AMT Application Guidance Framework

Purpose and Scope

The purpose of this framework is to provide a starting point for discussions with NRC stakeholders on potential guidance regarding the use of advanced manufacturing technologies (AMTs), which include those techniques and material processing methods that have not been traditionally used in the United States (U.S.) nuclear industry and have yet to be formally standardized by the nuclear industry (e.g., through nuclear codes and standards, through a submittal, or other processes resulting in NRC approval/endorsement). AMT is used as an umbrella term to cover a broad range of novel and non-standardized manufacturing methods, and in some cases the associated raw materials. AMTs can include new ways to fabricate or join components, surface treatments, or other processing techniques to provide a performance or operational benefit. This framework describes at a high level a review philosophy and approach to guide NRC licensees and staff with a new AMT application.

General Review Philosophy:

The review framework and any associated guidance that is developed is intended to be both sufficient and flexible. Sufficiency ensures that all important (i.e., safety-significant or safety-related) attributes of a specific AMT application that are unique to the use of AMT within that application are addressed. Flexibility is intended to allow a variety of both technical and regulatory approaches to demonstrate that these important attributes are addressed. The guidance will not impose additional regulatory requirements for AMT-manufactured systems, structures, and components (SSCs) or SSCs that are modified using an AMT (e.g., cold spray). Also, technical and regulatory burden will be minimized to the extent practical. However, it should be recognized that the requirements and the applicable technical basis may vary among specific applications and with the chosen AMT(s) based on the safety-significance of the application and the maturity of the AMT. These considerations will determine the potential gaps or differences between AMT and conventional manufacturing that need to be addressed in a particular application.

AMT Implementation Approaches

There are two conventional approaches for demonstrating that the AMT is acceptable for a proposed application. First, the equivalency approach demonstrates that the attributes of the AMT SSC are sufficient to meet the original design and performance requirements for the SSC. Consider an application that requires a minimum yield strength of 100 MPa to ensure adequate margins against plastic deformation, and the original material specification, specifies minimum yield strength of 120 MPa. If the AMT-manufactured SSC has a minimum yield strength of 110 MPa, which also meets the design requirement, then it is equivalent to the conventional SSC for this criterion. If all AMT properties deemed essential to the function of the component are equal to or greater than those for conventional materials, generic adoption of the AMT without further review of the design requirements could be considered. Building off the prior example, if the specified AMT-manufactured minimum yield strength is 130 MPa, then it can be substituted for a conventional material with a minimum yield strength of 120

MPa in an existing application without consideration of the actual minimum yield strength design requirements.

Additional considerations for specific properties, materials and AMTs, beyond the original design and performance requirements, should also be considered based on the differences when compared to conventional manufacturing. For example, if the original component design specified the use of austenitic stainless steel, fracture toughness requirements may not have been specified given that austenitic stainless steel is an inherently tough material and is not required to be toughness tested by the American Society of Mechanical Engineers (ASME) Code. However, an austenitic stainless steel fabricated by AMT may not exhibit high toughness that is taken for granted with conventional product forms.

If equivalency cannot be demonstrated for all design requirements, then a second approach is an engineering design modification to demonstrate the adequacy of the AMT SSC. The design modification would provide a technical basis for changing the existing requirement(s). This modification would be coupled with a demonstration that the AMT will meet the modified requirement(s). Using the simple example above, assume that the AMT-manufactured SSC has a minimum yield strength of 95 MPa, or less than the original 100 MPa design requirement. The engineering design modification would then need to demonstrate that all applicable regulations (e.g., applicable code margins, technical specifications), are met. The basis for this design modification could include deterministic or risk-informed approaches.

Regulatory Pathways

There are several traditional regulatory pathways that could be followed to implement an AMT-manufactured SSC depending on its safety-significance and governing regulatory requirements. These pathways include the 10 CFR 50.59 process, submitting a license amendment (technical specification change, etc.), requesting an alternative to a regulatory requirement (e.g., 10 CFR 50.55a(z)(1) or (2)), or rulemaking. ASME code cases could provide a path for generic approval of certain AMTs. In addition, NRC approval of topical reports could lessen the burden on applicants seeking to use AMT’s.

