

MICHAEL D. TSCHILTZ

Senior Director, New Plant, SMR and Advanced Reactors

1201 F Street, NW, Suite 1100
Washington, DC 20004
P: 202.739.8083
mdt@nei.org
nei.org



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Ms. Vonna Ordaz
Acting Director, Office of New Reactors
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Avoiding Delays in Issuance of NRC Combined Licenses due to Design Certification Errors

Project Number: 689

Dear Ms. Ordaz:

On behalf of its members, the Nuclear Energy Institute, Inc. (NEI)¹ has recently engaged the NRC staff on the need to develop an effective process for resolving errors in 10 CFR Part 52 standard design certifications when those errors arise during review of a combined license (COL) application, without the need to delay issuance of the COL. In a July 18, 2016 NRC letter to NEI,² the NRC stated that the only established methods for resolving such errors are initiation of a design certification rulemaking or case-by-case NRC reviews of proposed departures from the design control document (DCD).

While acknowledging that there might be other approaches, e.g., use of license conditions and/or design acceptance criteria (DAC), the NRC staff identified challenges with both of those methods, and stated that combined license applicants "should apply a relatively high threshold when considering the use of approaches other than the established departure and rulemaking process." The NRC also proposed a public meeting to discuss industry proposals and other possible approaches, after which the staff would communicate its views to the Commission.

The industry appreciates the careful consideration that the NRC staff has given to this important issue over the last several years. Unfortunately, the staff's approach leaves open the potential that future COLs could

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

² July 18, 2016 letter from Jennifer Uhle, NRC, to Anthony R. Pietrangelo, NEI, "Management of Certified Design Errors in Combined License Applications."

be subject to substantial delays that are not necessary to assure safety. NEI has therefore identified alternatives for resolving this issue generically. We respectfully request that the staff consider these options for addressing the issue and engage the industry on a recommended regulatory path forward. NEI recognizes that adoption of some of these approaches would necessitate the need for a SECY paper for submission to the Commission.

Need for NRC Action

A number of COL applications (COLAs) have referenced the design certification for the Westinghouse AP1000. Late during the NRC's review of two of those applications (for the William States Lee and Levy County plants), design errors were identified in the AP1000 DCD. Citing DC/COL-ISG-011, *Finalizing Licensing-Basis Information*, the NRC staff required that those errors be corrected by means of departures from the AP1000 DCD prior to issuance of the COLs for those plants.

Development of the design modifications to correct the errors, submission of the departures to the NRC, and NRC review of the departures caused significant delay in issuance of the COLs for the Lee and Levy plants. The other option, rulemaking to correct the DCD, would have resulted in substantially longer delays, given the procedural requirements associated with NRC rulemaking. In the meantime, other AP1000 plants with previously-issued COLs, such as Vogtle Units 3-4 and Summer Units 2-3, were allowed to resolve the design errors during the construction process, without delays and without any impact on safety.

It is possible that the experience of the Lee and Levy plants will not be unique, and that future COL applicants may face a similar prospect of delay. Certainly, the issue presents a previously unforeseen risk that prospective applicants must now weigh. For COL applicants that desire to begin construction upon issuance of a COL, the costs of delay in issuance of the COL can be substantial; *e.g.*, the interest on capital expended in obtaining the COL during the period of delay and the costs of the construction work force to the extent that it has been mobilized. Even in the case of the Lee and Levy COLs, where construction was not affected, the affected NRC licensee (Duke Energy) experienced costly delays in completion of the NRC licensing reviews. Such delays are inefficient for both the NRC staff and the affected licensee.

NEI believes applicants should not have to incur such project delays and additional costs when those delays are not necessary to ensure plant safety. Both the Vogtle 3-4 and Summer 2-3 AP1000s were allowed to continue with construction pending resolution via license amendment of the errors in the design certification.

