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General Comment

Industry Comments on the Regulatory Basis for Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (Docket ID: NRC-2009-0196)

Attachments

05-14-21_NRC_NEI Comments on Draft Regulatory Basis with Attachments -Rev 1

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Office of Administration
MS TWFN-7A06
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Program Management, Announcements and Editing Staff

Subject: Industry Comments on the Regulatory Basis for Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (Docket ID: NRC-2009-0196)

Submitted via regulations.gov

Project Number: 689

Dear Program Management, Announcements and Editing Staff:

On behalf of the Nuclear Energy Institute's (NEI)[1] members (hereinafter referred to as industry), we provide the following comments on the NRC's draft Regulatory Basis for Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (January 15, 2021). We appreciate the staff's efforts to address the lessons learned from Part 52 licensing activities as a part of the development of the draft regulatory basis as well as the opportunity to comment on the draft and encourage your consideration of all stakeholder comments prior to finalizing the Regulatory Basis for the rulemaking. The development of the draft Regulatory Basis represents a significant effort by both the staff and the industry that identifies many opportunities for improving the efficiency and timeliness of licensing new reactors. The timespan of the staff's efforts to conduct this rulemaking are anticipated to encompass a decade from start to finish and the outcomes are extremely important to the future of the industry. With that in mind, the staff should make every effort to take advantage of this once in a decade opportunity to improve the regulations to be less burdensome while still assuring a high level of safety.

[1] 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.

The NRC's draft regulatory basis proposes significant enhancements to the efficiency and clarity of Parts 50 and 52, which address identified challenges with implementing the current regulations and/or associated guidance. Therefore, we support the NRC's recommended changes, except in the few areas discussed in our comments. Most notably, the in the NRC's effort to add the requirement to perform a probabilistic risk assessment (PRA) for a Part 50 application, in alignment with Part 52 requirements, the NRC must ensure that the added requirements for a PRA under Part 50 are clear and that they do not create undue burden for a construction permit application (CPA). Our concern is that requiring a PRA for a CPA has the potential to effectively eliminate the difference between the level of finality of the design and analysis required for a construction permit application (CPA) under Part 50, and a combined operating license application (COLA) under Part 52. Changes that require a greater degree of finality in the design for a CPA create challenges to the use of the Part 50 licensing process. Thus, we recommend that the NRC maintain Parts 50 and 52 as viable licensing pathways, each with distinct features, in terms of needed finality of design and analysis, and resulting finality. Consequently, the NRC should not impose the requirement for a PRA on a CPA.

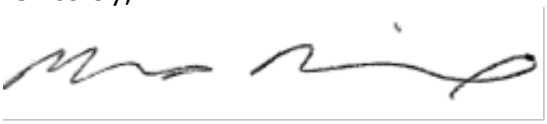
The industry believes that there are two lessons learned that are of significant importance to the industry that the staff's proposed actions in the draft Regulatory Basis document do not resolve. These are the issues of 1) allowing changes to Tier 1 information during construction without prior staff approval, and 2) creation of a regulatory process to avoid delays in the issuance of COLs due to errors noted in the referenced Design Certification. The industry has advocated for changes to address these issues and proposed solutions for several years. The industry has suggested changes that maintain safety while reducing the potential for delays in licensing and/or construction that could have significant cost consequences. With regard to allowing changes to Tier 1 information without prior staff approval, the staff in its analysis notes that this change could be implemented without impacting safety, and the changes would make the regulatory framework more efficient; however, the staff has chosen not to pursue these enhancements. With regard to issuing a COL referencing a DC with a known error, we disagree with the staff and believe that the solutions proposed by the industry are permitted by the Atomic Energy Act.

NEI believes that resolution of these two issues is central to a potential applicant's decision concerning whether or not to use the Part 52 licensing process. Thus, we believe that, due to the importance of these issues to the viability of Part 52 for future applicants, the staff should elevate these issues to the Commission to seek direction as policy issues.

NEI is including in its response answers to the Specific Regulatory Issues identified in the Federal Register Notice (Federal Register 7513, Vol. 86, No. 18, January 29, 2021) as Attachment 1. In addition, NEI is providing its comments on the draft Regulatory Basis as Attachment 2. The comments provided on the draft Regulatory Basis are focused primarily on where the industry has a differing view from the staff's recommendation. There are additional areas identified for consideration as a part of the rulemaking. These include recommended changes to the document that could impact the staff's recommendation and some editorial corrections.

We appreciate the NRC's effort in developing this draft guidance and encourage your consideration of all stakeholder comments prior to finalizing the draft Regulatory Basis. We trust that you will find these comments useful and informative as you finalize the draft and we look forward to future engagement on this important matter. Please contact me at mrn@nei.org or (202)739-8131 or Mike Tschiltz at mdt@nei.org (202) 471-0277 with any questions or comments about the content of this letter or the attached responses and comments.

Sincerely,



Marcus R. Nichol

Attachments

c: Ms. Andrea Veil, NRR, NRC
Mr. Kevin Coyne, NMMS, NRC
Mr. Robert Taylor, NRR, NRC
Ms. Anna Bradford, DNRL, NRR, NRC

Attachment 1: Responses to Specific Regulatory Issues Questions Posed by NRC in FRN

1) **Topic 1: Emergency Planning - Significant Impediments to Development of Emergency Plans – As required by § 52.17(b)(1), the site safety analysis report for an ESP application must include an evaluation of the physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans.**

FRN Question 1. The NRC is considering revising the guidance in Regulatory Guide 4.7, ''General Site Suitability Criteria for Nuclear Power Stations,'' and NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,'' Chapter 13, ''Conduct of Operations,'' on how to meet the requirements of § 52.17(b)(1) and the siting criteria in 10 CFR part 100, ''Reactor site criteria,'' as it relates to siting and emergency planning for ESP reviews.

The NRC is seeking comment on the appropriate distance within which to perform the analysis to demonstrate compliance with the siting criteria for identifying site characteristics that could pose significant impediments to the development of emergency plans. Please provide a basis for your response.

Response

First, it should be noted that the Commission currently has several policy matters under consideration that could affect the response to this topic area. These policy matters include (1) the use of a radiological consequence-based emergency planning zone (EPZ) and (2) changes in siting policy to permit greater population density within areas surrounding a potential plant location.

Notwithstanding the Commission's ongoing policy deliberations, NEI provides the following comments.

1) NRC guidance should describe a flexible approach by which an ESP applicant can determine the appropriate distance for which site characteristics that could pose significant impediments are evaluated. Ultimately, the decision on the extent of significant impediments review is a commercial one; i.e., the NRC's determination that significant impediments are not present or are mitigated does not prejudge the adequacy of the applicant's actual emergency plans. In accordance with 10 CFR 52.39(b), an applicant referencing an ESP must update the EP information previously provided under 52.17(b). Updated information that "materially changes the basis for compliance with NRC requirements" would not be resolved for the licensing proceeding. Accordingly, an ESP applicant that conducts a significant impediments evaluation for an area that is later (once an EP is developed) determined to be too small would need to evaluate and mitigate impediments within the full range necessary to support their EP. If previously unconsidered significant impediments were identified, they would need to be mitigated or, in an extreme case, the ESP might need to be modified or amended. Thus, based on the information available for the design or range of designs under consideration for the site, ESP applicants can determine an appropriate boundary for review of significant impediments to ensure that their ESP provides the degree of finality they seek.

2) Where a complete and integrated EP is proposed, the significant impediments within the needed area are addressed as part of that plan; the applicant will conduct the significant impediments review of an area necessary to support their development of the complete and integrated EP. For such an applicant, an approach for scoping the evaluation for physical characteristics that would pose a significant impediment to the plume exposure pathway EPZ is provided in NUREG/CR-7002, "Criteria for Development of Evacuation Time Estimate" (ETE). Specifically, NUREG/CR-7002 Section 5.7, "Early Site Permits," states in part, "an ETE analysis may also be used to determine whether there are any physical characteristics of a proposed site that could pose a significant impediment to the development of emergency plans." This is echoed in the staff's SRP Acceptance Criteria discussed in NUREG-0800 Section 13.3, "Emergency Planning," and associated guidance in NUREG-0654/FEMA-REP-1 Supplement 2 Section 1 Part G. NUREG/CR-7002's Abstract notes: "The evacuation time estimate (ETE) is a calculation of the time to evacuate the plume exposure pathway emergency planning zone (EPZ)." Because the ETE is a way to satisfy the regulatory requirement, and the ETE is focused on the EPZ, it makes sense that the evaluation of site physical characteristics focus on the EPZ radius, which may vary with plant design. Note that the guidance also includes discussion on how to consider shadow evacuations, thereby allowing an applicant to address any impediments just outside the EPZ which may influence emergency planning per the regulatory requirement.

3) Where the ESP application includes only major features of an EP but includes an EPZ, the applicant will have reasonable confidence in the area within which major impediments need to be considered. For such an applicant that is proposing a facility with no offsite EPZ, the appropriate distance within which to perform the significant impediments review could be the Exclusion Area. This analysis would demonstrate compliance with the Part 100 siting criteria for purposes of identifying site characteristics that could pose significant impediments to the development of emergency plans where the ESP applicant anticipates meeting the dose criteria in the proposed 10 CFR 50.160 at the exclusion area boundary. Otherwise, the distance could be the distance of the EPZ radius proposed by the applicant (e.g., 5 miles if proposing a 5-mile EPZ). In some locations, it may be appropriate to add some additional distance beyond the EPZ to identify any impediments just beyond the EPZ that could impact an evacuation (e.g., in cases where there is only one evacuation route). Alternatively, the dose limits of the EPZ are sufficiently conservative that it would not require a look beyond the EPZ to consider evacuation limitations. The finality considerations discussed in the paragraph 1, above, would influence the applicant's decision.

4) Where neither major features nor a complete EP are proposed in the ESPA, the applicant has an incentive to choose an appropriate area for review to maximize the finality of the ESP. In either of these cases where the ESPA does not include a complete and integrated EP, for the resulting ESP to be reasonably referenced in a future license application, its conclusion on site suitability must be meaningful. That is, the applicant and the NRC need reasonable assurance that the proposed site will in fact be acceptable once the complete and integrated EP is developed for the facility and site. Thus, NRC guidance should include some basic minimum thresholds for the areal size of the significant impediments review for these ESP applications. Where the dose assessment required by 10 CFR 52.17(a)(ix) shows that doses are expected to meet the protective action guide (PAG) thresholds at the exclusion area boundary, review of significant

impediments beyond the exclusion area boundary should not be required. For large LWRs, where experience and regulatory requirements indicate a 10-mile EPZ is likely needed, significant impediments within the probable evacuation zone of the eventual EP should be considered (e.g., about 5 miles). For distances between these two limits, the NRC should provide guidance to applicants to inform their choice of an appropriate area for the significant impediments review, consistent with the Commission's forthcoming policy guidance.

2) **Topics 2 & 3: Part 52 Process - Part 52 Process Standard Design Approvals Duration, Manufacturing License Renewal and Manufacturing License Expiration Date - As described in § 52.147, standard design approvals (SDAs) are valid for 15 years from the date of issuance and may not be renewed. For manufacturing licenses (MLs), § 52.173 specifies that a license authorizing manufacture of nuclear power reactors is valid for no more than 15 years from the date of issuance. As part of this rulemaking, the NRC is considering the removal of the 15-year duration for DCs established in § 52.55 and DC renewal requirements in §§ 52.57, 52.59, and 52.61 and 10 CFR part 52 DC appendices. This would result in DCs that never expire and, therefore, do not need to be renewed every 15 years. The 2007 10 CFR part 52 final rule provided the term of an SDA to be for 15 years and the term of an ML to be for no less than 5, or no more than 15 years from the date of issuance. The Commission established the 15-year maximum term for SDAs and MLs to be consistent with the maximum term for a standard design certification. The 5-year minimum term was established by the Commission to encourage the use of an ML for the manufacture of more than one nuclear power reactor.**

FRN Question 2. If the NRC eliminates the renewal requirements for DCs, should the NRC consider eliminating or changing duration requirements for MLs?

