NUREG-0800 INTRODUCTION, PART 2 - SUMMARY OF PUBLIC COMMENTS AND NRC RESPONSES

Affected Section	Public Comment/Basis	Public Recommendation	NRC Resolution
1. General	Purpose, Last Paragraph, Page 2, states: "The framework is used for iPWR design certification (DC) and COL applications made under 10 CFR Part 52." The SRP scope also includes other 10 CFR Part 52 applications (ESP, SDA, ML). Is it the staff's intent to limit the iPWR risk-informed framework to DCAs and COLAs?	Clarify the applicability to other 10 CFR Part 52 applications. Note that the resolution of this comment affects numerous similar statements throughout the document.	Staff agrees with this comment since the SRP can be applied for all types of 10 CFR Part 52 applications. Therefore, the use of a DSRS and the use of the risk-informed and integrated review framework could also be applied across application types. The scope has been clarified to include applicability to all types of applications currently described in 10 CFR Part 52.
2. Scope of review of license applications, Page 5	States: "However, for a 10 CFR Part 52 application review, the verification that the as-built facility conforms to the approved design is performed through the [ITAAC] verification process." The underlined phrase was added to this document versus the current SRP introduction. Verification of conformance of the as-built facility occurs only for a COL, whereas this implies it occurs for both DC and COL applications. Also, ITAAC verification occurs later, not during application review.	Delete the phrase, "for a 10 CFR Part 52 application review."	Staff agrees with this comment as ITAAC only applies to 10 CFR Part 52 applications. Therefore the language as originally phrased is redundant. Comments accepted, incorporated in text.

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3.	Subsections titled "Deviations from the SRP by Applicants," and "Six-Month Application Reviews by iPWR Applicants," Page 5, and "Six Month Pre-Application Reviews by iPWR Applicants," Page 13	The subject subsections state that the iPWR applications are to include an evaluation of the facility against the SRP or DSRS revision "in effect six months before the docketed date of the application." The above statement is consistent with the requirements in 10 CFR 50.34(h), 10 CFR 52.47(a)(9) and 10 CFR 52.79(a)(41). However, for practical purposes, iPWR applicants will be evaluating their designs against applicable SRP or DSRS sections in effect six months prior to the application date instead of the docketed date of the application.	Recommend including text in this section similar to that provided in SRP Chapter 1.0, Item 9, to clarify that although the NRC regulations specify a review of the SRP "in effect 6 months prior to the docket date," the NRC's practice for implementation of this requirement has been to allow applicants to conduct this evaluation based on the SRP or DSRS in effect 6 months before an application is submitted.	Staff agrees with this comment based on current practice and guidance. A cross-reference to SRP Chapter 1.0 has been incorporated.
4.	Deviation from the SRP by Applicants, First Paragraph, Page 5.	This subject subsection includes an explanation regarding how applicants can address deviations from the SRP by using alternative approaches to the SRP acceptance criteria. This subsection should indicate that the same approach will be used for deviations from the DSRS.	Revise subsection title to state: "Deviation from the SRP/DSRS by Applicants." Also, the subsection titled "Six Month Pre-Application Reviews by iPWR Applicants," on Page 13 should refer to the subsection on how to address deviations to the DSRS.	Staff agrees with this comment based on inclusion of DSRS usage in the new SRP Introduction. Comments have been incorporated in the text.

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5. Section II, Acceptance Criteria, Page 7	States: "These criteria can generally be classified as design-based acceptance criteria or as performance-based acceptance criteria." Design-based AC and performance-based AC are foundational terms for this framework. They should be clearly defined so that the framework can be consistently understood and implemented by applicants and staff.	Provide a concise definition of design-based and performance-based acceptance criteria.	The NRC has no regulatory definition of these terms. However, examples of each type of acceptance criteria have been added to the text. Each applicant and reviewer will make an individual determination based on the examples provided.

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6. iPWR Design Pre-Application Reviews and Application Reviews, Page 9	States: "Use of this framework does not relieve the requirements for SSCs that are important to safety to meet NRC regulations for design-basis capability to perform their safety functions regardless of the safety significance categorization…" The term "safety significance" has not been defined in this document. SSCs that are important to safety have not been defined for SMRs. Also see comment #16.	Replace "safety significance categorization" with "risk significance categorization."	The staff agrees with this comment in part and the comment is partially incorporated. The concept of safety significance is generally defined in the NRC Glossary available at http://www.nrc.gov/reading-rm/basic-ref/glossary/full-text.html and in NUREG-1350, the Information Digest. In this framework, safety significance is not equivalent to risk significance. Applicants will define the SSCs that are important to safety for their particular SMR design. The NRC staff will independently assess the applicant's classification of SSCs that are important to safety as well as the SSC risk significance classification determined by the applicant.

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7. iPWR Design Pre-Application Reviews and Application Reviews, Page 10	States: "As used throughout this discussion of the framework, the term 'reviewer' means all NRC staff in all disciplines involved with the pre-application and post-application reviews of specific DSRS sections and creation of the associated SERs." This probably intends to refer to the reviewer of the application itself, not the reviewer of the DSRS.	Replace "DSRS" with "application."	Staff agrees with this comment. The usage clarification is incorporated in the text.

