United States Nuclear Regulatory Commission
DRAFT Action Plan for Advanced Manufacturing Technologies (AMTs)

1.0 Background and Objective

On January 04, 2018, the Executive Director for Operations (EDO) issued a memorandum [1] to all Nuclear Regulatory Commission (NRC) staff that acknowledges that the introduction of "new and novel technologies" in the nuclear industry will challenge our current regulatory framework and that, without changes in our regulatory approach, licensees have indicated that they will be unwilling to initiate plant modifications. The memo identifies "new materials and manufacturing approaches" in the context of emerging novel technologies. The overall message to the NRC staff is: identify, encourage, and implement innovation and transformation so that the NRC will realize enhancements in our effectiveness, efficiency, and agility. The emphasis on taking a more proactive posture for new technologies is also reflected in SECY-18-0060 [2] issued by the EDO to the NRC Commissioners. The enclosures to SECY-18-0060 indicate that the NRC staff should: engage early with ongoing industry research; develop codes and standards that support the use of new materials and manufacturing methods while ensuring the safety of these techniques; address updates to NRC guidance documents; and conduct other appropriate activities. Enclosures 1 and 8 of [2] note that the "NRC is currently developing an advanced manufacturing action plan that will address appropriate guidance updates and other activities."

Advanced manufacturing refers to a family of activities relating to the use and coordination of information, automation, computation, software, sensing, networking, and interoperability to manufacture existing products in new ways, or to manufacture new products emerging from the use of new technologies [3]. Advanced manufacturing technologies (AMTs), which are of interest to the NRC, 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). In this document, 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 make or join hardware[1], surface treatments, or other processing techniques to provide a performance or operational benefit. The potential uses of AMTs are of increasing interest to the U.S. nuclear industry [4]. The NRC recognizes that the nuclear industry is likely to use AMTs in applications that require regulatory oversight. Consistent with the NRC mission, EDO direction, and Agency Principles of Good Regulation, the Agency must be prepared to perform an independent and efficient evaluation of topics for which it has regulatory responsibility. The purpose of this NRC action plan is to develop a strategy that will enable the NRC staff to effectively, efficiently, and transparently regulate components manufactured using AMTs.

Traditionally, structural materials and manufacturing methods for safety-related nuclear hardware are controlled and managed through consensus codes and standards that are endorsed through regulatory guides or incorporated into the NRC regulations. Safety-related hardware that is not produced using an NRC endorsed code or standard is required to comply with alternate requirements, which may or may not require NRC review and approval. It is anticipated that licensees may pursue any of these regulatory paths for utilizing AMTs. During the development of this action plan, the staff has not identified nor does the staff anticipate that

[1] Hardware is generically used to refer to the end product which can be a component, part, feature, or assembly. These terms will be used interchangeably through this document.

regulatory changes will be necessary for licensees to utilize AMTs; however, guidance may be needed for both staff and licensees to ensure efficient review of applications that include AMTs.

Past experience (see Appendix A for examples) has demonstrated that NRC approval can be granted when non-traditional materials, manufacturing, or processing methods are used for safety-related hardware and the current regulatory paths are used; however, there are efficiencies that can be gained. Some broad lessons learned[2] from these examples to ensure efficient reviews of non-traditional manufacturing technologies include:

- Early communication and pre-coordination between the staff and applicant/licensee is essential
- Quality and completeness of applications affect review efficiencies
- Staff knowledge of technology prior to submittal is needed
- Staff knowledge on how the technology meets (or fails to meet) the consensus codes and standards and/or regulations prior to submittal is needed
- Staff knowledge of past research and ability to conduct appropriate confirmatory research to strengthen basis for reasonable assurance of adequate safety are needed

This action plan is aimed at utilizing these lessons learned to aid in preparing the staff for AMT submissions prior to formal requests from the industry.

The objectives of this action plan are to:

- Identify the AMTs most likely to be used for nuclear hardware that requires NRC approval,
- Prepare the NRC staff to review regulatory submittals containing hardware manufactured using AMTs,
- Identify and address AMT characteristics pertinent to safety that are not managed or controlled by codes, standards, regulations, etc.,
- Provide guidance and tools for review consistency, communication, and knowledge management for the efforts associated with AMT reviews,
- Provide transparency to stakeholders on the process for AMT approvals.