Response

Yes. As addressed for the DC duration proposal, there is no safety reason to limit the duration of MLs. An ML holder can safely manufacture reactors indefinitely so long as it maintains compliance with requirements of NRC's regulations and the license (e.g. maintaining quality assurance). NRC has the means and experience to modify the ML if a safety issue arises that yields a needed improvement in the design authorized for manufacture. The Atomic Energy Act does not impose a cap on the duration manufacturing licenses, as such a license does not authorize the commencement of operations (AEA §103.c). Moreover, an ML holder has other responsibilities and incentives to maintain compliance with its ML, beyond the minor impacts to a DC applicant discussed in other comments. Insofar as an ML holder may not desire an indefinite license duration, it can request a specific term in its license application. Alternatively, an ML holder can seek to terminate the license when it is no longer needed.

FRN Question 3: If the NRC eliminates the renewal requirements for DCs, should the NRC consider eliminating or changing the duration requirements for SDAs?

Response

Yes. The same considerations addressed for the DC duration proposal apply here; there is no safety reason to limit the duration of SDAs. A design receiving an SDA has been determined by the NRC to provide reasonable assurance of adequate protection. Absent new information, that

determination should not change over time. Should a new safety issue arise that calls that determination into question, or a cost-justified safety enhancement is warranted, the NRC has the means and experience to ensure the SDA design addresses the issue. In addition, the applicant still must demonstrate compliance when it submits a construction permit or combined license application.

Specifically, an SDA does not affect the authority of the Commission, Atomic Safety and Licensing Board Panel (ASLBP), or presiding officer to impose new requirements. Changes can be imposed on the approved design, or on a license application referencing the design, if necessary and appropriately justified. Therefore, a predetermined SDA duration is arbitrary and imposes an undue regulatory burden.

FRN Question 4: Expired Design Certifications in 10 CFR Part 52 - As part of the proposed rule, the NRC is considering the removal of the 15-year duration for DCs established in § 52.55 and DC renewal requirements in §§ 52.57, 52.59, and 52.61 and 10 CFR Part 52 DC appendices. This would result in DCs that never expire and, therefore, do not need to be renewed every 15 years. However, there are presently two DCs contained in the appendices to 10 CFR Part 52 (AP600 and System 80+) that have already expired.

Should the NRC remove expired DC rules from the appendices to 10 CFR Part 52 in the proposed rule?

Response

No. The approved design certification rules should not be removed from the appendices in 10 CFR Part 52 in the proposed rule. The existing design certification rules represent a significant investment by the applicants to develop both the design certification documents and the underlying engineering technical supporting documentation and analyses. These designs were certified by the NRC as being safe and meeting regulations. The NRC has regulations in place to ensure any new safety question related to these certifications would be addressed during the review process for a COLA referencing the design.

3) **Topic 4: Relationship to Advanced Reactors - The current regulations in 10 CFR Parts 50 and 52 were largely written during a period when the NRC was licensing light-water-reactors. Today, significant stakeholder interest exists in licensing new advanced non-light-water reactor designs. As such, in the proposed rule and in subsequent rulemakings addressing new licensing regulations for advanced reactors, the NRC wants to ensure that it considers stakeholder feedback on how regulatory changes would impact potential nonlight-water reactor applicants.**

For example, the NRC recommends revising § 50.34(f) so that the TMI requirements in § 50.34(f) apply to new power reactor applications submitted under 10 CFR part 50, with the same exceptions given for 10 CFR part 52 applicants. Section 50.34(f) requires 10 CFR part 52 applicants to provide information necessary to demonstrate compliance with any ''technically relevant'' positions of the requirements in § 50.34(f)(1) through (3) with the exception of § 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v). The NRC is still considering whether and how these regulations would apply to non-light water reactors.

FRN Question 5: Please provide feedback on impacts of the TMI requirements on non-LWR applicants the NRC should consider in the scope of the proposed rule. Please provide the basis for your answer.

Response

The NRC should evaluate the entirety of TMI requirements for their original basis and determine whether that basis is still applicable for non-LWRs or any future generation plant (as discussed in the comments on the Regulatory Basis Document, similar issues on continued need for and applicability of the TMI requirements exists for newly licensed LWRs). As a part of this evaluation, the staff should perform a regulatory and safety assessment of the need to apply the TMI requirements to non-LWRs as a part of the regulatory basis for this rulemaking. The NRC should use the assessment to determine which TMI requirements may be applicable to non-LWRs and apply only those needed to address safety and risk issues not covered by other regulations and guidance. This approach would save future non-LWR applicants the cost of justifying non-applicabilities and the potential need for exemptions and provide greater clarity and certainty in licensing. Although the overall cost/benefit analysis is dependent upon the number of non-LWR applicants that choose to apply under Part 50 or Part 52 and their specific technologies, the improved regulation clarity and regulatory certainty may well offset the quantified costs.

The staff should also evaluate and address disparities in "entry conditions" for applying certain Part 50 and 52 regulations that that may result in different licensing actions based solely on the wording of the regulations rather than substantive technical differences in the designs under review (e.g., 52.79(a)(42), which references 50.63, requires Part 52 non-LWR applicants to submit an exemption versus 50.63 being deemed "not-applicable" for Part 50 non-LWR applicants). Changes should be made in the entry conditions to regulations to avoid requiring different licensing actions simply based on the language structure of the rules.

As a part of this effort, the staff's proposed incorporation of "technically relevant" language is a positive development and is strongly encouraged. The use of the term "technically relevant" allows for applicants to demonstrate that certain regulations do not apply to their new designs. However, as demonstrated by current application lessons learned, the onus is still on the applicant to justify why technology-specific requirements do not apply to their particular technologies. Therefore, incorporation of the "technically relevant" concept does not obviate the unnecessary regulatory burden on applicants to provide evidence that a problem unique to LWRs is not present in non-LWR technologies. Since a PRA is utilized to evaluate a given technology for potential accidents, the staff must be willing to accept that the PRA review process (as an acceptable alternative to a conservative deterministic approach) will identify the complete range of postulated events that could occur for a specific design, and for which there must be appropriate prevention or mitigation capabilities included in the design. The use of the PRA review process extends beyond the direct application of the TMI requirements but goes to all requirements for unique evaluations of design-- basis or beyond-design-basis events.

The NRC's mission "to provide reasonable assurance of adequate protection of public health and safety and to promote the common defense and security and to protect the environment" is predicated on assumptions about the technology in the language of each requirement. Given

these assumptions, the burden of proving “technically relevant” – even when the regulation is clearly written for a specific technology – creates undue burden on the applicant and unnecessary barriers to entry for new nuclear technologies. In addition, relying on the exemption process to address numerous non-applicabilities also imposes burden on the NRC staff in its reviews, especially given that many Part 52 new reactor technology applicants may be compelled to seek such exemptions. An example is the need to demonstrate a "...control room design that reflects state-of-the-art human factor principles prior..." per 10 CFR 50.34(f)(2)(iii). However, this Part 50 requirement is predicated on the safety significance of operator action being taken in a timely manner. Many proposed designs (LWR or non-LWR) have long accident sequences with minimal need for early human action, if any at all. Therefore, this requirement should better reflect the importance of human involvement in preventing or responding to off-normal events, rather than a prescriptive requirement for all LWRs.

Additionally, the staff should evaluate the non-applicabilities document[1] to identify potential improvements related not only to TMI requirements, but to all areas where entry conditions may trigger exemption requests for types of reactors to which the requirements at issue clearly do not apply.

[1] NRC Staff Draft White Paper, “Analysis of Applicability of NRC Regulations for Non-Light Water Reactors.” (ML20241A017)

NEI Comments on the Regulatory Basis for the Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing
RIN Number: 3150-AI66, NRC Docket ID: NRC-2009-0196

Affected Section	Comment/Basis	Recommendation
1. General	While the desire to align regulations in Part 50 and Part 52 is understood, it is important that the NRC ensure that new requirements for CP applications are not overly burdensome. The NRC should preserve the concept that a CPA may be submitted with preliminary information and its approval does not provide the applicant with a license to operate the plant. If the NRC proceeds with the stated expectations for the finality of the design and analyses for a Part 50 CPA, then this level of finality would be equivalent to what is currently expected for a Part 52 COLA. This would effectively eliminate the viability of Part 50, since an applicant would have to progress the design and analysis to the same point whether they pursue a Part 50 CPA or Part 52 COLA, and since the Part 52 COL includes more finality in the operating license, there would be no benefit to a CP. It should be recognized that a PRA for an advanced plant (LWR and non-LWR alike) will potentially be very different at the CP stage than the OL stage and the subsequent PRA developed in support of operations. Although a CP applicant of an advanced plant can use PRA to inform the design, the information required for a full final PRA in many instances will not be available during the development of the CP application. A PRA is not necessary to establish the safety basis for a preliminary safety analysis or for the NRC to make the necessary safety determination based on the preliminary information adequate to support a CPA. Some specific areas where this is problematic are noted in subsequent comments concerning the development and use of a PRA for a CP application.	The NRC should maintain Parts 50 and 52 as viable licensing pathways, each with distinctive features, in terms of needed finality of design and analysis, and resulting finality. Since the NRC's expectations for finality of design and analysis for a CPA are centered around the expectation that the CPA include a PRA, the NEI recommends that the staff provide additional clarity in NRC expectations for a PRA at the CP application stage. Specifically, the NRC should clarify that a PRA is not required as part of the preliminary safety analysis and that a preliminary risk assessment is all that is required at the CP application stage. It would be beneficial for the staff to develop draft regulatory guidance in parallel with the rulemaking. The guidance should identify acceptable approaches for the development and use of PRA at each stage of licensing of an advanced plant. NEI recommends that the scope and role of the PRA at the CP application stage should be limited and should not be extended to non-power reactors licensed under Part 50 and that the staff clearly define what constitutes a preliminary risk assessment