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8. General	Overview, Page 10, states, "Example [programmatic] requirements include 10 CFR Part 50, Appendices A and B (general design criteria and quality assurance program)…" It's unclear how the GDCs are considered a programmatic requirement in this sense. While some of the GDCs impose general performance, inspectability, and reliability design criteria, those criteria are satisfied by other means. The GDCs are not themselves a program, but only a mandate to have such a program: typically the SRP acceptance criteria state an acceptable means of demonstrating a GDC is satisfied, but not vice versa as suggested here.	Clarify the use of GDCs as a programmatic requirement; perhaps provide an example as to the use of a GDC in the manner suggested here. Note that the resolution of this comment could affect numerous similar statements throughout this document.	The staff agrees with this comment in part. GDC Criteria 1 through 5 are overall requirements and may be considered as programmatic in a sense. However, the use of "programmatic" requirements as used throughout the document has been revised to use "selected" requirements since other types of requirements that are potentially useful in the risk-informed and integrated review framework are also not programs per se. Technical reviewers will determine which requirements may be used in the framework to demonstrate satisfaction of design-based or performance-based acceptance criteria. The selected requirements will be identified in the applicable DSRS sections.

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9. Overview, Page 11	States: "under the framework, the staff also has the flexibility to use these programmatic requirements to demonstrate satisfaction of design-based acceptance criteria for the SSCs with low safety/risk significance." The slash is ambiguous. Under the framework, programmatic requirements can be used to demonstrate satisfaction of design-based acceptance criteria for either of the non-risk significant SSC categories (A2 and B2). For the A1 and B1 categories, which include non-safety related but risk significant SSCs, design-based acceptance criteria are reviewed using the current processes.	Replace "with low safety/risk significance" with "that are not risk significant."	The staff agrees that the original usage is ambiguous. The comment has been incorporated in the text.

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10. Pre-application Activities, Page 12	States: "Early submittal of settled design information for reference use by the staff will minimize rework of the DSRS sections." What degree of finality does the staff expect for "settled design information;" e.g., should the applicant wait until there is very little possibility of the design changing, or submit the design information earlier when the design is still evolving?	Please elaborate on what is meant by "settled."	The staff agrees with the comment and the use of the word "settled" has been replaced with the terms "...finalized or near-final..." The staff recognizes that the normal design process will allow progressive development of DSRS sections as SSC designs are developed and become mature. There is not likely to be a single point in time that the design all SSCs become finalized or near-final. Applicants should submit SSC design information for support of the DSRS development as soon as major features, interfaces with other SSCs, operational envelopes, and safety/risk characteristics have been confirmed.

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11. DSRS Preparation, Second Paragraph, Page 12	The DSRS Preparation subsection includes the following statement: "The staff's goals are to complete and publish the public draft DSRS one year prior to submittal of the application, and to issue the final approved DSRS for use not later than the time of docketing of the application." The staff should consider revising its goals to resolve comments and issue final DSRS at least 6 months prior to the application submittal.	Revise as follows: "The staff's goals are to complete and publish the public draft DSRS one year prior to submittal of the application, and to resolve outstanding comments and issue the final DSRS at least 6 months prior to submittal of the application."	The staff does not agree with this recommendation. Based on early experience with the preparation of mPower™ and NuScale DSRSs, the recommended timing has not yet been demonstrated to be practicable. While the design of some SSCs may be finalized early, allowing completion of the associated DSRS sections, experience has shown that some SSC design will not be finalized until much later, delaying finalization of the completed DSRS. If industry is able to improve the schedule associated with adequate design maturity to support DSRS finalization, this recommendation could be re-assessed.

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12. Six Month Pre-Application Reviews by iPWR Applicants, Page 13	States: "Alternatively, iPWR applicants may evaluate the facility against the DSRS revision in effect six months before the docketed date of the application." It is expected that in many cases the Rev. 0 of a DSRS will not be issued until or at or near application submittal. This subsection does not address the process used to reconcile differences between the draft DSRS used for submittal and the final approved DSRS. The currently stated goal is to issue approved DSRSs no later than the time of docketing.	Revise this subsection to provide the option to allow the use of a public draft DSRS for pre-application review if a final approved DSRS has not been issued. Suggest this section specifically describe how the differences between draft DSRS conformance and final DSRS conformance will be reconciled without causing a delay in docketing.	The staff disagrees with the comment to include a description of how reviewers will reconcile DSRS section version differences. The finalization timing selected in the current language was chosen to allow a window of time for DSRS review and adjustment during the period that the application acceptance review is being conducted (in preparation for docketing). In current practice, the same need to reconcile guidance versions used can occur with SRP sections undergoing periodic updates. Staff will continue reconcile the differences as they are identified, whether the SRP or a DSRS is used.
13. Risk-Informed Categorization of SSCs, Page 15	States: "categorize SSCs as (1) either safety-related on non-safety-related…" "On" is a typographical error.	Replace "on" with "or."	The staff agrees with this comment and the typographical error has been corrected in the text.