Characteristics of this plan include:

- The plan is a living document and modifications will be incorporated as needs dictate, with an initial expected review and revision cycle of approximately 6 months[3].
- The plan is technology neutral and relies on identification of performance-based criteria that are considered essential in providing reasonable assurance of safe and reliable implementation of AMT hardware. A near term assessment of the most likely initial AMT will be completed.
- The plan is not meant to develop a new regulatory process but will develop tools to aid the staff in efficiently reviewing submittals that utilize AMTs. The plan is also forward looking, and its deliverables need not apply to submittals with currently pending regulatory action.
- The plan will be discussed at a public meeting, and public comments will be considered during revision.

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[2] Continued review of history in reviewing non-traditional methods, development of lessons learned, and incorporation of these into this living document will occur naturally and are not a direct part of this action plan.

[3] Updates to the plan that include changes to the schedule and resources will be approved at the Division Director level, while all other changes will be approved at the Branch Chief level.

2.0 Performance-based AMT Application Characteristics
The regulatory framework for NRC review and approval of components is highly dependent on the type of system in which the part is used (e.g., reactor coolant pressure boundary, non-safety system for nuclear reactors, fresh fuel fabrication, or spent fuel storage containers) and the part's intended functions. Regardless of materials or manufacturing processes, safety-related components for light water reactors (LWRs) are required to be designed, constructed, inspected, tested, and/or maintained to a high level of quality as defined by 10 CFR 50, Appendix B. Discussion of how these topics relate to safety goals is addressed by 10 CFR 50 Appendix A, "General Design Criteria for Nuclear Power Plants," specifically general design criteria (GDC) 1, 2, 4, 10, 14, 15, 30, 31, 32, 36, and 37, and could include other GDC depending on the specific reactor system. In addition to the design criteria, current regulations provide rules for the design, manufacture, use, and maintenance of nuclear components. A partial listing of the applicable regulations for AMTs can be found in Appendix B of this document.

2.1 Regulatory Paths
There are several regulatory paths available to a licensee for utilizing an AMT in a nuclear application. A brief overview of the following four regulatory paths is provided below:

- Develop a Code or standard that can be incorporated by reference (IBR) in 10 CFR 50.55a.
- Select an unregulated in-service application.
- Submit generic technical reports or plant-specific submittals for NRC approval.
- Implement the 10 CFR Part 50.59, 10 CFR Part 70.72, or 10 CFR Part 72.48 process.

One method to meet the NRC safety objective and to assess whether there is reasonable assurance of the capability, availability, and integrity of a component is compliance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code (hereafter the ASME Code) as IBR in 10 CFR 50.55a, "Codes and Standards." If the manufacturing and use of a component meets the current codes, standards, and regulations, then no submittal to the NRC is required. Incorporating codes and standards into regulation is a reliable approach that ensures operational safety; however, it is also recognized that the incorporation of updates and new technologies in the codes and standards is time consuming. The rapid development of AMTs can challenge the practicality of relying on consensus codes and standards for initial acceptance. Likewise, NRC approval is not required for unregulated in-service applications that use AMTs.

As an alternative to complying with 10 CFR 50.55a, the submittal of generic topical reports or plant-specific submittals for NRC approval can be used to demonstrate the acceptability of alternatives to codes and standards requirements in accordance with 10 CFR 50.55a(z). These alternatives are reviewed to determine that they provide an acceptable level of quality and safety; or that they demonstrate that the requirements of ASME Code present a hardship without a compensating increase in quality or safety. Past examples of approval of non-traditional material, manufacturing, or processing methods can be found in Appendix A.

