THE NRC STAFF HAS PREPARED THIS DRAFT DOCUMENT AND IS RELEASING IT TO SUPPORT THE SEPTEMBER 8, 2021, PUBLIC WEBINAR ON DRAFT GUIDELINES FOR ADVANCED MANUFACTURING TECHNOLOGIES. THIS DRAFT DOCUMENT IS SUBJECT TO CHANGE AND ITS CONTENT SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. SUBSEQUENT TO THE PUBLIC WEBINAR, THE NRC STAFF PLANS TO CONTINUE WORKING ON THIS DOCUMENT AND COULD INCORPORATE STAKEHOLDER FEEDBACK RECEIVED AT THE PUBLIC WEBINAR.

DRAFT ADVANCED MANUFACTURING TECHNOLOGIES REVIEW GUIDELINES

Purpose and Scope

When finalized, this document will provide guidelines to assist the U.S. Nuclear Regulatory Commission (NRC) staff that reviews submittals requesting the use of advanced manufacturing technologies (AMTs). AMTs include techniques and material processing methods that have not traditionally been used in the U.S. nuclear industry or that have yet to be formally standardized by the nuclear industry (e.g., through nuclear codes and standards, or through other processes resulting in NRC approval or endorsement). AMT is used as an umbrella term to cover a broad range of novel and non-standardized manufacturing methods. AMTs can include new ways of fabricating or joining components,[1] new surface treatments, and other processing techniques that provide performance or operational benefits.

The guidelines in the final version of this document will identify the range of information that could be necessary in a submittal seeking approval for the use of an AMT. The actual information provided for the review of such a submittal would depend on many factors, including the maturity of the AMT in the codes and standards arena, prior precedent, and the safety and risk significance of the intended use of the AMT. In addition, the final version of these guidelines may also apply to the staff's reviews of the use of new materials (e.g., of alloys not previously approved through the American Society of Mechanical Engineers (ASME) for nuclear use) and of materials for new or advanced reactors. Although the NRC intends for the final version of these guidelines to be applicable to the use of AMTs in nuclear power plants, the concepts could also be considered for other facilities within the NRC's purview, such as transportation and storage facilities under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, and Part 72.

The final version of Appendix A will identify information that the staff should expect to see in requests to use an AMT. The final version of Appendix B will give an example of a qualitative graded approach to identifying the depth of information that may be needed in a submittal, depending in part on the maturity of codes and standards available for the process used.

[1] The term "component" broadly refers to new and replacement components, repair activities for existing components, and specific fabrication elements (e.g., welds, coatings) of a component.

To supplement the generic information that will be provided in the final version of this document, the NRC is developing separate AMT-specific draft guidelines documents on the following topics:

- the differences between the AMT relative to traditional manufacturing methods
- the safety significance[2] of the identified differences
- the aspects of each AMT that are not currently addressed by codes and standards or regulations

As stated in the NRC's AMT Action Plan (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19333B980), "These documents will focus on performance-based considerations between components made using AMT and traditional manufacturing." The draft guidelines documents will address five AMTs that have been identified based on current industry interest:

- laser powder bed fusion (LPBF)
- directed energy deposition (DED)
- powder metallurgy – hot isostatic pressing (PM-HIP)
- electron beam (EB) welding
- cold spray

General Review Philosophy

These guidelines are intended to be both sufficient and flexible. Sufficiency means that all important (i.e., safety-significant or safety-related) attributes for the specific application of an AMT that are unique to its use within that application are addressed in sufficient technical depth to justify its use. Flexibility allows for a variety of both technical and regulatory approaches to demonstrate that these important attributes are addressed. The final version of the guidelines will focus on any unique aspects or differences as a result of using an AMT (e.g., cold spray). Also, they will aim to minimize unnecessary technical and regulatory burden. However, the level of detail in which a submittal must address the applicable requirements and technical basis may vary depending on the safety significance of the application and the maturity of the AMT. These considerations will determine the potential gaps or differences between an AMT and traditional manufacturing that might be relevant for a particular application.

Regulatory Pathways

There are several regulatory pathways that could be used to implement an AMT, depending on its safety significance and governing regulatory requirements. These pathways include the change process in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, "Changes, tests and experiments"; a license amendment (e.g., technical specification change); an alternative to a regulatory requirement (e.g., using 10 CFR 50.55a(z)(1) or (2)); or a change in regulations through the rulemaking process. ASME Code Cases could provide a path for generic approval

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[2] In the context of this document, the term "safety significance" refers to the impact on component performance. The overall impact to plant safety is a function of component performance and the specific component application (e.g., its intended safety function).

of specific AMTs. In addition, use of topical reports could be an efficient process for licensees or applicants seeking to use an AMT. The staff is preparing a separate document detailing the evaluation of a licensee's 10 CFR 50.59 evaluation of an AMT under the AMT Action Plan. A draft of this document is available under ADAMS Accession No. ML20317A007.

