR 50.59 for AMT components[2]. If challenges are identified, the intent is to communicate these challenges to the appropriate NRC stakeholders. The second topic is identification of any additional support the regional staff might need if they choose to inspect a licensee's implementation of QA criteria and/or 10 CFR 50.59 for AMT components. The goal of the second topic is to provide sufficient information to the regional inspectors to permit them to conduct an efficient and effective review of a licensee's implementation of these requirements, should such a review be deemed appropriate. This includes the development of documentation and briefing materials to support the NRC staff in preparation for and during inspection activities.

<u>Scope and Purpose of this Document</u>

Consistent with the above topics, the purpose of this paper is to document the staff's generic review of how a change to use an AMT component for a safety-related application could be implemented at a plant in accordance with QA requirements in Appendix B to 10 CFR Part 50

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[1] NRC stakeholders for this review include the AMT working group, AMT oversight group, and HQ and regional counterparts who implement regulatory programs addressing QA and 10 CFR 50.59.
[2] Throughout this document, an "AMT component" or "AMT item" is intended to include AMT replacement items (e.g., part "change-outs") and repair activities that use AMT material addition processes (e.g., cold spray deposition) to restore a component to its service condition. Terms such as "component," "item," and "part," etc. are defined in Section 3.0 of this document.

[3], and in accordance with 10 CFR 50.59. The information in this document may be used to support the staff in performing inspections of a licensee's implementation of these requirements for AMT components should such inspections be deemed appropriate.

This paper documents completion of the staff's initial review of QA and 10 CFR 50.59 requirements for AMT applications based on the consideration of NRC stakeholder comments and the current status for industry deployment of AMT items at U.S. nuclear power plants (NPPs). This document does not represent a complete and final analysis of all aspects of these requirements or guidance that might be applicable to the use of AMT components at U.S. NPPs. This document does not create new regulatory requirements or establish new regulatory positions with respect to the use or manufacture of AMT components for nuclear power plants. The scope of this document is limited to the review of existing requirements and guidance to address AMT components and the consideration of potential regulatory and technical challenges. This document may be subject to future revision, as additional insights and operating experience for use of AMT components are gained.

## 2.0 Background and Overview

During the development of the initial AMT Action Plan, the staff was aware that the Additive Manufacturing (AM) process was being used by multiple original equipment manufacturers (OEMs) to produce demonstration components for nuclear applications [4 – 7]. Concurrently, industry groups revised guidance documents to address AM replacement parts [8, 9]. On April 18, 2019, the staff identified the first "candidate AMT application" [10], the Westinghouse Electric Company (WEC) AM thimble plugging device (TPD) hybrid design. The WEC AM TPD was installed in Exelon's Byron Generating Station, Unit 1 during the plant's spring refueling outage (March 2020) via the 10 CFR 50.59 process.

The industry identified the 10 CFR 50.59 process as the regulatory path for the initial AM components, including the WEC AM TPD. In 2019, the staff initiated review of 10 CFR 50.59 for a generic AMT application. Following this initial review, the staff solicited comments from NRC stakeholders in the HQ program offices and in the regions. Based on the consideration of these inputs and comments, the staff determined that a review of 10 CFR 50.59 was not sufficient in and of itself to address potential safety and regulatory process issues for AMT components; a review of relevant QA criteria in Appendix B to 10 CFR Part 50 and associated requirements and guidance was also needed to adequately address the use of AMT components for safety-related and safety-significant applications.

<u>Objective of 10 CFR 50.59</u>

10 CFR 50.59 establishes the conditions under which licensees may make changes to their facilities (e.g., repair or replacement activities using an AMT component) as described in the FSAR[3]; make changes to their procedures as described in the FSAR; and conduct tests or

[3] Throughout this document, use of the term "FSAR" refers to the FSAR, as updated (also called UFSAR), consistent with the definition in 10 CFR 50.59(a)(4).

experiments not described in the FSAR, without obtaining a license amendment pursuant to 10 CFR 50.90. There are other regulatory requirements and processes beyond 10 CFR 50.59 that contribute to determining the safety of a planned change, test, or experiment. Other requirements and processes include elements of procedure review, QA requirements (including design control, procurement, vendor oversight, and document control), technical specifications, post-modification testing, surveillance testing, maintenance activities, in-service inspection, etc., all of which must be adhered to by licensees.

The licensee is responsible for operating the plant safely in accordance with NRC regulations irrespective of whether NRC approval of a planned change, test, or experiment is required. For changes in the facility that involve the use of AMT components, it is important to distinguish between licensee design reviews to address the safety of physical alterations versus licensee 10 CFR 50.59 reviews to determine whether a license amendment is required. These reviews are for different purposes and require different approaches. Licensees are required to design, purchase, fabricate, and test safety-related structures, systems, and components (SSCs) in accordance with QA requirements in Appendix B to 10 CFR Part 50. These QA activities include mandated controls for the selection, procurement, and acceptance of items (including associated fabrication processes) for repair and/or replacement of safety-related SSCs. 10 CFR 50.59 provides the regulatory threshold for determining when NRC approval of this type of change is necessary in order to preserve the basis upon which the NRC issued the facility operating license.

Guidelines addressing implementation of 10 CFR 50.59 are provided in NEI 96-07, Revision 1, November 2000 [11]. The NEI 96-07 guidelines were formally endorsed by NRC Regulatory Guide (RG) 1.187, Revision 0, November 2000 [12]. RG 1.187, Revision 2 [13], issued June 2020, is the latest version and did not change the NRC's endorsement of NEI 96-07. Additional perspectives on the 10 CFR 50.59 process can be found in the NRC white paper dated February 25, 2015 [14]. An industry perspective on the entire engineering change process, which includes QA activities and the 10 CFR 50.59 process, is provided in the Electric Power Research Institute (EPRI) report 1008254 [15][4].

The staff's generic review of the implementation of 10 CFR 50.59 for changes to use AMT components is addressed in Section 4.0 of this document and follows the guidelines in NEI 96-07. Consistent with Section 4.0, "Implementation Guidance," of NEI 96-07, the NRC staff's generic review of the 10 CFR 50.59 process for AMT components is separated into three primary steps: (1) applicability of 10 CFR 50.59, (2) 10 CFR 50.59 screening, and (3) 10 CFR 50.59 evaluation. Figure 1 of NEI 96-07 illustrates this process for all proposed changes, tests, and experiments, which are collectively identified as "activities" in NEI 96-07. As shown in Figure 1 of NEI 96-07, adopted below for a change to use an AMT component, an appropriate technical evaluation of the proposed change must be performed prior to implementing these three 10 CFR 50.59 process steps to ensure the proposed change is "safe and effective."

[4] EPRI report 1008254 [15] has not been reviewed or approved by the NRC.

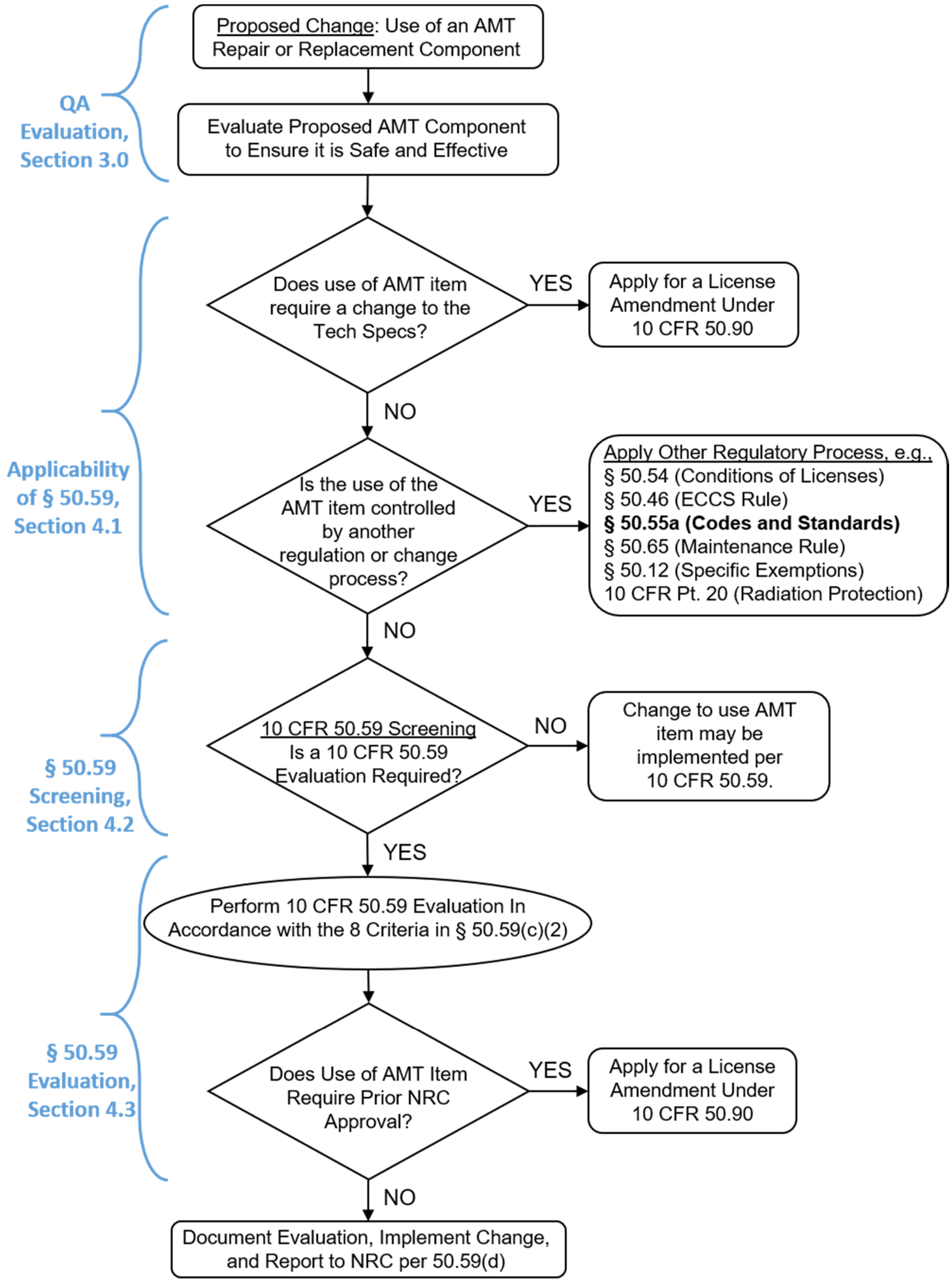


Figure 1 – High-level flowchart depicting the general 10 CFR 50.59 process for an AMT component, based on Figure 1 of NEI 96-07 [11].

