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## Submitter Information

**Name:** Hilary Lane

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## General Comment

See attached file(s)

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## Attachments

02-08-21\_NRC\_NEI Comments on Draft Regulatory Basis

**HILARY LANE**

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February 8, 2021

Jennifer Borges  
Office of Administration  
ATTN: Program Management, Announcements and Editing Staff  
Mail Stop: TWFN-7-A60M  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Subject:** Industry Comments on Draft Regulatory Basis Document, "Implementation of Quality Assurance Criteria and 10 CFR 50.59 for Nuclear Power Plant Components Produced Using Advanced Manufacturing Technologies," Docket ID NRC-2020-0253

*Submitted via regulations.gov*

**Project Number: 689**

Dear Ms. Borges:

The Nuclear Energy Institute (NEI)<sup>1</sup>, on behalf of its members, submits the following comments on the draft Regulatory Basis document, "Implementation of Quality Assurance Criteria and 10 CFR 50.59 for Nuclear Power Plant Components Produced Using Advanced Manufacturing Technologies," which represents Sub-task 2A on the NRC's Advanced Manufacturing Technologies (AMT) Action Plan. We appreciated the opportunity to discuss this draft with NRC staff at the recent January 14, 2021 public meeting. Furthermore, the issuance of a revised Federal Register Notice (FRN) on December 10, 2020, was most welcomed, as it extended the comment period from 45 days to 60 days, and allowed the industry a greater timeframe for review.

AMT applications are of significant interest to both the current operating fleet and advanced reactor developers. There are numerous AMTs that are technologically mature for use in the nuclear industry, and in fact many are already being used in other industries. Testing and qualification efforts by suppliers, the Electric Power Research Institute (EPRI), DOE National Laboratories, universities, and others are well

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<sup>1</sup> The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

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underway to further expand AMT use in safety-related applications for the nuclear industry. Many of these activities were discussed at length at the NRC's recent AMT Workshop, on December 7-10, 2020, which we found to be very productive and informative.

We recognize that the intent of this draft document is not to create new regulatory requirements or establish new regulatory positions. We also understand that this draft document may be subject to future revision, and support the notion that such future revisions would factor in additional industry operating experience and insights. We feel this is one of several components in creating a risk-informed regulatory framework for AMTs. We also believe that AMT experiences and insights from other industries can play a role in regulatory decision making.

The nuclear industry's first AMT deployment using the § 50.59 pathway occurred in Spring 2020. We expect to see many other applications of AMT pursue a § 50.59 pathway, with additional deployments in the pipeline, continuing as early as Spring 2021. Provided the provisions of § 50.59 are satisfied, this well-defined, pre-existing regulatory approach allows the industry a straightforward and efficient method to deploy AMT components, without the need for a license amendment or prior approval. As such, we want to emphasize that there is considerable and continuing interest in utilizing the § 50.59 regulatory pathway for future applications. We support the NRC's conclusion that the current QA criteria and § 50.59 regulations are sufficient for AMT applications.

As industry interest continues to grow, we underscore the importance of communication amongst multiple stakeholders, in furthering the development of these transformative technologies. We look forward to further engagement on AMT and working together throughout the progression of the NRC's AMT Action Plan.

Our more detailed comments can be found in the attachment to this letter. Please do not hesitate to contact me ([hml@nei.org](mailto:hml@nei.org) or 202.341.7951) should you have any questions.

Sincerely,

  
Hilary Lane

Attachment

c: Mr. Hipolito Gonzalez, NRR  
Mr. Isaac Anchondo-Lopez, NRR

**Attachment: NEI Detailed Comments on Draft Regulatory Basis, "Implementation of Quality Assurance Criteria and 10 CFR 50.59 for Nuclear Power Plant Components Produced Using Advanced Manufacturing Technologies"**

Section	Comment	Proposed Resolution
Pg. 8	<p>The third paragraph has the following sentence:</p> <p align="center"><i>"However, for plant-specific applications, all relevant information related to specific AMT components and the component that will be replaced needs to be identified and analyzed for site-specific <b>efforts</b>."</i></p>	<p>Clarification is requested on whether the word "efforts" should instead read "effects."</p>
Pg. 25	<p>The following statement makes an assumption about the current state of AMT Codes and Standards:</p> <p align="center"><i>"It is also assumed that the AMT material/fabrication method has <u>not</u> yet been codified by the U.S. nuclear industry in a national consensus standard that has been formally endorsed by the NRC."</i></p>	<p>There are several SDO activities currently under review, including a code case submission to ASME Section III in August 2020, that would change the stated assumption.</p> <p>By the nature of the NRC's statement, it begs the question as to whether the presence of an endorsed code case would change the outcome of applying the § 50.59 Screening (as outlined in Fig. 1 and in Section 4.2, Page 27). In fact, it seems reasonable that at this point in the process, the presence of an endorsed code case should automatically eliminate the need to perform a full § 50.59 Evaluation in conjunction with the 8 evaluation criteria. This is oftentimes referred to as "screening out."</p> <p>We recommend including a statement in Section 4.0 that would clarify and delineate how the presence of an endorsed code case would streamline the overall process for licensees, including any efficiencies through the § 50.59 process, including "screening out."</p>
Pg. 29-30	<p>We noticed that certain terms in the document are <i>italicized</i>. We assume this is to mean that they are defined terms, but that was not made clear.</p>	<p>Changing pre-defined terms may lead to confusion with the reader and/or licensee, and should be avoided. Consider keeping the terminology consistent with previously endorsed NEI 96-07 and related documents.</p>

	<p>Furthermore, certain italicized terms do not explicitly match the terms in NRC-endorsed NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation." One specific example of this was the defined term "Methods of Evaluation" (Rev. 1, Sec. 3.10).</p> <p>NRC's draft document uses a different italicized term, to the effect of "<i>element of an evaluation method.</i>"</p> <p>There are also instances when the original defined term "method(s) of evaluation" are used (see Pages 25, 29, 30, 33), however it is not italicized in line with other key terms.</p>	<p>Further, terms or definitions should be identified consistently throughout the document, whether it is determined to be quotation marks and/or italics.</p>
<p>Pg. 31, Figure 3</p>	<p>The process conclusion on the bottom left would be more accurate if it stated that the change "...may be <b>documented and implemented</b> per 10 CFR 50.59."</p> <p>The difference being that in the other two process conclusions, a § 50.59 evaluation will be documented with an outcome of either 1) the licensee may implement per § 50.59, or 2) a license amendment request is necessary per § 50.90. Thus, all three flowchart end states could result in "may be implemented per 10 CFR 50.59;" the difference is in the point in the § 50.59 process where that conclusion is reached.</p>	<p>N/A</p>
<p>Pg. 33</p>	<p>Consider changing the following phrases from "as" a departure to "for" a departure.</p> <p>This avoids pre-judging the outcome of the evaluation and response to criterion (viii).</p>	<p>Revised language could read as follows:</p> <p>(1) "Adverse changes to elements of a methodology are treated <b>for</b> a departure from a <i>method of evaluation.</i>"</p> <p>(2) "For AMT components, material properties or other component design parameters should be considered methodology elements if they meet either of the above criteria; adverse changes to these elements should be evaluated <b>for</b> a departure from the <i>methods of evaluation</i> in accordance with 10 CFR 50.59(c)(2)(viii)."</p>