AMT Implementation Approaches

There are two approaches for demonstrating that an AMT is acceptable for a proposed application. The first is to demonstrate that the attributes of an AMT are sufficient to meet the licensee's current licensing requirements. For example, consider a material for which one of the required material properties is a minimum value to ensure adequate margins, while the original material specification indicates a higher minimum value than that required by the current licensing basis. If an AMT has a higher minimum value than that required to ensure adequate margin, which meets the design requirement, it is considered to be equivalent to the traditionally manufactured material for this application. Furthermore, if all the properties of the AMT that are deemed essential to component function equal or exceed those of traditional materials, adoption of the AMT without further review of the design requirements can be considered.

If the first approach cannot demonstrate that the attributes are sufficient to meet all current design and licensing requirements, then a second approach is to modify the design to demonstrate the adequacy of the AMT. The modification of the AMT design would provide a technical basis for changing the existing design requirement(s). A modification would be coupled with a demonstration that an AMT will meet the modified requirement(s).

It should also be considered whether a material produced by an AMT differs, in any relevant properties, from the traditionally manufactured version of the same material. For example, if the original component design specified the use of austenitic stainless steel, it may not have included fracture toughness requirements, since austenitic stainless steel is an inherently tough material for which the ASME Boiler and Pressure Vessel Code (ASME Code) does not require toughness testing. However, an austenitic stainless steel fabricated by an AMT may not exhibit the high toughness assumed for traditionally manufactured products. Therefore, additional evaluation of the performance implications of potential lower toughness may be necessary.

Process Flowchart

The flowchart in Appendix A describes an approach to the qualification and performance considerations for AMTs, including considerations related to the underlying materials and fabrication processes. The NRC's review of a submittal to use an AMT would focus on the qualification and performance attributes specific to the AMT component (as opposed to those of its traditionally manufactured counterpart) and on their relevance to design requirements and component performance. For example, if an AMT component differs from a traditionally manufactured component in its defect characteristics and density, and these properties affect cracking susceptibility, then the effect of this difference in cracking susceptibility should be considered when analyzing the AMT (assuming that cracking susceptibility could affect the ability of the component to perform its intended safety-related function).

The flowchart illustrates an approach covering a broad range of AMTs and outlines the types of information that a submittal could include to facilitate the NRC's review. A submittal does not necessarily have to include all of the information in the flowchart. Additionally, to address some elements of the flowchart, such as process qualification, a submittal may leverage relevant aspects of ASME Code, Sections II and III, as well as ASTM International standards that prescribe certain testing requirements (e.g., related to chemistry and mechanical properties) for traditionally manufactured items.

An AMT's inservice performance may be demonstrated through either supplemental testing (see element 3 in Appendix A) or performance monitoring (see element 4 in Appendix A), both of which could provide assurance that the component will meet the design requirements over its intended service life in the applicable environment.

As described in Appendix B to this document, no information is required to be submitted to the NRC for use of an AMT that is in an ASME Code Case endorsed in Regulatory Guide 1.84, "Design, Fabrication, and Materials Code Case Acceptability, ASME Section III," or Regulatory Guide 1.147, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1," and incorporated by reference in 10 CFR 50.55a, "Codes and standards"; or that is in a code provision in an edition or addendum of ASME Code, Section III or XI, that has been incorporated by reference in 10 CFR 50.55a does not require any additional information to be submitted to the NRC beyond that required by other regulatory requirements. Appendix B to this document describes other circumstances that could affect the amount of information in a submittal.

APPENDIX A

Framework for Advanced Manufacturing Technologies Review Guidelines; Flowchart Definitions and Descriptions

Figure 1 shows a flowchart with the elements that could support a submittal requesting approval for the use of an advanced manufacturing technology (AMT). Five of these elements (numbered 1 to 5 in Figures 1 and 2) are directly applicable to this document. Figure 2 provides additional details on these five elements.