Consistent with the 10 CFR 50.59 objective and process, the NRC staff's generic technical review for addressing quality and safety aspects associated with the use of AMT components (i.e., to ensure the change is "safe and effective") precedes the three 10 CFR 50.59 process steps described above. As addressed in the subsequent sections of this document, the results of the technical evaluation will determine how the change to use an AMT component is processed under 10 CFR 50.59 since the 10 CFR 50.59 review relies on adequate technical inputs.

Status of NRC Review for AMT Applications

The AMTs of interest to the NRC include those material processing and component fabrication methods that have not been traditionally used in the U.S. nuclear industry and have yet to be formally standardized by the nuclear industry – specifically, through industry codes and standards that are incorporated by reference in 10 CFR 50.55a, the approval by the NRC of an industry submittal, or through other regulatory processes that have resulted in NRC approval or endorsement. The term AMT is used as an umbrella term to cover a broad range of novel and non-standardized manufacturing methods, fabricated product forms, and in some cases the associated raw materials. As such, the use of AMTs should be considered as a potential factor affecting product design and manufacture over the entire nuclear component supply chain. Accordingly, QA is the appropriate framework for addressing quality and safety aspects for use of AMT components prior to performing a 10 CFR 50.59 evaluation.

The staff's generic review is intended to be technology neutral (i.e., not AMT-specific). The staff recognizes that there is substantial complexity in applying QA and 10 CFR 50.59 requirements generically to newer technologies. Thus, the staff has taken efforts to make representative assumptions when necessary – for example, where information is unknown, or where the QA and 10 CFR 50.59 processes diverge based on plant-specific or component-specific information. However, for plant-specific applications, all relevant information related to specific AMT components and the component that will be replaced needs to be identified and analyzed for site-specific efforts. In general, the identification and review of AMT applications for U.S. NPPs, such as the Byron, Unit 1 AM TPD, can assist the NRC staff in gaining a better understanding of how to perform adequate technical and 10 CFR 50.59 evaluations for AMT components.

## 3.0 Quality Assurance Criteria for AMT Components

Prior to implementation of the 10 CFR 50.59 process, technical evaluation of the suitability of a change to a plant's SSCs—such as that associated with the use of AMT fabrication—must be performed to ensure the proposed change is "safe and effective." As a regulatory basis for performing a technical evaluation of this change, the NRC staff's review is primarily focused on QA criteria in Appendix B to 10 CFR Part 50 [3] and associated requirements in 10 CFR Part 21 [16] related to design control and procurement; these requirements generally govern the selection, specification, and acceptance of AMT items for repairs and/or replacements for *safety-related SSCs*[5]. 10 CFR 50.2 [17] defines *safety-related SSCs*[6] as those SSCs that are relied upon to remain functional during and following design basis events to assure:

(1) The integrity of the reactor coolant pressure boundary (RCPB);
(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
(3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 10 CFR 50.34(a)(1) or 10 CFR 100.11, as applicable.

Appendix B to 10 CFR Part 50 establishes programmatic criteria that are required to ensure the quality of *safety-related SSCs*. Appendix B states that "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that an SSC will perform satisfactorily in service (i.e., that it will perform its safety-related function when required).

### 3.1 Design Control and Procurement for Safety-Related SSCs

NPPs include SSCs designated as either *safety-relate*d or *non-safety-related*. SSCs or *parts*[7] [18] thereof (collectively referred to as *items*[8] [18]) that are accepted for use in performing *safety-related functions* (i.e., *design functions* [18] needed to assure at least one of the three conditions in the 10 CFR 50.2 definition cited above) are identified as *basic components* [16]. Throughout this section, the use of the term *basic component* relies on the definition in 10 CFR Part 21 [16], Section 21.3 (10 CFR 21.3, "Definitions"). Appendix B to 10 CFR Part 50 mandates planned and systematic actions to control the quality of basic components during all phases of product design, manufacture, and procurement.

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[5] NOTE – Definitions for all *italicized terms* pertaining to SSC safety classifications, procurement, design control, and 10 CFR 50.59 can be found in the footnotes or the cited references accompanying the terms.
[6] Throughout this document, the term "*safety-related*" is strictly defined as being applicable to those SSCs and associated design functions that meet the definition in 10 CFR 50.2. All *safety-related SSCs* are thus controlled as *basic components* in accordance with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21.
[7] *Part* refers to the most basic unit from which a component is assembled [18].
[8] *Item* is an all-inclusive term for plant hardware; it can refer to an SSC, a subcomponent, or a constituent part of a component [18].

Appendix B to 10 CFR Part 50 provides the following requirements for design control and procurement of basic components.

- Criterion III, "Design Control," states, in part, that measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components [to which Appendix B applies].

- Criterion IV, "Procurement Document Control," states, in part, that measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors.

- Criterion VII, "Control of Purchased Material, Equipment, and Services," states, in part, that measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

Additional manufacturing criteria are further specified in Appendix B, such as Criterion VIII (Identification and Control of Material, Parts and Components), Criterion IX (Control of Special Processes), Criterion X (Inspection), and Criterion XI (Test Control). The mandated Appendix B controls are achieved by designing and manufacturing basic components in accordance with QA programs that meet the requirements of Appendix B to 10 CFR Part 50.

As addressed in the NRC-endorsed[9] industry guidelines in EPRI Report 3002002982 [18], many situations occur where obtaining a safety-related item (i.e., a basic component) that was designed and manufactured under a QA program complying with Appendix B to 10 CFR Part 50, is not practical. These situations often call for the use of a *commercial grade item* [16], which is an item that was <u>not</u> designed and manufactured under a QA program complying with Appendix B to 10 CFR Part 50. The regulation in 10 CFR 21.3 (Definitions) states that commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected [16]. A common example of a commercial grade item is a component that is purchased based on product specifications published in a supplier's catalog (i.e., an "off the shelf" purchase), where the supplier does not have a QA program complying with Appendix B to 10 CFR Part 50.

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[9] RG 1.164, Revision 0, June 2017 [19] endorses, with exceptions and clarifications, the industry guidelines in EPRI Report 3002002982 [18]. The NRC staff's exceptions and clarifications on the use of these EPRI guidelines are provided in Part C of the RG.

Before it can be used as a basic component, a commercial grade item is required to undergo an acceptance process referred to as *dedication* [16]. *Commercial grade dedication* is a method of accepting commercial grade items for use as basic components in safety-related applications. As addressed in RG 1.164, Revision 0 [19], 10 CFR Part 21 establishes the required framework for the commercial grade item acceptance process under the definition of *dedication* in 10 CFR 21.3. Dedication of a commercial grade item is undertaken to provide reasonable assurance that the item will perform its intended safety-related function. 10 CFR 21.3 states that this assurance is achieved by identifying the *critical characteristics*[10] [16] of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party *dedicating entity* after delivery, supplemented (as necessary) by additional methods specified therein. In all cases, the dedication process must be conducted in accordance with the applicable provisions of Appendix B to 10 CFR Part 50 and is considered complete when the item is designated for use as a basic component.

Generic Letters (GLs) 89-02 [20] and 91-05 [21] provide NRC staff recommendations for licensee commercial grade item procurement and dedication programs. These GLs address methods for complying with the pertinent QA controls for these programs, as specified in Criteria III, IV, and VII of Appendix B to 10 CFR Part 50. The following terminology from GL 91-05 is of particular relevance to AMT replacement items (as well as AMT material additions to items that are to remain in service) for safety-related applications. Specifically, GL 91-05 states that a *like-for-like replacement* is defined as the replacement of an item with an item that is *identical*. One way the replacement item may be considered *identical* (and thus a *like-for-like replacement*) is if the user can verify that there have been no changes in the design, materials, or manufacturing process since procurement of the item being replaced [21]. If differences from the original item are identified in the replacement item, then the replacement item is not *identical*, but *similar* to the item being replaced, and *technical evaluation*[11] is necessary to determine if any changes in the design, material, or the manufacturing process could impact the functional characteristics and ultimately the item's ability to perform its required safety-related function [21]. GL 91-05 states that engineering involvement is necessary for performing these activities. The term *alternate (or alternative) replacement* item[12] is used in NRC Inspection Procedure 43004 [22] and industry guidance documents cited below to identify a replacement item that is not identical to the original (i.e. not a "like-for-like replacement").

