Response to Public Comments on Draft Regulatory Guide (DG)-1325
"Applications for Nuclear Power Plants"
Proposed Revision 1 of Regulatory Guide (RG) 1.206

On June 15, 2017, the NRC published a notice in the *Federal Register* (22 FR 28101) that Draft Regulatory Guide, DG-1325 (Proposed Revision 1 of RG 1.206), was available for public comment. The Public Comment period ended on September 18, 2017. The NRC received comments from the organizations listed below. The NRC has combined the comments and NRC staff responses in the following table.

Comments were received from the following:

Michael D. Tschiltz, Senior Director
New Plant, SMRs and Advanced Reactors
Nuclear Energy Institue (NEI)
1201 F Street, NW, Suite 1100
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ADAMS Accession No. ML17265A049

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1. Title	The title of the regulatory guide (RG) should reflect its focus as described in under Purpose and Applicability.	Revise title to: "Applications for Nuclear Power Plants Under 10 CFR Part 52"	Partially Disagree: The current title "Applications for Nuclear Power Plants" is intentionally broad and includes guidance relative to regulatory requirements outside of 10 CFR Part 52 and has relevance to applications for construction permits (CP) and operating licenses (OL) issued under 10 CFR Part 50 that may reference an ESP issued under 10 CFR Part 52. Furthermore, in the 2014 periodic review of RG 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)," NRC staff referenced a later phase of updating RG 1.206, "Combined

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			License Applications for Nuclear Power Plants, (LWR Edition)" envisioned that would provide guidance for applications for CP and OL. This planning from 2014 has not been revisited in the context of current competing priorities related to guidance.
2. General	The industry supports the migration of appropriate RG 1.206 technical guidance into the standard review plan (SRP). A major lesson learned from recent licensing experience is that as a result of the SRP, requests for additional information (RAIs), and less formal processes, applications have grown to include more information than is necessary to support the required reasonable assurance findings by the staff.	In connection with the migration of RG 1.206 technical guidance into the SRP, the NRC should re-evaluate the Review Areas and Review Criteria in each SRP section and revise, consolidate, or eliminate those that seek information beyond that necessary to support required reasonable assurance findings by the staff. The NRC should seek extensive stakeholder participation in the migration effort.	Partially Disagree: The comment and recommendation do not relate to the revision of RG 1.206. However, the staff plans to consider stakeholder participation in the planned knowledge management document containing detailed technical application guidance for a COL FSAR. With regards to future SRP updates, stakeholder input will be sought. It should also be noted that NRC recently presented an initiative related to SRP revisions that reinforces the focus on reasonable assurance of adequate protection. The summary of the public meeting can be found at ADAMS Accession No. ML18242A260.
3. General	[Editorial]	Fix numerous punctuation problems, including frequent double punctuations such	Agree: Revised in multiple locations.
4. A. Introduction, Related Regulations and Guidance, bullet on Appendix A, pg. 3	Given recent work on Advanced Reactor Design Criteria (ARDC), it would be worthwhile to mention that principal design criteria for non-light-water reactors (non-LWRs) are informed by ARDCs.	Add a note or parenthetical statement regarding ARDCs.	Agree: Revised text by adding: "The NRC issued RG 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors", to provide guidance on how the general design criteria (GDC) in 10 CFR Part 50, Appendix A, may be adapted for non-light-water reactor (non-LWR) designs".

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			RG 1.232 was also added to the references.
5. A. Introduction, Related Regulations and Guidance, bullet on Appendix B, pg. 3	The discussion of application for a construction permit and associated preliminary safety analysis report are inappropriate for this document.	Change discussion to reflect Part 52 licensing processes.	Partially agree: This has been revised to reflect Part 52 licensing processes. The revised text is as follows: "10 CFR Part 50, Appendix B, "Domestic Licensing of Production and Utilization Facilities," sets forth the requirements for quality assurance programs for nuclear power plants and is applicable to applications for ESPs, DCs, and COLs as per 10 CFR 52.17(a)(1)(xi), 10 CFR 52.47(a)(19) and 10 CFR 52(a)(25) and 10 CFR 52(a)(27)".
6. A. Introduction, Related Regulations and Guidance, bullet on RG 1.70, pg. 4	Given the staff's announced plans to transition RG 1.206 and NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Powers (LWR)," toward replacing RG 1.70, the citation here (with no clarification) is confusing.	Clarify that this RG and changes to NUREG-0800 will eventually replace RG 1.70.	Partially Agree: The staff will clarify in the Federal Register Notice for the update to RG 1.206 that RG 1.70 is not being withdrawn. The staff may, however, set a date beyond which applicants should no longer rely on RG 1.70 for licensing applications under 10 CFR part 50 and may develop alternate guidance in the future.
7. A. Introduction, Related Regulations and Guidance, pg. 4	[Editorial] Several of the documents listed appear to be incorrectly formatted (indented) making them appear as sub-tier documents.	Correct formatting.	Agree: Corrected.
8. A. Introduction, Related Regulations and Guidance, bullets on COL/ESP-ISG-026 and 027, pg. 4	There is no discussion here of the pending plan to supersede these documents as discussed later in document.	Make at least parenthetical note of the fact that these are being superseded.	Disagree: Staff does not expect to supersede COL/ESP-ISG-026 and COL/ESP-ISG-027 before issuance of the revision of RG 1.206. This portion of the introduction simply references

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			guidance documents and does not provide status updates on planned revisions.
9. B. Discussion, Background, pg. 8, 2nd paragraph	[Editorial] After "NUREG-0800", there are redundant references to "SAR" and "Safety Analysis Reports."	Correct editorial error.	Agree: Corrected.

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10. B. Discussion, Background, pg. 8, 3rd paragraph	"First, the staff creates an interim application guidance document (IAG) that is referenced in the SRP introduction section" is not very clear. Is there a document number? How does the timing compare to the RG and SRP revisions? The text says that the IAG will include "lessons learned since the issuance of RG 1.206, Revision 0." Stakeholders should be provided an opportunity to comment on this new information.	The NRC should highlight changes to RG 1.206 technical guidance to be migrated into the IAG on its way to the SRP, provide additional clarification on timing and construct of IAG, and provide opportunity for stakeholder comment.	Partially agree: Text has been revised to reflect uncertainties regarding the long term planning for the IAG as discussed in the DG issued for public comment. The near term goal is to make updated application guidance available via an ISG, NUREG or other public document. The new knowledge management document is considered a near term product to be completed during FY 2019. The revised text is as follows: *The technical application guidance for a SAR that was previously included in RG 1.206, Revision 0, is being updated to reflect lessons learned and will be developed into interim staff guidance (ISG), a NUREG, or other knowledge management document Stakeholders will be provided an opportunity for input to the document via a FRN requesting public comments. The document is expected to be useful to both applicants and to staff working on future updates to the SRP and related RGs; however, direct incorporation of applicant guidance in the SRP is not expected.*