An AMT product may be implemented by 10 CFR 50.59 if it meets the criteria established for demonstrating applicability to use 10 CFR 50.59 instead of pursuing a license amendment. If the 10 CFR 50.59 screening or evaluation criteria are satisfied, the licensee could implement the change without prior NRC approval. The NRC’s role in these cases would be to ensure, through the inspection process, that the 10 CFR 50.59 screening and evaluation process was followed correctly. One potentially important consideration for AMTs is that possible indirect consequences of product failure (e.g., loose part analysis) should be analyzed as part of the screening and, if applicable, evaluation. More guidance on evaluating a licensee’s 10 CFR 50.59 implementation of AMT is being prepared.

Use of an AMT produced component to replace an ASME Code component could be requested under 10 CFR 50.55a (z)(1) or (z)(2). Under (z)(1), use of the AMT component would need to provide an acceptable level of quality and safety. A request would need to show that the component meets the same design requirements as an ASME component. For example, if an AMT component material is not produced using an approved ASME Code material specification and is not equivalent to the original code material, the component may be considered acceptable if it meets ASME Code Section III design allowable requirements and fulfills the intended function of the component.

Under an application to use (z)(2), an applicant would need to show that compliance with the specified requirements, to meet ASME Code, would result in hardship or unusual difficulty without a compensating increase in the level of quality and safety. This situation could arise if an AMT component were not equivalent to the original material, did not meet the original design requirements, but did fulfill the intended function of the component. As an example, if an ASME Code Class 2 or 3 pump housing component can no longer remain in service because it is leaking, and a suitable Code-compliant component will take several months or longer to procure, an AMT replacement part may be acceptable under (z)(2) if the replacement part fulfills the intended function of the component.

Process Flow Chart

The flowchart in Appendix A, along with definitions and short descriptions, describes a holistic approach to the qualification and performance considerations for any SSC, including the underlying material and fabrication process. Review of an AMT-manufactured SSC should only focus on those unique attributes associated with AMT qualification and performance --- compared to conventionally manufactured SSCs that may affect the SSC's capability to perform its intended functions and meet the intended design requirements. For example, if the AMT SSC has different defect characteristics and density than the conventionally manufactured SSC, and these defect characteristics affects cracking susceptibility, then the effect of this difference in cracking susceptibility should be considered when analyzing the AMT SSC (assuming that crack susceptibility has the potential to affect the performance of the SSC to perform its intended safety-related function).

The flow chart is intended to cover a broad range of AMTs and be a guide which outlines the types of information that could be included in a request to facilitate the NRC's review. Some of the information contained in the flow chart may not be necessary, depending on the AMT process and its use. The flow chart is not intended to imply that all of the following information is to be included in an application to use an AMT manufactured SSC.

The approach to address some elements of the flow chart, such as Product Evaluation, may leverage relevant aspects of ASME Section II and Section III, and ASTM International standards that prescribe certain testing requirements for conventionally manufactured items, such as chemistry and mechanical properties.

APPENDIX A

AMT Application Guidance Framework

Definitions and Short Descriptions of the Associated Flow Chart

1. **Quality Assurance –** Process followed during the manufacture and implementation of AMTs to proactively ensure adherence to quality assurance (QA) requirements (e.g., 10 CFR Part 50, Appendix B) and/or established methods. While the existing nuclear industry QA framework is sufficient to address AMT implementation, it should be recognized that QA programs will need to be established for those aspects of AMT manufacturing or implementation that are novel or unique. QA will need to be established for process qualification and control and it will possibly be needed for aspects of calibration, product evaluation, in-service management and inspection, and post-service evaluation. Any of the following QA processes/approaches may be appropriate, given the safety significance of the application, for these programs.
    a. **Appendix B –** the product is governed by a QA program that meets 10 CFR Part 50, Appendix B requirements
    b. **Commercial Grade Dedication (CGD)–** Process by which a commercial-grade item (CGI) is designated for use as a basic component. This acceptance process is undertaken to provide 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 completing a 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," endorsed in Regulatory Guide 1.164.
2. **Processing**[1] – the steps needed to build or fabricate the AMT product[2].
    a. **Process Qualification** –The steps taken to develop, and then demonstrate, that the product will be produced with characteristics that will meet the intended design requirements.
        i. **Essential Variable Identification** – Determining the process and post-processing parameters that need to be controlled to ensure acceptable product performance.
        ii. **Product Evaluation –** This entails an evaluation, over the allowable essential variable range(s), of the corresponding product properties that are required for meeting the design requirements. Examples include chemical composition, microstructure, defect characteristics, weldability, and both basic mechanical properties (e.g., tensile, hardness, Charpy) that are important for any