[10] As defined in 10 CFR 21.3, *critical characteristics* are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety-related function. As addressed in EPRI Report 3002002982 [18], 10 CFR 21.3 *critical characteristics* for acceptance are just a subset of the "critical characteristics for design" (also called "design characteristics") that need to be evaluated for performing an equivalency evaluation.

[11] Throughout this document, *technical evaluation* means an evaluation performed to ensure that the correct technical requirements for an item are specified in the *procurement document*; this is the definition used in NRC-endorsed EPRI Report 3002002982 [18].

[12] NRC Inspection Procedure 43004, Section 03.01.b refers to a non-identical replacement item as an "alternate replacement item."

With respect to the *critical characteristics* that are verified during the commercial grade dedication process, GL 91-05 states that "the NRC staff has not taken the position that all design requirements must be considered to be critical characteristics." Therefore, a *technical evaluation* of just the critical characteristics for commercial grade dedication, as defined in 10 CFR 21.3, is not sufficient to determine that an *alternate replacement* item is equivalent to the original in its ability to perform its required design function since all design requirements[13] for an alternate replacement item must be considered, not just the critical characteristics.

This important concept is made clear in the NRC-endorsed[14] industry guidelines for commercial grade dedication in EPRI Report 3002002982 [18]. As discussed in this report, commercial grade dedication provides reasonable assurance that the item procured meets the specified requirements and is therefore capable of performing its intended safety-related function(s). The report emphasizes that commercial grade dedication (in particular, the identification and verification of *critical characteristics* for acceptance of the item per 10 CFR 21.3) is <u>not</u> intended for use in establishing the suitability of a design or qualifying a design for the intended safety-related application. The suitability of a certain design for performing a safety-related function, such as a proposed design for an alternate replacement item incorporating AMT fabrication techniques, should be established prior to initiating procurement of the item.

EPRI Report 3002002982 explains how the commercial grade dedication process should consist of *technical evaluation* and an *acceptance process*. A *technical evaluation* should ensure that the correct technical requirements for proposed replacement items are specified in the *procurement document*[15] [16]. *Acceptance process* activities to meet commercial grade dedication requirements in 10 CFR 21.3 must provide reasonable assurance that the item received meets the technical requirements specified in the *procurement document* and is thus capable of performing its intended safety-related functions. This acceptance is achieved by verifying each of the critical characteristics (as defined in 10 CFR 21.3) using one or more of four dedication acceptance methods described in EPRI Report 3002002982. For commercial grade items, the critical characteristics to be verified during the acceptance process are identified and documented as part of the technical evaluation.

EPRI Report 3002002982 states that technical evaluations are not limited to commercial grade items; they also may be performed for non-safety-related items and safety-related items that are supplied as basic components. In particular, the technical evaluation for replacement items (commercial grade items, basic components, and non-safety-related items) should involve a determination of whether a proposed replacement item is *identical* to the original (i.e., a *like-for-like replacement*), or whether it is an *alternate replacement*. For proposed alternate (non-

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[13] The term "design requirements," as used in GL 91-05, is not specifically defined in the GL. However, for this document, it may be interpreted to have the same meaning as the terms, "design characteristics" (defined below) and "critical characteristics for design," which are equivalent terms defined in EPRI Report 3002002982 [18].
[14] EPRI Report 3002002982 is endorsed with exceptions and clarifications in RG 1.164.
[15] As defined in 10 CFR 21.3, *procurement document* means a contract that defines the requirements which basic components must meet in order to be considered acceptable by the purchaser.

identical) replacement items—this includes any potential AMT replacements—the technical evaluation might include an *equivalency evaluation*.

For AMT replacement items, an *equivalency evaluation* might be performed to determine whether any changes in the *design characteristics*[16]—in particular, those resulting from changes to material and fabrication process—will impact the item's ability to perform its required design functions. The equivalency evaluation should determine whether the proposed alternate replacement item is equivalent to the original in its ability to perform its required design functions (i.e., an *equivalent change*), or whether an *engineering design modification* is necessary. If the item is not equivalent to the original, an *engineering design modification* is typically initiated to address the change to the applicable SSC design functions.

### 3.2 Technical Evaluation of AMT Replacement Items

In order to ensure the correct technical and quality requirements for initiating procurement of a proposed repair or replacement item, an adequate *technical evaluation* of the item must first be performed. EPRI Report 1008256 [23] provides guidelines for performing technical evaluations of replacement items as specified in the original industry QA standard, ANSI N18.7/ANS 3.2-1976[17] [24], to support compliance with NRC requirements in Criteria III and IV of Appendix B to 10 CFR Part 50. The guidelines address engineering activities needed to specify technical and quality requirements for generating a *procurement document*; they are recommended for use in conjunction with EPRI Report 3002002982 [18] to address the technical evaluation, procurement specification, and acceptance (i.e., dedication) of commercial grade items for safety-related applications.

The procurement scenarios for proposed AMT replacement items are as follows:

- Safety-related item procured as a basic component;
- Safety-related item procured as a commercial grade item – requires completion of the commercial grade dedication process to be accepted for safety-related use;
- Non-safety-related item procured as an *augmented quality* item;
- Non-safety-related item without augmented quality requirements;

[16] Throughout this document, use of the term *design characteristics* is consistent with the definition in EPRI Report 3002002982 – specifically, *design characteristics* (and the equivalent term "critical characteristics for design") means those properties or attributes that are essential for the item's form, fit, and functional performance. These are the identifiable and/or measurable attributes of a replacement item that provide assurance that the replacement item will perform its design function.

[17] ANSI N18.7/ANS 3.2-1976 is endorsed in RG 1.33, Revision 2, "QA Program Requirements (Operation)," February 1978 [25], as the original standard addressing QA controls for replacement items. RG 1.33, Revision 3 (June 2013) [26] updates the endorsement and referencing for the industry QA standards, but does not change the NRC endorsement of the underlying guidance for the technical evaluation of replacement items.

For each of the above four categories, the NRC and EPRI guidance documents [18, 21, 22, 23] recognize two possibilities for replacement items:

- *Like-for-like replacement* – replacement with an item physically *identical*[18] to the original, or
- *Alternate replacement* – replacement with an item not physically *identical* to the original. Per GL 91-05 [21], technical evaluation of alternate replacement items for safety-related applications is necessary to determine if any changes in the design, material, or the manufacturing process could impact the functional characteristics and ultimately the item's ability to perform its required safety-related function.

AMT items proposed as replacements for non-AMT items (and AMT material additions to items that are to remain in service) should be technically evaluated as alternate items. This is because the use of AMT fabrication methods may involve a significant change to the design, material, and manufacturing process when compared to the processes used in fabrication of components fabricated using traditional methods, as specified in GL 91-05 [21]. Changes to the material and fabrication process could introduce significant changes to intrinsic material properties, and depending on the component, potential changes to other *design characteristics* (e.g., dimensional characteristics, interface tolerances, etc.). Therefore, a proposed AMT item should not be considered "identical" (i.e., a "like-for-like replacement") when compared to the original non-AMT item.

### 3.2.1 Deterministic and Risk-Informed Safety Classifications for SSCs

The traditional *safety classification* of SSCs and their constituent parts as "*safety-related*" versus "*non-safety-related*" (NSR) is based only on whether or not the item performs a design function needed to assure one of the three plant conditions specified in the 10 CFR 50.2 definition of "safety-related SSCs" cited above. This is a deterministic safety classification framework. It is not based on plant risk significance, nor is it based on physical design, qualification requirements, or referencing in plant licensing documents like the technical specifications and the FSAR [27]. The fact that an item is subject to design or qualification requirements in an *industry consensus code or standard*[19] or in 10 CFR Part 50 does not imply that it must be safety-related since NSR items may also be subject to such requirements [27]. The plant technical specifications include limitations for many NSR, but potentially risk-significant, systems

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[18] As addressed in Section 3.1 of this document, a replacement item may be considered *identical* (and thus a *like-for-like replacement*) only if the user can verify that there have been no changes in the design, materials, or manufacturing process since procurement of the item being replaced [21].

[19] *Industry consensus code or standard* refers to industry standards, such as those required by governmental authorities, that specify detailed requirements for design, fabrication, construction, testing, inspection, etc. of passive components. The consensus standards of particular interest include material/fabrication standards that specify detailed requirements for various product forms that are used for construction of NPP components. Such requirements usually include material composition, material processing (e.g., cold work, heat treatments, etc.), material properties, and testing. Examples include the ASME Boiler and Pressure Vessel Code, Section II material specifications (e.g., SA, SB, and SFA specs.), ASTM standards, and ANSI standards.

to minimize situations that would result in the initiation of safety-related functions and to assure the readiness of items required to perform safety-related functions.

In the context of 10 CFR 50.59, NSR design functions described in the FSAR may include risk-significant functions that, if not performed, could initiate a transient that the plant is required to withstand [11]. Therefore, design functions that are risk significant and/or are relied upon to meet regulatory, licensing, or code requirements may be applicable to either safety-related or NSR items.

*Augmented Quality* (AQ) is a plant-specific subset of NSR SSCs that are included within licensees' plant-specific QA programs. AQ items are, by definition, always considered to be NSR since they do not perform safety-related functions [18, 23]. Licensees may volunteer to implement plant-specific QA controls for their NSR-AQ items, typically to address regulatory requirements or commitments associated with performance of NSR functions. Examples of NSR-AQ items might include seismically supported items, potential sources of internally generated missiles, meteorological and post-accident monitoring items, items for spent fuel handling and radwaste management, items for fire protection, and security-related items [27].