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11. B. Discussion, Background, pg. 8, last paragraph	The use of "regulatory positions" here is a bit confusing.	Replace "positions" with "guidance."	Agree: Changed.
12. B. Discussion, Background, pg.9, last paragraph	[Editorial] The appendices referred to for Section C.2.7 and C.2.18 are actually "supplements." In the last sentence, C.2.8 should be C.2.18.	Correct terminology by replacing "appendices/appendix" with "supplements/supplement." Change "C.2.8" in the last sentence to "C.2.18."	Agree: Corrected.
13. B. Discussion, Background on License, Certification, and Approval Processes under 10 CFR Part 52, pg. 9, 1st paragraph	The first paragraph of this section leaves the impression that an early site permit (ESP) and design certification (DC) are required. This is clarified later but could be confusing as written.	Clarify that use of ESP and DC are options, or rearrange discussion to make this point clearer. Perhaps a simple edit such as "The regulations in Title 10 CFR Part 52 provide options for early resolution of safety and environmental issues before authorizing construction" would suffice.	Agree: Changed.
14. B. Discussion, Background on License, Certification, and Approval Processes under 10 CFR Part 52, pg. 10, 2nd paragraph	The paragraph that begins, "A holder of a COL issued under 10 CFR Part 52 obtains materials licenses issued under 10 CFR Parts 30, 40, and 70…" could be confusing.	Clarify that these materials licenses are typically applied for.	Agree: Changed and added a reference to Section C.2.13.
15. B. Discussion, Harmonization with International Standards, pg. 10	This section is ambiguous with regard to the extent to which the staff acknowledges or uses international standards.	Clarify whether the staff intends to endorse or accept use of international standards or delete section.	Agree: Added the following statement: "NRC staff does not intend to endorse or accept use of any specific international standards via this regulatory guide".
16. C.1 Application Format and Content, pg. 12, 1st paragraph	The last sentence of the first paragraph states, "Furthermore, each application should adhere to the standard format and content identified herein."	Clarify that this variability is acceptable.	Agree: On page 12 revised to state that "NRC staff recommends…" and added following text:

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	Certain aspects of applications have been subject to variation in the past, e.g., different "Parts" used for same or similar content. This comment also applies to the subsection "Application Parts," on page 13 and various other places in document; e.g., C.1.X, "Part X of the application under Part 52 includes…" implies that this structure is mandatory under the regulation.		"Though the standard format facilitates the application and review processes and is useful for organizing guidance, adherence to the standard format is not required by regulation". Added the following text on page 13: "Though use of the standard format is not required by regulation, organization of content by the parts described in Table 1 facilitates the application and review processes as well as the organization of guidance".
17. C.1 Application Format and Content, pg. 12, 3rd paragraph	Clarify "The NRC staff considers the guidance in Section C.1 on application format and content is applicable to any type of reactor (i.e., nonlight-water reactors (non- LWRs))." While purely editorial, use of "i.e." implies non-LWRs are the only "other" type of reactor. Yet, not all aspects of content will be applicable.	Suggest an edit along the lines of: "The NRC staff considers the guidance in Section C.1 on application format and content to be generally applicable to other reactor types (e.g., non-light- water reactors [non-LWRs])."	Agree: Changed as suggested. Also made similar change on page 1.
18. C.1 Application Format and Content, Application Transmittal Letter, item e., pg. 12	Application transmittal letter, item e does not include discussion of Export Control Information (ECI).	Consider additional discussion/guidance on applicant submittal of ECI, particularly applicant obligations under ECI regulations and what responsibility NRC staff accepts regarding control of ECI once received.	Agree: Additional guidance was provided in Section C.1 under the subheading entitled "Transmittal Letter".

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19. C.1 Application Format and Content, Application Parts, Table 1, pg. 14	Part 8 of the application should be expanded to include Tier 1 information.	Expand the Table 1 title of application Part 8 to be: License Conditions; Tier 1 Information; ITAAC. In addition, Section C.1.8 should be expanded to address the inclusion in Part 8 of Tier 1 information, as applicable, (i.e., if a design certification is referenced).	Disagree: No change to Table 1. Staff disagrees with the recommended change to guidance and specifically the suggestion that all of Tier 1 should be included in Part 8. Tier 1 information, excluding ITAAC, represents the certified portion of material that is required in FSAR under 10 CFR Part 52.47(a). The colocation of related Tier 1 and Tier 2 technical information will additionally result in more efficient reviews by tying high level certified technical information to the supporting detailed technical information. Similarly, colocation will make more efficient reviews of technical issues for later COL LARs rather than separating linked information based solely on different change processes. This comment is referenced by comment #28 which was referenced by comment #61. It is also related to comments # 22, 59, and 92.
20. C.1.2 SAR, pg. 16, 1st paragraph	Correct typos in "…COLA in 10 in CFR 52.79…"	Correct editorial error.	Agree: Corrected.
21. C.1.2 SAR, Combined License Application, pg. 16-18	The discussion of a combined license application (COLA) that incorporates by reference (IBRs) a DC, and of COLA that IBRs a DC and an ESP, imply that a COLA that IBRs an ESP but not a DC is not an option. There is also no discussion of a COLA that incorporates neither a DC nor an ESP.	Mention these additional options for completeness.	Agree: Text revised to clarify that the requirements of 10 CFR 52.79(a) applies the various options.

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22. C.1.2 SAR, Design Certification Application, pg. 18,1st paragraph	A sentence in the paragraph states "…The DCR appendices to 10 CFR Part 52 are similarly structured and contain a common set of definitions and terminology that includes defining the DCD for a DC as being analogous to the FSAR required by 10 CFR 52.47, "Contents of Applications; Technical Information. Additionally, the DCRs establish a two-tier hierarchy of design-related information (Tier 1 and Tier 2)." The sentence misstates the design certification definition of design control document (DCD). Moreover, the DCD is not analogous to the FSAR.	We recommend that this guidance be corrected and clarify that 1) Tier 2 of the DCD is analogous to FSAR information required by 10 CFR 52.47(a), and 2) Tier 1 is separate from the FSAR and includes ITAAC required by 10 CFR 52.47(b).	Disagree: Slight revision to reflect the fact that though the term "analogous" may be appropriate, it is not clearly stated in the definitions section of the appendices. Staff, however, disagrees with the statement that Tier 1 is separate from the FSAR. SECY-90-377 stated on page 6 that: "An application (Tiers 1 and 2) will contain a depth of design detail similar to that of a final safety analysis report (FSAR) at the operation license (OL) stage for a recently licensed plant (1985-90), minus site-specific and as-built information." (underlining for emphasis) The Tier 1 & 2 definitions are used to separate material that has been approved rather than approved and certified. The DC FSAR contains material required under 10 CFR 52.47(a) regardless of whether it is ultimately certified. Note: Comments 19, 22, 28, 59, 61, and 92 are all related to the question of whether Tier 1 is considered part of the FSAR.

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23. C.1.2 SAR, Early Site Permit Application, pg. 19	The term "design information" should be used to describe the content of applications (ESP and others), rather than "design details" as found in the first full paragraph on page 19.	In the 2nd sentence, change "design information" to "design details."	Agree: The staff believes that the commenter meant to recommend changing "design details" to "design information". Revised by changing "design details" to "design information".
24. C.1.2 SAR, Early Site Permit Application, pg. 19	The first full paragraph on page 19 defines PPE as "plant perimeter envelope." "Perimeter" should be "parameter" as used in item b. of the list following the paragraph.	Revise to state, "…plant ~~perimeter~~ parameter envelope (PPE)…"	Agree: Corrected.
25. C.1.2 SAR, Early Site Permit Application, pg. 19	The first full paragraph on page 19 would benefit from clarification on two points related to "controlling PPE value, or bounding parameter value."	Further illustrate what a "controlling PPE value" is and clarify that a COLA may reflect a design that exceeds the plant parameter envelope, but that the COLA must explain/justify any such variance and that the ESP "finality" would be at risk. Revise the paragraph to state, "…one that necessarily controls the value of a site characteristic in the context of site suitability (e.g., site meteorology X/Q values established within the PPE for the purposes of evaluating the postulated design performance). As the PPE is intended … bounding parameter values. Following selection of a design, if a design value exceeds the PPE bounding value, such variances must be explained in a COL application. As illustrated in…"	Agree: Revised but noted that a variance request would be required by the COL applicant. With regards to any risk to the finality of an ESP, the finality of the ESP is not otherwise affected by a variance in a COL or COLA that references the ESP.
26. C.1.5 Emergency Plans, pg. 23	The list of application parts is prefaced with, "Part 5 of the COLA, or as applicable in an ESP application…" It is not clear which items are/are not applicable in an ESP application.	Provide additional clarification on when the content that follows is applicable for an ESP.	Disagree: The paragraph that precedes the list in question cites the applicable regulations and explains that there is a large range of levels associated with EP related information for an ESP.