2. General	The regulatory basis for the rulemaking does not address certain discrepancies in the applicability of regulations between Parts 50 and 52, as identified in the NRC's draft "Analysis of Applicability of NRC Regulations for Non-Light Water Reactors" White Paper (ML20241A017). While the draft regulatory basis makes it clear that a specific review of the regulations against non-LWRs was not being performed as part of this effort, there are obvious examples, as demonstrated in the paper noted above, that could resolve inconsistencies between Parts 50 and 52 where there is a clear reduction in regulatory burden. Specific examples include regulations in Part 52 that do not state that they are applicable to LWRs only, but cross-reference Part 50 regulations that are applicable to LWRs only (e.g., 52.79(a)(5) reference to 50.46).	NEI recommends that the staff revise the draft regulatory basis to include an evaluation and disposition of the non-applicabilities identified in the staff white paper for inclusion in this rulemaking. This will help to avoid the regulatory burden of reliance on the formal exemption process for future applicants.
3. General – Creation of a regulatory process to avoids delays in the issuance of COLs due to errors noted in the referenced DC	In section 6.1.2 (pg. 6-3) of the staff's draft regulatory basis the staff noted that NEI had proposed the need to address this issue several different times during the development of the regulatory basis. At the April 29, 2020, Category 3 public meeting, the NRC indicated that because the Atomic Energy Act of 1954, as amended (42 U.S.C. § 2011 et seq.) requires that the NRC resolve all open safety issues prior to issuance of a license, the NRC did not see any regulatory changes that would solve this concern. The NRC staff also summarized its position on this issue in a September 8, 2020 letter to NEI regarding "Addressing Delays in Issuance of Combined Licenses Due to Errors in Certified Design." (ML20156A308). NEI disagrees with the staff's decision not to address this issue as a part of this rulemaking. This issue was identified during a Part 52 Lessons Learned workshop and was identified as a concern to the NRC in an NEI letter dated January 27, 2017, on the subject of "Part 52 Licensing Lessons Learned" (ML17058A334). In the letter NEI noted that "[I]it is vitally important to the future of our industry	As NEI noted in an August 4, 2017 letter to the staff (ML17236A489), "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 be subject to substantial delays that are not necessary to assure safety." NEI believes that future COL applicants should not bear the risk of incurring such project delays and additional costs when they are not necessary to ensure plant safety. Indeed, this issue – if left unresolved – could hinder the industry ability to bring future innovative and advanced reactor designs to market. Accordingly, NEI respectfully requests that the NRC staff elevate this issue to the Commission for consideration as a generic policy issue. This issue warrants consideration by the Commission for reasons explained by NEI in its letters to NRC dated September 30, 2015 (ML15279A408) and August 4, 2017 (ML17236A489). Additionally, the 2019 Nuclear Energy Innovation and Modernization Act (NEIMA) directs the NRC to conduct "predictable, efficient, and timely reviews." To that end, Section 102(c) of NEIMA requires the NRC to develop performance

	that the licensing process for new nuclear plants be as efficient, effective, timely and predictable as possible to encourage future applicants to bring forward innovative designs, while continuing to assure public health and safety." The letter also requested NRC support for actions to improve new reactor licensing efficiency and reduce regulatory impact on the time-to-market for future new plant applicants. With those objectives in mind, a process solution is needed to avoid unnecessary delays in licensing when the need for changes in a referenced design certification is identified while a COL application is under review. Issuance of COLs without delay is appropriate because existing change processes assure that errors identified in a referenced design certification will be corrected prior to construction of affected SSCs. Several COL applicants suffered costly delays in the issuance of the COL due to errors found in the certified design	metrics and milestone schedules for "requested activities of the Commission", including new reactor licenses and permits. In response to that directive, the NRC has developed generic milestone schedules for requested activities that involve the issuance of a final safety evaluation. NEIMA also establishes certain reporting requirements for the NRC in the event the NRC issues a final safety evaluation later than the NRC-established milestone schedule date. For Part 52 COLs (LWR or non-LWR) referencing a certified design, the NRC's generic milestone to a final safety evaluation is 30 months. This 30-month review schedule demands that the NRC and industry avoid delays in COL issuance due to issues that do not affect the safety of the as-built plant. The design error issue raised in this comment and the above-referenced NEI letters proved to be particularly problematic during previous COL reviews. A number of the COL applications referenced the design certification for the Westinghouse AP1000. Late in the NRC's review of two of those applications (for the Lee and Levy 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 delays 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.) Significantly, other AP1000 plants that held previously-issued COLs, such as Vogtle Units 3 and 4 and Summer Units 2 and 3, were allowed to resolve the same design errors during the construction process, without delays and without any impact on safety. Specifically, the Vogtle and Summer AP1000 licensees

		were allowed to continue construction pending resolution of the errors in the design certification via license amendment. From a technical and safety standpoint, this clearly is an incongruous result, given that both the Lee/Levy COL applicants and Vogtle/Summer COL licensees were affected by the same DCD errors. Consequently, in the above-referenced letters, NEI proposed several alternative methods for addressing DCD errors while avoiding delays in issuance of COLs: (1) issuance of a license condition, (2) use of design acceptance criteria (DAC) or ITAAC, and (3) use of a hybrid COL and construction permit. This example is insightful for two reasons. First the design error in question, while it may have had an impact on the safety determination, was not a significant safety issue. This is evident by the fact that the NRC allowed continued construction of the Vogtle and Summer units, since an immediate and significant safety issue would have resulted in a stop work order for the plant. While the NRC's resolution for Vogtle and Summer utilized NRC processes for issue resolution that minimized the impacts to these projects, the NRC's refusal to take a similar approach to leverage issue resolution processes available to issue the COLs resulted in significant and unnecessary business impacts for these COLs. Second, there is no substantive difference to the use of NRC measures (i.e., license conditions and DAC) to address the need for additional information or validation of the design assumptions (for which the NRC routinely uses these provisions) and the use of these measures to address a known design error. The NEI proposed options constitute NRC regulatory measures that can be relied upon to provide assurance that these errors are corrected to the NRC's satisfaction prior to constructing the plant. In this context, it is not necessary for such errors to be corrected at the time of the COL issuance so long as there is assurance that the errors will be corrected prior to construction. In its draft regulatory basis (see page 6-3), the NRC staff evidently has rejected these proposed alternatives as being potentially inconsistent with the Atomic Energy Act (AEA) of 1954,

		as amended. For reasons detailed in NEI's prior letters to NRC, particularly the August 4, 2017 letter, NEI does not believe that the AEA categorically forecloses the alternatives proposed by NEI as a legal matter – particularly in light of the Commission's broad discretion under that statute – or that those alternatives improperly curtail hearing rights under Section 189a of the AEA. Notably, in its July 18, 2016 letter (ML15351A021) to NEI, the NRC staff noted that "[t]he 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." Thus, the staff has acknowledged, at least implicitly, that a license condition could be a viable option if it "provide[s] a sufficient and objectively verifiable basis for the NRC staff to conclude that all legal and regulatory requirements have been fulfilled." Finally, NEI also urges the staff and Commission to consider whether the issue of design error corrections can be explicitly addressed in future design certification rules to avoid the types of delays that occurred in the Lee and Levy COL proceedings. It is well established that "the choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency." SEC v. Chenery Corp., 332 U.S. 194, 203 (1947). The Commission could consider incorporating specific processes or mechanisms in future design certification rules to provide greater clarity on acceptable means for addressing design errors while averting prolonged delays like those seen in prior COL proceedings. As documented the NRC's January 24, 2018 meeting summary (ML18011A037), this possibility was briefly discussed during a December 13, 2017 NRC public meeting held on NEI's August 4, 2017 letter. The meeting summary (p. 6) notes that "both NEI and NRC have developed a preliminary list of potential issues to be addressed in the rulemaking [i.e., the Parts 50 and 52 Alignment and Lessons Learned Rulemaking] and an alternative DC correction path may be worth including on either or

		both lists in preparation for future dialogue." NEI believes that this alternative DC correction path does in fact warrant further consideration by the staff and Commission. NEI recommends that the staff raise this concern to the attention of the Commission to determine the path forward for addressing this issue as it remains as an unresolved lesson learned from the industry perspective.
4. Appendix A - Applying the Severe Accident Policy Statement to New Part 50 License Applications	The NRC staff's recommendation of Alternative 2, "Rulemaking," to revise Part 50 to require applicants to provide descriptions and analyses of severe accident design features does not specify what is necessary to accomplish this. One concern with the lack of specificity is that a Part 50 CP applicant would be required to provide a description and analysis of design features for the prevention and mitigation of severe accidents that is supported by a detailed PRA. The concern is that the detailed analysis required to satisfy this requirement may not be available at the CP application stage of licensing. This concern is validated in that the draft regulatory basis specifies that the revision to Part 50 should include requirements analogous to paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23), which require applicants under Part 52 to provide descriptions and analyses of severe accident design features. This is problematic since the level of detail and design maturity available at the CP stage of Part 50 may not be suitable to fully meet 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23).	NEI notes that the Severe Accident Policy Statement sets an expectation that CP applications include a preliminary risk analysis. The staff should develop a more detailed description of Alternative 2 in the regulatory basis and develop the associated guidance to support this change in parallel with the rulemaking. The guidance should include specifically what needs to be accomplished and documented in a preliminary risk analysis for a CP application. Adding this description would help to ensure that an CPA would not require design information or level of detail beyond what may be available at the time of a CP application.
5. Regulatory Scope of a Parts 50 and 52 Alignment and Lessons Learned	Table 1, Industry Costs and Benefits, Staff's Recommended Alternatives (page 4-3), identifies the greatest benefit of the regulatory changes proposed is to the Architect/Engineer Firms pursuing DCs, when removed from the analysis, Utilities will have only a small (approximately $4 million net present value (NPV)) benefit by this analysis. The cost	NEI recommends that the staff revise the cost benefit analysis to increase the benefit to Utility Licensees for allowing the Generic application of ASME BPV Section XI and Tier 1 conforming changes. Total NPV reinstatement of these regulatory changes to the NRC is ~$500k, with an additional significant benefit to Utility Licensees.

	Rulemaking Table 1, Industry Costs and Benefits, Staff's Recommended Alternatives	benefit analyses for the Generic application of ASME BPV Section XI and Tier 1 conforming changes to Utility Licensees, significantly underestimates the value of making these changes.	
6.	App A, §1.0	The discussion of the existing regulatory framework for severe accidents omits several existing regulations pertinent to the Commission's severe accident policy statement. Per the Policy Statement, acceptability for severe accident conditions includes demonstration of compliance with the TMI requirements and demonstration of resolution of applicable Unresolved Safety Issues and medium- and high-priority Generic Safety Issues. While amendments pertaining to 10 CFR 50.34(f) are addressed in Appendix C, the severe accident framework discussion should be complete.	NEI recommends that the staff add discussion in the regulatory basis to identify other aspects of the regulatory framework relevant to the severe accident policy.
7.	App A, §§1.0 and 2.0	The discussion states "applicants would need to address the severe accident issues analogous to the requirements of Part 52 for the NRC to make its adequate protection determination," and "the NRC would require these applicants to address the severe accident issues required of Part 52 applicants to enable the NRC to make its adequate protection determination under the AEA." This statement contradicts the severe accident policy statement, which states that a "plant-specific review of severe accident vulnerabilities using this approach is not considered to be necessary to determine adequate safety…"	NEI recommends that the staff clarify that consideration of severe accident phenomena is not an adequate protection issue.
8.	App. A, General	In the staff's consideration of the need for the description and analysis of severe accident design features in a CP application, the NRC should evaluate the potential for variabilities in the applicant's state of design and analysis available at the CP stage. Consistent with other requirements in 10 CFR 50.34(a), the required information	NEI recommends that the staff clarify the regulatory basis to note that the rules for a CP application would specify only preliminary information with respect to severe accident features. This clarification should also be included in the proposed revision to SRP Section 19.0.

	for severe accidents should be preliminary in nature (see, e.g., 10 CFR 50.34(a)(3) and (4)).	
9. App A, General, including §§3.2 and 4.0	The Part 52 requirements for demonstrating resolution of applicable Unresolved Safety Issues and medium- and high-priority Generic Safety Issues are an implementation of the Severe Accident Policy Statement but are not included in the proposed alignment of Part 50, either here or in App. K.	NEI recommends that the staff address whether Part 52 requirements for resolution of applicable Unresolved Safety Issues and medium- and high-priority Generic Safety Issues are applicable to Part 50 applicants.
10. Appendix B	It is unclear what the staff intends when it states to follow the guidance in 50.34 (f)- Additional TMI-related requirements. The detail that is required to complete a PRA may not be available during the development of a construction permit application. The staff should clarify what is sufficient to fulfill these requirements. "*(1) To satisfy the following requirements, the application shall provide sufficient information to describe the nature of the studies, how they are to be conducted, estimated submittal dates, and a program to ensure that the results of these studies are factored into the final design of the facility. ….. In addition, each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 of this chapter shall demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(1) through (3) of this section, except for paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v). (1) To satisfy the following requirements, the application shall provide sufficient information to describe the nature of the studies, how they are to be conducted, estimated submittal dates, and a program to ensure that the results of these studies are factored into the final design of the facility.* For licensees identified in the introduction to paragraph (f) of this section, all studies must be completed no later than 2 years following the issuance of the construction permit or manufacturing license. For all other applicants, the studies	NEI recommends that the staff clarify its intentions and limit the requirements for PRA to 50.34(b) as part of the operating license approval.