Licensees may implement 10 CFR Part 50.59, 10 CFR Part 70.72, or 10 CFR Part 72.48 to demonstrate that the use of AMTs does not require an application to the NRC for approval. These regulations provide a threshold for determining when NRC approval of changes, tests, or experiments is necessary to preserve the basis on which the NRC issued the facility operating license. The NRC regional staff may inspect the licensee implementation of these change processes in accordance with NRC inspection procedures. Taking this approach runs some regulatory risk for the applicant/licensee as the NRC may not concur with the licensee's conclusions that NRC approval was not required. As a result, these cases may be dispositioned through enforcement.

2.2 Technical Evaluation Areas

The depth of the NRC staff review will be commensurate with the safety significance of the component produced by the AMT. The degree to which a topic requiring regulatory oversite is impacted by AMTs may vary significantly and in a manner that is direct (i.e., component performance) or indirect (defense-in-depth). The objective of the technical evaluation is to determine if there is reasonable assurance of adequate protection. Generically, the type of information needed to demonstrate the acceptability of parts fabricated using an AMT will address these areas:

- Design and performance considerations
- Material and processing considerations
- Demonstration and data considerations
- In-service considerations

The technical evaluation of an AMT produced component will be conducted in the context of the final in-service application. Specifically, a determination will be made by the NRC staff on the ability of a component, produced utilizing an AMT, to safely perform its intended function. However, the focus of any review will be on those performance characteristics pertinent to safety that deviate from the traditional manufacturing requirements. The remainder of this subsection will provide high-level generic considerations for performing a technical evaluation.

2.2.1 Design and Performance Considerations

The identification of the component-specific design requirements and performance criteria is critically important because this information will determine the acceptance criteria for the review. It should be recognized that the design requirements and performance criteria for the component may not be identical because of implicit assumptions made for traditionally manufactured components and/or unique operational considerations. Performance criteria[4] may include physical properties, mechanical properties, dimensionality, functionality, and reliability. Substantiation of performance criteria through the evaluation of data and/or demonstration testing (discussed in Section 2.2.3) should not be confused with identifying the component-specific criteria to be used as review criteria.

Translating the component-specific performance criteria into applicable/relevant AMT-specific review items is a necessary and important step in the technical evaluation. Successfully executing this step early in the review process is critical in achieving an effective and efficient review. It should be recognized that not all performance criteria will map to review items, nor will the safety significance of all performance criteria be equivalent. Focus will be on those items important to safety that are not covered by traditional manufacturing requirements. Communication, coordination, and transparency will facilitate the successful execution this step.

2.2.2 Material and Process Considerations

The term processing is generically used to describe all steps in transforming a raw material to a finished product. The processing of a nuclear component may be complex, involve diverse procedures, and include many steps. It should be recognized that an AMT may involve unique feed stock and product forms, such as powder metallurgy and additive manufacturing. The staff evaluation of the processing will consider procedures unique to the AMT and/or directly affected by an AMT. For example, product form dependent strength and allowable stress values for stainless steel, type 304L can be found in ASME Section II for welded tube, seamless tube, bar,

[4] In this document it is assumed that performance criteria always include design requirements.

plate and forgings. Since additive manufacturing and powder metallurgy utilize a powder form of feedstock material, the staff should consider how the powder is produced, controlled, and processed, and how it meets the current codes and standards for materials. The staff evaluation will focus on aspects of the material and processing critical to the quality, reliability, and performance of the finished product that deviate from those requirements associated with traditional manufacturing. The staff evaluation will determine if there is reasonable assurance that the AMT processing produces a consistently repeatable product of a known and acceptable quality.

Consistent with 10 CFR Part 50 Appendix B requirements, each processing step is to be performed using a quality assurance procedure with appropriate documentation. This procedure may be performed to the requirements of an industry consensus standard or site-specific standard (e.g., in-house procedures). Critical processing parameters will be identified in submittals, along with the parameter values and a technical basis for the values. The compliance with requirements of the pertinent processing standard shall be confirmed in an appropriate manner, such as process logs, inspection, and testing.