For each of the elements identified in Figures 1 and 2, submittals should focus on the aspects in which the design, fabrication, and operation of an AMT differ from those of traditional manufacturing, in order to demonstrate that the AMT can perform its intended functions and meet the design requirements. The following list describes elements 1–5 from Figures 1 and 2 in detail and gives a high-level summary of expected submittal contents for each one:

(1) **Quality Assurance (QA):** This is a process followed to ensure that an AMT adheres to quality requirements (e.g., a program meeting the criteria in Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic licensing of production and utilization facilities") or to established methods. While the existing nuclear industry QA framework is sufficient for AMTs, the applicable QA programs will need to specifically address the novel or unique aspects of the manufacturing or implementation of the AMT. An applicable QA program will need to establish requirements for process qualification and production process control, and possibly also for aspects of calibration, supplemental testing, and performance monitoring. Any of the following QA processes or approaches may be appropriate, depending on the safety significance of the application:

- **a.** **Appendix B:** The safety-related component is governed by a QA program that meets the requirements in 10 CFR Part 50, Appendix B.

- **b.** **Commercial-Grade Dedication (CGD):** This is a process for designating a commercial-grade item (CGI) for use as a basic component. It provides reasonable assurance that a CGI to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, QA program. This assurance can be achieved by following the CGD process described in Electric Power Research Institute (EPRI) 3002002982, Revision 1 to EPRI NP-5652 and TR-102260, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," issued September 2014, which the U.S. Nuclear Regulatory Commission (NRC) endorsed in Regulatory Guide 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants." Note that specific elements could be either generic or component/application specific.

SUBMITTAL CONTENTS—QUALITY ASSURANCE:

Submittals to implement an AMT identify the QA provisions for all novel or unique aspects of the manufacturing or implementation of the AMT.

(2) **Process Qualification:** This refers to the steps taken to develop processes for fabricating the component and to demonstrate that the resulting component will meet the design requirements. These steps may include input from other flowchart elements, such as qualification testing, to show that the material produced will meet the basic material requirements (i.e., that the processes can produce high-quality material with acceptable basic properties). In addition, supplemental testing may be necessary to show that components fabricated using the qualified process will meet the design requirements for their intended service life in the appropriate environment (see element 3 below). Qualification testing for a process is generally conducted in air at ambient temperature as the default environment, whereas supplemental testing is at service conditions and may be specific to the geometry of the component (e.g., valve body, tee). Supplemental or qualification testing may also provide information on component inspectability and on potential defect characteristics that could adversely affect the component's performance, including defect density, size, and type (e.g., porosity, linear indications).

a. **Essential Variable Identification:** This consists of determining the process and postprocessing parameters that need to be controlled to ensure acceptable component performance.

SUBMITTAL CONTENTS—ESSENTIAL VARIABLE IDENTIFICATION:

Submittals to implement an AMT identify the essential variables applicable to the AMT and the acceptable ranges for those variables. They also specify the essential variables and ranges for all postprocessing steps (e.g., heat treatment or other steps) that are necessary to ensure adequate performance of the materials fabricated by AMTs.

b. **Qualification Testing:** This entails an evaluation, over the allowable essential variable range(s), of the properties relevant to the design requirements (e.g., tensile strength, yield, hardness, chemistry, Charpy). Because the AMT will be integrated into a broader system, qualification may include consideration of the acceptability of any necessary joining techniques (e.g., welding). Qualification testing may leverage relevant aspects of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (ASME Code), Sections II and III, as well as ASTM International standards that prescribe certain testing requirements for traditionally manufactured items, such as chemistry and mechanical properties. Qualification testing should also include determination of the material design allowable stresses for a material used for an AMT, unless the material is equivalent to an existing approved specification for which the design allowable stresses can be applied.

***SUBMITTAL CONTENTS—QUALIFICATION TESTING*:**

Submittals to implement an AMT describe the specific qualification testing used, including the results of the testing and the acceptance criteria. Submittals identify any codes and standards used to inform the testing and specify whether these codes or standards were used to define the acceptance criteria.

(3) **Supplemental Testing:** This is used to demonstrate that the material and component properties will meet the design requirements in the applicable service environmental conditions. Therefore, supplemental testing confirms that the performance of the component in service will be acceptable. For example, testing could be performed on a prototype of the actual component to be used in service, or on witness samples that are shown to be representative of the component. Some of the items described in this section may have been covered by qualification testing (element 2.b).