27. C.1.7 Exemptions, Departures, and Variances, pg. 25-26	The guidance provided in Sections B and C is, in part, not clear and redundant, and, in part, requesting information that is beyond the scope of the design certification rulemakings.	Revise the guidance for Part 7 to read as follows: "In accordance with Section X of 10 CFR Part 52 appendices, a COL applicant who references a certified design shall prepare and maintain written evaluations which provide the bases for making plant-specific departures under Section VIII of the certification appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal). Section X also requires each COL applicant to provide in its initial application submittal a report that contains a brief description of any plant-specific departures from the referenced DCD, including a summary of the evaluation of each. These summary reports should be similar in format and level of detail as reports submitted by operating reactors as required by 10 CFR 50.59. This report should be included in Part 7. For departures that do not require prior NRC approval per Section VIII, no additional departure description information needs to be included in Part 7. For a COLA that is a "subsequent" COLA (or S-COLA), it is anticipated that previous COL applicants (i.e., a reference COLA, or R-COLA) or COL holders referencing the same design certification will have developed these reports for "standard" departures approved per Section VIII ("standard" departures are presumably applicable to all applications that reference the same design). A COL applicant may incorporate by reference these reports in lieu of repeating the information in Part 7, provided that each departure evaluation is reviewed and found applicable to the COL applicant's site/plant. If, because of plant-specific considerations, additional evaluation of the departure is necessary, the COL	Agree: Revised as requested with some modifications and additional specificity.

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		applicant should supplement the referenced reports with a summary of the plant-specific evaluation. For departures/exemptions requiring prior NRC approval, Part 7 should include the following information: a) The scope and summary of the request; b) Justification relative to the specific application with cross-references to applicable regulatory guidance and/or requirements; c) A technical and regulatory evaluation relative to safety significance and regulatory acceptance criteria (e.g., 50.12, Section VIII of referenced DC rule); d) For exemptions, an evaluation against the exemption criteria; and e) A statement identifying the need for NRC approval or need for an exemption However, if a COL holder referencing the same design certification has obtained NRC approval for the same departures or exemptions, the S-COL applicant may incorporate by reference into Part 7 the evaluations submitted in those license amendment/exemption requests, in lieu of repeating this information in Part 7, and also reference the NRC letter enclosing the applicable safety evaluation (SE). This information will aid the NRC staff in determining that no additional staff review of these changes is necessary. With respect to requests for variances, Part 7 should include the following information: a) A description of the variance b) A justification for the variance	

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28. C.1.8 License Conditions and Inspections, Tests, Analyses, and Acceptance Criteria, Inspections, Tests, Analyses, and Acceptance Criteria, pg. 26, 3rd paragraph	The last sentence states, "The applicant may (1) include the entirety of Tier 1 information in Part 8 of the application or, (2) include the Tier 1 design descriptions, significant interface requirements, and significant site parameters in Part 2 of the application and provide the ITAAC in Part 8." This paragraph confuses the issue of whether Tier 1 is part of the FSAR. See comment #19.	To avoid confusion, the guidance should make clear that Tier 1 is not part of the FSAR and thus should be included in Part 8 of the application.	Disagree: Minor correction of a typographical error to reflect that ITAAC may be included in Part 2 along with other Tier 1 information. Staff disagrees with the statement that Tier 1 is not part of the DC FSAR. The passage now states "The applicant may (1) include the entirety of Tier 1 information in Part 2 of the application or, (2) include the Tier 1 design descriptions, significant interface requirements, and significant site parameters in Part 2 of the application and provide the ITAAC in Part 8." In response to comment #16, the text has been revised to clarify that "Application Parts" as laid out in this guidance are not mandatory. The guidance provided here is representative of this flexibility, however, 10 CFR 52.47(a) requires that a DC applicant submit an FSAR. NB: Comments 19, 22, 28, 59, 61, and 92 are all related to the question of whether Tier 1 is considered part of the FSAR.
29. C.2 Application Regulatory Topics, pg. 29, 2nd paragraph	The first sentence should be clarified.	Revise to read "…generally apply to both LWR and other types of power reactors."	Agree: Changed with modification: "…generally apply to LWR and to potentially apply to ….".

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30. C.2 Application Regulatory Topics, pg. 29, 2nd paragraph	The last sentence states, "However, the guidance on specific regulatory and technical issues (e.g., 10 CFR Parts 30, 40, and 70 material licenses for COLs and design- specific review standards (DSRS) for SMRs) focuses on LWR technology and has limited applicability to non-LWR applicants." Certain such topics do have applicability.	Replace "has limited applicability" with "may have limited applicability."	Agree: Changed as suggested.
31. C.2.1 Preapplication Activities, pg. 29 et seq.	This section does not reflect recent discussions within the Advanced Reactor community regarding the use of Regulatory Engagement Plans or the various regulatory tools available to reduce licensing risk through more systematic NRC staff feedback. As an alternative to "staged" application reviews and approvals (e.g., development of so-called conceptual design assessments), the staff has suggested that existing tools, such as those used for PRISM's PSER, are available for new reactor developers to seek early staff feedback on specific topics. Prior pre-application interactions have suffered at times from inconsistent levels of staff engagement and lack of feedback to multiple submittals, such as technical reports, and these sorts of tools can help enhance pre-application engagement.	Enhance this discussion to reflect recent discussions between the staff and the Advanced Reactor community.	Agree: Discussion added regarding concept of regulatory engagement plans which should support better engagement between applicants and staff and clearer expectations regarding scope, schedules and costs of review. This section also now includes a discussion of staff's enhanced safety-focused review approach (ESFRA) which is important for pre-applicants to understand in the pre-application phase.

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32. C.2.1 Preapplication Activities, pg. 29 et seq.	Section C.2.1, Preapplication Activities, is disappointing with regard to the expectation [importance] for NRC to provide meaningful feedback during the pre-application process. As written this looks like a one way information flow from the applicant to the staff with no expectation on the staff to provide any meaningful feedback. While it is clear that pre-application engagement is generally not binding, the staff should be expected to provide meaningful written feedback that will help the applicant address any potential technical issues prior to submitting an application. There has to be some meaningful documented feedback from NRC to make pre-application activities worthwhile and improve the efficiency of the regulatory process.	Public and Non-public meetings (Page 30) – The RG should establish an expectation for staff to issue meaningful minutes identifying and documenting any issues identified that NRC believes would benefit from resolution prior to submittal of an application. Plans and Schedules (page 31) – The RG should require NRC staff to provide meaningful feedback on plans and schedules submitted so that the applicant can adjust accordingly or work to align on schedules.	Partially agree: Revision made to reflect flexibility with reference to the concept of regulatory engagement plans as a vehicle for more concise discussion and agreement between NRC staff and a potential future applicant regarding the level of NRC staff feedback along with associated costs and schedule impacts during pre-application. Vehicles for feedback to potential applicants already exist; such as “gap” letters or meeting summaries. The level of feedback provided is often commensurate with the level of detail and certainty provided by the applicant.
33. C.2.1 Preapplication Activities, GUIDANCE, Meetings, Subsequent Meetings, pg. 33	This section does not discuss or delineate any need for, or venue for, formal staff feedback during or after these pre application meetings are conducted.	The RG should establish a clear expectation that the NRC staff provide meaningful meeting minutes that clearly identify any potential technical or process issues that would benefit from further dialogue and resolution prior to submittal. In addition the guidance should reflect that the NRC licensing PM, with input from NRC staff and management attendees, should document a detailed meeting summary that provides clear feedback from the staff on the subjects discussed along with any decisions or significant staff comments.	Partially agree: See response to comment 32.