2.2.3 Demonstration and Data Considerations

The submittal must demonstrate that the AMT will produce components that meet the design requirements and performance criteria (review criteria identified in Section 2.2.1) for the in-service application. The demonstration data may be produced using a combination of standardized test methods, application-specific test methods, relevant OE, or other credible method/source. The pedigree of data used to substantiate performance is one consideration. Data used to substantiate acceptable performance is generated using processing parameters that conform to the applicable processing standard controlling the production of the components. The statistical significance of performance data (e.g., typical values, average values, exceedance values, ratioed values, limits, ranges) and derivation of the values should be considered. The validity and appropriateness of benchmarking is to be considered on a case-by-case basis commensurate with the safety significance. The validity and appropriateness of performance indicators is to be considered on a case-by-case basis commensurate with the safety significance. As with all technical evaluation areas, the staff review should focus on those aspects of the AMT that may affect the safety function of the component and deviate from the traditional manufacturing requirements.

The in-service performance of AMT produced components may be sensitive to the as-fabricated defects, including the defect characteristics and their populations. Of specific interest are the types of defects, their size, their spatial distribution, and their impact on structural integrity. The application should provide information on these topics and planned pre-service inspection, as coupled with Inspectability in Section 2.2.4.

2.2.4 In-service Considerations

2.2.4.1 Degradation Management

In-service degradation is related to aging effects such as material property degradation (e.g., reduction in fracture toughness, hardening) and physical degradation (e.g., loss of material due to corrosion, cracking, dimensional changes). Understanding how a component will behave in its service environment, or how it may behave differently from a traditionally manufactured component, is critical to enable appropriate monitoring of the performance of the part. The staff should also verify that adequate information on degradation of the part over time is available to assure the part will continue to perform safely over the time frame for which it is approved. A graded approach in proposing various levels of aging management based on the level of information that is provided should be considered. An AMT produced component that is shown to have no difference in degradation than its traditionally manufactured counterpart, may not need any change in aging management.

This review area could utilize service performance information from other industries with similar operating environments, accelerated laboratory data (with a proper accounting for the differences in the service environments), or coupons exposed to the same environmental stressors as the installed part.

2.2.4.2 Inspectability

The inspectability of parts is a critical consideration in their use. This includes “pre-service” inspections (in-process and post-fabrication) and in-service inspection.

Inspections and quality assurance must be considered and applied during all phases in the life-cycle of a safety-related or safety-significant part. Beginning with the design of the AMT part, in-process, post-process, and in-service inspection must all be addressed. Inspection and verification of performance criteria is a method by which reasonable assurance of adequate performance is attained. The performance criteria that must be verified and the inspection methods that will be utilized should be identified and considered by the staff in its review.

The inspection of AMT processes and parts should enable identification of important defect types, defect geometries, and spatial distributions of defects that likely will be unique to the AMT. The emphasis of these inspections is on the defects that could challenge the structural integrity of the AMT part or that adversely affect performance of safety functions. In-process inspection techniques that allow immediate identification of defects and repair of the part, if repair is possible, should be identified in the application.

3.0 Near-term needs – Task 1

Through discussions at workshops, conferences, and public meetings, the NRC staff acknowledge that the use of nuclear components manufactured by AMTs is imminent. A PWR vendor has suggested that an in-core item manufactured with Additive Manufacturing (AM) might be the first AMT component used in PWRs in the spring of 2019. Whatever the first use may be, a licensee may pursue the use of the 10 CFR 50.59[5] process. Therefore, a near-term goal of this plan is to provide support to Regional staff during this expected near-term implementation. The main assumption in this near-term effort is that a single AMT produced component will be installed within the next 12 months. There is a possibility that no components will be installed, or that multiple components may be installed within that time frame. The actions in this plan may not be sensitive to this possibility, but the schedules and resources listed in Section 8 and the action plan table will need to be revisited if more than one AMT component is implemented within the next 12 months.

To provide this support, the headquarters (HQ) staff needs to determine the possible AMT processes under consideration and proactively determine the regulatory path planned for the expected application. Public forums such as the Regulatory Information Conference (RIC; an AMT technical session will be held at the 2019 RIC [5]), quarterly materials technical exchange meeting with industry groups, and ASME BPV Code Week attendance will be used to communicate with the industry, vendors, and contractors the need to proactively prepare for the first AMT use and gather information about the plan.