	must be submitted as part of the final safety analysis report."	
11. Appendix B §1 Probabilistic Risk Assessment Requirements - Use of Probabilistic Risk Assessment in Design	The draft regulatory basis states that the NRC intends to extend the requirement for a PRA (as written in Part 52 for DC, COL, etc.) to be included in the requirement for an application for both a CP and OL. For certain CP applicants, the development of PRA information for the CP application at that stage in design may be unnecessary and overly burdensome, especially if it is expected to be reviewed in accordance with the endorsed PRA standard. Additionally, while the Commission statement on PRA does state that the "use of PRA technology should be increased in all regulatory matters," it also states that it should done "in a manner that complements the NRC's deterministic approach." The Commission statement on PRA goes on to state that "PRA and associated analyses…should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices."	NEI recommends that the staff note that the increased use of PRA at the CP stage should be voluntary for details beyond those developed as a part of a preliminary risk analysis. An applicant may voluntarily choose to go beyond what would be required for a preliminary risk analysis in situations where they are seeking to utilize other risk informed applications, as appropriate. Other applicants should be allowed to provide only a preliminary risk analysis at the CP stage and follow a deterministic approach to demonstrate compliance with regulatory requirements. The draft regulatory basis should be revised to specifically state that a PRA is not a requirement for CP applicants and that development beyond a preliminary risk analysis at the CP stage is voluntary. In this usage, a preliminary risk analysis should not require quantification in a PRA, and should accommodate qualitative approaches.
12. App. B, §§1.1 - 1.3	The discussion of the existing Part 50 regulatory framework does not address environmental report requirements under Part 51. Under those regulations and associated case law and guidance, it seems a Part 50 application would need to include a consideration of severe accident mitigation alternatives (SAMAs) which would include insights obtained from a PRA.	NEI recommends that the staff clarify what a Part 50 applicant would need to include in a preliminary risk analysis to be able to satisfy environmental report requirements under Part 51 when developing the analysis for the consideration of SAMAs.
13. App. B, §1.3	Any requirement related to providing a description and results of the plant-specific PRA for a CP application should be voluntary and accommodate a variable state of design at the CP stage. Consistent with other requirements in 10 CFR 50.34(a) (see, e.g., 10 CFR 50.34(a)(3) and (4)), the CP PRA cannot be expected to be completed to a comparable	NEI recommends that the staff clarify the regulatory basis to state that the rules for a PRA for a CPA would require only preliminary risk analysis based on the preliminary design described in the application. This would also impact proposed revision to SRP Section 19.0.

	level or accuracy as a Part 52 or OL PRA. Using the results from a preliminary PRA, the NRC should be able to appropriately risk-inform review of the CP and reach a preliminary conclusion that the final design is reasonably expected to meet the Safety Goals.	
14. App. B, §1.5	As described in a previous comment, because of the preliminary nature of the design described in a CPA, the existing PRA guidance is not sufficient for a CPA. For example, it is impossible for a CPA to include a PRA that would allow for risk-informed applications under RG 1.200. However, if a PRA is to be required for a CPA, the use of that PRA in the application should be accommodated without creating a de facto requirement for a complete and final design at the CP stage. Therefore, new guidance on the use of a preliminary risk analysis to reach preliminary conclusions would be needed.	NEI recommends that the staff revise §1.5 to discuss issues related to CPA PRA guidance. NEI also believes that the draft PRA guidance documents that address only preliminary risk analysis at the CP application stage should be developed in parallel with the rulemaking.
15. App. B, §1.1-1.3	The discussion of the existing regulatory framework omits the applicability of 10 CFR 50.34(f)(1)(i) to Part 52 applications.	NEI recommends that the staff include a discussion of the applicability of 10 CFR 50.34(f)(1)(i) to Part 52 applications and address its relationship to the other PRA rules in Part 52.
16. App. B, §1.6.2.1	Per the previous comment, a CPA may already need to address SAMAs in order to complete an environmental report. Therefore, it's unclear if there's a new "opportunity to develop their design to avoid or mitigate severe accident vulnerabilities found using the PRA" (§1.6.2.1, page B-6) based on this proposed requirement.	NEI recommends that the staff clarify the impact of Alternative 2 for Part 50 applications.
17. App. B, §1.6.2.2	This section states, "in addition, the applicants would be able to take advantage of risk-informed licensing actions significantly earlier in the process, allowing for reduced regulatory burden." As noted in a previous comment, it is unlikely that a CPA could include a PRA based on the "preliminary design of the facility" (10 CFR 50.34(a)(3)) that would satisfy NRC's expectations for risk-informed licensing actions. This use of the PRA is essential to the benefit derived from the proposed requirement, and therefore must be reconciled with the regulatory framework and guidance.	NEI recommends that the staff clarify expectations for the use a preliminary design-based PRA in risk-informed licensing actions.

18. App. B, §1.6.2.2	Because the CPA PRA must necessarily be based on a preliminary design, the effort of upgrading the PRA for an OL would likely far exceed 1,000 hours. At the OLA stage the applicant would develop a PRA based on the final design, and complete validation of all the inputs. Therefore, the OLA PRA effort would be comparable to a new PRA for the design. Based upon recent cost estimates to perform a PRA upgrade the NRC appears to have underestimated the costs associated with PRA upgrade and maintenance.	NEI recommends that the staff update the cost of the PRA at the OLA stage to a level of effort commensurate with the initial CPA PRA (approximately 15,000 hours).
19. App. B, §1.6.2.2	This section mentions the SAMA analysis for the first time, but does so in the context of "after licensing," which is incorrect. Consistent with previous comments, the discussion of SAMA analysis should be expanded and corrected.	NEI recommends that the staff should clarify the timing and role of PRA for performing an applicant's SAMA analysis.
20. App. B, §1.6.2.3	It remains in question whether there has been any material benefit from the staff's previous efforts to "risk inform" application reviews. The level of effort for recent reviews does not seem to bear that expectation out. Moreover, it's uncertain whether the preliminary risk analysis for a CPA would satisfy NRC's expectations to support a risk-informed review.	NEI recommends that the staff clarify that a preliminary risk analysis can be used to risk-inform a review and to support preliminary risk-informed applications at the CPA stage, per previous comments. Delete or provide support for the qualitative conclusion that "NRC expects the benefits would exceed the costs."
21. App. B, §2.5	See comments for App. B, §1 with respect a CPA PRA. As noted in those comments, the existing guidance on the technical adequacy of a PRA is inconsistent with the preliminary design that may be described in a CPA and the PRA based on that design. The adopted regulation and associated guidance would need to reflect how a preliminary risk analysis at the CPA stage could support initial implementation of 10 CFR 50.69. The update of the facility's safety analysis report and PRA at the OLA stage would confirm the results of the preliminary 50.69 implementation for a CP applicant/holder.	NEI recommends that the staff update the regulatory analysis to address changes to guidance needed and how a preliminary risk analysis at the CPA stage could support initial implementation of 10 CFR 50.69. The guidance should recognize that implementation of 50.69 is voluntary, and that applicants should have flexibility regarding the point in time at which they choose to utilize 50.69. For example, some may wish to implement 50.69 in the CPA, some may wish to wait for OLA, some may submit a topical report in between the CPA and OLA to implement it in between, and others may wish to implement 50.69 after the OL is issued.

22. App. B, §2, Risk Informed Categorization of Structures, Systems, and Components	In §2.2, NRC notes that "For Part 52 licensees under construction, even changes similar to those authorized under 10 CFR 50.59, "Changes, tests and experiments," are likely to entail a license amendment. This is because they are likely to involve a departure from the design referenced in the COL application or alteration of the ITAAC that are part of the COL." Likewise, other applicants will also confront obstacles in implementing 50.69. For example, a license applicant referencing a DC that did not implement 50.69 would likely need numerous departures and exemptions from the DC rule. Those exemptions would probably satisfy special circumstance 10 CFR 50.12(i) in that application of the Design Certification rule would conflict with 10 CFR 50.69. Still, under 52.63 the COLA would further need to demonstrate that the special circumstances outweigh the decrease in standardization. This process has an uncertain outcome and is an undue burden where implementation of 50.69 for COL holder or applicant is already approved. Similar questions are raised for an applicant referencing an SDA. As discussed in a later comment, no departure process exists or is proposed for an SDA. Therefore, it's unclear how an applicant referencing an SDA would implement 50.69, and if they did what the resulting impact on SDA finality would be. Therefore, when NRC amends 10 CFR 50.69, conforming changes are needed through the regulatory framework to ensure the process can be implemented, and can be implemented without undue regulatory burden.	NEI recommends that the staff address conforming changes to Part 50 and 52 requirements to ensure 50.69 can be implemented without undue regulatory burden associated with demonstrating that the special circumstances outweigh the decrease in standardization. This process has an uncertain outcome and is an undue burden in situations where implementation of 50.69 for COL holder or applicant has already been approved.
23. App. B, §2.6.4.2	Allowing a DC applicant to utilize 50.69 has additional potential benefits for reducing burdens on applicants and licensees. For example, either a manufacturing license (ML) applicant or a COL applicant could currently implement	NEI recommends that the staff revise the impacts of Alternative 3 to include the potential savings from allowing DCAs to implement 50.69.

	50.69 and can reference a certified design. Implementing 50.69 at the DCA stage would avoid the costs of doing so for license applications referencing the DC.	
24. Appendix B § 3.0	Alternative 3 is viewed as the best approach for clarification. Scope of prior to fuel load as-built walkdowns should also be included as part of this rulemaking. Developing a PRA to the endorsed standards at issuance of the COL resolves uncertainty regarding modeling, however the current endorsed standard is written with more towards applying to operating plants in that requirements for "as-built" walkdowns have been found to not align with the plant construction sequence. As a result, incorporation of as-built walkdown results should be given a larger window of time than "at fuel load" as many parts of the plant are only ready for walkdowns just prior to fuel load.	NEI recommends that the staff further clarify the requirements for "as-built" walkdowns during plant construction and include in the rulemaking to provide a larger window of time than "at fuel load."
25. Appendix B, §3.0	The NRC states in this section that "one licensee has already requested a license amendment to address this problem." For clarity, this was specific case involved an exemption request and not a license amendment.	NEI recommends that the staff revise the statement to reflect that an exemption was granted.
26. Appendix B, § 3.0	Paragraph 50.71(h)(3) requires that each holder of a COL upgrade the PRA to cover all modes and all initiating events before applying to renew the plant's license. It would be helpful to clarify what "all modes and all initiating events" means in this context?	NEI recommends that the staff clarify the statement in 50.71(h)(3) to be consistent with both the draft regulatory basis and the Interim Staff Guidance Probabilistic Risk Assessment Information to Support Design Certification and Combined License Applications. The draft regulatory basis and the Interim Staff Guidance indicate that, "*The PRA must be upgraded to cover initiating events and modes for which consensus standards on PRA are endorsed by the NRC*." 50.71(h)(3) should be revised to be consistent with these statements and require that each holder of a COL upgrade the PRA to cover "*initiating events and modes for which consensus standards on PRA are endorsed by the NRC,"* before applying to renew the plant's license.