Demonstrations of acceptable component performance can be either generic or tailored to the intended application. A generic demonstration could use conservative acceptance criteria to show that design requirements governing different component geometries are met. If such generic requirements are met, then for each component it is only necessary to verify the application-specific acceptance criteria (taking into consideration environmental effects such as fatigue life, corrosion, creep, and irradiation). If aspects of the component performance are application specific, generic demonstrations may still suffice to show acceptability in another application without further evaluation. In this case, the submittal must show that the demonstration and results are equivalent or conservative with respect to those needed for the other application. For example, if a component's resistance to high-temperature fatigue has been demonstrated for one application, and if a similar component produced by the same process will be used in an application with an identical or less-severe high-temperature fatigue requirement, additional high-temperature fatigue testing may not be needed for the second application; verification of the relevant material or mechanical properties (e.g., surface finish, porosity, microstructure, strain-life behavior) may suffice.

The use of other testing types, such as fatigue testing, fracture toughness testing, environment testing and evaluation (TE), component TE, or life-cycle TE,[3] would depend on the attributes required of the component. For example, initial mechanical testing as part of process qualification would evaluate requisite properties in air at room temperature, while the supplemental testing might entail environmental TE to evaluate requisite properties at temperatures, environments, and loads that either bound or represent the expected inservice conditions. Both mechanical and environmental testing are typically conducted on specimens machined from prototypes or on witness specimens (with appropriate demonstration of witness specimen applicability), using established, standardized testing techniques. Witness specimens can support benchmarking of the component's performance, if they are included in production process control and verification (see element 4 below). This testing is intended to

3 Component and life-cycle TE will be application-specific.

establish basic property information that can be used to demonstrate, possibly with additional analysis, that design requirements are met.

Component testing can be used to directly demonstrate that certain design requirements are satisfied. Typically, component testing is of short duration and may or may not consider environmental effects. (One example is burst testing of a pressure-retaining component.) Life-cycle testing is an important type of component testing that involves bounding or representing the service conditions over the component's intended lifetime. Life-cycle testing simulates the various stressors that the component will experience over its service life, considering environment, applied stress (i.e., both constant and transient history effects), degradation mechanisms, fatigue, and other conditions that could adversely affect performance.

***SUBMITTAL CONTENTS—SUPPLEMENTAL TESTING*:**

A submittal to implement an AMT describes the specific supplemental testing that was performed to demonstrate that the component will meet the design requirements over its intended service life; it also includes the results of the testing and the acceptance criteria. The submittal identifies any codes and standards used to inform the scope of the supplemental testing and specifies whether these codes or standards were used to define the acceptance criteria.

If performance monitoring (see element 5 below) will be used to demonstrate adequate performance of an AMT over its service lifetime (e.g., through periodic removal of the component for evaluation), the submittal identifies the specific steps to be applied, along with the acceptance criteria for the performance monitoring.

(4) **Production Process Control and Verification:** This refers to the steps taken to ensure that each component will be produced in accordance with the qualified process defined in element 2 above, as well as the steps taken to reestablish the qualified process if the production process fails to meet the qualification essential variables.

a. **Process Control:** This refers to the approach, techniques, and frequency of evaluating the process to ensure quality components. It involves directly monitoring, controlling, or evaluating the essential variables during production to make sure they fall within the qualified ranges. Process control may include in situ monitoring during the production process (e.g., to measure temperatures or porosity).

***SUBMITTAL CONTENTS—PROCESS CONTROL*:**

A submittal to implement an AMT describes the specific process control activities that will be applied, including the recovery actions if the essential variables are not met.

b. **Product Verification:** This is a strategy to verify the quality of each fabricated product. Product verification can take many forms, including property verification (e.g., through witness testing), component testing, and postprocess examination. It may consider aspects such as chemistry, microstructure, density, defect characteristics, hardness, strength, fracture toughness, and surface finish.

Witness testing is typically used to measure material, mechanical, or other properties that have been demonstrated during process qualification, to verify that the properties of the product are acceptable. Often, witness testing is performed on separately produced specimens (e.g., weld run-off tabs), extraneous parts of the product (e.g., prolongation), or, as in the case of laser powder bed fusion, specimens fabricated on the build plate with the component (as described in “Criteria for Pressure Retaining Metallic Components Using Additive Manufacturing,” a draft document from the ASME Board on Pressure Technology Codes and Standards/Board on Nuclear Codes and Standards Special Committee on Use of Additive Manufacturing for Pressure Retaining Equipment). Alternatively, completed products can be periodically sampled and destructively evaluated to confirm their performance characteristics.

In addition, component testing, such as burst or other testing, can be conducted on product samples.