In an effort to move the discussion forward and facilitate a generic resolution of this issue, we discuss below several alternative methods for addressing DCD errors while avoiding delays in issuance of COLs. We request that the Staff consider these proposals, all of which we believe are viable. Of course, an applicant also would be free to correct the error through a departure from the DCD or design certification rulemaking prior to issuance of the COL, as the NRC has noted. Our recommended additional alternatives are discussed below.

Issuance of a License Condition

The least complicated method and the preferred approach for addressing DCD design errors is through a license condition. However, the NRC's July 18, 2016 letter to NEI indicates that a license condition is not appropriate to address a DCD design error, because a license condition must represent "a ministerial act on the part of the NRC to confirm a requirement has been fulfilled," and cannot rely upon additional review by the NRC staff. This statement appears to be derived from the Commission decision in *Private Fuel Storage* (Independent Spent Fuel Storage Installation), CLI-00-13, 52 NRC 23, 33 (2000), where the Commission stated that a license condition should be "ministerial" in nature.

Some license conditions related to DCD errors may be ministerial in nature. For example, the licensee, vendor or NRC could propose rulemaking to correct the DCD error, to be completed after issuance of the COL.³ A license condition that addresses the design issue based upon the rulemaking would be ministerial — it would simply require NRC staff to confirm that the rule correcting the DCD has been issued, and that the amended DCD applies to the licensee's plant. Similarly, a license condition that required the licensee to obtain a license amendment to resolve the issue prior to operation would be ministerial — it would simply require the NRC staff to confirm that the license amendment had been issued.

With respect to non-ministerial license conditions, the staff's letter accurately reflects the Commission's decision in *PFS* regarding ministerial acts. However, that decision reflects a policy decision by the Commission, rather than a legal requirement. The Commission's decision in *PFS* does not cite any requirement in the Atomic Energy Act or the Administrative Procedure Act that would limit the NRC's ability to use license conditions that are not ministerial in nature. Instead, the *PFS* decision merely refers to "longstanding agency practice." *Id.* We believe the Commission may determine that it is reasonable and appropriate to use a license condition to address a design certification error. Furthermore, to the extent that *PFS* and similar cases reflect any legal considerations at all, those considerations relate to not deferring to post-licensing those issues that could be affected by the results of a hearing — in other words, to preserve hearing rights. *Id.* As stated by the Commission in a subsequent *PFS* decision, CLI-03-8, 58 NRC 11, 20 (2003), the principle that only ministerial issues should be deferred to post-license issuance is designed to preserve the "required hearing opportunity."

Accordingly, NEI believes that the Commission has the authority to change the position expressed in NRC staff's July 2016 letter regarding the nature of license conditions, such that a license condition need not be ministerial in nature, provided that hearing rights are preserved. To preserve hearing rights, implementation of any non-ministerial license condition should require a license amendment with associated hearing rights

³ Construction or installation of the item in question would not necessarily need to await completion of the rulemaking. For example, in anticipation of the amended design certification rule, a licensee could make a departure from the DCD in accordance with Section VIII of the design certification rule and then construct or install the item. However, the license condition could not be closed until the amended design certification rule was issued and the licensee confirmed that its previous departure conforms to the amended design certification rule. If the rulemaking is not completed prior to fuel load, the licensee would need to submit a license amendment request to remove the license condition based upon the departure.

pursuant to Section 189 of the Atomic Energy Act. Alternatively, the administrative hearing rights may be rendered moot through the notice and comment rulemaking process for a design certification amendment following issuance of the COL. Furthermore, to prevent any adverse impact on safety, the license condition should require that the license amendment or design certification amendment be issued prior to authorization for fuel load under 10 CFR § 52.103(g).

NEI recommends that the Commission adopt the following form for a license condition to resolve DCD design errors identified late during the staff's review of a COLA:

- Identify the design error;
- Require a license amendment (or design certification amendment) to correct the error prior to the 10 CFR § 52.103(g) finding; and
- Specify the design methodology for correcting the error and the acceptance criteria for the design.