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[1] Note that specific elements or steps could be either generic or product/application-specific

[2] The term product refers to an SSC that is fabricated, modified, or repaired using AMT

application but also properties that may only be important to a specific application (e.g., fatigue life, SCC resistance). Additional product performance details are discussed below in #2.

b. **Process Control** – The steps taken to verify that each product will be produced in accordance with the qualified process (1a), and if the process becomes unqualified, the steps taken to reestablish the qualified process.

    i. **Evaluation Requirements**– The approach, techniques, and frequency used to evaluate the qualified process. The approach should evaluate all essential variables either individually or in appropriate combinations to ensure that they fall within qualified ranges. Common techniques for ensuring essential variable control include **in-situ inspection** during the production process (e.g., to measure temperatures, porosity), direct monitoring or **testing of essential variables** (e.g., powder size, wire feed rate, inert gas composition), and/or aspects of **product evaluation**. It is not expected that all the elements of product evaluation needed to qualify the product are necessary to ensure that process control is met. However, aspects such as chemistry, microstructure, density, defect characteristics, hardness, strength, and surface finish may be considerations. Special categories of product evaluation include **witness testing** and **post-process inspection**. Witness testing is typically used to measure the material, mechanical, or application properties that have been demonstrated during process qualification to ensure that they remain acceptable. Often, witness testing is performed on separately-produced specimens (e.g., weld run-off tab) or an extraneous part of the product (e.g., prolongation). Post-process inspection could entail both non-destructive or destructive evaluation to, for example, characterize defects, chemistry, or microstructure. The frequency associated with the evaluation requirements determines how often the evaluation is conducted. The process can be evaluated for every manufactured product, by periodically sampling a subset of like products or processes, or when aspects of the production changes. The approach may use different evaluation frequencies to confirm different aspects of the qualified process.

3. **Product Evaluation[1] -** The product is the component or system that is manufactured using AMT. Its performance either needs to be demonstrated or coupled with performance monitoring actions (see #4 below) to provide assurance that the design requirements are met over the product's intended service life. Because the AMT product will be integrated into a broader system, the acceptability of any necessary joining techniques may also need to be considered as part of the evaluation. The approach to address Product Evaluation may leverage relevant aspects of ASME Section II and Section III, and ASTM International standards that prescribe certain testing requirements for conventionally manufactured items, such as chemistry and mechanical properties.

a. **Performance Demonstration –** The objective is to demonstrate that those material, product, and system properties that are required to meet the design requirements are acceptable. That is, that the performance of the product will be acceptable. There are certain fundamental attributes such as **chemical composition**, **microstructure**, and **defect characteristics** that ultimately determine the product's performance. A suitable combination of **material** (i.e., basic properties such as density, modulus, conductivity that are generally a function of the composition and defect characteristics) and **mechanical** testing (i.e., basic properties such as hardness, strength, toughness that are generally a function of the composition, microstructure, and defect characteristics), **environmental** testing and evaluation (TE), **product** TE[3], and **lifecycle** TE[3] may be used. Mechanical testing would be used to evaluate requisite properties in air at room temperature while environmental TE would be used to evaluate requisite properties at temperatures, environments, loads that may either bound or represent the in-service conditions expected for the product. Both mechanical and environmental testing are typically conducted on either witness specimens or specimens machined from the product using established, standardized testing techniques. This testing is intended to establish basic property information that can then be used to demonstrate, through additional analysis, that the design requirements are met. Product (i.e., component and/or system) testing can be used to directly demonstrate that certain design requirements are satisfied. Typically, such testing is short duration and may, or may not, consider environmental effects. Burst testing of a pressure retaining component is one example. Lifecycle testing describes an important subset of product testing that is intended to bound or represent the service conditions over the product's intended lifetime to demonstrate that the design requirements are met. These tests should address environmental and load (i.e., both constant and transient) history effects as well.