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14. Application of the Integrated Review Approach, Page 17	States: "The staff preparing the DSRS…makes an initial determination of which programs could be used as an alternate method for demonstrating the satisfaction of the performance-based acceptance criteria." Statement should also include design-based acceptance criteria.	Insert "and design-based" before "acceptance criteria."	The staff agrees with this comment since Categories A2 and B2 could include design-based acceptance criteria to be addressed by the review framework. The comment is incorporated in the text.
15. Application of the Integrated Review Approach, Page 17	See comment #8 regarding GDCs as programs that could be used to demonstrate the satisfaction of design-based or performance-based acceptance criteria.	Delete or clarify consistent with the response to comment #8.	See the discussion for comment number eight for resolution of this comment.

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16. Application of the Integrated Review Approach, Page 19	For B1 category, this subsection states: "For design-based acceptance criteria, the review is similar to the review for A1 SSCs based on their importance to safety under Appendix A to 10 CFR Part 50." This statement combined with the statement on "important to safety" (in the subsection titled, "iPWR Design Pre-Application Reviews and Application Reviews," at the bottom of Page 9) introduces a number of concerns. • SSCs that are important to safety are not defined for SMRs. • As stated, the GDCs were developed for plant designs that differ from SMRs. How would Appendix A to 10 CFR Part 50 be used to determine what is important to safety? • A D-RAP list is compiled to determine which SSCs need reliability and availability assurance. SSCs that were listed under D-RAP lists for recent DCDs were not considered important to safety. Several SSCs on these lists would not have made the cut to be on the maintenance rule for plants in the current fleet. • This creates the impression that design-based acceptance criteria will be applied to SSCs that would not have been considered important to safety for large plants. Consider that these SMR SSCs and the functions they perform are not equivalent in terms of importance in comparison to SSCs at	Appendix A to 10 CFR Part 50 does not define what SSCs are important to safety, so categorization as B1 should not assume that these SSCs are important to safety. Therefore, revise to clarify that the B1 category review is similar to the review for A1 SSCs in terms of risk significance, but that it takes into consideration the non-safety designation of the B1 categorization	The staff has addressed the concerns expressed in this comment by removing the portion of the text "…based on their importance to safety under Appendix A to 10 CFR Part 50." The point of correlating the satisfaction of design-related acceptance criteria for A1 and B1 SSCs in a similar manner is to ensure that reviewers used traditional design review methods for B1 SSCs due to the risk-significance of the SSCs. The risk-informed and integrated review framework does not equate risk significance with importance to safety. NUREG 0800, Section 17.4, "Reliability Assurance Program," states under Areas of Review that "The RAP applies to those systems, structures, and

Location	Comment	Recommended Change	Staff Response
	large reactors. ● The criteria and design requirements for risk-significant SSCs and SSCs important to safety are not equivalent.		components (SSCs), both safety-related and non-safety-related, identified as risk-significant (or significant contributors to plant safety)." Further, Figure 1 in Part 2 of the SRP Introduction clearly shows a test for risk significance (RAP list) applied to both safety-related and nonsafety-related SSCs.
17. Application of the Integrated Review Approach, Page 19	States: "At the B2 level, both the design-based review and the performance-based acceptance criteria are anticipated to be minimal." "Review" seems misplaced in this context.	Delete "review."	Staff agrees with this comment and the incorrect usage of the word "review" has been deleted from the text.
18. Application of the Integrated Review Approach, Page 19	States: "Review levels A1 through B2 reflect a graded approach to reviews in that performance-based activities within programmatic requirements are increasingly applied to satisfy performance-based acceptance criteria." Programmatic requirements are also increasingly applied to satisfy design-based acceptance criteria for A2 and B2.	Recommend deleting "performance-based."	Staff agrees with this comment since both types of acceptance criteria are addressed by the framework. The recommended change is incorporated in the text.

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19. Application of the Integrated Review Approach, Page 20	States: "When a technical reviewer has determined that a particular program requirement will be used to satisfy a specific performance-based acceptance criterion…" Also applies to design-based acceptance criteria.	Recommend deleting "performance-based."	Staff agrees with this comment since both types of acceptance criteria are addressed by the framework. The recommended change is incorporated in the text.
20. Application of the Integrated Review Approach, Page 20	States: "The requirement to perform this acceptance test will be documented by the applicant in Tier 1 of the DCD for DC applicants or in the Licensing Conditions and plant ITAAC for COL applicants." For A2 SSCs as used in this example, descriptive information that is not certified should be sufficient to confirm that: 1) SSCs are in this category and 2) that they do not have adverse interactions with safety related and highly risk significant SSCs.	Recommend replacing "Tier 1" with "Tier 2" and reconsidering whether an ITAAC is necessary.	The staff agrees that the example could be clarified and notes that the example shown is hypothetical. The text has been revised to better describe the intent of the example and the options available to reviewers when determining whether to use a programmatic method of satisfying design-based or performance-based acceptance criteria.