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34. C.2.1 Preapplication Activities, GUIDANCE, Documents, pg. 33-35	All documents submitted by the applicant should receive some level of written feedback. This section does not include letters from the prospective applicant to the NRC.	The RG should state that NRC provides written feedback on documents submitted – not just Topical Reports. A fourth type of document, letters, should be added to this section after white papers. A letter formally documents key regulatory subjects and should be responded to by the NRC in a letter within a reasonable time frame of no more than 90 calendar days.	Partially agree: See response to comment 32. RG revised also regarding letters.
35. C.2.1 Preapplication Activities, GUIDANCE, Documents, Topical Reports, pg.34	The criteria for a topical report should include the fourth criteria regarding licensing efficiency. In addition the RG should expand on improving regulatory efficiency for new reactors or novel designs such that a Topical Report can and should be used to improve the application review process for singular but very important technical issues regardless of whether it can be used by multiple applicants. This should obviate the need for exhaustive justification from the applicant as to why the topical report is appropriate. If Staff believes this requires a change to LIC-500 that should be pursued in concert with the RG revision. This comment is based on experience where staff has been resistant to a Topical Report for a “one-off” critical technical issue.	Revise the criteria for a topical report to include the fourth criteria regarding licensing efficiency and to expand on improving regulatory efficiency for new reactors or novel designs such that a Topical Report can and should be used to improve the application review process for singular but very important technical issues regardless of whether it can be used by multiple applicants.	Agree: Revised as recommended with minor modifications.

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36. C.2.1 Preapplication Activities, GUIDANCE, Documents, Technical Reports and White Papers, pg.34 and 35	Reiterating comment #31, "The staff may issue RAIs, but will not publish issue-specific SE reports; instead, the staff will incorporate the technical reports and its associated evaluation into the overall review/evaluation of the application" reflects what can become a one-way exchange that does not benefit the prospective applicant or reflect sufficient value for what can be a significant expenditure of time and resources to try to secure early feedback for technical topics. Lack of any commitment to provide NRC staff feedback on white papers beyond the option to "informally request clarification or supplemental information" similarly results in limited benefit for significant investment of time and resources. Both sections should specify some expectation for typical review schedules and documented feedback mechanisms.	Reflect a more flexible approach to providing meaningful staff feedback to technical reports and white papers. Expand the Technical Reports section to state that, Technical Reports are a legitimate vehicle for early staff feedback and review prior to an application. While this early review would not result in and SER, staff will be expected to provide meaningful documented feedback. Additionally, if the NRC provides RAIs, staff will document their acceptance of RAI responses and will document clarification meetings on the technical report in a detailed and meaningful summary letter. The RG should require staff to provide written feedback on white papers with identification of issues that would benefit from further dialogue or resolution prior to submittal of an application. Expand the White Papers section to state that the NRC will document clarification or supplemental information meetings on the white paper in a detailed and meaningful summary letter.	Partially agree: See response to comment 32.
37. C.2.1 Preapplication Activities, GUIDANCE, Documents, White Papers, pg.35	Under Documents, it does not appear to be correct that White Papers, including those submitted via NEI, do not receive a formal review and evaluation by the staff.	Clarify/revise the last paragraph text under White Papers regarding the use/handling of white papers by the NRC staff to reflect that, depending on the paper content, the staff may perform a formal review and evaluation of white papers.	Partially agree: See response to comment 32 and revisions of RG relative to white papers..
38. C.2.1 Preapplication Activities, GUIDANCE, Safety and Environmental Issues, pg.35, 2nd paragraph	The last sentence before the bullets should be more precise with respect to the level of detail to be sought from applicants.	Revise to state, "…, to support required safety and environmental findings ~~its anticipated reviews~~ on such issues as ….	Agree: Changed as recommended.

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39. C.2.1 Preapplication Activities, GUIDANCE, Environmental Preapplication Activities, pg. 36-37	DG-1325 states that an NRC site tour should be completed early in the pre-application process, and that the NRC may request a tour of alternative sites. Some applicants may not desire a site tour or a tour of alternative sites during the pre-application review.	These pages should be revised to site explicitly that NRC's tours are up to the discretion of the pre- applicant and may deferred until after submission of the application.	Agree: Changed by adding the following: Though strongly recommended, a site tour is at the discretion of the pre-applicant and may be deferred until after submission of the application.
40. C.2.1 Preapplication Activities, GUIDANCE, Environmental Preapplication Activities, pg. 36	DG-1325 states that during the pre-application review, the NRC may seek information on a number of different topics, including historical site information, alternative sites, and socioeconomics. Some applicants may not desire the NRC to review such information during the pre- application review.	This page should be revised to site explicitly that the scope of NRC's pre-application environmental review is up to the discretion of the pre-applicant and that the pre-applicant does not need to submit the listed information.	Agree: Changed by adding the following: The applicant's response to NRC staff pre-application environmental review requests is up to the discretion of the pre-applicant. The pre-applicant is not required to submit information in advance of the submission of the application.
41. C.2.1 Preapplication Activities, GUIDANCE, Environmental Preapplication Activities, pg. 36, 2nd paragraph	The sentence before the bullets should be more precise with respect to the level of detail to be sought from applicants.	Revise to read "… NRC staff will seek information, in sufficient ~~level of~~ detail, to support required environmental findings ~~its anticipated reviews~~ on such issues as …"	Agree: Changed as recommended.
42. C.2.2 Pre-application Readiness Assessment, pg. 37 et seq.	This section does not reflect recent significant challenges with pre-application assessments that indicated no significant issues associated with a draft application, only to be changed after the assessment was conducted, followed by an acceptance review that took several months. The readiness assessment process still cites 2014 procedural guidance that apparently has not been updated to reflect lessons from these experiences.	Amend guidance or reflect in this RG the clarifications needed to address improvements in expectations, communications, and predictable outcomes for readiness assessments.	Partially agree: Minor changes to reflect earlier discussion of regulatory engagement plans in Section C.2.1, "Pre-application Activities". The pre-application readiness assessment is voluntary and does not predetermine whether the application will be accepted and docketed as stated in this section. The assessment can be focused on selected topics and can also reflect a regulatory engagement plan if developed for an application.

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43. C.2.2 Pre-application Readiness Assessment, OVERVIEW, pg. 38	Discussion of planned exemption requests at the readiness assessment 6-months before application will not support an efficient and timely review of the DCA if this is the first time this subject is addressed with the NRC.	Include specific pre-application engagement on planned exemption requests in meetings and white papers in Section C.2.1, before the readiness assessment in Section C.2.2. Interaction on this subject at six-months before application does not allow sufficient time for staff and NRC management evaluation and feedback to the prospective applicant.	Agree: Revision made to Section C.2.1 that identify exemptions as a long lead time activities that need to be identified in the pre-application phase. The applicant readiness assessment can be conducted earlier than six-months before application submittal.
44. C.2.2 Pre-application Readiness Assessment, GUIDANCE, pg. 38, 3rd paragraph	The statement that, "the readiness assessment neither conforms to nor is part of the NRC's acceptance review process," is incorrect and misleading. The staff does use the readiness assessment in its acceptance review because issues identified during the assessment are re-visited and focused on during acceptance review. One of the key criteria used by the staff during acceptance review is the examination of topics identified during the readiness assessment. A recent example is the NRC readiness assessment of the NuScale DCA. In this case, general and detailed readiness assessment comments were reiterated in the subsequent NRC DCA review schedule letter to NuScale.	Revise the statement as follows, "Although not part of the NRC acceptance review, the NRC uses results from the readiness assessment to focus on identified topics, evaluate if changes have been made to specific sections of the DCA, and confirm the identified topics from the readiness assessment have been adequately addressed for purposes of the acceptance review."	Agree: Revised as recommended.