b. **Program Scope –** the demonstration of acceptable product performance can be done either **generically** or be tailored to the intended **application**. A generic demonstration would address conservative acceptance criteria that could be used to demonstrate that the design requirements that govern several products are met. If such generic design requirements can be met, each product would only need to demonstrate that unique acceptance criteria that are applicable to the intended product application are met, including a consideration of environmental effects (e.g., fatigue life, creep). If aspects of the product evaluation are application-specific, it may still be possible to demonstrate that those results could be used to demonstrate acceptability in another application without further evaluation. In this case, it needs to be demonstrated that the evaluation and results are equivalent or conservative to the other application. For example, if a product's resistance to a high-temperature fatigue requirement is demonstrated for a certain application, another similar product produced using a similar process and having an identical or less-severe high-temperature fatigue requirement

[3] These elements will be application-specific only

may only need to demonstrate that the relevant material or mechanical properties (e.g., surface finish, porosity, microstructure, or strain life behavior) are acceptable without additional high-temperature fatigue testing.

4. **Performance Monitoring[1] –** the mitigative actions taken to provide assurance that the product will continue to meet its design requirements until the end of its intended service life. While the principal in-service mitigative actions are associated with managing the effects of age-related degradation, inspection is an important component of most aging management programs and has therefore been separated in the flowchart. For AMTs where there may be less data on performance in similar operating environments and conditions, in-service activities can allow flexibility in demonstrating that the component will maintain its intended function through the operating period. For example, applications that demonstrate a significant design margin or data on performance in similar operating environments and conditions may need less in-service examination and less rigorous aging management activities. Applications with a less robust design basis or less confidence in performance in similar operating environments and conditions could improve their safety case through various in-service activities, including inspection, surveillance, aging management, and post-service evaluation of performance.
    a. **Inspection –** An inspection program should be considered as a means to detect age-related degradation, and then determine appropriate mitigation actions. Initially, as part of the product design process, those areas that are most critical to product performance, and where age-related degradation could potentially result in product failure, should be identified. These are the locations that should be inspected. Next, the amount of degradation that can be tolerated at these locations for relevant age-related degradation mechanisms should be determined. Based on these considerations, an appropriate inspection technique, inspection frequency, and acceptance criteria can be determined for the product. This evaluation should, if possible, adhere to existing approved methodologies, such as ASME Section XI. The goal of the inspection program should be to identify those manufacturing defects, product non-conformance features (e.g., improper dimensional tolerances), or service-induced degradation that may result in unacceptable product performance. Ideally, codified inspection techniques should be used. Otherwise, the acceptability of the inspection program will need to be demonstrated by the licensee.
        i. **Inspectability –** An important consideration in the development of an effective inspection program is the inspectability of the product. Aspects of the microstructure, material interfaces, defect characteristics, component and system design (e.g., accessibility, geometric complexity, product thickness) that most challenge an effective inspection program for the product should be identified and assessed. Both pre-service and in-service inspectability should be considered, especially how accessibility is affected once the product is installed.
        ii. These aspects, coupled with the degradation mechanisms of interest, will determine the **pre-service** and **in-service** inspection techniques that will be most effective for the product. For example, if fatigue degradation at a blind stress riser is a prominent concern, pre-service inspection could use computed