Safety classification per the deterministic criteria discussed above is typically done at the design stage; once design functions are established, making updates to traditional classifications is difficult. In 2004, the NRC adopted a new regulation, 10 CFR 50.69 [28], on risk-informed categorization and treatment of plant SSCs. 10 CFR 50.69 does not replace the existing safety-related and NSR classifications. Rather, 10 CFR 50.69 divides these classifications into two risk subcategories based on high or low safety significance. Per 10 CFR 50.69(a), an SSC performs a safety significant function if it performs a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk. 10 CFR 50.69 is specified for voluntary implementation through a plant-specific license amendment. The rule allows for greater flexibility in categorizing the SCCs and their treatment based on a combination of the traditional deterministic safety classification and the level of safety significance (high or low) from risk insights. Under 10 CFR 50.69, there are four risk-informed safety classes (RISCs):

- *RISC-1 SSCs* are safety-related SSCs that the risk-informed categorization process determines to perform safety-significant functions. Licensees must continue to ensure that RISC-1 SSCs perform their safety-significant functions consistent with the categorization process assumptions, including those safety-significant functions that go beyond the functions defined as safety-related for which credit is taken in the categorization process.

- *RISC-2 SSCs* are NSR, although the risk-informed categorization process determines that they perform safety-significant functions. Some RISC-2 SSCs may not have existing special treatment requirements (such as under the NSR-AQ classification). Accordingly, 10 CFR 50.69 requires an increased focus on their safety-significant functions for which credit is taken in the risk-informed categorization process.

- *RISC-3 SSCs* are safety-related SSCs, although the risk-informed categorization process determines that they perform low safety-significant functions. Special treatment requirements, such as some QA criteria in Appendix B to 10 CFR Part 50, are removed for RISC-3 SSCs and replaced with more flexible requirements. These SSCs are still expected to perform their safety-related functions under design basis conditions, albeit at a reduced level of assurance compared to traditional safety-related SSCs. 10 CFR 50.69 does not allow RISC-3 SSCs to lose their functional capability.

- Finally, *RISC-4 SSCs* are NSR, and the risk-informed categorization process determines they perform low safety-significant functions. 10 CFR 50.69 does not impose alternative treatment requirements for RISC-4 SSCs. However, as with the RISC-3 SSCs, changes to RISC-4 SSC design bases must be made in accordance with applicable design controls and licensing basis controls, such as 10 CFR 50.59.

The technical evaluation process for proposed alternate repair or replacement items includes *functional classification*[20] and *equivalency evaluation*[21] [18, 23] to support subsequent procurement specification. Technical evaluation elements are considered to be "design control activities" implemented to support Criterion III of Appendix B to 10 CFR Part 50, whereas specification of technical and quality requirements in a procurement document (based on the results of the technical evaluation) is to support Criterion IV.

EPRI Report 1008256 emphasizes that licensees should determine the extent to which equivalency evaluations may be needed for alternate NSR items. The recommended factors licensees should consider when making this determination include risk significance, importance to plant reliability, impact on personnel safety, importance to plant security, and importance to operating performance. Since the technical evaluation process for AMT items <u>always</u> involves determining the suitability of a proposed AMT item for performing an intended design function, this process may be used for all deterministic and risk-informed SSC safety classes discussed above for which design and licensing controls are required. As noted above, a plant's voluntary use of the risk-informed safety categorization framework in 10 CFR 50.69 does not alter its obligation to control changes to the applicable SSC *design bases*[22].

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[20] In this document, the term *functional classification* collectively refers to the determination of an item's design function, safety classification, and functional mode, as addressed further below. This is consistent with the functional classification process described in Section 3.2 of EPRI Report 1008256.
[21] EPRI Reports 3002002982 and 1008256 [18, 23] define *equivalency evaluation* as a technical evaluation performed to confirm that an alternate replacement item not identical to the original item will satisfactorily perform the design function of the original item.
[22] As defined in 10 CFR 50.2, *design bases* means information which identifies the specific functions to be performed by an SSC and the specific values or ranges of values chosen for controlling parameters as reference bounds for design.

### 3.2.2 Functional Classification of Components and Parts

Section 3.2 of EPRI Report 1008256 includes guidance for determining *design functions*, *safety classifications* (*safety-related* vs. *non-safety-related*), and *functional modes* (i.e., *active* vs. *passive*) of components and parts. EPRI Report 1008256 clearly distinguishes between the functional classification of "*components*" versus the functional classification of the constituent "*parts*" of components.

The EPRI Report 1008256 guidance is based on a hierarchy of *structures*/*systems*, *components*, subcomponents, and individual *parts* of components, where *parts* represent the most basic unit of assembly. AMT repair and/or replacement items could potentially be applied at the component, subcomponent, or part level within the SSC hierarchy – that is, a proposed AMT item could be a component or subcomponent of a larger SSC (the "parent" SSC), or it could be an individual part of a component (the "parent" component).

With respect to an item's *functional mode* (*active* vs. *passive*), the review herein considers all potential AMT items as "passive" since the AMTs of interest generally encompass fabrication of items that do not undergo "a mechanical or electrical change of state" in performing their design functions [18, 23]. In other words, a proposed AMT item would not, of itself[23], perform mechanical motion or cause the flow of electrical power in order to function as designed [27]. Further, the use of passive AMT items is generally considered for parent SSCs that perform structural or mechanical design functions, as opposed to systems and components that perform electrical or electronic control functions. For passive structural or mechanical items, knowledge of the item's design function and safety classification should provide sufficient information to determine the effect(s) of a loss of structural integrity on the design function performance of the parent SSC.

For components, design functions and safety classifications might be determined directly from existing design documents. However, if this information cannot be readily determined from the existing design records, EPRI Report 1008256 provides guidance for determining component-level design functions and safety classifications based on review of the design functions of the parent system and evaluating the component's role in supporting the parent system design functions. For safety-related systems, the component's role in supporting the parent system's safety-related functions should be evaluated to determine the component's safety classification, as per the following criteria.

- Components that have safety-related functions or that are determined to affect the performance of the parent system's safety-related functions should be classified as safety-related.

[23] For this AMT review, a passive item could be a part of a larger active component. For example, a pump or a valve is an active component that performs a mechanical design function. However, the pump impeller blade or valve stem is passive, since the part does not, of itself, perform mechanical motion (even though it is in motion) during the performance of its design function.

- Components that do not have safety-related functions and do not affect the parent system's safety-related functions would be classified as non-safety-related (NSR) but might be further evaluated to determine if they are NSR-AQ.

As addressed in EPRI Report 1008256, parent SSC design functions and safety classifications may be determined based on a review of design and licensing documentation (e.g., FSAR, technical specifications, design specifications, system descriptions, plant engineering drawings and analyses), physical location in the plant, operating procedures, equipment supplier data, and/or other documents as applicable.

For proposed replacements at the individual part level, the part's function and its effects on the design functions of the parent component must be determined. The parts of a component are classified according to the following criteria:

- If the parent component is classified as NSR, the constituent part is also NSR.
- If the parent component is safety-related, an evaluation is needed to determine the part's role in the performance of the parent component's safety-related functions:
  - If the part is required for the parent component to perform its safety-related function, the part is safety-related.
  - If not, an additional evaluation is needed to determine if the part's *failure modes* would affect the parent component's safety-related function.
    - Parts with failure modes that affect the parent component's safety-related functions are safety-related.
    - If the part's failure modes do not affect parent component safety-related functions, the part may be classified to a safety level below that of the parent component (NSR or NSR-AQ), as appropriate.

Given knowledge of a parent SSC's design function and safety classification, the *failure modes and effects analysis (FMEA)*, discussed below, may be used as a basis for determining the design function and safety classification of a subsidiary item (e.g., a component, subcomponent, or part) for which an alternate replacement item is proposed.

### 3.2.3 Failure Modes and Effects Analysis

As addressed in EPRI Report 1008256, the *FMEA* is performed to determine credible *failure mechanisms* and associated *failure modes* for a proposed item, and the "effects" those failure modes have on the design function of the parent SSC.

For passive structural items, credible failure mechanisms often tend to degrade the item's ability to support the design function of the parent SSC over time. The credible failure mechanisms of an item are identified based on its physical design characteristics, service conditions, and the design function of the parent SSC. Failure modes are the actual failed conditions for an item that result from the credible failure mechanisms – e.g., the actual loss of an item's structural integrity. The "failure effects" on the parent SSC are determined by evaluating the item's failure modes against the design function of the parent SSC – specifically, an item's failure modes are evaluated to determine whether they might prevent or adversely affect the accomplishment of the applicable SSC design function. At the component level, the FMEA evaluates the effects that component failures have on the parent system design functions. At the part-level, the FMEA evaluates the effects that part failures have on the parent component's design function.

Examples of credible failure mechanisms and associated failure modes for passive structural or mechanical items include:

- Metal fatigue (failure mechanism) that could lead to the fracture (failure mode) of bolting (item) under cyclic loading (service condition) of sufficient load intensity and/or number of accumulated load cycles.
- Localized corrosion, such as pitting (failure mechanism), that could lead to unacceptable thru-wall leakage (failure mode) of a fluid-containing component in a chemically reactive process environment (service condition).

Failure mechanisms and associated failure modes need not be considered if the failure mechanism is not credible. Examples of non-credible failure mechanisms that do not need to be considered include:

- Fatigue-induced fracture is not credible if the system design bases ensure that the intensity and/or number of load cycles for cyclic loading of the item are below the cumulative fatigue usage limit.
- Corrosion leading to thru-wall leakage is not credible if the material of construction and its process environment are within required metallurgical and electrochemical limits.