Comment Number/Affected Section	Comment/Basis	Recommendation	NRC Staff Disposition and Resolution
45. C.2.4 Application Acceptance Review, GUIDANCE, Acceptance Review Process, pg. 43	Consistent with comment #42 regarding readiness assessments, this guidance does not reflect recent experience indicating a dramatic failure of the acceptance review process. The level of assurance being required by the staff has resulted in effectively the first round of RAIs occurring during the acceptance review. The escalation in NRO-REG-100 from "commence the review" to "conduct the review" has not been sufficiently vetted with industry or with the staff to ensure a consistent understanding of the change in acceptance threshold. The use of "high level of certainty that the staff can complete the detailed technical review within a predictable timeframe," while potentially acknowledging industry requests for improved schedule adherence, appears to elevate the desire for schedule certainty above the level of "reasonable assurance" required for public health and safety. This was never the industry's intent. Additionally, recent experience has led to the implication that providing copies of certain references cited in the application is a prerequisite to acceptance of the application, thereby indicating an increase in regulatory burden with no regulatory basis.	Industry respectfully suggests additional discussion around the issue of increased predictability in acceptance reviews without the significant increase in regulatory burden that recent implementation of NRO-REG-100 has created.	Disagree: No revision. NRO-REG-100 references COMDEK-07-0001/COMJSM-07-0001 (ADAMS Accession No. ML071090128) and associated SRM that confirms that the technical sufficiency review should ensure that the application contains sufficient information for staff to conduct its detailed technical review within a predictable timeframe.

Comment Number/Affected Section	Comment/Basis	Recommendation	NRC Staff Disposition and Resolution
46. C.2.4 Application Acceptance Review, GUIDANCE, Completeness and Sufficiency, pg. 44	The first paragraph includes "For the environmental review, the staff has developed the "Office of New Reactors Environmental Report Acceptance Review Tables" (Ref.58) as an aid in performing the acceptance review." We understand that the tables "provide the NRC with a deliverable for the Environmental Report Acceptance Review that will assist them in implementing Office Instruction NRO-REG-100." The memo transmitting the tables in March 2016 states that "[a]pplicants can use these tables to perform their own review of their application before submitting it to the NRC which should result in fewer acceptance review items being identified by the NRC staff." However, the tables themselves say that "[t]he PNNL version of Table 1 [presumably this version of the table] varies somewhat from Table 1 of Attachment D found in the office instruction."	There should be a single set of review criteria.	Agree: Revised to delete the reference to the tables of Reference 58 in DG-1325. Table 1 of attachment D in NRO-REG-100 is just a form with no review criteria. The review criteria are contained in an environmental acceptance review checklist for ESP and COL applications referenced NRO-REG-100 which is available in ADAMS Accession No. ML072250354) The checklist is based on RG 4.2, "Preparation of Environmental Reports For Nuclear Power Stations," and NUREG-1555 which are in the process of being revised. The staff may update the checklist when the revisions to RG 4.2 (DG-4026 ADAMS Accession No. ML1611A068) and NUREG-1555 are completed.
47. C.2.4 Application Acceptance Review, GUIDANCE, Completeness and Sufficiency, pg. 44	With respect to docketing acceptance reviews, DG-1325 defines technical deficiency in the application as including "improper, inadequate, or incorrect technical information." Such a definition has the tendency to convert the acceptance review into a review of the merits of the application.	The second paragraph should be revised to delete the references to "improper, inadequate, or incorrect technical information." Instead, DG-1325 should state that a technical deficiency exists if the application does not provide the information specified in applicable NRC guidance, such as the SRP or DSRS.	Disagree: No change. The terminology used here is not newly created in DG-1325. The staff uses the referenced office instruction, NRO-REG-100, and the definition is attributed to and taken directly from that office instruction.
48. C.2.5 Application Review and Requests for Additional Information, OVERVIEW, pg. 45, 1st paragraph	The last sentence should be clarified to reflect current practice when RAIs cannot be responded to in 30 days.	Revise to read "…or within such other time as may be agreed upon between the NRC staff and the applicant specified by the NRC."	Agree: Revised.

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49. C.2.5 Application Review and Requests for Additional Information, OVERVIEW, pg. 45, 2nd paragraph	The stated intent of RAIs to obtain "all relevant" information needed to make a regulatory decision is too broad and potentially confusing.	1) Delete "all relevant" from the 3rd sentence. 2) Expand the last sentence of paragraph 2 to read "RAIs may address varied regulatory and technical subject matter as needed to make regulatory decisions on the application.	Agree: Revised as suggested.
50. C.2.5 Application Review and Requests for Additional Information, GUIDANCE, Application Review and RAIs, pg. 46, 1st paragraph	While providing courtesy copies of certain references for the NRC staff's convenience might enhance efficiency, industry does not agree that failure to provide what may amount to hundreds or thousands of supporting references constitutes a lack of "transparency." The proposed language in the last sentence also seems to set an expectation on the part of the staff, as opposed to a recommendation for improved efficiency.	Clarify and replace the last sentence of the first paragraph as follows: "The applicant may consider providing to the staff courtesy copies of certain references cited in the application, but not readily available. Such courtesy copies are not considered part of the docketed application. The applicant should be mindful of requirements and limitations on providing such copies, such as copyright restrictions, etc."	Agree: Revised with some modification. Applicants should note that courtesy copies received by the NRC may become Federal records.
51. C.2.6 Combined License Application Referencing a Design Certification or Early Site Permit, or Both, GUIDANCE, Material Referenced, pg. 51	The section on referenced material (i.e., secondary references) in an application only discusses material incorporated by reference, and references for information only. It does not address other types of references in applications.	This section should be expanded to include a third category of referenced material; i.e., references to information that, in context, are intended to be requirements. In particular, an applicant may not desire to incorporate by reference an entire document or section of a document, but instead to treat as a requirement only a particular issue or aspect discussed in a referenced document. This may be particularly true with respect to some referenced NRC documents. The context of the discussion of the reference in the application will indicate whether the information in the reference is intended to be a requirement or for information only. If a document is merely listed without any discussion in the application or designation as incorporated by reference, the document should be construed as being for information only.	Partially agree: It would be inappropriate to incorporate by reference a "particular issue" from a secondary reference as discussed in the recommendation, however, a marked excerpt may be appropriate in some cases. The applicant should be clear regarding what information is being treated as a requirement rather than for information only. Revised via the following addition: "If an applicant does not wish to incorporate by reference an entire document or section of a document, but instead to treat as a requirement only a particular issue or aspect discussed in a referenced document, the applicant should clearly identify the portion of material to be incorporated by reference."

