

**Industry Comments on NRC staff initiative to update RG 1.206,
"Combined License Applications for Nuclear Power Plants" received on January 22, 2015**

Affected Section	Comment/Basis	Recommendation	NRC staff response
1. General	The industry supports the NRC staff initiative to update Regulatory Guide (RG) 1.206 as a key step in preparing for the next wave of new plant applications, including small modular reactors (SMRs). The proposed scope and organization of the RG 1.206 revision appears on track to provide the necessary guidance for future applicants, as well as a useful tutorial for applicants that may be less familiar with the NRC process. The specific comments that follow identify a few additional topics that would be helpful to include within the scope of the RG.	None	None
2. General	Coordination and prioritization will be important to ensure industry and NRC resources can support both the RG 1.206 revision initiative and near-term applications, e.g., SMR applications.	As the initiative proceeds, assure adequate resources for both work on RG 1.206 and industry/NRC actions necessary to facilitate near-term applications, e.g., SMR applications expected in the 2015-2020 timeframe. Please provide a project schedule for the RG 1.206 revision and stakeholder interactions that is of sufficient granularity to enable planning and resource allocation.	Initial project schedule was presented at public meeting on 3/31/15. Stakeholders have been engaged via 6 public meetings in which changes in the structure and content of the proposed revision were discussed.
3. General	We understand that Interim Staff Guidance Associated with Combined License (COL), Design Certification (DC), and Early Site Permit (ESP) Applications for New Reactors (DC/COL ISGs) are being integrated into RG 1.206 and the Standard Review Plan (SRP). We expect applicable NEI guidance documents that are approved for use by the staff will also be reflected in the revised chapter guidance, e.g., NEI 08-01, <i>Industry Guideline for the [inspections, tests, analyses, and acceptance criteria] ITAAC Closure</i>	Please provide a roadmap of where and how DC/COL ISGs and approved NEI guidance documents are being integrated into RG 1.206 and the SRP.	The introduction of the DG includes indicates 3 interim guidance documents will be retired or sunsetted when the revised regulatory guide is issues. These include: <ul style="list-style-type: none"> • COL/ESP-ISG-04, "Definition of Construction and on Limited Work Authorizations" (via C.2.18) • DC/COL-ISG-08, "Necessary Content of Plant-Specific Technical Specification When a Combined License is Issued" (via C.1.4 and C.2.11)

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	<i>Process under 10 CFR Part 52, and NEI 96-07, Appendix C, Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52.</i>		<ul style="list-style-type: none"> • DC/COL ISG11, “Finalizing Licensing Basis Information” (via C.2.16) • ESP/DC/COL-ISG-015, “Post Combined License Commitments” (via C.2.11) <p>RG 1.206 is does not endorse any specific NEI guidance documents. Revision 1 of NEI 98-03, “Guidelines for Updating Final Safety Analysis Reports” is referenced in section C.2.11. NEI 15-02 Draft A, Revision 0, “Industry Guideline for The Development of Tier 1 and ITAAC Under 10 CFR Part 52” is mentioned in C.2.9.</p>
4. General	To facilitate stakeholder review and discussion, revisions to RG 1.206, including new guidance aimed at avoiding excessive requests for additional information (RAIs), should be provided in redline form (vs Rev. 0)	Updates and enhancements to material provided in RG 1.206, Rev. 0, should be provided for stakeholder review in redline form.	The proposed revision represents a significant re-organization and re-scoping that is not amenable to a redline copy.
5. Section B, Page 1, third paragraph	Part 52 consists of multiple steps/phases, some optional, some required, including ESP, DC, COL and ITAAC closure. Although some have simplistically described Part 52 as a “one-step” licensing process, it is not accurate or helpful to do so, especially in a guidance document that addresses all steps/phases of Part 52.	Remove reference to “one-step” licensing.	Removed.
6. Section B, Page 1, last paragraph, and Page 2, first two paragraphs	Explaining the intent of the three different applications (for ESP, DC, and COL), and how they are related to one another is useful. However, it would be difficult for a person new to this process to understand the big picture from these three paragraphs.	Clarify this portion of the discussion to address an audience who is new to the process. This would include explaining the intent of each document, what each applicant gains from obtaining the document, and perhaps what the document does not cover (e.g., the certified design only covers standard design; it does not cover design of any systems, structures, and components (SSCs) that are site-specific).	The discussion, section B, has been rewritten to better lay out the different applications and how that affects the content of the associated safety analysis reports. This is further discussed in section C of the revised guidance.