For safety classifications of components and parts, the FMEA should be used to provide a basis for classifying subsidiary items to a safety level below that of the parent SSC. In order to justify a lower safety classification, the FMEA should demonstrate that the item has no direct role in performing the safety-related (or NSR-AQ) design function of the parent SSC and that applicable failure modes have no effect on the safety-related (or NSR-AQ) design function for the parent SSC.

For proposed alternate replacement items, such as AMT items, the FMEA should be used as a basis for selecting *design characteristics* for performing an *equivalency evaluation*, as discussed further below.

### 3.2.4 Equivalency Evaluation of Alternate Replacement Items

EPRI Report 1008256 emphasizes that a valid *equivalency evaluation* of a proposed alternate replacement item must demonstrate that the design function(s) of the original item will be maintained. If the design function(s) will be maintained, the processes for *engineering design modification* would not need to be performed to address changes to the item's physical design characteristics.

The selection of an alternate replacement item based on a valid equivalency evaluation[24] involves a change to one or more physical design characteristics, whereas SSC design function(s) have not been altered. For this reason, use of an alternate replacement item based on a valid equivalency evaluation is sometimes referred to in industry guidance as an "*equivalent change*," as opposed to an *engineering design modification*. EPRI Report 1008256 also uses the term "engineering design change" to refer to changes that affect SSC design function(s). As used in this document, the term *engineering design modification* refers to a change that may affect SSC design function(s).

Along these same lines, ANSI N18.7/ANS 3.2-1976 [24], Section 5.2.13 states:

> "…procedures shall be established and implemented to assure that purchased materials and components associated with safety-related structures or systems <u>are purchased to specification and codes equivalent to those specified for the original equipment</u>, or those specified by a properly reviewed and approved revision. In those cases where the original item or part is found to be commercially "off the shelf," or without specifically identified quality assurance requirements, spare or replacement parts may be similarly procured but care shall be exercised to assure at least equivalent performance. In those cases where the Quality Assurance requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall assure that interface, interchangeability, safety, fit and function requirements are not adversely affected or contrary to applicable regulatory or code requirements. The results of these evaluations <u>shall be documented</u>." (Emphasis Added)

For the AMT review, it is emphasized that this QA standard includes a requirement that replacement materials and components for safety-related items are purchased to codes/specifications equivalent to those for the original items, or those specified by an approved revision. The design requirements for the original item might include a requirement that the construction and/or fabrication of the item conform to an *industry consensus code or standard;* as discussed below, a comparable requirement may be needed for the AMT repair or replacement item.

The use of an AMT repair or replacement item may involve significant changes to the design, material, and fabrication process. If the design of the original item includes construction and/or fabrication requirements specified in an *industry consensus code or standard*[25], the use of an

[24] As addressed in Section 3.1 of this document, an equivalency evaluation is not itself a sufficient basis for acceptance of commercial grade items for safety-related use. Acceptance of commercial grade products for safety-related use must also include dedication acceptance activities to verify that the item received meets the requirements specified in the procurement document, consistent with 10 CFR 21.3 and Appendix B, Criterion VII.

[25] Examples include those published in the ASME Boiler and Pressure Vessel Code, ASTM International, or ANSI standards.

AMT item would likely require that an equivalent code or standard be available covering the AMT material and fabrication technique for the intended application. The AMTs of interest to the NRC include material processing/fabrication methods that, at the present time, have yet to be formally standardized by the U.S. nuclear industry (i.e., through consensus codes and standards covering design, construction, and fabrication of NPP components). Therefore, for these cases, an equivalency evaluation may not be the appropriate technical process for a change to use an AMT replacement item; rather, an engineering design modification might be required to address potential adverse impacts of the non-standardized AMT fabrication method on the performance of intended SSC design function(s).

For cases where original design requirements for an item do not require conformance with a construction/fabrication consensus code or standard, EPRI Report 1008256 describes two approaches for performing an equivalency evaluation for a proposed alternate replacement using an AMT component. The selection of the best approach should be based on factors such as the complexity of the item, the item's design functions, and the available design/technical information for the original item. The two approaches are:

1. Evaluation of the effects of the proposed alternate replacement item on the *bounded technical requirements* for the parent SSC.
2. Determination of the *design characteristics*[26] for the item and comparison of the *design characteristics* for the proposed alternate replacement item with the *design characteristics* for the original item that is being replaced.

*Evaluation of Effects on Bounded Technical Requirements*

The first approach should ensure that the proposed alternate AMT component will not adversely affect *bounded technical requirements* for the original component and/or its parent system. Bounded technical requirements are those technical requirements that are necessary to ensure that the applicable SSC *design bases* and plant licensing bases are maintained – accordingly, this method is an established technical basis for making a favorable 10 CFR 50.59 screening determination for equivalent changes to SSCs that are described in the FSAR, as addressed in EPRI Report 1008254 [15].

Per EPRI Report 1008256 [23], the first approach is more appropriate for evaluation of proposed alternate components in plant systems where the design output documents (e.g., engineering specifications, drawings, etc.) are typically controlled by the licensee's design control program. The existing technical requirements are used to determine whether the replacement component is equivalent or requires an engineering design modification. The bounded technical requirements approach is addressed in further detail in EPRI Report 1008254 [15]. For proposed AMT items, the bounded technical requirements approach might be appropriate for the replacement of higher complexity components (potentially consisting of

[26] See Footnote 16 regarding use and definition of the term "design characteristics".

one or more AMT items) in a plant system where existing design documentation provides well-defined performance-based technical requirements.

*Determination and Comparison of Design Characteristics*

The second approach addressed in EPRI Report 1008256 requires the determination of design characteristics for the item and comparison of the design characteristics for the original item with the corresponding characteristics for the proposed alternate replacement item. This process is used to determine if the alternate item is "equal to or better than the original." Design characteristics include both physical and functional properties that describe the item's "form" (e.g., material, fabrication method, geometry); "fit" (interface with other items within the parent SSC); and "functional performance." This approach is often more appropriate for evaluation of alternate items at the subcomponent and part levels where the existing technical requirements for the item are not well defined under the licensee's design control program – this is often the case for subcomponents and parts of plant components. Any differences in physical properties identified as a result of the comparison of design characteristics, including those caused by changes to fabrication method, should be evaluated for their effects on the item's design function, credible failure mechanisms, and failure modes, as determined through the functional classification and FMEA processes addressed above.

The required design characteristics for an item are derived from the item's design function and safety classification, based on the results of the FMEA. The FMEA links the item's design function to the physical characteristics and properties (including those determined by the fabrication method) necessary for it to perform those functions. The bounding service conditions for each function and failure mode, including environmental and seismic conditions, should be established in accordance with applicable regulatory requirements (e.g., 10 CFR 50.49 for applications requiring environmental qualification). The bounding service conditions are parameters such as loading, temperature, humidity, exposure to elements, and radiation that influence an item's ability to perform its function or that contribute to its credible failure mechanisms.

To perform a valid comparison of design characteristics, it is necessary to determine the physical properties and attributes (both numerical properties and qualitative attributes, as applicable) that an item must possess to perform its design function under the bounding service conditions. For proposed AMT items, determination of material properties and other physical design characteristics associated with this new fabrication method that are relied on mitigate failure mechanisms and ensure functionality under bounding service conditions are critical to performing a valid equivalency evaluation. Determination of design characteristics should include the item's interchangeability and interaction with other SSCs and their constituent parts. EPRI Report 1008256 provides detailed guidance and examples on how to determine and compare design characteristics for passive items that are required to maintain structural integrity in order to accomplish their design functions. These guidelines and examples are relevant to the use of AMT replacement items for the structural applications considered herein.

*Additional Considerations for AMT Components*

For an AMT item used as an alternate replacement for a traditionally fabricated (i.e., non-AMT) item (or for an AMT process that adds material to repair a component), a valid equivalency evaluation should consider the potential for the AMT fabrication process to cause significant changes to the material structure (i.e., macro and microstructural characteristics) and material properties. Examples of changes to material structure include macro and microstructural characteristics that are inherent to the AMT fabrication process, such as grain structure, material phase structure, porosity, and fabrication defects (e.g., defect sizes, shapes, density and distribution of defects, etc.). The potential for these types of changes to impact material properties and associated safety function performance should be addressed as part of the analysis. The potential impact of the AMT fabrication process on material properties may include (but is not limited to) yield strength, ductility, hardness, fracture toughness, anisotropy, thermal properties, surface characteristics, and resistance to stress corrosion cracking and/or environmentally-assisted fatigue. These are just examples of properties, both qualitative and numerical, that could be impacted by a change in the component fabrication process to AMT; changes to such properties could have the potential to impact the item's functional performance under design basis conditions. As part of equivalence determination, the evaluation should consider the variables in the AMT fabrication process that would affect the material characteristics and the material's performance.

## 3.3 Procurement Documentation and Interface with the 10 CFR 50.59 Process

The results of the item's functional classification, FMEA, and equivalency evaluation should be documented in accordance with the licensee's QA program. EPRI Report 1008256 provides recommendations for the technical information to be included in plant documentation and in the procurement specification. When the technical evaluation activities described above are complete, sufficient information should be available to allow for the generation of an adequate *procurement document* to specify the licensee's requirements for the alternate repair or replacement item. The procurement document should specify technical requirements, quality requirements, and supplier documentation requirements.