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52. C.2.6 Combined License Application Referencing a Design Certification or Early Site Permit, or Both, GUIDANCE, Combined License Action Items, pg. 53, 2nd paragraph	The second paragraph states, "Applicants should note that the terms "COL action item" and "COL information item" have been used interchangeably; however, this RG uses the term "COL action item" for consistency throughout the document." This should be stated earlier, where "COL action item" is used several times. Also "COL information item" is used in the Appendix A example table of contents (TOC).	Provide this note earlier in the RG upon the first mention of "COL action item," e.g., in C.1.2. Change the Appendix A example TOC or include a note reiterating the use of "COL action item" for consistency in the RG despite the label used in the actual example.	Agree: Revised as suggested.
53. C.2.6 Combined License Application Referencing a Design Certification or Early Site Permit, or Both, GUIDANCE, Departures from the Design Certification, pg. 54, 1st paragraph	[Editorial] Sentence fragment at the end of the first paragraph.	Correct sentence fragment.	Agree: Deleted sentence fragment.
54. C.2.6 Combined License Application Referencing a Design Certification or Early Site Permit, or Both, GUIDANCE, Evaluation against the Standard Review Plan and Regulatory Guides, Standard Review Plan, pg. 56, 3rd paragraph	There are two different SRPs referenced in this section.	In the 3rd paragraph, insert "environmental" in front of SRP to differentiate from NUREG-0800.	Disagree: No change. This references the NUREG-0800 that is relevant to a site safety analysis of an ESP application. The "environmental SRP" (NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants)" provides guidance to staff regarding the review of the applicant's environmental report used by NRC to develop an Environmental Impact Statement (EIS).
55. C.2.7 Design Center Review Approach, GUIDANCE, Left Margin Annotation in Combine License Applications, pg. 60	The discussion implies the convention used in AP1000 constitutes a *de facto* standard. Other design centered working groups (DCWGs) may have an equally effective, but different approach.	Augment the discussion to indicate that specific choice of annotation is up to the DCWG, i.e., may vary from examples shown, but should be clear and consistent between R-COLA and S-COLAs.	Agree: Revised as suggested.

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56. C.2.8 Design Acceptance Criteria, GUIDANCE, Design Certification Applications, pg. 66, sentence after first bullet c.	Availability of design information is not a sufficient basis to include the information in the DCD.	Delete sentence.	Agree: Change incorporated as suggested.
57. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, pg. 67 et seq.	The guidance should indicate that based on lessons learned to date, the industry and NRC are engaged in an effort to develop First Principles for the scope of Tier 1/ITAAC, as well as standardized ITAAC for use by future applicants. It is expected that completion of that effort will lead to an update of RG 1.206 and the applicable sections of the SRP.	Include reference to ongoing review and development of NEI 15-02, "Industry Guideline for the Development of Tier 1 and ITAAC under 10 CFR Part 52."	Disagree: No change: NRC continues to interact with NEI on these issues and understands that new draft guidance is likely to submitted for NRC review in lieu of a revision to NEI 15-02.
58. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, OVERVIEW, pg. 68	The first full sentence on the page contains awkward and atypical language on the focus of the ITAAC hearing.	Revise to state, "…and analyses are ~~not currently~~ met or will ~~not~~ be met."	Agree: Revised as suggested.
59. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Requirements for Inspections, Tests, Analyses, and Acceptance Criteria, Design Certification, pg. 72, 1st paragraph	The DCD is not the same as a design certification FSAR.	Revise the 5th sentence to state, "…instead submit an FSAR with all the information required under 50.47(a), plus a Tier 1 document of certified design material, including ITAAC required by 50.47(b)(1)."	Partially agree: Change with modifications. The FSAR required under 52.47(a) represents information that includes both information that has been approved (Tier 2) and information that has been certified and approved (Tier 1). SECY-90-241, clearly indicates that information that is ultimately certified in the rulemaking is a subset of information required as part of the application. Regarding industry's proposed two tier system referenced as Level 3, it states: *"In Levels 1 and 2 essentially the entire application will be certified. In Level 3 the design certification will contain much less detail …"* SECY-92-287, "Form and Content for a Design Certification Rule" (ADAMS

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			Accession No. ML003707899), dated August 18, 1992, introduces the term DCD. Enclosure 2 of SECY-92-287 further states: *"The decisions on how to bifurcate the DCD into Tier 1 and Tier 2 are currently part of the ongoing design review process."* Revised text is as follows: *To date, all DC applications were originally submitted and docketed before a 2007 revision of 10 CFR Part 52 and have incorporated by reference a DCD. A DC applicant, however, is currently required to submit an FSAR with all the information required under 10 CFR 52.47(a). A DC applicant must additionally submit ITAAC required by 50.47(b)(1) and may additionally provide any information needed to distinguish certified design material (CDM) from approved material if desired.* Note: Comments 19, 22, 28, 59, 61, and 92 are all related to the question of whether Tier 1 is considered part of the FSAR.
60. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Requirements for Inspections, Tests, Analyses, and Acceptance Criteria, Design Certification, pg. 72, 2nd paragraph	The last sentence could be revised to illustrate its point more clearly.	Revise to read, "For example, a single ITAAC that requires verification of the design functions of multiple motor-operated valves may refer to a specific table listing them."	Agree: Changed as suggested.

61. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Requirements for Inspections, Tests, Analyses, and Acceptance Criteria, Combined License, pg. 73, last paragraph	The last sentence states, "The applicant may (1) include the entirety of Tier 1 information in Part 8 of the application or, (2) include the Tier 1 design descriptions, significant interface requirements, and significant site parameters in Part 2 of the application and provide the ITAAC in Part 8." This paragraph confuses the issue of whether Tier 1 is part of the FSAR. See comment #28.	To avoid confusion, the guidance should make clear that Tier 1 is not part of the FSAR and thus should be included in Part 8 of the application.	Disagree: This section refers to a COL that references a DC. The existing DCRs state under IV.A.2.a that a COL that references the DCR will include a "*plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD ….. as modified and supplemented by the applicant's exemptions and departures".* The text has been revised to read as follows: *The COL applicant should include the proposed ITAAC in Part 8 of the COLA. Title 10 CFR 52.80 identifies ITAAC as additional technical information required in the application. Therefore, Part 8 of the COLA containing the ITAAC is not part of the facility's FSAR. If the COLA references an existing DC, however, the COL applicant should follow Section IV.A.2.a of the applicable 10 CFR Part 52 appendix regarding the organization and numbering of the FSAR, but may include applicable generic ITAAC from the DCD in Part 8 along with site-specific ITAAC.* Note: Comments 19, 22, 28, 59, 61, and 92 are all related to the question of whether Tier 1 is considered part of the FSAR.

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62. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Basis, pg. 74, 3rd paragraph	Clarification of second sentence.	Delete "Therefore."	Agree: Changed as suggested.
63. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Format and Content, pg. 75	DG-1325 states that in situ testing, where possible, is the preferred means of ITAAC verification. This statement does not account for testing of modules or components at the location of manufacture. This should be clarified to make sure that applicants understand that other forms of ITAAC, including inspection, analyses, type-testing and factory testing are also acceptable when used appropriately.	At a minimum, revise the second sentence to state, "In situ testing of the as-built SSCs is the preferred method of ITAAC verification, but is not required or expected in all cases. This page should be revised to discuss ITAAC verification of modules or components at the location of manufacturing, and should indicate that such testing is acceptable provided that subsequent fabrication, handling, installation, and testing do not alter the properties of the module or component.	Partially agree: First part of change incorporated as suggested. Additional discussion regarding testing of modules at a fabrication facility is not incorporated. Performance of ITAAC at a manufacturing facility has not been fully resolved. Testing of as-built SSCs remotely is an execution and closure issue and not something that needs to be discussed in a document for providing guidance for submittals.
64. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Format and Content, pg. 75, 6th paragraph	The paragraph following bullet d. should be clarified.	Revise the third sentence to state, "… failure to properly implement the design commitment."	Agree: Change incorporated as suggested.