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7. Section B, Page 2, first paragraph	This paragraph states that the COL applicant has the option “to reference an ESP, a DC, both an ESP and DC...” However, if an applicant chooses to “reference” an ESP and/or DC, the COL application (COLA) must “incorporate by reference” the subject document. “Reference” and “incorporate by reference” have distinct meanings and care should be taken in their consistent and intended use.	Throughout the RG, use consistent terminology when discussing incorporating the ESP/design certification document (DCD) by reference and providing guidance on how this is accomplished.	The text has been revised in various parts of the DG. 10 CFR 52.79 (d)(1) states a COLA FSAR need not contain information or analyses in connection with DC, <i>provided, however</i> , that the FSAR must either include or incorporate by reference DC final safety analysis report.
8. Section B, Table 1 & Note 2, Pages 4 & 5	ITAAC are required for an ESP application that includes a complete and integrated emergency plan per Section 52.17(b)(3).	Table entry in the Early Site Permit column for Part 8 - ITAAC should be “Optional,” not “Not Applicable.”	Revised Table 1 in Section C.1 for ESP to reflect “Yes, if Applicable” for Part 8. Part 10 CFR 51.50(b)(4) requires the inclusion of: <i>“any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter”.</i>
9. Section B, Page 6, second paragraph	It would be helpful to provide more of an explanation of what is within the scope of the COL safety analysis report (SAR), but outside the ESP and DCD. For example, explain that the ESP provides the information required to site a plant at a specific location, the DCD defines requirements for a standard plant design, and the COLA (not just the SAR) provides the additional information that is not contained in the ESP or DCD,	Include an explanation, with examples, of what is within the scope of the COL SAR, but outside the ESP and DCD.	Text has been revised to in response.

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10. Section C.2, Applications - Policy & Regulatory Topics	<p>The topics seem reasonable and we suggest a more chronological order for their organization within Section C.2. Additionally, we suggest subsections on Applicability of Standards, Planning and Conduct of Application Review, Reference COLA (R-COLA)/Subsequent COLA (S-COLA), and Finalizing Licensing-basis Information:</p> <ul style="list-style-type: none"> • Applicability of Standards: More guidance is needed regarding the applicability of standards for areas where some generic design (DCD) and some site specific design (COLA) is applicable. • Planning and Conduct of Application Review: It would be helpful to have additional information, clarity, and consistency regarding how the Early Site Permit Application (ESPA) and COLA reviews will be planned and conducted, e.g., use of audits or inspections, scopes of audits or inspections. Additionally, it would be helpful to see more coordination between the safety and environmental reviews, and the content of those documents. • Reference COLA (R-COLA)/Subsequent COLA (S-COLA): Add a subsection to clearly endorse and explain the RIS 2006-06, <i>New Reactor Standardization Needed to Support the Design-Centered Licensing Review Approach</i>, design-centered approach to licensing reviews (in particular, the one issue, one review, one position strategy). • Finalizing Licensing-basis Information: DC/COL-ISG- 011, Finalizing Licensing-basis Information, contains information that should be included in RG 1.206, i.e., freezing the application in order to complete the NRC review. 	<p>Order, and add, the Policy & Regulatory Topics as follows:</p> <ol style="list-style-type: none"> 1. Pre-application Interactions 2. Final Safety Analysis Report (FSAR) Numbering Scheme 3. Small Modular Reactors with a Design- Specific Review Standard (DSRS) 4. Applicability of Standards 5. Pre-application Readiness Assessment 6. Application Electronic Submittal 7. Application Acceptance Review 8. Planning and Conduct of Application Review 9. Request for Additional Information (RAI) Process 10. . Reference COLA (R-COLA)/Subsequent COLA (S-COLA) 11. . Finalizing Licensing-basis Information 12. . Limited Work Authorization 13. . Change Processes (Tier 1, 2, and 2*) 14. 10 CFR 30, 40, and 70 Materials Licenses 	<p>The order of section C.2 has been revised in keeping with the suggestions.</p>