Postprocess inspection could entail either nondestructive or destructive evaluation, for example, to characterize defects or determine density, chemistry, or microstructure. The process can be evaluated for every manufactured product, as is required by ASME Code Case N-834 for stainless steel components made using powder metallurgy with hot isostatic pressing; by periodically sampling a subset of like products or processes; or when aspects of production change. The approach may use different evaluation frequencies for different aspects of the qualified process.

***SUBMITTAL CONTENTS—PRODUCT VERIFICATION*:**

A submittal to implement an AMT describes the product verification that will be used. The submittal identifies the specific testing, inspection, evaluation, or other activities that will be conducted to verify the quality of each fabricated product. As applicable, the submittal includes the acceptance criteria (and basis) for each activity. This description may leverage relevant parts of ASME Code, Sections II and III; ASTM International standards; and other applicable standards for product verification.

(5) **Performance Monitoring:** This refers to the actions taken to provide assurance that the component will continue to meet design requirements until the end of its intended service life. While performance monitoring typically consists of inspections or examinations to confirm adequate performance and to identify unacceptable degradation, it may also include aging management programs or postservice evaluations. For AMTs for which there are few data on performance in similar operating environments and conditions, performance monitoring can be a flexible way to show that

the component will maintain its intended function throughout the operating period. An AMT with a significant design margin or one that has demonstrated acceptable performance under similar operating environments and conditions may require less rigorous performance monitoring, while activities such as inspection, surveillance, aging management, and postservice evaluation could improve the safety case for an AMT with a less robust design basis or more uncertainty about performance.

Although this section identifies three common examples of performance monitoring activities, submittals may propose other approaches.

a. **Inspection:** An inspection program should detect age-related degradation and ensure that the component meets service requirements, allowing for corrective actions in the event of adverse findings. Initially, the component design process should identify the areas that are most critical to component performance, where age-related degradation could cause component failure. Inspections should focus on these areas. Next, it should be determined how much age-related degradation can be tolerated at these locations. These considerations will inform the choice of appropriate inspection techniques, frequencies, and acceptance criteria for the component. This evaluation should, if possible, adhere to existing NRC-approved methodologies, such as ASME Code, Section XI, requirements. The goal of an inspection program is to detect and monitor those manufacturing defects, component nonconformance features (e.g., improper dimensional tolerances), and service-induced degradation that may lead to unacceptable performance. Ideally, the inspection program should use codified techniques and acceptance criteria that have been demonstrated or justified to be sufficient for the AMT. Otherwise, the program's acceptability will need to be demonstrated.

   In developing an effective inspection program for an AMT, it is important to consider the inspectability of the component, which may differ from that of traditionally manufactured components. The submittal should identify and assess the aspects of the microstructure, material interfaces, defect characteristics, and component and system design (e.g., accessibility, geometric complexity, product thickness) that would most challenge an effective inspection program. It should consider both preservice and inservice inspectability, including accessibility for inspection once the component is installed.

   These factors, coupled with the degradation mechanisms of interest, will determine the most effective preservice and inservice inspection techniques for the component. For example, if fatigue degradation at a blind stress riser is a prominent concern, preservice inspection could use computed tomography to evaluate the surface finish, material substructure, and porosity near the stress riser. Inservice inspection could use an eddy current technique to periodically determine whether cracks have formed.

***SUBMITTAL CONTENTS—INSPECTION*:**

Submittals to implement AMTs describe the inspections that will be performed to identify any unacceptable component conditions. The inspection description identifies inspection type(s), location(s), frequency, and acceptance criteria.

b. **Aging Management:** Aging management can be used to identify, monitor, assess, and mitigate the effects of age-related degradation so that the component continues to meet the design requirements throughout its intended service life. Formalized aging management programs (AMPs) are used for license renewal and subsequent license renewal for in-scope systems, structures, and components beyond their original design life. NUREG-1801, Revision 2, "Generic Aging Lessons Learned (GALL) Report," issued December 2010, and NUREG-2191, "Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report," Volume 2, issued July 2017, identify the 10 elements of a formalized AMP. One way to demonstrate that the component remains acceptable throughout its intended service life is to address the relevant program elements as part of the technical evaluation package. The following four AMP elements are likely to be most relevant for AMTs: detection of aging effects, monitoring and trending, acceptance criteria, and operating experience.