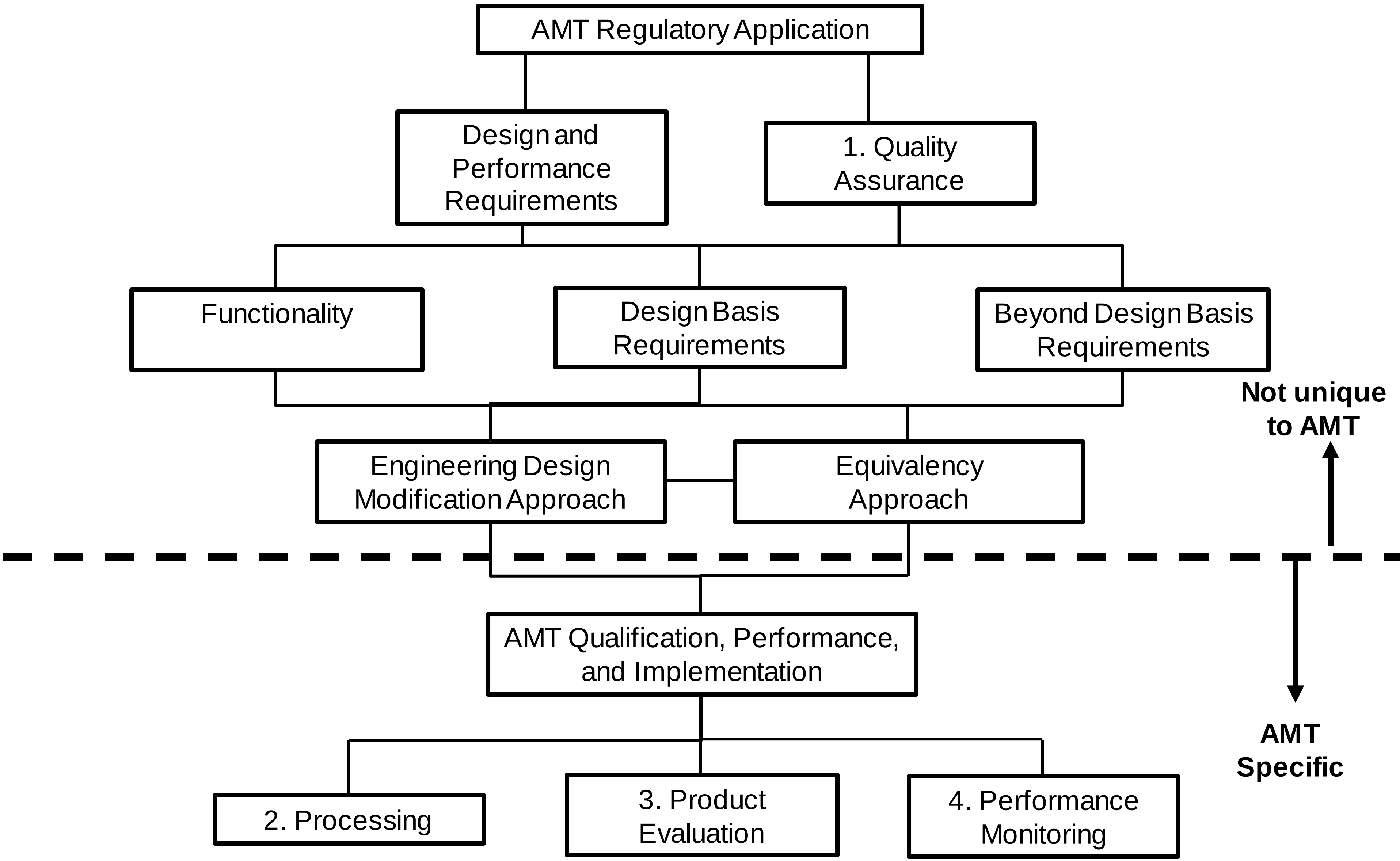
tomography (CT) to evaluate the acceptability of the surface finish, material substructure, and porosity near the stress riser. In-service inspection could use an eddy current technique (ET) to periodically determine if a crack has formed. If a crack is found and no means exists to track crack growth during the remaining service life, then various repair or replacement options may need to be considered. **Post-service** inspection is also another consideration that may support aging management (see below) or be used to develop or qualify inspection techniques.

b. **Aging Management –** the process used to identify, monitor, assess, and mitigate the effects of age-related degradation so that the design requirements continue to be met over the product's intended service life.

    i. **Traditional AMP Elements –** If the product is part of a safety-significant system, structure, or component (SSC), aspects of the 10 program elements of an aging management program (AMP) identified in the GALL Report should be addressed in some manner. Addressing appropriate program element aspects as part of the technical evaluation package is important to demonstrate that the product remains acceptable over its intended service life. The following four of the AMP elements are likely to be most relevant for AMTs: **Detection of aging effects, monitoring and trending, acceptance criteria**, and **operating experience**.

    ii. Post-service Evaluation – Post-service evaluation is optional and may be considered alongside in-service inspection as a way to demonstrate safety by gaining information on material properties and performance after time in service, where it may not be possible due to other factors, including time, cost or technical limitation, to generate such data in advance. Applications with a less robust design basis/margin could supplement their safety case through post-service evaluation of performance. For example, a small number of representative or bounding components could be identified for removal from service and destructive testing after a predefined service period, while leaving the remainder in service, based on the results from the post-service evaluation. Many of the initial AMT applications will be first of a kind. Once the initial service period of these components has been completed, it will likely be valuable to evaluate how they performed in service compared to acceptance criteria and associated design requirements. These evaluations can be used to provide confidence for future related AMT applications that may have a higher safety significance. Such evaluation could include dimensional and surface inspection, material testing and evaluation, mechanical and environmental testing, non-destructive and destructive evaluation, as well as remaining product-life testing.