27. App. B, §3.6	The impact analysis appears to presume that the proposal of App. B, §1, Alternative 2 is also adopted, because the impacts of Alternatives 2 and 3 of this section would be greater alone. For example, if adopted alone, these Alternatives would create a new requirement for CP holders to develop and maintain a plant-specific PRA. This would potentially extend to non-LWR applicants depending on the rule language.	NEI recommends that the staff clarify the discussion of the Alternatives and their impacts to discuss the relationship with the proposed changes of App. B §1.
28. App. C, General	Most of the introductory paragraph of 10 CFR 50.34(f) is moot. Deleting the applicability to previously-pending applications would improve clarity.	NEI recommends that the staff delete the portions of 10 CFR 50.34(f) that describe applicability to inactive construction permits and manufacturing licenses.
29. App. C, General	50.34(f) paragraphs (1), (2), and (3) prescribe the type of information needed to satisfy the requirements and the timing. These paragraphs are relevant only to the original CP and ML applications to which the TMI requirements applied. They present substantial confusion, as, for example, an SDA or DC applicant might be led to believe that 28 requirements of 50.34(f)(2) don't need to be met until the "operating license stage," and thus are "not technically relevant." Individual requirements contain other language concerning timing that is not relevant to all applicants. For example, (f)(2)(iii) requires that a control room design be provided for review "prior to committing to fabrication." In an effort to clarify the TMI requirements, and consistent with NRC's intent to extend applicability to new Part 50 applicants, paragraphs (f)(1), (2), and (3) should be deleted and replaced with clear direction on the application content needed and timing thereof for the various application types, with similar changes to individual TMI requirements that contain irrelevant or misleading language on timing of implementation.	NEI recommends that the staff delete 50.34(f) paragraphs (1), (2), and (3) and replace with clear direction on the application content needed and timing thereof for the various application types and; clarify individual TMI requirements that contain irrelevant or misleading language on timing of implementation. NEI supports NRC proposed Alternative 2 and recommends that NRC provide additional detail to clarify which parts of 50.34(f)(1) to (3) content is required at the CPA stage as compared to the OLA stage. It should be noted that a PRA capable of performing the evaluation of the specified events may not be available at the CP stage.

	In addition, the applicability of 10 CFR 50.34 (f)(1) to (3) to CP or OL applications should additionally address the different content (PSAR vs FSAR) requirements.	
30. App. C, General	The TMI rules each contain a designation corresponding to the related action plan items in NUREG 0718 and NUREG–0660. Footnote 10 indicates they are provided "for information only." However, without the information contained in those NUREGs and NUREG-0737, the requirements and intent thereof are ambiguous and uncertain. Thus, the "guidance" of the NUREGs is treated as a rule. The revision to 50.34(f) should either provide clearer articulation of the rules and acceptance criteria, avoiding the need to treat the NUREGs as requirements, or provide new guidance that clarifies the final, technology-neutral requirements and intent for each rule.	NEI recommends that the staff remove the reference to the TMI action plan items, and develop new guidance to describe the applicability and acceptance criteria of the TMI requirements for all designs.
31. App. C, General	Numerous TMI requirements are irrelevant to new designs or redundant to other rules. The Regulatory Basis indicates NRC will "conduct a regulatory and safety assessment to determine which TMI requirements may be applicable to non-LWRs." The same assessment is needed for all new applicants, not just non-LWRs. Prior to extending applicability to Part 50 applicants, the rules should be scrubbed of those requirements that are no longer necessary. The previously discussed 10 CFR §§50.34(f)(1)(xii), (f)(2)(ix), (f)(2)(xxv), and (f)(3)(v) are three obvious cases, but there are others that are unnecessary. For example: • 50.34(f)(1)(i) requires a PRA, "the aim of which is to seek such improvements in the reliability of core and containment heat removal systems as are significant and practical and do not impact excessively on the plant." On its face, this rule does not actually require an applicant to make those improvements. Other rules address a PRA and severe accident design features for Part 52 applicants, and this rulemaking will address those requirements for Part 50	NEI recommends that the staff extend the planned "regulatory and safety assessment" to evaluate not only applicability to non-LWRS, but for all designs. Specifically, evaluate the continued need for each TMI requirement in light of other regulations and guidance, and delete those requirements or portions thereof that are not relevant to new reactor applications.

	applicants. Therefore, this TMI rule is redundant and unnecessary. • 50.34(f)(2)(vi) is redundant to 10 CFR 50.46a. • 50.34(f)(2)(xxviii) addresses control room habitability under severe accident conditions, which was a necessary upgrade for certain plants with early licensing bases. For all new plants this same requirement is imposed via GDC 19, which considers the same severe accident source term imposed by way of 10 CFR 50.34 footnote 6, 52.47 footnote 3, et al. Thus, (f)(2)(xxviii) is no longer needed. Beyond these few examples, an in-depth review of the TMI requirements and the NUREG guidance that informs them will demonstrate that many of these requirements were necessary backfits for the plants to which they originally applied, but are suitably addressed by other regulations and associated guidance for newly designed and licensed plants.	
32. App. C, §3.2	Alternative 2 states that CP and OL applicants would be excepted from the same paragraphs as are Part 52 applicants. These paragraphs currently apply to no application, as none of the CP or ML applications to which they originally applied remain pending. Therefore, there will never be an application to which these paragraphs apply and they should simply be deleted.	NEI recommends that the staff delete 10 CFR §§50.34(f)(1)(xii), (f)(2)(ix), (f)(2)(xxv), and (f)(3)(v). Make conforming changes in 50.34(f) introductory paragraph and Part 52 to reflect elimination of these paragraphs.
33. Appendix C, Alternative 2	Table C-2 shows rulemaking costs for developing a Regulatory Guide; however, the description of Alternative 2 in Section 5.0 states that no new regulatory guidance would need to be developed.	NEI recommends an editorial correction to ensure consistency. As stated in Comment 30, development of a Regulatory Guide should be considered.
34. Appendix E §3.2.1	The draft guidance states that NRC would amend paragraph 55.31(a)(4) to require facility licensees of new reactors under construction to provide information on NRC Form 398 to explain how the knowledge, skills and abilities of applicants for an operator license would be maintained when the facility licensee requests an NRC examination to be administered well before the applicants would be	NEI recommends that the staff provide additional, more specific, guidance regarding what is required to ensure that knowledge, skills and abilities will be maintained.

	expected to complete all requirements to receive operator licenses. This does not appear to provide any specific guidance on how the knowledge, skills and abilities of applicants would be maintained, but simply a place for the licensee to provide an explanation. This would not provide any consistency in how this is accomplished by the licensees and would require NRC to evaluate/review every Form.	
35. Appendix H.1 "Design Certification Renewal", Page 229	SECY-19-0084 listed two items to be included in the Regulatory Basis related to renewal. (1) Elimination of DC rule expiration dates and DC renewal requirements; and (2) Consolidating and simplifying the change process requirements for DCs and changes that will align the DC change process with the requirements in 10 CFR 50.59. The first item has been addressed in the Regulatory Basis. The NRC staff's recommended Alternative 4 "Removal of Duration of DCs and Renewal Requirements through Rulemaking" is the best approach for resolving inconsistencies in the information submitted in DC renewal applications and inefficiencies in the NRC's reviews of DC renewal applications. There is no health or safety benefit to requiring renewal every 15 years. We encourage the staff to continue to pursue the removing the DC durations of all design certifications to date. However, the second item (simplifying the change process requirements for DCs) was omitted in the Regulatory Basis and not addressed.	NEI recommends, as discussed at several public meetings, that the rulemaking include changes that permit a design certification vendor to voluntarily align the DC with a constructed reference plant's licensing basis. Under the current regulations requiring DC renewal, changes within the renewal application that align with an operating facility's UFSAR should be considered resolved and need no further NRC review and approval. New changes (not found in the operating facilities UFSAR) should be evaluated under the 10 CFR 50.59 like process to determine the need for NRC review and approval. An operating facility's UFSAR has already been determined by the NRC to be safe, meet regulations and have no adverse impact on the facility. Therefore, implementing those same changes into a DC is safe and meets regulatory requirements.
36. App. H.1, §§3.4, 6.4 and 9.0	Industry agrees with Staff's recommendation to pursue Alternative 4. As Staff note, there is no health or safety benefit to requiring renewal, and there is no detriment to public health and safety by eliminating DC expiration. The provisions of 10 CFR 52.63(a) provide the Commission the means to impose changes on a certified design that are either necessary or justified. This authority assures that any	NEI recommends that the staff eliminate DC duration requirements.

	necessary or justified design changes that would have been addressed through renewal can likewise be addressed on an as-needed basis. The rulemakings of 10 CFR 50.150 and 50.155 demonstrate that the NRC is able to effectively consider the impacts of safety issues and new requirements on certified designs and determine an appropriate means for implementing those requirements for existing designs. While industry agrees with NRC's ultimate conclusion, the staff's description of negative, albeit minor, impacts from this change are overstated. For example, section 6.4.2 and 6.4.3 discuss a potential need to address departures that may have been addressed in a renewal. Section 3.4.2 speculates that COL applicants might voluntarily change the design to address new information. These considerations are highly speculative and, regardless, could also apply to COLAs during the current 15-year DC duration. A renewal provides no assurance of a "better" design that will have less departures because any design changes during renewal would either (1) meet the same criteria for which NRC can impose changes on the DC under 52.63(a), or (2) be voluntary design changes that the DC renewal applicant determines are warranted to pursue by amendment. Assuming amendment remains available (see comment 35), there is no reason to speculate that renewal might reduce departures or increase standardization.	
37. App. H.1, §7.0	This section states, "the changes to NRC regulations and guidance in Alternatives 2 through 6 would affect future DC renewal applicants, and Section 50.109 does not apply to future DC renewal applicants." The impacts of Alternative 4 are modeled using the assumptions of Alternative 2, which in turn is modeled based on impacts to the 5 existing DCs. Thus, the Alternative was modeled assuming that the removal of DC durations would affect the existing DCs. This is inconsistent with the statement in section 7.	NEI recommends that the staff modify Alternative 4 and Section 7 to clarify that the elimination of DC durations would apply to existing DCs. The staff should also consider changes to requirements that would ameliorate the impacts of indefinite reporting obligations on previous and future DC applicants for certified designs that do not expire.

	The elimination of DC duration, if proposed, should apply to existing certified designs. The justifications for eliminating DC duration apply equally to new applications and existing DCs. Because this change would not modify the "certification information" (10 CFR 52.63(a)(1)) it does not raise issue finality considerations. Nevertheless, there would be an impact on the original applicants for those DCs in that the record keeping requirements of the DC (Section X.A of the respective certification rules) and various reporting requirements (including 50.46, Part 21, 52.6(b)) would continue indefinitely. This impact is minor and is justified by the reduction in unnecessary regulatory burden. Current NRC positions on deferring Part 21 reporting and expected changes to 50.46 reporting requirements minimize this burden. Additionally, the applicant for the DC appendix could seek an exemption from reporting requirements if the DC is "inactive," or seek to voluntarily rescind the DC if they determine they no longer wish to fulfill ongoing obligations. Such petition for rescinding the DC would seem to satisfy criterion 10 CFR 52.63(a)(1)(iii); however, in eliminating DC durations for both existing and new DCs, it may assist regulatory clarity to amend 52.63 to explicitly allow rescission by the original applicant with minimal regulatory burden to do so.	
38. Appendix H.2 § 2.2 Change Process - Processes for Making Tier 1 Conforming Changes and Formatting Changes and Tier 2 Changes to Organization	NEI believes that the NRC should make changes to regulations that specify the processes for an applicant or licensee under Part 52 to depart from information in a certified design, including both Tier 1 and Tier 2 information. There should be a change process to allow alignment (i.e., editorial or conforming changes) between Tier 1 and Tier 2 details without using the formal license amendment process. These changes are needed to provide greater flexibility and reduce the regulatory burden on COL holders and applicants in making changes to the generic DCD, including Tier 1 and	NEI recommends that the staff should include in the rulemaking a process that would allow a COL licensee to make administrative change the Tier 1 information in its PS-DCD (or FSAR) without having to request a license amendment and an exemption in cases where there is no safety significance to the change may improve regulatory efficiency. Such a change might involve a change in the format of the DCD or a conforming change that aligns Tier 1 information with a non-safety-significant Tier 2 change. NEI recommends that alternative 3 provides the most benefits to both existing and future COL holders and applicants and that the