[5] It is recognized that 10 CFR Part 72.48 may also be used for the first application. The deliverables generated here will be tailored to either 10 CFR 50.59 or 72.48, whichever is applicable.

The staff will develop a memorandum describing the AMT technology proposed and its schedule for implementation within 3 months of approval of this action plan[6]. The staff will develop a similar memorandum for each AMT proposed. This information gathering effort will continue beyond the near-term needs (See Section 4) as other AMTs are considered for implementation.

Using the information from these interactions, information from Section 2 of this report, additional staff training, site visits, contractor support, and the data gathered from earlier efforts [4,6], **the staff will develop a document within 4 months of the approval of this action plan that describes the initial AMT characteristics important to safety, the essential safety differences between the proposed initial AMT produced component relative to traditional manufacturing, and the aspects of the technology not addressed by codes and standards or regulations.**

Within 4 months of the approval of this action plan, the headquarters staff will develop briefing materials (e.g., documents, presentations, etc.) for the Regional staff as they review the use of AMT produced components through 10 CFR 50.59. Topics to be addressed will include if the components create a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety, if AMT use results in a departure from a method of evaluation described in the FSAR, etc. Additional support to the Regions will be provided as requested by the Regional staff. These briefing materials will be updated as other AMTs are proposed.

4.0 Continuing needs – Task 2

Since the 10 CFR 50.59 process may not be appropriate in all cases, the use of AMT produced components might be submitted through other regulatory processes (e.g., topical report or 10 CFR 50.55a(z)). The longer-term goal of this action plan is to prepare staff for efficient and effective review of AMT produced components submitted to the NRC for review and approval. The staff needs to appropriately understand each proposed AMT, its characteristics important to safety, how the technology meets (or does not meet) the current regulations, and which AMT characteristics pertinent to safety are not addressed by codes and standards. To meet this goal, the following activities will be completed.

Staff will continue interactions with a variety of external organizations, including codes and standards developers, other government organizations (both regulatory and non-regulatory), industry (collective groups such as EPRI, NSSS vendors, and manufacturers), and international organizations (multinational such as the IAEA, CNRA, OECD/NEA and OECD/CSNI, regulatory organizations, R&D organizations and plant operators). Staff will engage with these organizations as appropriate to gain an improved understanding on the use and performance of AMT parts. Identification and descriptions of each of these organizations is provided in Appendix C. This effort will also build on the interactions supporting the actions in Section 3.

A detailed plan for interacting with the full range of external organizations will be developed within 2 months of the approval of this action plan. For each proposed external organization interaction, this plan will specify the purpose, identify the lead staff organization (RES, NRR, etc.), provide a short description of the interaction, provide a detailed schedule and estimate the needed resources. For similar government agencies, the interactions will include discussions of their action plans and areas that the NRC may need to enhance in this plan.

In addition to these external interactions, staff will continue internal interactions to ensure all the information gathered is available and communicated to all Offices. The inter-office AMT team,

[6] The bold items in this action plan represent the major plan deliverables.

which was developed to generate this document, will continue to meet on a regular basis to discuss progress and emergent information and coordinate communication to affected technical staff and management within the agency.

As more AMTs are proposed, management and staff will consider available staffing options, as needed to support regulatory objectives. Some of the options to consider include:

- Hiring of AMT experienced staff
- Intensive training program for current staff member(s) (e.g., Senior Graduate Fellowship Program)
- Rotational assignments to improve cooperation and communication with other organizations actively working on relevant AMTs (i.e., DOE-NE, NASA, DOD, NIST, FAA)
- Temporary assignment of personnel between agencies within the Federal Government, colleges and universities, federally funded research and development centers, and other eligible organizations, in accordance with the Intergovernmental Personnel Act (IPA) Mobility Program

Using the information and knowledge gathered, the staff will develop a document within 6 months that describes the generic technical information needed in AMT submittals. That report will be discussed at a public meeting and modified accordingly. That report will build on the general characteristics discussed in Section 2 of this plan and will identify broad areas where AMT technology deviates from traditional manufacturing from a regulatory perspective. The focus of the report will be on the current state of knowledge, and it may only be applicable for those AMTs planned in the next 2-5 years. That report will serve as a resource for staff reviewers of AMT submittals and may be updated as more information about AMTs becomes available.