A license condition that adheres to these principles will preserve any hearing rights related to resolution of the DCD design error.

Furthermore, such a license condition will enable the NRC to make its reasonable assurance finding supporting issuance of the COL, as required by the Atomic Energy Act and NRC regulations. See 10 CFR § 52.97. As the NRC has long recognized, the reasonable assurance finding required for licensing is "predictive" in nature. *See, e.g., Pacific Gas & Electric Co.* (Diablo Canyon Nuclear Power Plant, Units 1 & 2), ALAB-811, 21 NRC 1622, 1627 (1985). The finding may be based on a required process for identifying a resolution of an issue. Thus, for example, while the NRC must make a reasonable assurance finding for issuance of a construction permit in accordance with 10 CFR §§ 50.35(a) and 50.40(a), that finding may account for resolution of certain design issues during the construction process subject to further NRC review and approval and hearing rights at the operating license stage. In sum, there is no statutory or regulatory bar to the use of license conditions at the COL stage requiring resolution of design issues prior to operation, subject to appropriate hearing rights.

Use of Inspections, Tests, Analyses and Acceptance Criteria (ITAAC)

The NRC's letter of July 18, 2016 indicates that the use of design acceptance criteria (DAC) might be a possible means for addressing design errors in a DCD, but then states that the staff does not have a sufficient basis to propose use of DAC for that purpose. To date, DAC is a concept that has been utilized for design certifications but not COLs. In any event, NEI believes that DAC are unnecessary for resolution of DCD design errors. Instead, we propose that an existing ITAAC or a newly developed ITAAC could be used to resolve many (if not all) DCD design errors at the COL stage.

Many ITAAC currently take the following forms:

Design Commitment	Inspections, Tests, Analyses	Acceptance Criteria
The XXX system is designed to perform [safety function].	An inspection and [functional performance] analysis will be performed of the XXX system.	The XXX system can perform [safety function].
The XXX system is designed to perform [safety function].	A test will be performed of the XXX system.	The as-built XXX system performs [safety function].

Furthermore, Tier 2 of the DCD typically identifies the analytical method for assessing the design function. Because most design errors do not adversely affect the safety function or the analytical method but instead pertain to implementing details, it should be possible to develop an ITAAC along the lines depicted above to address many DCD design errors at the COL stage.

Such an ITAAC would enable the NRC staff to make its reasonable assurance finding for issuance of the COL, while allowing the details of the error resolution to be determined during construction. In most cases, development of the ITAAC would be much faster and less resource intensive than trying to develop and justify a departure prior to COL issuance. Furthermore, because satisfactory completion of the ITAAC is subject to an opportunity for hearing pursuant to 10 CFR § 52.103, this alternative would preserve such hearing rights.

Use of a Hybrid COL and Construction Permit

Pursuant to 10 CFR § 52.97(a)(1), the NRC may issue a COL if:

- (i) The applicable standards and requirements of the Act and the Commission's regulations have been met;
- (ii) Any required notifications to other agencies or bodies have been duly made;
- (iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations.
- (iv) The applicant is technically and financially qualified to engage in the activities authorized;
- (v) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public; and
- (vi) The findings required by subpart A of part 51 of this chapter have been made.

In contrast, pursuant to 10 CFR § 50.35(a), the NRC may issue a construction permit (CP) if:

- (1) the applicant has described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and has identified the major features

or components incorporated therein for the protection of the health and safety of the public; (2) such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the final safety analysis report; (3) safety features or components, if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and that (4) on the basis of the foregoing, there is reasonable assurance that, (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in part 100 of this chapter, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

In the case where a DCD error has been identified late during NRC's review of a COL application, NRC could take advantage of both of these provisions to issue a hybrid COL and CP for a plant. Under such an approach, the NRC would issue a COL for those portions of the plant that are unaffected by the DCD error, and would issue a CP for those portions of the plant subject to the DCD error. With respect to those portions covered by the COL, the design would have finality and be subject to the applicable ITAAC and finding under 10 CFR § 52.103(g).