***SUBMITTAL CONTENTS—AGING MANAGEMENT*:**

A submittal to implement an AMT describes the aging management approach that will be taken, in particular those aspects related to detection of aging effects, monitoring and trending, acceptance criteria, and operating experience. This approach may use the inspection protocol of element 5.a above and may also incorporate prevention or mitigation activities.

c. **Postservice Evaluation:** Postservice evaluation can yield information on material properties and performance after time in service, in particular providing data that could not have been generated through inservice inspection because of time, cost, or technical limitations. Postservice evaluation can supplement the safety case for an AMT with a less robust design basis or margin. For example, a small number of representative or bounding components could be removed from service and destructively tested after a predefined period to demonstrate that the components remaining in service will perform adequately. Once an AMT component's initial service period has been completed, it may be useful to evaluate its performance against acceptance criteria and design requirements. Such evaluations could support related future AMT applications with higher safety significance. Postservice evaluations may include dimensional and surface inspection, material testing and evaluation, mechanical and environmental testing, nondestructive and destructive evaluation, and remaining-component-life testing.

***SUBMITTAL CONTENTS—POSTSERVICE EVALUATION*:**

A submittal to implement an AMT describes the specific postservice evaluation activities that will be conducted, as well as the approach for incorporating their results into the evaluation of the AMT components left in service. The description specifies which parts will be removed and how the service environment of these parts compares to that of the remaining parts, the type(s) of evaluation that will be used, the acceptance criteria for the evaluation(s), and any remedial or corrective actions should the acceptance criteria not be met.