and Section numbering	Tier 2 information, that do not have an appreciable safety impact, under the following three circumstances: 1. Tier 1 changes to address format inconsistencies between a COL and the referenced DCD that currently require a license amendment request and an exemption request. 2. Tier 2 changes to a COL holder's licensing basis that require conforming changes in corresponding Tier 1 information. The COL holder is currently required to request both a license amendment and an exemption for such changes regardless of the safety significance of the changes. 3. A COL applicant referencing a DCD must include as part of its application a PS-DCD containing the same type of information and using the same organization and numbering as the generic DCD. A COL applicant must receive an exemption from this regulatory requirement to deviate from the organization and numbering of the generic DCD.	NRC has underestimated the benefits of this change to both current and future COL holders. The cost benefit analysis for the Generic application of Tier 1 conforming changes to Utility Licensees significantly underestimates the value of making this change. In addition, the noted cost in the draft regulatory basis to COL holders referencing the existing Part 52 certified design appendices to revise their internal procedures for processing Tier 2 changes is small compared to the benefit provided by being able to make changes to the generic DCD, including Tier 1 and Tier 2 information, that do not have an appreciable safety impact without NRC approval.
39. Appendix H.2 § 2.2	In its own discussions of the need for prior approval of changes to Tier 1 information, the staff explicitly recognizes that allowing departures from Tier 1 information without prior NRC approval would reduce burden on licensees while not necessarily resulting in safety concerns. Notably, COL-ISG-025, which describes the PAR process (which requires a "no objection" finding before initiating construction changes but *not* prior approval of the LAR itself for Tier 1 changes/departures) states:	NEI believes that resolution of this issue is central to a potential applicant's decision concerning whether or not to use the Part 52 licensing process. As such, NEI recommends that this issue be elevated to the Commission for consideration as a policy issue. This recommendation is consistent with industry feedback provided to NRC over the last several years. For example, on January 23, 2018, NEI, NIA, USNIC issued a joint letter to Chairman Svinicki (ML18030A771), which forwarded the paper "Ensuring the Future of U.S. Nuclear Energy: Creating a

	The PAR process preserves the design configuration control mechanisms while avoiding unnecessary construction delays by creating a process whereby a licensee can opt to submit a request to the NRC seeking a determination on whether the NRC objects to the licensee proceeding with construction changes, subject to strict conditions, before the NRC's review of the LAR is complete. If the NRC determines it has no objection to the licensee's request, the licensee may proceed with the construction change, but the licensee is required to return the facility to its CLB should the related LAR be withdrawn or denied. [COL-ISG-025, at 2-3] In addition, RG 1.237 (which allows licensees to submit LARs to authorize technical specification (TS) or facility changes or departures from Tier 2/Tier 2* of the plant-specific DCD within 45 days *after* the licensee approves the change and begins construction of the SSC) acknowledges that: "*For plants under construction under 10 CFR Part 52, the determination comparable to placing the SSC in use in facility operations ("operability" for SSCs controlled by TS for a 10 CFR Part 50 facility) occurs when the licensee notifies the NRC pursuant to 10 CFR 52.99(c)(1) that the prescribed inspections, tests, and analyses for that SSC have been performed and that the prescribed acceptance criteria have been met. Similar to an operating facility in which a system is not operable while it is out of service for maintenance and testing, there are no immediate nuclear safety consequences for a new facility if facility construction has not been completed and fuel has not been loaded." RG 1.237 at 7.*	Streamlined and Predictable Licensing Pathway to Deployment." In the letter, the three organizations noted that "to ensure that advanced reactors are licensed and built in the U.S., near-term regulatory reforms are necessary." Among other things, they recommended that the Commission provide "additional flexibility for changes during construction." In an October 2018 white paper titled "Assessment of Licensing Impacts on Construction: Experience with Making Changes during Construction under Part 52" (ML18305B421), NEI elaborated on this point: "[U]tilities and other end-users that will build future reactors need the ability to make changes during construction, without unduly slowing construction. The need for prior NRC approvals of the changes, no matter how minor, has increased costs, both by causing construction delays or by maintaining the engineering and licensing organization on standby, ready to quickly develop and submit license amendments. These issues, in part, will be addressed by reducing the level of detail in the licensing basis and thereby reducing the need for license amendments. Ensuring Tier 1 obligations are focused on safety significant features and eliminating the NRC's use of the Tier 2* designation will also help provide flexibility. However, additional process improvements are needed for situations which require license amendments to allow construction to proceed without delays. To fully accomplish this objective, new or revised guidance will be needed and revisions to Part 52 may be needed." NEI recognizes that the current two-tiered framework in Part 52 reflects longstanding Commission policy and the historically disparate legal treatment of Tier 1 and Tier 2/2* information in design certification rules (DCRs), and that modifying the framework poses certain challenges. However, NEI submits that the benefits of establishing a more flexible change process for Tier 1 information in future DCRs, particularly for new advanced reactors/non-LWRs, will outweigh those challenges. Those

	"[*S]uch construction will be subject to certain conditions that the licensee must satisfy before it submits the ITAAC notification letter for the SSC to the NRC under 10 CFR 52.99(c)(1) or 10 CFR 52.99(c)(2). This would be consistent with current practice for operating plants, under which licensees may install and test modifications (e.g., during an outage) in parallel with NRC review of required license amendment requests. Before a 10 CFR Part 52 licensee constructing a facility declares an ITAAC complete by submitting an ITAAC closure notice, the design of the SSCs required to meet that ITAAC must be consistent with the design described in the FSAR, as updated, and Tier 2 of the plant-specific DCD." RG 1.237 at 7.* *"Licensee configuration management programs ensure that changes are properly controlled. The configuration management programs, along with inspections and the ITAAC process itself, provide assurance that the plant is constructed in accordance with the license."* "*Through the NRC's Construction Inspection Program (CIP), the NRC staff uses inspections of construction activities to independently verify that the licensee successfully carries out construction activities and identifies and corrects deficiencies that may have an impact on the ITAAC or other construction activities. . . . CIP activities can continue while a licensee is constructing SSCs whose design departs from the FSAR, as updated. If the inspection program identifies an SSC that does not match the design described in the FSAR, which would otherwise have been reported as a*	benefits, which would inure both to licensees and the NRC, include: • avoiding reliance on the PAR process and the associated costs to licensees and NRC; • eliminating or reducing the need for exigent licensee submittals and NRC staff review thereof to avoid construction schedule/sequencing impacts; • reducing burden on licensees to maintain an unduly large licensing and engineering staff to manage and expedite numerous PARs/LARs; and • reducing the potential for construction delays due to emergent conditions that involve changes requiring prior NRC approval. As the NRC staff itself acknowledges in the draft Regulatory Basis (see excerpts at left), these reductions in regulatory burden can be achieved without nuclear safety consequences. Accordingly, the NRC should amend its regulations to address this issue and revise the associated regulatory guidance (i.e., RG 1.237) to allow licensees to make changes to Tier 1 information without prior NRC approval. However, before a licensee can declare a changed SSC operable or place it in service, it still would need to obtain all required amendments pertaining to the change. Based on the rationale provided in the regulatory basis for RG 1.237, there is no safety-based reason to preclude changes to Tier 1 information without prior NRC approval in RG 1.237. The following observations provide additional support for the recommended change in approach: • Although limiting the amount of detailed design information designated as Tier 1 could help reduce impacts, the need to make changes to Tier 1 information will continue to arise, especially for first-of-a-kind construction of any design. Therefore, the notion that allowing such changes unacceptably erodes design

	construction finding, the NRC staff will consider the as-found condition of the SSC in connection with pending license amendments, requests for new amendments, and changes to or departures from SSC designs made without NRC approval in accordance with the change processes in Section VIII of the appendices to 10 CFR Part 52 or 10 CFR 50.59." RG 1.237 at 7-8. Finally, in the draft Regulatory Basis document, the staff notes: *"As implemented under Part 52, after a plant has been licensed, Part 52 imposes an additional burden on the licensee to depart from Tier 1 design information, compared to a Part 50 licensee. For example, when comparing a Part 50 licensee and a Part 52 licensee that have similar information in their FSARs, the Part 50 licensee would be able to make certain changes without a license amendment or exemption using the Section 50.59 process, while the Part 52 licensee making the same changes would—if the information was specified as Tier 1 information—be required to obtain a license amendment and exemption. Current NRC policy supports this difference based on the benefits of standardization, but this policy did not consider the burden associated with making Tier 1 changes that have low safety significance, as was experienced during recent AP1000 plant construction. Draft Regulatory Basis, App. H at H-38.* The staff also notes that allowing COL holders to make certain changes to Tier 1 information in their PS-DCDs without either a license amendment or an exemption (thereby allowing COL holders to have noncompliance with	standardization is not well founded. For example, as of December 2017, Southern Nuclear Company had implemented or proposed approximately 625 departures at Vogtle 3/4 in accordance with the AP1000 design certification change process. This number of changes is not unexpected given the nature of this complex, first-of-kind project in the United States. • As NEI noted in its October 23, 2018 letter to NRC (ML18305B421), the staff has repeatedly acknowledged that the more flexible change process advocated by NEI could reduce regulatory/resource burdens for both licensees and the staff. This staff recognition also is reflected in the draft Regulatory Basis. • In SECY-19-0084, the staff noted its intent to "refine the general principles for Tier 1 content, including avoiding unnecessary detail so that NRC approval will not be required for design changes of minimal safety significance." This change in practice will help reduce the need for changes to Tier 1 information. However, it does not address the industry's overriding concern—i.e., licensees' current inability to make changes to Tier 1 information during construction without prior NRC approval. • As the staff notes in the draft Regulatory Basis, the actual cost savings that would result are difficult to predict with certainty because the number of avoided licensing actions is difficult to estimate. However, the following excerpt from NEI's October 2018 white paper (ML18305B421) fully describes the PAR/LAR-related licensing impacts on plant cost and construction: "The relatively mild impact on construction can largely be attributed to significant licensee resources dedicated to managing the Vogtle 3/4 licensing basis and the responsiveness of NRC when expedited action on PAR/LARs was necessary.