AMT Application Guidance



AMT Application Guidance

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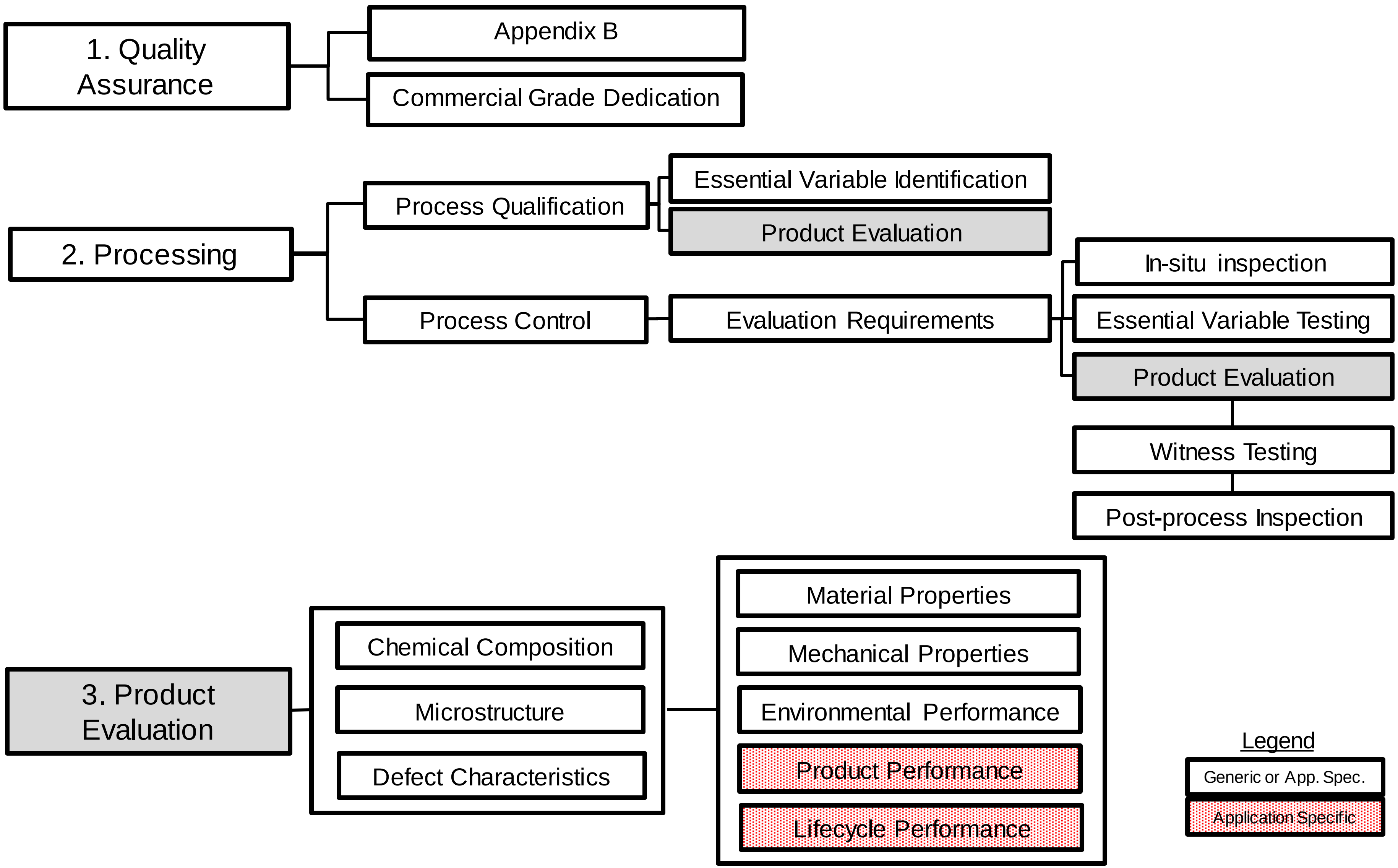

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