Input for Consideration in the Staff's Development of Revised RG 1.206 Guidance received on January 22, 2015

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1. Section C.1	Clarification is needed regarding what materials need to be incorporated by reference into a COLA versus just referenced in a COLA or a design certification application (DCA). See comment 7, above.	Include guidance on what materials need to be incorporated by reference into a COLA versus just referenced in a COLA or a DCA.	NRC staff revised the text in response to this comment. An additional regulatory topic on consensus standards was also added.
2. Section C.1	Guidance is needed regarding how and where to incorporate design control document (DCD) Tier 1 into the COLA to facilitate standardization. Also, provide guidance on where it belongs post COL issuance, i.e., beyond Appendix C of the license which goes away after 103(g) finding.	Include this guidance in Section C.1.	NRC staff revised the text in response to this comment.
3. Section C.1, Part 4 – Technical Specifications (TSs)	Guidance is needed regarding technical specifications for areas not addressed by NUREG standard technical specifications (i.e., 10 CFR 50.36(c)(2)(ii)(D), Criterion 4) given the NRC's position in SRM-SECY-97-168, "Issuance for Public Comment of Proposed Rulemaking for Shutdown and Fuel Storage Pool Operation," where the Commission rejected the staff's proposal to implement new regulatory requirements for shutdown Technical Specifications, deciding instead to continue reliance on the industry's voluntary risk management programs, particularly NUMARC 91-06, "Guidelines for Industry Actions to Assess Shutdown Management."	Include guidance to specify that there is no need for technical specifications for areas not addressed by NUREG standard technical specifications.	Section C.1.4 addresses technical specifications (TS) for COL that incorporate a DC by reference. These include site specific TS, generic TS from the DC, TS associated with departures from the DC, and exemption requirements associated with departures from generic TS.
4. Section C.1, Part 8 – Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)	It is important that ITAAC guidance include guidance on design acceptance criteria (DAC), including piping DAC. Note that guidance is currently in development on standardized ITAAC.	RG 1.206 should refer to the forthcoming NEI guidance document on standardized ITAAC and include guidance on DAC, including piping DAC.	NRC has not endorsed the NEI proposal at this time. DAC is covered in sections C.2.8.

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5. Section C.1, Part 8 - ITAAC	Should the section on ITAAC also include Tier 1?	Consider where to locate guidance on the content of Tier 1.	This is discussed in sections C.1.8 and C.2.9.
6. Section C.2, Applications - Policy & Regulatory Topics, Change Processes (Tier 1, 2, and 2*)	NRC staff has ongoing Part 52 post-COL lessons learned activities including a series of public meetings on the appropriate scope of information to be designated as Tier 2* in future DCAs under 10 CFR Part 52. NEI summarized industry views on Tier 2* in future DCAs in a letter from R. Bell to M. Mayfield on December 19, 2014.	RG 1.206 should reflect the outcome of current interactions related to the scope of Tier 2* information in future DCAs.	This area of guidance is unresolved and thus is not covered in this update to RG 1.206.
7. Appendices A, C, and D	COL information text related to COL information items is often located within DCD text that is outside of the COL Information Item Section at the end of the DCD Section. This DCD text typically expands the discussion of the item, but it is not readily identified like conceptual design information is with double brackets. COL applicants must identify and replace COL information text with plant-specific information, oftentimes leading to NRC questions about why the text being replaced is not identified as a departure. Addressing COL information items is not considered a departure.	<ul style="list-style-type: none"> • Include guidance for identifying COL information item text within DCD paragraphs outside the COL Information Item section at the end of the applicable DCD section, similar to the approach used for conceptual design information. 	COL information items are discussed in section C.2.11. The technical details found referenced in the comment as being in Appendices A, C, and D are no longer a part of the DG.
8. Appendix A – Combined License FSAR	Appendix A guidance for Combined License FSAR should reflect the latest I&C review guidance from the Generation mPower DSRS. This recent effort by NRC and stakeholders to update I&C review guidance should be leveraged in the RG 1.206 revision.	Incorporate latest I&C review guidance from the Generation mPower DSRS in Appendix A.	The technical details found referenced in the comment as being in Appendices A, C, and D are no longer a part of the DG. NUREG 0800 will hold relevant information on the technical details for FSARs going forward.