	their COLs and with applicable NRC regulations justified by a 50.59-like process) could result in cost savings to COL holders referencing a certified design and to the NRC. Draft Regulatory Basis, App. H at H-39. Despite these acknowledgments, the NRC staff concludes that it cannot permit Tier 1 changes or departures (1) given the manner in which Section VIII.A of each of the current design certification rules (i.e., appendices to Part 52) is drafted, and (2) absent a substantial change in Commission policy. For example, in RG 1.237, the staff states: *The foregoing background and discussion applies only to the design of a facility described in an FSAR, as updated, including Tier 2, Tier 2*, but not Tier 1, as described below. The rationale set forth in the final Statements of Consideration for the 1999 rule amending 10 CFR 50.59 for the Commission's position with respect to operating plants applies to changes requiring amendments governed by 10 CFR 50.59, which corresponds to the change process in Sections VIII.B.5 and 6 for Tier 2 and Tier 2* information. That rationale does not correspond to any provision of Section VIII.A, which governs generic changes to and plant-specific departures from Tier 1. Accordingly, the foregoing rationale for the process applicable to operating plants under Part 50 applies under Part 52 only to the information in the FSAR, as updated, including Tier 2 and Tier 2*, but not Tier 1 for a facility under construction pursuant to a COL covered by 10 CFR 52.98(c). Nonetheless, a licensee may employ the PAR*	While direct impacts on construction schedules were limited, the need for unnecessary (e.g., nonsafety-significant Tier 2* changes) LARs and the need for PARs has had an adverse cost impact on the project. The process has required additional time and resources on the part of both the SNC and NRC. On average SNC estimates the cost for preparation and NRC review of a typical LAR to be $200-$300K. And beyond the direct cost of the licensing action, the interpretation that construction must be in accordance with the licensing basis at all times creates the ongoing risk and potential for the change process to delay construction and requires the licensee and design authority to maintain licensing and engineering staffs that are larger than would otherwise be necessary to be ready to address emergent conditions and minimize that risk. In addition to the resource burden on licensees, the current NRC interpretation that construction cannot at any time deviate from the licensing basis creates unnecessary ongoing risk during the entire construction period and the potential for costly construction delays due to emergent conditions that require prior NRC approval of LARs or PARs. That risk is not justifiable from a public health and safety perspective and is exacerbated by unnecessary use of the Tier 2* designation." • As discussed in the SRM for SECY 90-377, the Commission established the two-tier design certification structure to balance the goal of design standardization with the flexibility needed by licensees to procure equipment and construct the facility. The NRC's policy for new reactors is to encourage, not require, standardization. The NRC intended the use of Tier 1 to prevent licensee changes that impact safety and therefore need NRC approval. The NRC recognized that Tier 1 has a collateral benefit of standardization by minimizing the number of changes to certain information by including it in Tier 1. Thus, the NRC did not intend to use Tier 1 to reject changes simply because it would reduce standardization, but rather rely on the more resource and time consuming process of LARs to provide a natural disincentive

	process for both Tier 1 and Tier 2 as described in COL-ISG-025 if the facility license includes that condition. [RG 1.237 at 8] In the draft Regulatory Basis document, the Staff, while considering an alternative approach (Alternative 2 in Section 2.0 of Appendix H), recommends against adopting it. It states: *Alternative 2 would result in regulations that would allow a COL holder to make certain changes to Tier 1 information without a license amendment or exemption. However, rulemaking on this issue would be complex because the NRC would have to restructure the entire tiered process for certifying designs given that, as the process stands today, Tier 1 information is "approved and certified," in each DC rulemaking. The Commission approved the two-tier structure in the staff requirements memorandum for SECY-90-377, "Requirements for Design Certification Under Part 52," (NRC 1990-TN6274), so a change of this nature would be a policy issue, as discussed below in Section 2.5.2. In addition, a change that made it easier for licensees to revise Tier 1 information could contribute to the erosion of design standardization, which was one of the stated goals of Part 52.* [Draft Regulatory Basis, App. H at H-35 to H-36] In rejecting Alternative 2 in favor of the status quo, the staff further notes:	against the erosion of standardization (i.e., a burdensome regulatory change process will prevent LARs that have trivial benefit.) Experience with the process proves the above point in that the NRC has rarely if ever rejected a change to Tier 1, or otherwise, because it would erode standardization. NEI thus concludes that the risks and costs arising from the need to obtain prior NRC approval of changes to Tier 1 information can be substantial and have a significant negative impact on a new plant construction project. NEI further believes that the needed changes can be accomplished by revising RG 1.237 and clarifying the regulations. As the staff noted in its regulatory analysis, "adding clarifying language to the regulations would not result in additional requirements necessitating NRC actions, such as backfit evaluations. However, removing ambiguity from the regulatory language would potentially result in a more efficient regulatory process, thereby reducing the time needed to respond to necessary requests and questions from industry and ultimately saving NRC staff time and resources." The basis the NRC provided for allowing changes during construction to Tier 2 and Tier 2* information that would ultimately require a license amendment without NRC prior approval would also seem to apply to changes to Tier 1 information with the addition of the need for an exemption. NEI believes that these changes can be allowed by revising RG 1.237 and that the regulations should be clarified, as the NRC noted in its regulatory analysis, "adding clarifying language to the regulations would not result in additional requirements necessitating NRC actions, such as backfit evaluations. However, removing ambiguity from the regulatory language would potentially result in a more efficient regulatory process, thereby reducing the time needed to respond to necessary requests and

	For the sub-items involving change processes for certain Tier 1 changes in a PS-DCD (Sub-items A and B), the staff recommends Alternative 1, "No-Action." A rulemaking in this area would involve changing a longstanding NRC policy regarding standardization. In addition, a change in this policy would involve multiple complicating issues, including determining the criteria for what sort of changes would qualify for the new change process and a new process for maintaining consistency between the two copies of Tier 1 information in the PS-DCD and Appendix C of the COL. In addition, because the Tier 1 change issues have, to date, involved only a single certified design, it is not clear that the issues that gave rise to the problems in Tier 1 information exist for any other certified designs. Recent and ongoing DC submittals also may not experience this issue, because lessons learned from previous reviews are being applied to those designs. Finally, lessons learned about improving and correcting Tier 1 information could be addressed generically through a future renewal of a certified design. [Draft Regulatory Basis, App. H at H-44]	questions from industry and ultimately saving NRC staff time and resources." In NEI's comments on the draft regulatory guide (DG-1321) it was pointed out that this alternative approach (i.e., allowing changes to Tier 1 information without NRC prior approval), if adopted by the NRC, would provide a number of significant benefits. Specifically, it would help avoid construction delays due to emergent conditions that involve changes presently requiring prior NRC approval. In the same vein, it also would eliminate the need for the Preliminary Amendment Request (PAR) process and associated costs as well as the need for development of exigent submittals and NRC staff reviews to avoid construction schedule impacts. Finally, it would remove the burden on licensees to maintain larger than otherwise necessary licensing and engineering staffs to manage and expedite PAR/LARs needed to address emergent issues and maintain construction schedules and sequencing.
40. Appendix H.2 §2.3 - Change Process - 10 CFR Part 52 Appendix A-E Sections	NEI does not agree with this recommendation being limited to Tier 2 and Tier 2* information. The industry believes that it should also include changes to Tier 1. Changes during construction and construction to licensing basis challenges are created by NRC's position that as soon	NEI recommends that the staff should revise RG 1.237 to allow "at risk" changes to Tier 1, Tier 2* and Tier 2 (changes requiring an amendment). In addition, there should be corresponding changes to each Part 52 DC appendix, paragraph VIII.B.5.a. to recognize that prior NRC

VIII.5.B.A and VIII.5.B.B	as the COL is issued there is an approved licensing basis and the licensee, therefore, a licensee constructing a facility needs to be in compliance with Tier 1 of its licensing basis at all times regardless of whether there is any impact to the health and safety of the public. ITAAC verification and construction oversight via licensee programs (e.g., quality control), as well as implementation of operational programs, ensure that the facility has been constructed and will operate in accordance with its license. Thus, restrictions should be removed allowing temporary deviation from the approved licensing basis during construction where configuration control, corrective measures or license amendments are implemented that restore conformance of the plant with its licensing basis. 10 CFR 52 when created was intended to ensure better control over standardization. The unintended consequence of hindering construction was not fully understood at that time. NRC should change its interpretation to allow at risk construction not only for changes to Tier 2 and Tier 2* that require a license amendment, but also changes to Tier 1 that require both an amendment and an exemption. This interpretation would acknowledge the potential for LARs to be denied. Changes at risk would need to be subject to configuration control to ensure that if the LAR is not approved or the licensee does not or cannot process a 50.59-like change, the change at risk will be reversed in the field. It is also important to note that the NRC's implementation of Interim Staff Guidance (ISG) 025, "Interim Staff Guidance on Changes during Construction under 10 CFR Part 52," the NRC allows a licensee to proceed with construction changes,	approval is not required during construction to make changes to or departures from Tier 1 information, Tier 2* information, or the TS [technical specification], or requires a license amendment under paragraphs B.5.b or B.5.c of this section. For plants under construction under 10 CFR Part 52, it is understood that changes made without prior NRC approval are changes made "at risk" and must be reviewed and approved by the NRC prior to licensee notification of the NRC, pursuant to 10 CFR 52.99(c)(1), that the prescribed inspections, tests, and analyses for that SSC have been performed and that the prescribed acceptance criteria have been met.

	including changes to Tier 1 information before the NRC's review of the LAR is complete. Although this process is burdensome, and unnecessarily takes extra time and resources, it demonstrates that the NRC has determined that there are no restrictions in existing regulations to making changes to Tier 1 information without prior NRC approval.	
41. Appendix H.2 §5 – Change Process for ESP SSARs and LWA SARs	Currently, no regulatory mechanism allows an ESP holder to make changes to its SSAR that have a limited nexus to site safety without obtaining prior NRC approval through a license amendment, similar to the existing process for COL and OL holders, who are able to make certain changes to information in their FSARs without a license amendment or prior NRC approval when those changes meet preestablished criteria. The experience of the first licensees under Part 52 demonstrates a need for a change process for ESPs and LWAs. NRC should establish a 50.59-like change process for ESPs and LWAs. A change process similar to the 50.59 like process in Part 52 for DCD changes would be a benefit and is needed to eliminate unnecessary burden for ESP holders and make the regulatory change approaches consistent. The NRC has underestimated the future benefit of this change.	NEI recommends that the staff pursue Alternative 2: Rulemaking, to define a graded approach for making changes to ESP and LWA SARs. NEI does not agree with the No-Action Alternative for the ESP change process and recommends that the staff establish a 50.59-like change process for ESP SSARs, and a similar approach for holders of limited work authorizations (LWAs) that desire to change their safety analysis report (SAR), issued under Section 50.10, "License required; limited work authorization."
42. Appendix H.2, Processes for Making Tier 1 Conforming Changes and Formatting Changes and Formatting Changes and Tier 2 Changes to Organization	The NRC's evaluation has undervalued the operating impact to COL holders over the long-term by focusing on the construction phase. The impacts noted during construction will continue to be an issue during operations for Part 52 COL holders, although scope is unknown. If not a change process, an alternative that the NRC should consider is designating certain portions of the Tier 1 document as not requiring prior NRC approval for changes. This would be in-line with the recent effort among Part 50 Licensees to place TS TOC under Licensee control.	NEI recommends that the staff revise the cost/benefit analysis to include the continuing cost impacts to Licensees after construction phase and factor this into a decision to eliminate this portion of rulemaking.

and Tier 2 and Section Numbering, §2.6.1.2, Impacts on Applicants and Licensees	The NRC should also evaluate changes to regulations that would allow removing the "construction specific" designations of Tier 1 (e.g., construction/inspection/ testing/analyses) after completion of those portions in such a way that Licensees are allowed to maintain portions of Tier 1 themselves after the NRC makes its 10 CFR Part 52.103(g) finding. This would provide an alternative to the continuing need for license amendments and exemptions for changing this information.	
43. Appendix H.2, general	Part 52 Subpart E provides no change or departure process for an SDA. Under 10 CFR 52.145, NRC Staff and the ACRS must use and rely upon "an approved design" when a license application "incorporates by reference a standard design approved" by the NRC Staff under Subpart E. If a license application departs from an approved SDA in any respect, it could be inferred that the "approved design" is no longer being incorporated by reference, and thus Staff needn't rely on any part of the SDA. It is very unlikely a site-specific application can incorporate by reference and SDA with zero departures from the approved design; experience with comparable COLAs referencing DCDs bears this out. Thus, in order to make the SDA process usable and ensure the degree of finality intended by Subpart E, regulatory changes are needed to clarify the uncertainty regarding SDA departures. As with design certifications, a license applicant should be able to depart from an SDA using a 50.59-like process. Such departures would be subject to Staff's application-specific review, but the remainder of the SDA would still have to be relied upon by Staff and ACRS. An SDA does not include Tier 1 information, and as addressed in other comments does not need to. An SDA does not provide issue resolution binding upon the	NEI recommends NRC revise Appendix H.2 to include consideration of a new change process for license applications referencing a Standard Design Approval. This would allow a license applicant to depart from portions of an SDA due to design changes or site-specific needs, while maintaining finality for the remainder of the approved design that is unaffected by the departure.