AMT Submittal Guidelines

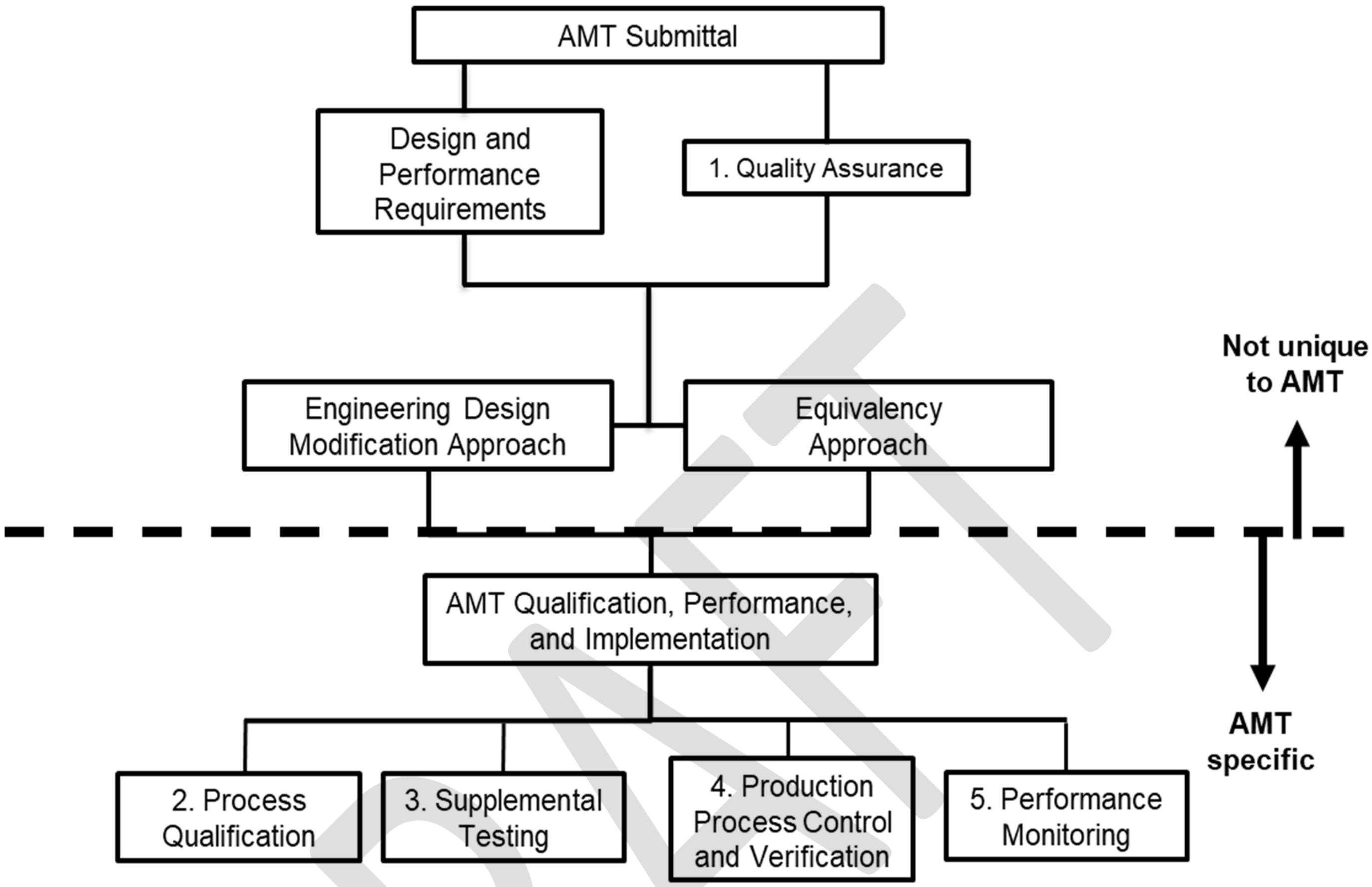

Figure 1 Overview of AMT guidelines

AMT-Related Elements Details

An AMT submittal should address differences between the AMT and conventional materials/processes.
A given submittal need not include all elements of this flowchart.

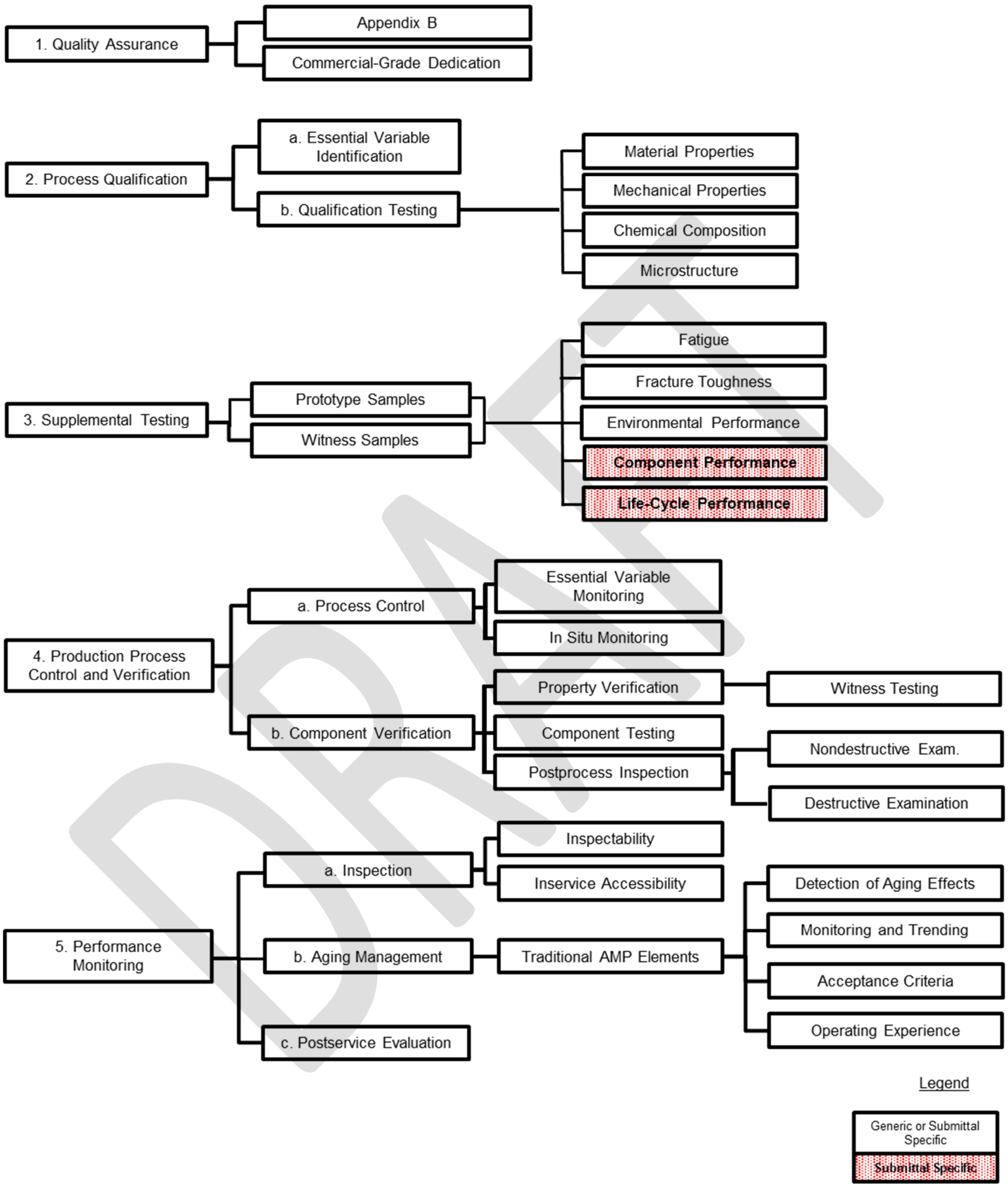

Figure 2 Additional details on elements 1–5 of Figure 1

APPENDIX B

Examples of Graded Approaches for Assessing Advanced Manufacturing Technology Submittals

