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Comparison of 10 CFR Part 52 Subpart B & E for i-SMR Licensing Strategy

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1. Introduction

The Innovative Small Modular Reactor (i-SMR) is designed to enhance safety, economic efficiency, and operational flexibility. To successfully enter the global nuclear market, i-SMR must comply with international regulatory frameworks, including those established by the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR Part 52 [1].

Among the regulatory pathways outlined in 10 CFR Part 52, Subpart B (Standard Design Certification, SDC) and Subpart E (Standard Design Approval, SDA) play critical roles in licensing new nuclear reactor designs [2].

- Subpart B – Standard Design Certification (SDC): A legally binding NRC approval for a reactor design, allowing direct reference in future licensing without reevaluation [1].
- Subpart E – Standard Design Approval (SDA): A pre-approval process for a reactor design, facilitating regulatory readiness but lacking legal enforceability [2].

This study compares Subpart B (SDC) and Subpart E (SDA) and proposes strategies for optimizing the i-SMR Standard Design Approval (SDA) process.

2. Overview of 10 CFR Part 52 Subpart B & Subpart E

2.1 Standard Design Certification (SDC) – Subpart B

- Definition & Scope.
  - SDC is a legally binding NRC approval that ensures a reactor design is certified and does not require further reevaluation during future licensing applications [1]
  - Certified designs remain valid for 15 years, with renewal options as per §52.57 [1]
- Key Features.
  - Regulatory Finality: Once certified, a design can be referenced in multiple construction projects without modification [1]
  - Mandatory Public Participation: The process involves public hearings and stakeholder engagement as required by §52.51 [2]
  - Limited Flexibility: Design changes after certification require formal amendments through §52.63 [2]

2.2 Standard Design Approval (SDA) – Subpart E

- Definition & Scope
  - SDA is a pre-approval process confirming a reactor design's compliance with regulatory criteria but does not carry legal finality [2]
  - Future licensing applications referencing an SDA must undergo additional NRC review before approval, as per §52.145 [2]
- Key Features.
  - Design Flexibility: SDA allows for subsequent design modifications without major regulatory barriers, unlike SDC [2]
  - Faster Approval: The SDA process is less rigid than SDC, enabling quicker regulatory feedback [1]
  - Limited Validity: SDA remains valid for 15 years but cannot be renewed, as specified in §52.147 [2]

Table 1. Comparison of SDC (Subpart B) and SDA (Subpart E) [1,2]

Aspect	Standard Design Certification (SDC, Subpart B)	Standard Design Approval (SDA, Subpart E)
Purpose	Legally certifies a reactor design for future licensing	Provides preliminary approval for a reactor design
Legal Enforceability	Can be referenced without reevaluation in future licensing	Requires additional NRC review in future licensing
Validity Period	15 years (renewable)	15 years (non-renewable)
Public Involvement	Public hearings required (§52.51)	Public hearings not required
Flexibility	Limited (fixed design, amendment required for changes)	Higher (design modifications allowed)

3 Application of SDC and SDA to i-SMR Licensing Strategy

3.1 Strategic Use of SDA for i-SMR

- Passive Safety System Validation: SDA can be used to demonstrate compliance with deterministic safety analysis (DSA) requirements, particularly in validating natural circulation cooling, decay heat removal performance, and passive containment cooling effectiveness under DBA/BDBA scenarios [3,4].
- International Regulatory Harmonization: SDA can support compliance with CNSC Vendor Design Review (VDR) and European Utility Requirements (EUR) [5].
- Hybrid Licensing Approach: SDA can serve as an intermediate step toward full Design Certification (SDC) or a Combined License (COL), as outlined in §52.155 [1].

3.2 Optimizing the Transition from SDA to SDC

- Utilizing SDA for Initial Design Review: Obtaining SDA first allows i-SMR developers to refine the design before pursuing SDC. This phased approach enables preliminary assessments of passive safety system performance, multi-module scalability, and external event resilience before committing to a legally binding certification [3,4].
- Leveraging SDA in International Licensing: SDA findings can be aligned with CNSC VDR and KINS SDA processes [5].
- Integration with COL: SDA can be directly referenced in a Combined License (COL) application (§52.155), streamlining the licensing process [1].

Table 2. Proposed SDC-SDA Integration Strategy for i-SMR [1,3]

Phase	Regulatory Focus	Application to i-SMR
Pre-SDA	Initial design review & approval	Passive safety validation & design optimization
SDA Approval	NRC safety review (§52.145)	Regulatory readiness for future licensing
Transition to SDC	Formal design certification (§52.55)	Establish legal finality for mass deployment
Integration with COL	SDA used in Combined License (COL) application (§52.155)	Ensures smooth transition to commercial operation

4. Conclusions

This study analyzed 10 CFR Part 52 Subpart B (SDC) and Subpart E (SDA) and their implications for i-SMR licensing strategies. The key findings include:

- SDA enables faster regulatory approval and design flexibility but lacks legal finality [2].
- SDC provides legally binding certification but requires extensive review and public hearings [1].
- For i-SMR, a phased approach—starting with SDA and transitioning to SDC—offers the most efficient regulatory pathway [3].

Future research should focus on:

- Developing best-estimate and uncertainty methodologies (BEAU) for SDA safety assessments [4].
- Exploring harmonization between NRC's SDA approach and CNSC's VDR process, particularly in aligning safety review methodologies, passive safety validation criteria, and probabilistic risk assessment (PRA) integration for SMRs [5].

By leveraging both SDA and SDC, KHNP's i-SMR can achieve regulatory approval while maintaining design flexibility and global market readiness [1].

REFERENCES

[1] U.S. NRC, 10 CFR Part 52, Subpart B: Standard Design Certifications, 2023.
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