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65. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, pg. 76-77	DG-1325 states that ITAAC should address the resolutions of unresolved safety issues, generic safety issues, NRC generic correspondence, TMI action plan items, and relevant industry operating experience. However, not all of that information is safety or risk significant and therefore does not warrant treatment in an ITAAC.	These statements should be deleted. Instead, NRC should adopt NEI's first principles for Tier 1 and ITAAC, which are based upon safety and risk significance and conformance to NRC regulations. The resolutions of unresolved safety issues, generic safety issues, NRC generic correspondence, and relevant industry operating experience may, but do not necessarily, relate to any matter that is safety or risk significant or	Disagree: No change. This guidance is consistent with the guidance in SRP Section 14.3.
66. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, pg. 76-77, 2nd paragraph, list, and following paragraph	This portion of DG-1325 provides a description of the scope of the design that is considered top-level design information and should be selected for verification by the ITAAC. However, not all of the criteria are consistent with NRC policy established through several NRC SECY papers published since the early 1990s. There are also several criteria for establishing ITAAC that are not included in the draft regulatory guide. For example, there does not need to be an ITAAC for every regulation in 10 CFR Part 20. NRC SECYs have discussed that regulations such as 10 CFR 20.1406 on minimization of contamination that do not specify requirements related to performance of safety-related or risk significant functions do not require an ITAAC, which is reinforced by the fact that previously approved DCDs do not include an ITAAC for this requirement.	Modify bullet g. on page 77 to reflect that ITAAC are not required on all regulations in Parts 20, 73 and 100, unless they specify requirements related to performance of safety-related or risk significant functions.	Agree: Modified to address NEI comment.

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67. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, pg. 77, item f.	ITAAC may be inspection, analyses, type-testing and factory testing and therefore saying that applicants should "Ensure that ITAAC emphasize testing of the as-built facility" is incorrect or at least misleading.	Delete item f.	Disagree: Section 14.3 of the SRP identifies in-situ testing as the preferred method of verification and the RG uses the term "emphasize" which is appropriate to denote this preferability.
68. C.2.9 Inspections, Tests, Analyses, and Acceptance Criteria, GUIDANCE, Basis; Format and Content; and Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, Inspections, Tests, Analyses, and Acceptance Criteria Design Descriptions, pg. 78, item i.	Item i. is SRP Section 14.3.10, Emergency Planning ITAAC. Generic emergency planning ITAAC do not follow the format guidance provided above. An additional discussion related to site specific ITAAC should be provided in the RG.	An additional discussion related to site specific ITAAC should be provided in this section of the RG.	Agree: Inserted table format for EP ITAAC with reference to SRP Section 14.3.10.
69. C.2.11 COL Action Items and Postlicense Commitments, pg. 79 et seq.	[Editorial]	"Postlicense" should be hyphenated, i.e., "post-license" throughout.	Agree: Changed throughout.
70. C.2.11 COL Action Items and Postlicense Commitments, GUIDANCE, Combined License Action Items that Cannot Be Resolved before Issuance of a License, Inspections, Tests, Analyses, and Acceptance Criteria, pg. 82	[Editorial]	Delete double use of "Successful completion of" in the last sentence of second paragraph.	Agree: Corrected.

Comment Number/Affected Section	Comment/Basis	Recommendation	NRC Staff Disposition and Resolution
71. C.2.11 COL Action Items and Postlicense Commitments, GUIDANCE, Combined License Action Items that Cannot Be Resolved before Issuance of a License, Final Safety Analysis Report Commitments, *Final Safety Analysis Report Information Commitment Included in a License Condition*, pg. 83	[Editorial]	Correct "2424" to "24" in the 3rd sentence.	Agree: Corrected.
72. C.2.11 COL Action Items and Postlicense Commitments, GUIDANCE, Combined License Action Items that Cannot Be Resolved before Issuance of a License, Final Safety Analysis Report Commitments, *Final Safety Analysis Report Information Commitment Included in a License Condition*, pg. 84	The paragraph following the bullets seems to suggest the expectation for one or more FSAR updates outside of the annual FSAR update requirement of 50.71(e)(3)(iii), i.e., prior to "fuel load, initial criticality, and exceedance of 5% power." This paragraph is unnecessary, conflicts with FSAR update requirements, and should be deleted.	Delete paragraph.	Agree: Revised as suggested.
73. C.2.11 COL Action Items and Postlicense Commitments, GUIDANCE, Combined License Action Items that Cannot Be Resolved before Issuance of a License, Final Safety Analysis Report Commitments, *Final SAR Information Commitments Included in a Routine Final SAR Update*, pg. 85	The last paragraph of C.2.11 concerns use of a license condition and belongs in the previous subsection.	Relocate the last paragraph of C.2.11 to the end of the subsection titled, *FSAR Information Commitment Included in a License Condition*.	Agree: Revised as suggested.
74. C.2.12 Operational Programs for Combined Licenses, OVERVIEW, pg. 85	[Editorial]	Add punctuation to the first paragraph.	Agree: Corrected.
75. C.2.12 Operational Programs for Combined Licenses, OVERVIEW, pg. 85, bullet c.	NRC does not inspect operational programs before issuing a license.	Revise bullet c to state, "The NRC staff inspects these programs prior to operation ~~before issuing a license~~ …."	Agree: Revised.

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76. C.2.12 Operational Programs for Combined Licenses, GUIDANCE, License Conditions, Operation al Program Options, pg. 87	The guidance in the first two sentences seems to be at odds. The first sentence acknowledges that "COL applicants may incorporate by reference a generic operational program…," but the next sentences seems to defeat the purpose of referencing the generic operational program because then the applicant "would" (not *may*) "submit to the NRC the plant-specific operational program…"	Revise the guidance to be clear that when incorporating by reference a generic operational program, the COL applicant adds some plant- specific details as appropriate in addition to implementation milestones. Language similar to that in the second paragraph would be clearer, e.g., the expectation to "fully describe the program" would met by a COL applicant that references an approved generic operational program description and adds plant-specific details as appropriate.	Agree: Revised as recommended.
77. C.2.13 10 CFR Parts 30, 40, and 70 Materials Licenses for Combined Licenses, GUIDANCE, Application Information for a 10 CFR Part 70 and Parts 30 and 40 Licenses	These discussions cite requirements for inclusion from NUREG-1520 and NUREG-1556, but do not acknowledge that the vast majority of this information is also required for a COLA under Parts 52 and 50.	Clarify areas where information is needed for materials licenses that has not already been provided in the COLA.	Agree: Text revised as recommended.
78. C.2.14 Information Change Processes for Combined License Applicants, pg. 93 et seq.	This section uses the term "changes" when it should use the term "departures." Applicants can depart from a design certification but cannot change a DC.	Correct references to changes to DC information and changes to Tier 1, Tier 2, or Tier 2*.	Agree: Revised and clarified the use of the terms "change, departures, and variances" in the Overview and initial paragraphs of the Guidance subsections. This regulatory topic is on change processes for COL applicants, and thus the term "change", as used in the existing DCD, is appropriate once explained.