5.0 Determine if updated or new guidance is necessary – Task 3

Periodically, the staff will assess whether any regulatory guidance (e.g., regulatory Guides, standard review plan sections, etc.) needs to be updated or created to clarify the process and procedure for reviewing submittals with AMT components. The need for revision will be based on the information gathered through this action plan and experience obtained through review of AMT component submittals. **The staff will develop a memorandum to the division directors recommending a path forward on guidance development or modification within 8 months.** Public meetings will be held if needed.

6.0 Knowledge management – Task 4

Once the information on AMTs is available and used in review of AMT-related submission, it's necessary to archive the knowledge so future staff unfamiliar with this process can readily access the information. Knowledge management (KM) will be handled through a living KM plan, and the documents and information generated will be updated on a periodic basis. For this task, the staff will develop, implement, and actively maintain KM activities related to AMTs. Potential KM activities include:

- AMT seminars - Provide quarterly seminars (with either internal or external presenters) on AMT approaches, including discussion of aspects related to the NRC technical evaluation areas.
- AMT Training – Assess the value of NRC staff attending external training and workshops.
- SharePoint - Complete development of a structured, transparent SharePoint site or similar repository for relevant AMT information.
- AMT KM - Propose effective means for communicating to staff technical information related to AMTs.
- Process KM - Propose effective means to communicate to staff the framework for review of AMT submittals.
- Options - Identify and characterize options for technical support of NRC review of AMT submittals

A KM plan will be developed within 6 months of the approval of this action plan. This plan will identify the lead staff organization (RES, NRR, etc.), provide details of the KM approach, and provide a detailed schedule and an estimate of resources.

7.0 Update Action Plan – Task 5

This action plan was developed based on the current state of knowledge and the assumption that the application of a single AMT component in a U.S. nuclear reactor would occur over the next 12 months. However, with the rapidly changing technical landscape, it is prudent to revisit this action plan on a periodic basis. **Therefore, the staff plans to revisit and revise this action plan (as needed) at approximately 6-month intervals.** This interval may be extended if the staff determines the technology development has not progressed enough to warrant a change. Updates to the plan that include changes to the schedule and resources will be approved by the cognizant Division Director(s), while all other changes will be approved by the cognizant Branch Chief(s).

8.0 Action Plan Basis to Prepare Staff for Performance-based AMT Submittal

The actions to be taken, schedule, resources, and responsible Office are given in the attached action plan table.

A public meeting will be held within one month of the issuance of this plan to inform stakeholders and ensure their perspectives and concerns are understood. The staff will consider this information when finalizing this plan. However, to meet the aggressive schedule in this action plan, work will begin concurrently with the development, conduct and resolution of the public meeting.

9.0 References

[1] Memorandum from V.M. McCree to all NRC Staff, “Innovation and Transformation at the NRC,” ADAMS Accession No. ML18004A021, January 4, 2018.

[2] SECY-18-0060, Achieving Modern Risk-Informed Regulation, ADAMS Accession No. ML18110A186, May 23, 2018.

[3] Office of Science and Technical Policy, National Strategic Plan for Advanced Manufacturing, Federal Register, Vol. 83, No. 24, February 5, 2018. pp 5147-5148.

[4] NUREG/CP-0310, Proceedings of the Public Workshop on Additive Manufacturing for Reactor Materials And Components, ADAMS Accession No. ML18221A109, Draft May 2018.

[5] 31st Annual Regulatory Information Conference, March 12-14, 2019, Rockville, MD https://www.nrc.gov/public-involve/conference-symposia/ric/

[6] McGinty, T.J., Research Assistance Request for Evaluation of Additive Manufacturing (3-D printing) of Metallic Parts by Direct Metal Laser Melting, Memo to B.T. Thomas, (ADAMS Accession No. ML17240A253), Aug 31, 2017.