	Commission and ASLB. Therefore, the SDA departure process for SDA only needs to address changes that do or do not require Staff approval, as with the DCD Tier 2 process. The change process should not require exemptions or license amendments for any departure.	
44. Appendix H.2 – Change Process, §3.3.2.1 Description of Alternative 2, and §3.8.2 Feedback from the Advisory Committee on Reactor Safeguards	Newly issued RG 1.237 includes the 45-day provision for submitting a license amendment, this timeframe has no explanation in the RG or in this Regulatory Basis. Understanding the staff's concern regarding a build-up of LARs preceding 103(g), other construction milestones/reporting requirements could have been used as a time-mechanism for submittal of LARs to allow Licensees to self-prioritize LAR submittals.	NEI recommends that either the NRC revise RG 1.237 to remove the 45-day provision for submitting a license amendment or identify the safety benefit in its justification for imposing the 45-day provision. This is an additional administrative requirement that is not directly linked to safety.
45. H.3, §1.2	NRC states "Currently, DC applicants are not required to include tiers in their applications." That is correct. Moreover, applicants are not currently required to provide a design control document at all. The process established in the regulations is for the applicant to include an FSAR, proposed ITAAC, and an ER; the NRC then certifies the design. All DCs to date have relied on an applicant-provided DCD, composed of Tiered information. But NRC should recognize that this proposed change codifies a new requirement: that the applicant provide the proposed DCD and that it contains Tiers.	NEI recommends that the staff modify the discussion in §1.2 and other sections to clarify the scope of the proposed change. Although the NRC statement that they have not issued a COL not referencing a DC is true, it would be useful to note that the NRC is currently reviewing a COL that does not reference a DC.
46. H.3, §1.3.2 and others	Here NRC states "This rulemaking would also amend the requirements for the contents of applications for a DC, COL, SDA, and ML in Sections 52.47, 52.79, 52.137, and 52.157 to require each applicant to identify Tier 1, Tier 2, and Tier 2* information in their FSAR."	NEI recommends that the staff modify Alternative 2 to delete changes affecting the SDA and COL applications. For the ML application, the NRC should consider less burdensome alternatives. It should also be noted that the staff has indicated that it only intends to use Tier 2* in situations when specifically requested by an applicant, but has reserved it for special exceptions.

	A new requirement for information tiers in applications other than a DCA is unfounded. No regulatory issue is identified that this proposal would resolve. The development of tiers for certified design DCDs reflects the unique role of a certified design rule in the NRC's licensing process. The original concept for a DC involved an applicant providing an FSAR and the NRC developing certification information for inclusion in the CFR (see the scope of application requirements of 10 CFR 52.47). Under such an approach, presumably the certification information would be narrower than the applicant's FSAR, and any departure from the certification information, because it is a regulation, would necessarily require an exemption. Subsequently industry and NRC developed the approach of an applicant developing a DCD for the NRC to incorporate by reference in the certification rule, and because this DCD would be expansive (including the FSAR), a tiered approach was needed as to not unduly restrict departures from the DCD. A custom COL, an SDA, and an ML are different. They are not rules that would require an exemption from them. They are licenses and approvals for which other change processes apply (or in the case of an SDA, is needed). There is no reason for a custom-COL, for example, to include Tier 1. Tier 1 serves to enforce an appropriate level of standardization amongst various facilities based on the same standardized design. A custom-COL is just that--custom--so requiring Tier 1 and an exemption from it for a COL to modify their own custom design is nonsensical. Changes would instead be governed by 10CFR50.59, which ensures that changes rising to the level of requiring NRC prior approval receive it; developing and requiring exemptions from a Tier 1 COL would be an unnecessary regulatory burden with no safety benefit.	With regard to the use of Tier 2* it should be noted that SECY-17-0075, "Planned Improvements in Design Certification Tiered Information Designations," dated July 24, 2017 noted the following: • NRC staff intends to continue use of the Tier 2* designation in the APR1400, NuScale, and other future design certifications. • Tier 2* should be applied only when an applicant determines the additional flexibility for making changes could be beneficial. Subsequently in SECY 19-0034, the staff stated that "[N]neither the Advanced Power Reactor 1400 (APR1400) design approval nor the NuScale design certification application contains Tier 2* information." Thus, if the definition of Tier 2* is included, the definition should state that it is not expected to be used and is reserved only for special exceptions when an applicant determines the additional flexibility for making changes could be beneficial.

	Similarly, an SDA is not a rulemaking and departures from it would not require an exemption. While an SDA achieves some of the goals of standardization, because issues are not finally resolved through an SDA, a COL referencing one is effectively a custom COL as well. A new Tier 1 requirement would not only constrain the COL applicant, but effectively constrain the changes the Commission (acting through the ASLB) could impose during the COL licensing proceeding, since exemptions would be needed to depart from those aspects of the design. Tier 1 for an SDA therefore represents a major shift in the way an SDA would work. Thus, Tier 1 for an SDA is, at least, meaningless regulatory burden (if exemptions from it will not be required) and, at most, a major shift in the role and function of an SDA in the regulatory framework. An SDA departure process is needed; creating Tier 1 for an SDA is not. See comment 43. For an ML, the license holder currently cannot make any changes from the licensed design without NRC approval. Therefore, it may be appropriate to include an option for Tiered information in the license to allow an ML holder to tweak the design prior to and during manufacturing without NRC approval. However, the same outcome could be accomplished by including an ML within the scope of 50.59.	
47. Appendix H.4, general	Part 52 Subpart E provides no process for amending or updating a Standard Design Approval. Currently, it is unclear how an SDA-holder would go about making generically-applicable changes to an SDA. While a new SDA application could be filed, there is no finality provision that would preclude re-review of unaffected portions of the previously-approved SDA.	NEI recommends Subpart E be revised to include a new rule allowing for amendment of an SDA by an SDA holder. Similar to the departure process described in Comment 46, the amendment process would allow the SDA-holder to change portions of the approved SDA without Staff re-reviewing the remainder of the approved design.

	Subpart E should be revised to include a new rule allowing for amendment of an SDA by an SDA holder. Similar to the departure process described in Comment 46, the amendment process would allow the SDA-holder to change portions of the approved SDA without Staff re-reviewing the remainder of the approved design. Only portions affected by the amendment would be reviewed by Staff and ACRS in approving the revised SDA This amendment mechanism has increased importance if NRC eliminates SDA durations, which NEI supports (see responses to FRN questions).	
48. Appendix H § 6	Recent lessons learned has identified additional administrative burden to licensees in 52.99(a) requirement submittal of ITAAC schedules at 6-month intervals until 1 year prior to fuel load, then monthly, without any benefit to public health and safety. The above submittal requirements reflect the assumption that ITAAC will be able to be closed on a steady basis throughout construction. Experience has shown that the majority of ICN submittals will not occur until the final 6 months of construction due to the nature of ITAAC. Inspection planning activities have proved more useful to the NRC staff than these submittals.	NEI recommends NRC revise 52.99(a) to reduce or eliminate this reporting requirement.
49. Appendix I §2	NEI agrees with the proposed changes to 51.50(a). However, consideration should be made to similar changes to Part 50 to incorporate ESP.	NEI recommends that NRC include revising the regulations to allow CP applicants to reference previous work that is available to COL applicants (e.g., ESP).
50. Appendix I §2.3.2.2 and §2.4	Text says, "By revising paragraph 51.51(a)…" Should this state 51.50(a)? Also, in Section 2.4, change "an applicant" to "a CP applicant".	NEI recommends that the staff make the noted editorial corrections.
51. Appendix I §2 Change to Clarify 10 CFR 51.50(A) that an Applicant for a Construction	Consideration for Alternative 2 conforming changes to a Part 50 application referencing an ESP is recommended.	NEI supports the staff's recommendation of Alternative 2 as well as making conforming changes to a Part 50 application referencing an ESP.

Permit can Reference an Environmental Assessment From a Certified Design		
52. Appendix K §4.0 - Technical Specifications Bases Control Prior to the 10 CFR 52.103(g) Finding, §4.2 Regulatory Issues	Clarification of paragraph: As an example, since the NRC issued the COLs for VEGP 3&4 in February 2012, the licensee has been constructing the units and improving and updating the plant-specific TS bases in accordance with the change process specified by the TSs Bases Control Program in Section 5.5, "Programs and Manuals," of the VEGP 3&4 plant-specific TSs. However, plant-specific TS Subsection 5.5.6, "TS[s] Bases Control Program," is not compulsory until the VEGP 3&4 plant-specific TSs are made effective by the paragraph 52.103(g) finding. It should be noted that VEGP had been voluntarily updating the PS-TS Bases under a general licensing document change procedure until the establishment of the TS Bases Control Program in 2019. The updated TS Bases have been voluntarily submitted to the to the NRC with the annual UFSAR submittal. Alternative 3 aligns best with providing a process to maintain the TS bases from an efficiency perspective related to processing of licensing changes. To not include the TS bases out of a licensing change that requires modifications to other licensing documents (like the UFSAR) doesn't make sense from a licensee workload/change management perspective. Also, from an Operations perspective, implementing a process for ensuring the TS bases are maintained in a timely manner is essential for operator training.	NEI recommends that NRC implement Alternative 3. It is in the best interests of both the NRC and licensee to ensure that the TS Bases are maintained up to date following initial licensing during the construction process. NEI also recommends that NRC consider revising "in accordance with" or place a footnote to acknowledge timing for implementation of the VEGP 3&4 TS Bases Program.

53. Appendix K §4	Upon issuance of the 52.103 (g) finding, all programmatic requirements need to be current, in this case, the TS Bases need to be reflective of the TS and consistent with the FSAR.	NEI recommends the selection of Alternative 3 to ensure there is a process to maintain fidelity between the FSAR and the Plant Specific TS Bases. This will help to reduce the likelihood of delays between issuance of the 52.103 (g) finding and commencement of fuel load. It would seem in the best interests of both the NRC and licensees to ensure that the TS Bases are maintained up to date following initial licensing during the construction process.
54. Appendix K, Table K-9	The rulemaking costs cited in this analysis are on-par with the NRC review fees Licensees have incurred from seeking Code Alternatives related to the use of Section XI. However, missing from the NRC's analysis is the costs Licensees incur with vendors, contractors, and industry agencies to develop Code Alternatives as well as the costs for Licensees to evaluate the construction sequence timing challenges for awaiting an ALT approval and workarounds investigated for avoiding an ALT.	NEI recommends that NRC revise the cost/benefit analysis to reflect the costs Licensees incur with vendors, contractors, and industry agencies to develop Code Alternatives as well as the costs for Licensees to evaluate the time challenges and workarounds.
55. Appendix K, § 6.9, Staff Recommendation	In this section the staff notes that "this recommendation is based on the small number of potential COL holders that might implement this regulatory relaxation, which does not support the expense of rulemaking at this time." Even a single COL holder in the future will benefit from this regulatory change. As stated in a comment above, the benefit to the Licensee from just the NRC fees associated with pursuing a Code Alternative makes this a low-cost initiative to support the industry. Additionally, VEGP Unit 3 continues to perform a cost-benefit analysis each time a repair is needed on Section III piping; the cost/time and risk of seeking a Code Alternative to use Section XI is weighed against the cost/time to do the repair under Section III. Because Staff feedback has historically been that Code Alternatives should be specific for the requested repair there is an overall additional cost added to the resources needed to make these business decisions	NEI believes that the staff's cost benefit analysis for the Generic application of ASME BPV Section XI and Tier 1 conforming changes to Utility Licensees, significantly underestimates the value of making these changes. NEI recommends that NRC reconsider its determination that Alternative 1 is the best course of action. NEI believes that Alternative 2 to allow the Generic application of ASME BPV Section XI is most appropriate and beneficial.

56. Appendix G, §5.5	While this section states that no guidance documents would be revised or developed, Alternative 2 says that associated guidance would be revised.	NEI recommends an editorial correction to ensure consistency.