The main body of this document and Appendix A provide a review philosophy and guidelines for the information to be included in a submittal requesting approval to implement an advanced manufacturing technology (AMT). The level of detail to which an AMT submittal addresses the five elements in Appendix A (quality assurance, process qualification, supplemental testing, production process control and verification, and performance monitoring) depends on many factors, including the following:

- the safety and risk significance of the AMT
- the maturity of the AMT in the codes and standards arena
- relevant experience (nuclear or nonnuclear) with the AMT

The U.S. Nuclear Regulatory Commission (NRC) staff has developed an example of a graded approach to qualitatively identify the type and level of information (within a specific flowchart element) that may provide a sufficient technical basis for an efficient review. This approach will leverage the existing structure of both the final version of this document and the Appendix A flowchart. As described in the main document, the generic examples below will be supported by AMT-specific draft guidelines documents that will identify important gaps for particular submittals to address.

The first flowchart element, quality assurance (QA), is not AMT specific, except in the requirement to “identify the QA provisions for all novel or unique aspects of the manufacturing or implementation of the AMTs,” as stated in Appendix A. Therefore, the general information within the final version of this document should suffice to address QA for any AMT submittal.

The other four flowchart elements may require different levels of detail depending on the maturity of the AMT and the particular application. The hypothetical scenarios below provide examples of possible graded approaches:

(1) Scenario 1: Nonnuclear Industry Standards

A vendor is following standards approved for use in other industries, has relevant nonnuclear experience but no nuclear experience, andthe application of the AMT is risk-significant. In this case, the submittal should take into account the nonnuclear standards and experience, while focusing on aspects of the nuclear application that differ or do not arise in nonnuclear applications. For example, suppose Company B, which has extensive experience using laser powder bed fusion to make high-quality, safety-significant components out of 316 stainless steel for space applications, and now wants to make the same Class 1 pump body as Company A. Company B may demonstrate the relevance of its nonnuclear process qualification, production process control and verification, and performance monitoring to the current application and would address aspects such as the different service environments, the different design requirements, and the unique verification issues in the nuclear context. In particular, Company B would have to consider the issues of high importance identified in the applicable AMT draft guidelines document that nonnuclear standards and operational experience do not address.

(2) Scenario 2: Non-NRC-Endorsed American Society of Mechanical Engineers (ASME) Code Provision

A vendor is following an ASME-approved Code Case that has not been endorsed in a regulatory guide or incorporated by reference in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.55a, “Codes and standards.” In this situation, although the submittal references an ASME-approved Code Case, it should provide a thorough technical justification for the use of the AMT because the Code Case has not been endorsed by the NRC. Such a technical justification could include relevant background information used in the development of the Code Case, such as test data, white papers, and other technical information.

(3) Scenario 3: NRC-Endorsed ASME Code Provision

A vendor is following either an ASME-approved Code Case that has been endorsed in Regulatory Guide 1.84, “Design, Fabrication, and Materials Code Case Acceptability, ASME Section III,” or Regulatory Guide 1.147, “Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1,” and incorporated by reference in 10 CFR 50.55a, or a code provision in an edition or addendum of ASME Boiler and Pressure Vessel Code, Section III or XI, that has been incorporated by reference in 10 CFR 50.55a. No additional information is warranted in this scenario beyond that required by other regulations.

(4) Other Circumstances

For situations not covered by Scenarios 1–3, the level of detail expected in a submittal would depend primarily on the three factors noted at the beginning of this appendix. First, a submittal for an AMT with greater safety significance would require more detail. Second, the maturity of the AMT, particularly in terms of nuclear codes and standards, but also in terms of nonnuclear industry standards, is a significant consideration. A submittal for a more mature AMT would require less detail. Finally, it is important to consider the level of experience with the AMT. Nuclear experience is most relevant, but nonnuclear experience should also be noted, particularly experience with similar materials in high-safety applications. A submittal from an applicant with more experience may require less detail. In terms of the relative importance of these three factors, safety significance carries more weight than AMT maturity and the applicant’s level of experience.