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79. C.2.14 Information Change Processes for Combined License Applicants, GUIDANCE, Combined License Application Referencing a Design Certification, pg. 94- 97	It is fortunate that the update of RG 1.206 spans the period during which the NRC has revisited the use of Tier 2* in design certifications. As discussed in a letter dated December 12, 2014, the industry recommends discontinuing the use of Tier 2* for current and future design certifications. While the staff has indicated that they are not prepared to go that far, we	Revise the guidance to clarify that going forward the focus will be on clearly determining the scope of Tier 1 information versus Tier 2 and that NRC staff will no longer identify certain Tier 2 information to be designated Tier 2*. Rather, the applicant will be given the option to self-designate certain information as Tier 2* that otherwise may have been included in Tier 1.	Agree: Revised text as suggested. Additional text changes were made based on SECY-17-0075 to more accurately reflect the history and the flexibility associated with Tier 2* information in the existing DCRs.
80. C.2.14 Information Change Processes for Combined License Applicants, GUIDANCE, Combined License Application Referencing a Design Certification, Change s to Operational Requirements, pg. 97	It would be helpful to provide an example of an operational program that is fully described and approved in the generic DCD.	Provide an example of an operational program that is fully described and approved in the generic DCD.	Agree: Deleted referenced sentence. Operational programs are generally not approved in a generic DCD.
81. C.2.15 Environmental Issue Finality for Combined License Applicants, GUIDANCE, Finality of Environmental Issues Associated with an Early Site Permit, pg. 99 et seq.	Good discussion on "new and significant," but no information regarding the staff's view of the "shelf life" of site characterization information.	Provide guidance indicating that, in the absence of new and significant information or other influencing factors, site characterization information in an ESP can be considered valid to a COLA submitted prior to the expiration of the ESP.	Agree: Provided guidance as recommended in the second paragraph after the subheading entitled "Finality of Environmental Issues Associated with an Early Site Permit."
82. C.2.16 Finalizing Licensing-Basis Information, GUIDANCE, General Guidance, pg. 102	The first full paragraph contains a sentence that should be clarified to reflect current practice when RAIs cannot be responded to in 30 days.	Revise to read "…or within such other time as may be agreed upon between the NRC staff and the applicant ~~specified by the NRC~~."	Agree: Revised as recommended.
83. C.2.16 Finalizing Licensing-Basis Information, GUIDANCE, General Guidance, pg. 102, last full paragraph	COL applicants and licensees and DC vendors will use established change control processes to manage all changes identified after the freeze point.	Delete "the majority of" from sentence 4.	Agree: Revised as recommended.
84. C.2.16 Finalizing Licensing-Basis Information, GUIDANCE, Finalizing Licensing-Basis Information for Design Certifications, pg. 103	Clarification	Revise sentence 2 to read, "…unless they are proposed by a license applicant or licensee as departures …."	Agree: Revised as recommended.

Comment Number/Affected Section	Comment/Basis	Recommendation	NRC Staff Disposition and Resolution
85. C.2.16 Finalizing Licensing-Basis Information, GUIDANCE, Finalizing Licensing-Basis Information for Design Certifications, pg. 103	[Editorial]	Revise sentence 3 to state, "…an update to a COLA, or in a periodic report…."	Agree: Revised.
86. C.2.16 Finalizing Licensing-Basis Information, GUIDANCE, Finalizing Licensing-Basis Information for Design Certifications, pg. 104	The first paragraph under Finalizing Licensing-Basis Information for Design Certifications (on pg. 103) is adequate and the two following paragraphs are unnecessary and potentially confusing with respect to DC renewal. The top paragraph on p. 104 could be misinterpreted to suggest that the renewed DC has an impact on a COL applicant that incorporated by reference a prior revision of the DC. Unlike a DC amendment, DC renewal does not impact existing applicants or licensees that incorporate by reference a prior revision of the DC. It is unnecessary and confusing to discuss renewal in connection with freeze point.	Delete the top two paragraphs on page 104.	Partially agree: Partial revision. The guidance is correct and relevant but has been simplified by excluding discussion of COL applicant options during the revision or renewal of a DC.
87. C.2.16 Finalizing Licensing-Basis Information, GUIDANCE, Errors in Design Certifications Referenced by Combined License Applications, pg. 104-105	DG-1325 states that significant DCD errors must be corrected prior to issuance of a COL. That position has resulted and could continue to result in significant delays in issuance of COLs. Further, it is premature to address this issue in the pending revision of RG 1.206 while the industry and NRC are still in discussions to resolve the issue. Reference NEI's letter to NRC dated August 4, 2017, *Avoiding Delays in Issuance of NRC Combined Licenses due to Design Certification Errors*.	This section of C.2.16 should be deleted because it is premature to address this issue in the pending revision of RG 1.206 while the industry and NRC are still in discussions to resolve it. Section C.2.16 should later be revised to reflect the outcome of ongoing discussions, e.g., other alternatives that assure safety without unduly delaying issuance of a COL.	Disagree: No revision made. The content of the DG provides current guidance and is factually correct.

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88. C.2.17 Small Modular Reactors and Design- Specific Review Standards, pg. 105 et seq.	The discussion here implies a DSRS is somehow unique to an SMR, when in fact the use of DSRSs for SMRs was largely a matter of timing of applications. Also, the use of DSRSs for mPower and NuScale is thought to have had mixed results; has this discussion been informed by a review of those outcomes?	Clarify DSRSs may be used for other types of reactor designs as well and is strictly optional. Inform the discussion based on staff and industry assessment of the questionable efficacy of prior DSRS development and use.	Agree: Minor revision to clarify the applicability of DSRS to applications other than LWR SMR and staff's ESFRA which is presented in Section C.2.1 and referenced in Section C.2.17.
89. C.2.17 Small Modular Reactors and Design- Specific Review Standards, OVERVIEW, Standard Review Plan and Design-Specific Review Standards, pg. 106	[Editorial]	Revise the first sentence to state, "… approaches that the staff finds ~~has found~~ acceptable…." Revise first sentence of 2nd paragraph to state, "Each DSRS … has the same objectives as ~~that~~ the SRP ~~has for non-SMR application reviews~~.	Partially agree: No change based on first recommendation. The SRP reflects approaches that have been found acceptable in previous reviews. Revised according to second recommendation.
90. C.2.18 Limited Work Authorization, OVERVIEW, pg. 110, 4th paragraph	[Editorial] For longevity of this RG 1.206 revision, strike "recently" in the first sentence of the 4th paragraph.	Revise first sentence of paragraph 4 to state, "…The NRC ~~recently~~ issued an LWA …."	Agree: Changed as recommended.
91. C.2.18 Limited Work Authorization, GUIDANCE, Applications, pg. 111	The requirements for COL ITAAC are covered outside of 10 CFR 50.10 and should not be included in the first list on page 111.	Delete item c on p. 111.	Disagree: No change. ITAAC is applicable to LWA. 10 CFR 50.10(d)(3) states the following and includes the underlined text which could include ITAAC: *" The application must include:* *(i) A safety analysis report required by 10 CFR 50.34, 10 CFR 52.17 or 10 CFR 52.79 of this chapter, as applicable, a description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a construction permit or combined license, but limited to those portions of the facility that are within the scope of the limited work*

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			authorization. The safety analysis report must demonstrate that activities conducted under the limited work authorization will be conducted in compliance with the technically-relevant Commission requirements in 10 CFR Chapter I applicable to the design of those portions of the facility within the scope of the limited work authorization";
92. Appendix A, pg. A-1	The title of this appendix states: EXAMPLE TABLE OF CONTENTS FOR DESIGN CERTIFICATION APPLICATION FINAL SAFETY ANALYSIS REPORT The title conflicts with the requirements for contents of a FSAR as specified in Part 52. Per 10 CFR 52.47(a), Tier 1 information is not required to be included in the FSAR.	Revise the title so it is clear that Tier 1 of the DCD is not considered part of the FSAR.	Disagree: Change with modifications. Revised text to indicate that content comes from a DCD that contains Tier 1 and Tier 2 information. NRC staff however disagrees that Tier 1 information, other than ITAAC, of the DCD would not be considered part of the materials required under 10 CFR 52.47(a) associated with a "DC FSAR". For the case of 10 CFR 52 Appendix D, Tier 1 information includes both ITAAC required under 10 52.47 (b) as well as design descriptions required under 10 52.47(a). Note: Comments 19, 22, 28, 59, 61, and 92 are all related to the question of whether Tier 1 is considered part of the FSAR.