With respect to those portions covered by the CP, the applicant would need to:

- identify the error as a matter for which further technical or design information is required to complete the safety analysis and which can reasonably be left for later consideration at the operating license (OL) stage,
- submit an OL application during construction that identifies the final design to resolve the DCD error and proposes a DCD departure (the OL application would be subject to hearing rights by interested members of the public), and
- demonstrate that construction associated with that resolution has been substantially completed in accordance with the CP and the OL application and the rules and regulations of the Commission, in addition to satisfying the other requirements in 10 CFR § 50.57 as applicable to the DCD error.

Upon making the requisite findings for issuance of the OL and at the time of the Section 52.103(g) finding, the NRC would issue the OL in the form of a COL amendment that would combine the COL and OL.

Such a hybrid approach is permissible under the Atomic Energy Act. Under the Atomic Energy Act and NRC regulations, multiple licenses for the same facility may be issued separately or may be combined.⁴ For example, for plants licensed under 10 CFR Part 50, the Commission has typically issued both a construction permit granting materials licenses for the plant pursuant to 10 CFR Parts 30, 40, and 70, and then an

⁴ See, e.g., Section 161(h) of the Atomic Energy Act and 10 CFR §§ 50.31, 50.52, and 52.8.

operating license to combine the Part 30, 40, and 70 licenses with the Part 50 license. An analogous approach could be taken for a hybrid COL and CP, which would eventually result in an OL being combined with the COL upon resolution of the DCD error and substantial completion of construction in accordance with that resolution (and completion of any necessary hearings).

NRC may be able to implement such a hybrid approach under the Commission's existing regulations, which already contain provisions dealing with notice of the application, hearing rights, issuance of CPs, issuance of COLs, and combining licenses. Thus, all essential features for implementing a hybrid COL and CP already exist. The details of the implementation process for a hybrid COL and CP could be developed on a case-by-case basis, or the NRC could issue guidance describing these details.

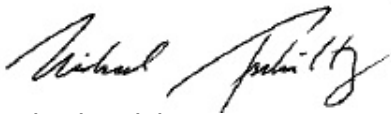
However, if the NRC decides to utilize the hybrid approach, NEI recommends that the agency initiate a rulemaking to address certain procedural issues, such as the process of converting a COLA into an application for a hybrid COL and CP, the separate treatment of COL and CP issues during construction, and the process for issuance of the OL and its combination into the COL through a COL amendment.

Conclusions

DCD design errors have been identified late during the NRC's review of COL applications for several AP1000 plants, resulting in delays in issuance of those COLs. To avoid costly delays in issuance of future COLs, the NRC should establish a generic process for resolving such DCD errors after issuance of the COLs and prior to commencement of fuel load. Such a mechanism would not adversely affect safety, as demonstrated by the experience of the AP1000 units at Vogtle 3-4 and Summer 2-3, and would facilitate implementation of generically applicable corrective action.

This letter identifies several alternatives for accomplishing this goal, some of which would likely need Commission approval. NEI requests that the NRC staff promptly consider the industry options proposed and determine which of these (or other) alternatives best provides a workable generic approach to resolve this issue.⁵ NEI looks forward to working with the NRC to develop a timely resolution to this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Tschiltz", with a stylized flourish at the end.

Michael Tschiltz

c: Mr. Frank Akstulewicz, DNRL
NRC Document Control Desk

⁵ We note that the NRC has proposed to address this issue in the update of RG 1.206 in section C.2.16 on Finalizing Licensing Basis Information for COLs (DG-1325, "Applications for Nuclear Power Plants," published for public comment in 82 FR 28101). As NEI plans to comment on DG-1325, we believe it is premature to provide guidance on this issue while industry and the NRC are still considering alternatives for resolving the issue, and before the Commission has had an opportunity to provide input.