The technical requirements specified in the procurement document should directly relate to the documented results of the functional classification, FMEA, and equivalency evaluation, as addressed in EPRI Report 1008256 [23]. For AMT replacements, the technical requirements specified in the procurement document should include the required design characteristics, the type of AMT fabrication process used for producing the item, the manufacturing process variables needed to ensure required design characteristics, and the bounding conditions that the item is required to satisfy [23].

Quality requirements for repair/replacement items are also specified in the procurement document to invoke the necessary supplier controls over manufacturing processes, design characteristics, sub-tier suppliers, and material sources to ensure that technical requirements are met. Quality requirements depend on the item's role in performing safety functions, technical complexity, applicability of production qualification requirements, and special manufacturing processes.  Specific quality requirements may be imposed to control the item's design characteristics via the manufacturing process.  AMT process variables for safety-related, safety-significant, and NSR-AQ components and parts should be controlled to provide adequate confidence that the product has the required design characteristics.  The applicable plant-specific quality requirements and commitments from licensee's QA program (including risk-informed QA program requirements) and FSAR should be included, as necessary, in the procurement specification to ensure compliance with applicable regulatory requirements.

For safety-related items procured as basic components, NRC QA controls (e.g., Appendix B to 10 CFR Part 50 and 10 CFR Part 21) are required to be imposed on the supplier, whereas those requirements normally are not applicable in the manufacture of commercial grade items. It is for this reason that the use of commercial grade items for safety-related applications requires the completion of the commercial grade dedication process to satisfy the applicable requirements in 10 CFR 21.3 and Appendix B to 10 CFR Part 50, as addressed in Section 3.1 of this document.  An equivalency evaluation is not itself a sufficient basis for accepting a commercial grade item for a safety-related design function.  Dedication of commercial grade products for safety-related use must also include *acceptance process* activities to verify that the item received meets the requirements specified in the procurement document, consistent with 10 CFR 21.3 and Appendix B, Criterion VII.  EPRI Report 3002002982 [18], as endorsed by RG 1.164 [19], provides detailed guidance concerning the acceptance of commercial grade items for safety-related applications.

<u>Interface with 10 CFR 50.59</u>

The results of the technical evaluation of the AMT item should be used to inform the 10 CFR 50.59 review, as addressed in Section 4.0 of this document.  The technical evaluation results, including both qualitative information and numerical results, should be used to determine the impact on applicable SSC design functions, as described in the FSAR, as well as associated analytical evaluations for demonstrating that FSAR-described design functions are accomplished.

A valid equivalency evaluation for a proposed AMT replacement item may demonstrate that the item is equivalent to the original in its ability to perform the required SSC design function(s).  As addressed in NEI 96-07 and EPRI Report 1008254 [11,15], the equivalency evaluation may constitute a sufficient technical basis for making a favorable 10 CFR 50.59 screening determination that no evaluation per the eight criteria in 10 CFR 50.59(c)(2) is required.  The use of an equivalency evaluation as a basis for making a 10 CFR 50.59 screening determination is addressed in further detail in Section 4.2 of this document.

If the technical evaluation determines that the proposed AMT replacement item is <u>not</u> equivalent to the original (or if the evaluation cannot determine equivalence), the use of the AMT item should be evaluated as an engineering modification to the applicable SSC design function(s). For these cases, the change to use the AMT item should be evaluated for its potential adverse impacts on SSC design bases according to relevant design criteria, regulatory requirements, and QA processes covering engineering design modifications. The potential adverse impacts of the AMT design modification on the FSAR-described design function(s) should be evaluated in accordance with the requirements of 10 CFR 50.59(c)(2), as addressed in Sections 4.2 and 4.3 of this document.

## 4.0 10 CFR 50.59 Process

After determining that a proposed change is safe and effective through appropriate QA, engineering and technical evaluations, the 10 CFR 50.59 process is applied to determine if a license amendment is required prior to implementation [11]. The NRC staff's generic review of the 10 CFR 50.59 process for AMT applications follows the guidance in Section 4.0, "Implementation Guidance," of NEI 96-07 by addressing (1) applicability of 10 CFR 50.59, (2) 10 CFR 50.59 screening, and (3) 10 CFR 50.59 evaluation. For the purpose of this generic review of the 10 CFR 50.59 process, it is assumed that an acceptable technical evaluation of the change to use an AMT component has been performed – specifically, if the AMT item is for a *safety-related* application, the licensee's use of the item is compliant with all applicable QA requirements in Appendix B to 10 CFR Part 50 and 10 CFR Part 21. It is also assumed that the AMT material/fabrication method has not yet been codified by the U.S. nuclear industry in a national consensus standard that has been formally endorsed by the NRC.

### 4.1 Applicability of 10 CFR 50.59

The first step in applying 10 CFR 50.59 to an AMT component is establishing the applicability of the regulation. As addressed in Section 4.1, "Applicability," of NEI 96-07, 10 CFR 50.59 is applicable to changes to the facility or procedures as described in the FSAR and to tests or experiments not described in the FSAR. Use of an AMT component could fall within the regulatory definition of change to the facility as described in the FSAR. As defined in 10 CFR 50.59(a)(1), a change is "a modification or addition to, or removal from, the facility or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished." Per 10 CFR 50.59(a)(3), facility as described in the FSAR[27] refers to the SSCs that are described in the FSAR; the design and performance requirements for such SSCs described in the FSAR; and the evaluations or methods of evaluation included in the FSAR for such SSCs which demonstrate that their intended function(s) will be accomplished. Consistent with Sections 4.1 and 4.2 of NEI 96-07, both the 10 CFR 50.59 applicability review and the 10 CFR 50.59 screening review address whether a change to use an AMT item constitutes a change to the facility as described in the FSAR. Section 4.2 below addresses the aspects of this determination relevant to the screening review, while the following paragraphs address the aspects relevant to the applicability determination.

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[27] The regulation at 10 CFR 50.59(a)(3) uses the phrase "FSAR (as updated)." Consistent with the discussion in Footnote 3, this document will instead use "FSAR" to avoid confusion.

Per 10 CFR 50.59(c)(1)(i), if the use of the AMT item requires a change to the technical specifications, the change must be made via the 10 CFR 50.90 license amendment process. 10 CFR 50.59(c)(4) further establishes that, "[t]he provisions in [10 CFR 50.59] do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes." NEI 96-07, Section 4.1.1, "Applicability to Licensee Activities," lists examples of regulations that meet the intent of 10 CFR 50.59(c)(4) and may take precedence over 10 CFR 50.59 for control of specific changes.

Section 4.1.2 of NEI 96-07 addresses the applicability of 10 CFR 50.65 (the Maintenance Rule). Maintenance activities are activities that restore SSCs to their as-designed condition, including activities that implement approved design changes. Maintenance activities that restore SSCs to their as-designed condition (e.g., identical replacements) are not subject to 10 CFR 50.59, but are instead subject to the provisions of 10 CFR 50.65(a)(4) as well as plant technical specifications. As discussed in Section 3.0 of this document, however, a change to use an AMT component is not an identical replacement. Therefore, such a change is not a maintenance activity subject to the Maintenance Rule. Consequently, 10 CFR 50.59 will take precedence over the Maintenance Rule.

10 CFR 50.55a, "Codes and Standards" [29] may establish more specific criteria for accomplishing the change to use an AMT item. For example, 10 CFR 50.55a(g) requires that inservice inspection (ISI) for American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code Class 1, Class 2, and Class 3 components (including supports); Class MC (metal containment); and Class CC (concrete containment) components meet the requirements, to the extent practical as defined in the regulation, set forth in Section XI of editions and addenda of the ASME B&PV Code, with certain limitations and exclusions as noted in 10 CFR 50.55a(g). Section XI of the ASME B&PV Code (ASME Section XI) includes Article IWA-4200, "Items for Repair / Replacement Activities." IWA-4200 requires that items used for repair or replacement activities meet the Owner's Requirements and the original construction code, a later edition of the applicable construction code, or the ASME B&PV Code, Section III, provided the codes are reconciled with the original construction code.

AMTs cover a broad range of novel and non-standardized manufacturing methods, fabricated product forms, and in some cases the associated raw materials. In the context of ASME Section XI, allowable metallic materials are limited to those manufactured to SA, SB, or SFA material specifications, other material specifications permitted in Section XI, or material specifications permitted in the applicable construction code. If reconciliation of the AMT repair or replacement item with the construction code is not possible, the AMT repair/replacement activity would constitute a proposed Code alternative. In this scenario, the proposed Code alternative to use the AMT repair/replacement would need to be submitted for NRC authorization in accordance with 10 CFR 50.55a(z). On this basis, 10 CFR 50.55a(g) establishes more specific criteria for accomplishing the change to use an AMT item and, therefore, takes precedence of over 10 CFR 50.59, pursuant to 10 CFR 50.59(c)(4).

Importantly, the above discussion of 10 CFR 50.55a(g) ISI requirements is limited to whether this regulation takes precedence over 10 CFR 50.59, per 10 CFR 50.59(c)(4). It is emphasized that during the technical evaluation of a change to design characteristics (covered in Section 3.0), licensees are required to ensure applicable codes and standards for construction and fabrication of SSCs are satisfied. This includes codes and standards required by 10 CFR 50.55a.

A change to use an AMT component may require related information in the FSAR to be updated. To the extent that FSAR changes are directly related to a change implemented via another regulation, applying 10 CFR 50.59 to that FSAR change is not required. Rather, such FSAR changes should be submitted to the NRC as part of the required FSAR update, per 10 CFR 50.71(e). Changes to the FSAR that are not related to a change implemented via another regulation may or may not require review under 10 CFR 50.59 considering the definition in 10 CFR 50.59(a)(3).

