

July 18, 2016

Anthony R. Pietrangelo
Senior Vice President and Chief Nuclear Officer
Nuclear Energy Institute
1201 F Street, NW, Suite 1100
Washington, DC 20004

SUBJECT: MANAGEMENT OF CERTIFIED DESIGN ERRORS IN COMBINED LICENSE APPLICATIONS

Dear Mr. Pietrangelo:

I am responding to a September 30, 2015,¹ letter from the Nuclear Energy Institute (NEI) regarding management of certified design errors in combined license (COL) application reviews. The NEI letter suggests that the Nuclear Regulatory Commission (NRC) staff engage with the Commission regarding use of license conditions to address such errors. The staff has considered NEI's proposal and wishes to discuss approaches to address these errors with NEI and other stakeholders in a public meeting. The staff plans to communicate with the Commission following consideration of feedback from this meeting.

In circumstances where it is suitable to address significant certified design errors through plant-specific action, the preferred option is for COL applicants to provide information demonstrating that a departure from the certified design meets regulatory requirements. This departure process is well established, and, once a technical solution has been developed by the vendor and applicant, the process can provide timely resolution of significant certified design errors to allow issuance of the COL. It also provides the greatest clarity regarding both technical and process requirements for all stakeholders.

The NRC expects that, in many cases, the rulemaking process would also be used to correct the certified design. However, rulemaking can be a lengthy and resource-intensive process, as compared to using the departure process to address certified design errors for a relatively small number of licensees and applicants, particularly if a common technical solution is adopted by those parties. Therefore, rulemaking is not necessarily a timely or efficient means to address individual errors in a certified design that may be identified in the course of a COL application review.

The NRC staff understands that there may be circumstances where a COL applicant might wish to address significant certified design errors in some other manner to resolve issues more rapidly than the departure or rulemaking processes. In addition to license conditions as discussed in NEI's letter, potential approaches that have been discussed include design

¹ Letter, Douglas J. Walters to Glenn Tracy, "Combined License Application Management of Design Changes," September 30, 2015, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15279A407.

acceptance criteria (DAC) or other inspections, tests, analyses, and acceptance criteria (ITAAC).

The acceptability of approaches other than the established departure and rulemaking processes heavily depends on the specific issue, and the ability to demonstrate that the approach ensures legal and regulatory requirements are met. To resolve a significant error which undermines safety findings made during the design certification review, a COL applicant must provide sufficient information to permit the NRC to conclude that regulatory requirements have been fulfilled. As discussed in the NRC's April 15, 2015, letter to Duke Energy,² a COL represents a final safety decision that all regulatory and legal requirements have been fulfilled, in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Section 52.97, "Issuance of combined licenses." This standard is also reflected in the NRC's interim staff guidance, "Finalizing Licensing-basis Information," DC/COL-ISG-011,³ which states that "under no circumstances will the NRC grant an application that does not satisfy the requirements of the Atomic Energy Act and the Commission's regulations." Therefore, any license condition or other mechanism used to address significant certified design errors in COL reviews must provide a sufficient and objectively verifiable basis for the NRC staff to conclude that all legal and regulatory requirements have been fulfilled. The staff's consideration of applicant proposals will be controlled by this requirement.

Verification that a license condition has been satisfied represents a ministerial act on the part of the NRC to confirm a requirement has been fulfilled. Such an act can not rely on conclusions from additional review by the NRC of the kind performed for a license amendment or other licensing action. By definition, the need for such additional review after a license has been granted means the NRC would not be able to find that regulatory and legal requirements have been met at the time a COL was issued. Therefore, a license condition requiring that the NRC complete a safety evaluation for a future licensing action is not an acceptable approach.

If applicants wish to pursue DAC as a means to resolve errors in certified designs, further information will be needed to develop a recommendation for the Commission's approval. The Commission has only approved DAC for certain topics, such as piping, human factors engineering, and digital instrumentation and controls. The NRC staff does not at this time have a sufficient basis to propose expansion of the use of DAC into other technical and programmatic areas. Similarly, further information is needed before some other mechanism can be considered as a means to resolve certified design errors.

The NRC staff believes that determining the viability of license conditions or other mechanisms for addressing a particular certified design error will require early engagement between the NRC staff, and the applicant and its representatives, including any contractors with cognizance of pertinent design engineering information. This early engagement should ensure a well-informed understanding of the safety significance of an issue and potential technical solutions, and transparent consideration of the viable courses of action, including the regulatory tools and processes to be applied, and proposed milestones for submittals and completing regulatory action.

² Letter, Glenn Tracy to Christopher Fallon, "Request for Guidance Clarifying Appropriate Methods for Resolving Generic Errors in Certified Design Information," April 15, 2015, ADAMS Accession No. ML15083A218.

³ ADAMS Accession No. ML092890623.

In order to support identification and development of a framework for constructive early engagement with COL applicants who find a need to address significant certified design errors through approaches other than the rulemaking and departure processes (e.g., license conditions or DAC), the staff proposes that a public meeting be held to discuss the details and implications of your specific proposal, as well as other possible approaches. It would be helpful if you provide specific examples of the proposed use of license conditions or other mechanisms that meet the criteria discussed above. All interested stakeholders will be given an opportunity to participate in the meeting to share their perspectives. The staff will determine the form and content of its Commission communication after obtaining this stakeholder feedback.

While the staff is assessing options, new certified design errors may be found that require resolution before combined license application reviews can be completed. Applicants should apply a relatively high threshold when considering the use of approaches other than the established departure and rulemaking processes to avoid unnecessary delay in completing the license application review.

We look forward to the opportunity to discuss this important matter with NEI and other stakeholders.

Sincerely,

/RA/

Jennifer Uhle, Director
Office of New Reactors

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/RA/

Jennifer Uhle, Director
Office of New Reactors

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ADAMS Accession Number: ML15351A021

*** via E-mail.**

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A. Pietrangelo

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Letter to Anthony R. Pietrangelo from Jennifer Uhle dated July 18, 2016

SUBJECT: MANAGEMENT OF DESIGN CHANGES IN COMBINED LICENSE
APPLICATIONS

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