As an example of a 10 CFR 50.59 applicability determination, the WEC AM TPD installed in Byron, Unit 1 is an alternate (i.e., non-identical) replacement for a non-safety-related, non-Code Class component. The original "thimble plugging assemblies" are described directly in the Byron FSAR. The change to use the WEC AM TPD at Byron did not affect the plant technical specifications. Therefore, 10 CFR 50.59 was applicable to the licensee's installation of the WEC AM TPD.

### 4.2 10 CFR 50.59 Screening

Once it is established that 10 CFR 50.59 is applicable, the second step in applying the regulation for a change to use an AMT component is screening. 10 CFR 50.59 screening should determine if the use of an AMT component is required to be evaluated against the eight criteria in 10 CFR 50.59(c)(2).

As addressed in Section 4.2, "Screening," of NEI 96-07, 10 CFR 50.59 screening determinations are made based on engineering, design, and other technical information supporting the change. Technical information which demonstrates that changes have either no effect or a positive effect[28] on FSAR-described SSC design functions, methods of performing or controlling SSC design functions, or evaluations to demonstrate that intended SSC design functions will be accomplished may be used as the basis for "screening out" the change from receiving evaluation per the eight criteria in 10 CFR 50.59(c)(2). Conversely, changes that could have an adverse effect on FSAR-described SSC design functions, methods of performing or controlling SSC design functions, or evaluations to demonstrate that intended SSC design

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[28] Section 4.2.1 of NEI 96-07 caveats this, however, by noting that any change that alters a design basis limit for a fission product barrier, positively or negatively, is considered adverse and must be screened in. Section 4.2.1.1 of NEI 96-07 states that this is because 10 CFR 50.59(c)(2)(vii) requires prior NRC approval any time a proposed change would "exceed or alter" a design basis limit for a fission product barrier.

functions will be accomplished "screen[s] in" and thus requires a 10 CFR 50.59 evaluation per the eight criteria in 10 CFR 50.59(c)(2).

Since a proposed AMT component may constitute a change to the facility, as described in the FSAR, the most relevant 10 CFR 50.59 screening guidance is found in Section 4.2.1.1 of NEI 96-07. This section addresses screening to determine whether a proposed change adversely affects FSAR-described SSC design function(s). The screening guidance in Section 4.2.1.3 of NEI 96-07 may also become relevant if the use of the AMT item requires a change to an element of an evaluation method described in the FSAR for demonstrating that the intended SSC design function(s) will be accomplished. A flowchart illustrating a hypothetical application of this screening guidance for a generic AMT replacement component is provided in Figure 3. The review of 10 CFR 50.59 screening for AMT components below follows the hypothetical process illustrated in Figure 3.

<u>Technical Evaluation Inputs.</u> As addressed previously, the 10 CFR 50.59 process does not constitute a technical evaluation of the safety of the proposed change. For physical changes to SSCs, such as those associated with the use of AMT components, an acceptable technical evaluation of the impact of the change on SSC design function(s) should be completed prior to entering the 10 CFR 50.59 process.[29] A valid technical evaluation should provide the results needed to support an acceptable 10 CFR 50.59 screening determination. The discussion below addresses how the results of the technical evaluation for an AMT item may be used to support the 10 CFR 50.59 screening, considering guidance in Section 4.2.1.1 and 4.2.1.3 of NEI 96-07.

<u>Consensus Codes and Standards.</u> An FSAR could contain information pertinent to the material and/or fabrication of the component. The application of the screening criteria should consider the degree of specificity pertinent to the material and/or fabrication of the AMT component. The application of the screening criteria should consider potential implications resulting from the lack of *industry consensus codes and standards* supporting the fabrication of the AMT component. Where the FSAR describes an *industry consensus code or standard* that specifies traditional (non-AMT) fabrication for the component (e.g., detailed specifications for product forms,[30] such as castings, wrought products, etc.), and a corresponding consensus standard is not available for the AMT component to establish equivalency, the use of the AMT component may need to screen in and be evaluated against the eight criteria in 10 CFR 50.59(c)(2). Alternatively, if the FSAR specifies a generic type of material (e.g., a 300-series stainless steel) for which an AMT may be used, without indicating an industry consensus code or standard that requires traditional fabrication, there would be no specific control over the fabrication method.

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[29] Consistent with Figure 1 of NEI 96-07, the 10 CFR 50.59 process is applied after determining the proposed change is "safe and effective" through the appropriate engineering and technical evaluations.
[30] Such specifications usually include material composition, material processing (e.g., cold work, heat treatments, etc.), material properties, and testing. Examples include the ASME B&PV Code, Section II material specifications (e.g., SA, SB, and SFA specs.), ASTM standards, and ANSI standards.

Impact on FSAR-Described SSC Design Function(s). Even if the FSAR does not reference an industry consensus code or standard that requires traditional (non-AMT) fabrication for the component, it is still important that 10 CFR 50.59 screening for AMT items address the potential for adverse effects on FSAR-described SSC design function(s). For this purpose, Section 4.2.1.1 of NEI 96-07 identifies that an "[e]quivalent replacement is a type of change to the facility that does not alter the [FSAR-described] design functions of SSCs". This section also states, "[l]icensee equivalence assessments, e.g., consideration of performance/operating characteristics and other factors, may thus form the basis for screening determinations that no 10 CFR 50.59 evaluation is required." It is clear from the context, definitions, and associated example (Example 4) in NEI 96-07 that the *equivalency evaluation* for alternate items, as described in Section 3.0 of this document, may be considered as a technical input into the 10 CFR 50.59 screening determination. In order to support a favorable 10 CFR 50.59 screening determination, the equivalency evaluation of an AMT component should demonstrate that there is no adverse effect on the applicable FSAR-described SSC design functions.

Section 4.2.1.1 of NEI 96-07 provides guidance on screening of changes affecting SSCs that are not explicitly described in the FSAR. A change to use an AMT item for a component, subcomponent, or part that is not explicitly described in the FSAR could affect the design function of a larger SSC (of which the item is a part) that is explicitly described in the FSAR. For such cases, Section 4.2.1.1 states that the approach for determining whether this involves a change to the facility as described in the FSAR is to consider the larger, FSAR-described SSC, of which the item is a part. If the use of the AMT item adversely affects the FSAR-described design function of the larger SSC, method of performing or controlling the SSC design function, or an evaluation demonstrating that intended SSC design functions will be accomplished, then a 10 CFR 50.59 evaluation should be performed.

If the technical evaluation discussed in Section 3.0 cannot determine equivalence or determines that use of AMT fabrication involves a modification to an FSAR-described design function, then the potential adverse effects of the AMT item should be evaluated against the eight criteria in 10 CFR 50.59(c)(2).

Changes to Numerical Inputs for FSAR-Described Evaluations. The change to use an AMT component may be expected to involve a change to one or more numerical inputs, such as material properties and/or other physical design parameters (e.g., dimensions, mechanical tolerances, surface characteristics, etc.). In general, technical evaluation of changes to such numerical inputs should be used to support the 10 CFR 50.59 screening determination of whether there is an adverse impact on SSC design function(s). These types of physical property changes could also impact evaluations or methods of evaluation described in the FSAR for demonstrating that intended function(s) will be accomplished.

The 10 CFR 50.59 screening determination should consider whether a change to a numerical input (as obtained from the technical evaluation) corresponds to a change to an *input parameter* for an FSAR-described evaluation, or a change to an *element of an evaluation method* described in the FSAR. A change to either an *input parameter* or an *element of an evaluation* *method* described in the FSAR for demonstrating that an SSC design function is accomplished is considered a change to the facility controlled by 10 CFR 50.59 and should be addressed as part of the 10 CFR 50.59 screening. Examples 3 and 4 in Section 4.2.1.3 of NEI 96-07 illustrate specific cases of screening for a change to an input parameter versus a change to an element of an evaluation method.

Section 3.8 of NEI 96-07 defines the term *input parameter* and explains the distinction between an *input parameter* and an *element of an evaluation method* described in the FSAR. This section of NEI 96-07 also describes when an input parameter is considered to be an element of an evaluation method and addresses how these types of changes should be screened for evaluation against the eight criteria in 10 CFR 50.59(c)(2)[31]. Section 3.10 of NEI 96-07 defines "methods of evaluation" as the calculational framework used for evaluating the behavior or response of an SSC. Section 3.10 states that replacement of an evaluation method or a change to any element of an evaluation method described in the FSAR are controlled under 10 CFR 50.59. This section also provides examples of elements of evaluation methods – it is noted that methods for selecting values of physical constants (e.g., a material property) are included in the examples of elements of evaluation methods in Section 3.10 of NEI 96-07.

<u>Application of the 10 CFR 50.59 Screening Criteria to the WEC AM TPD</u>: The WEC AM TPD installed in Byron, Unit 1 is a replacement component that is expected to perform the same design function as the original. The Byron FSAR states that the design function of the original "thimble plugging assemblies" is to limit core bypass flow in the fuel assemblies. The FSAR describes this component as an assembly of parts using fasteners, whereas the WEC AM TPD does not use fasteners. The parts of the original thimble plugging assembly are constructed from 304 stainless steel. The FSAR does not reference an industry consensus code or standard for the fabrication of this component. The FSAR also includes qualitative design characteristics associated with interface tolerances and surface finish; numerical values for these characteristics are not provided in the FSAR. Accordingly, the change to use the WEC AM TPD screened out from receiving a full 10 CFR 50.59 evaluation per the eight criteria in 10 CFR 50.59(c)(2).

A flowchart illustrating a hypothetical 10 CFR 50.59 screening of a change to use an AMT component is provided in Figure 3.

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[31] 10 CFR 50.59(c)(2) evaluation of changes to input parameters versus changes to methodology elements is discussed further in Section 4.3 of this document.

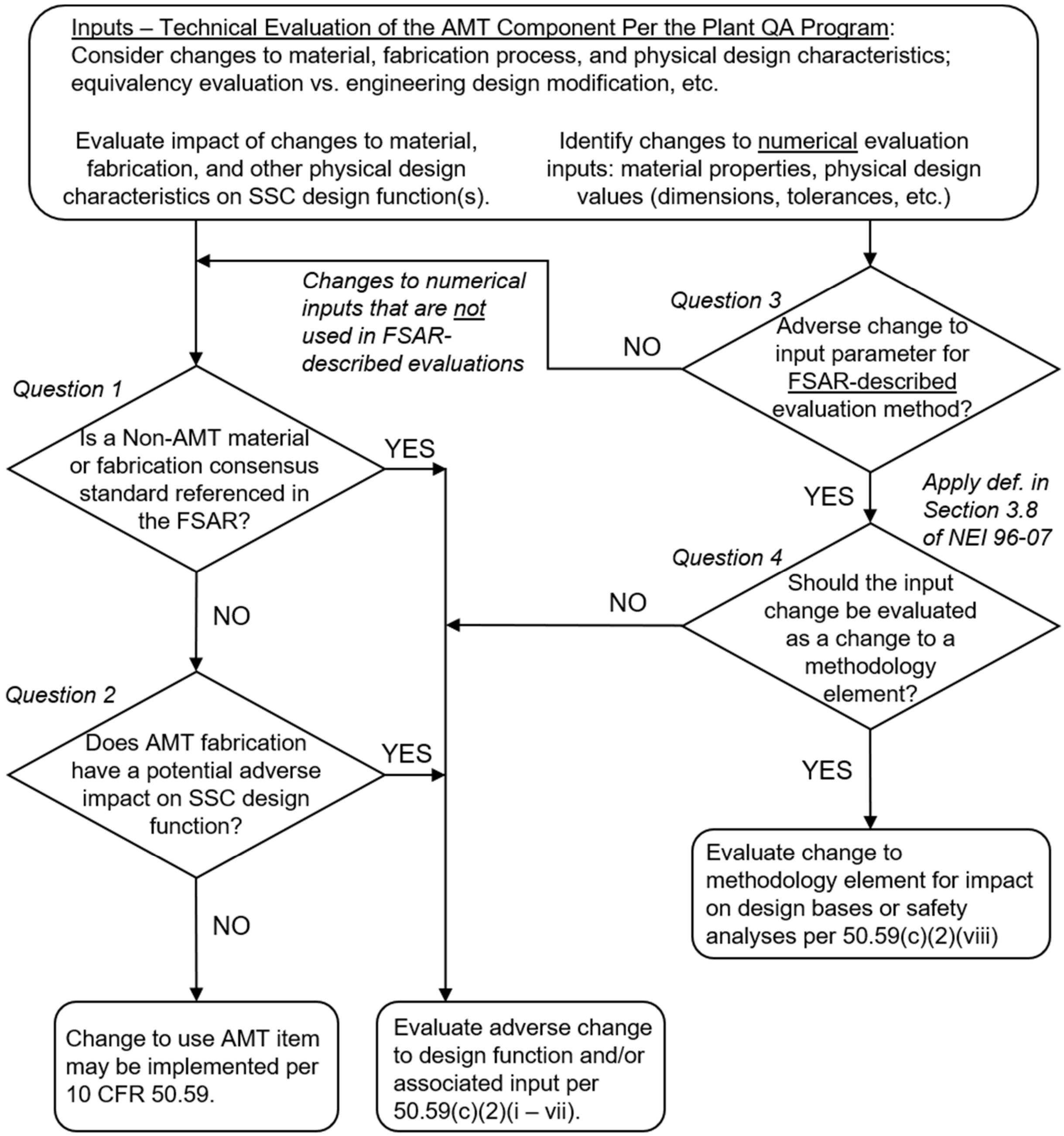


Figure 3 – Flowchart Illustrating a Hypothetical 10 CFR 50.59 Screening of a Change to Use an AMT Component

## 4.3 10 CFR 50.59 Evaluation

If the change to use an AMT component cannot be screened out, the third step in applying the regulation is the 10 CFR 50.59 evaluation. The objective of the 10 CFR 50.59 evaluation is to determine if the magnitude/consequence of a potentially adverse change requires NRC review and approval as a license amendment pursuant to 10 CFR 50.90 prior to implementing the change. The eight evaluation criteria in 10 CFR 50.59(c)(2) are provided below:

*A licensee shall obtain a license amendment pursuant to Sec. 50.90 prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:*

- *(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);*
- *(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);*
- *(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);*
- *(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);*
- *(v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);*
- *(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);*
- *(vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or*
- *(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.*

A 10 CFR 50.59 evaluation of an AMT component against the eight criteria may follow the guidance in Section 4.3 of NEI 96-07. As is the case for 10 CFR 50.59 screening, the technical evaluation of the AMT component for addressing applicable design and QA requirements should be used to inform the 10 CFR 50.59 evaluation in accordance with the eight criteria.

The evaluation of criteria (i) though (vii) should address the unique aspects of AMT fabrication and the potential adverse impact on FSAR-described SSC design function(s) and/or adverse changes to plant-specific input parameter(s) used in FSAR-described evaluations for demonstrating that SSC design functions are accomplished. Appropriate consideration should be given to the quality and statistical significance of the AMT component data/information being used to support the evaluation. Consideration should be given to any inherent assumptions for traditional materials that might not be applicable for AMT materials (e.g., mechanical/thermal properties, anisotropy, defect type and special distribution), relative to their impact on the evaluation.

For the evaluation of criteria (i) and (ii), Sections 4.3.1 and 4.3.2 of NEI 96-07 provide guidance and examples that may be relevant for the types of SSC changes that might use AMT items. Both sections state that "*departures from the design, fabrication, construction, testing and performance standards as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a 'no more than minimal increase' standard*" for these evaluation criteria. Therefore, if the FSAR describes an *industry consensus code or standard* that specifies traditional (non-AMT) fabrication for the component, the change to AMT fabrication should be evaluated to determine whether it constitutes such a departure from applicable licensing or GDC requirements; if it does, the change to AMT fabrication would require NRC review and approval as a license amendment pursuant to 10 CFR 50.59(c)(2). Example 2 in Section 4.3.1 and Examples 2 and 3 in Section 4.3.2 of NEI 96-07 are pertinent examples for the application of this guidance for SSC changes that use AMT items.

Evaluation Criterion (viii) addresses the departure from a method of evaluation described in the FSAR used in establishing the design bases or in the safety analyses. Adverse changes to elements of a methodology are treated as a departure from a method of evaluation. An input parameter is considered an element of the methodology if it meets either of the following criteria discussed more fully in Section 3.8 of NEI 96-07:

- The method of evaluation includes a methodology describing how to select the value of an input parameter to yield adequately conservative results;[32] or
- The development or approval of a methodology was predicated on the degree of conservatism in a particular input parameter or set of input parameters.

For AMT components, material properties or other component design parameters should be considered methodology elements if they meet either of the above criteria; adverse changes to these elements should be evaluated as a departure from the method of evaluation in accordance with 10 CFR 50.59(c)(2)(viii). In a situation where the FSAR describes an *industry consensus code or standard* that specifies traditional (non-AMT) fabrication for the component, and an input parameter is obtained or derived from this consensus document, the parameter should be reviewed to determine if it is an element of the methodology. For example, a consensus standard for traditional fabrication might describe how certain material property values are to be selected, or the development of the standard might have been predicated on conservative assumptions for material properties not representative of AMT fabrication. These types of scenarios could potentially result in an adverse change to an element of a methodology described in the FSAR, which would require NRC review approval as a license amendment if it meets the criterion in 10 CFR 50.59(c)(2)(viii).

[32] If a licensee opts to use a value more conservative than that required by the selection method, however, reduction in that conservatism should be evaluated as an input parameter change, not a change in methodology.

If the input parameter does not meet either of the above criteria from Section 3.8 of NEI 96-07, then an adverse change to the input parameter must be evaluated against the first seven criteria in 10 CFR 50.59(c)(2).

## 5.0 Conclusion

The primary challenge for changes in the facility that involve the use of AMT components is understanding how equivalency evaluations or engineering design modifications might be performed for proposed AMT items. A licensee's technical evaluation to address applicable quality and design criteria for the use of proposed AMT components (i.e., to ensure the change is "safe and effective") precedes the 10 CFR 50.59 process for evaluating the effects of the proposed change on the plant licensing basis and determining whether prior NRC approval is required.

The technical evaluation of a proposed AMT item within the generic QA framework discussed in Section 3.0 should address the vital interrelationship between SSC functional requirements, AMT product design characteristics, and the variables of the AMT manufacturing process that affect product design and performance, consistent with established requirements and guidance. Future NRC technical reviews should consider accumulated industry operating experience, AMT component test data, and materials engineering research results for AMT applications as it becomes available. Further developments in these areas may be used to inform future revisions of this document.

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