Development and Implications of 10 CFR Part 53 as a Regulatory Framework for Advanced Reactors in the United States

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1. Introduction

Unlike conventional large light-water reactors (LWRs), advanced reactors have evolved toward smaller-scale designs and the adoption of non-water coolants. These technological characteristics introduce substantial differences in design philosophy, safety approaches, and operational features. Consequently, the existing United States (U.S.) regulatory frameworks—10 CFR Part 50 and Part 52—originally developed for large LWRs, face structural limitations when applied directly to advanced reactors. This creates a risk that licensing processes may not adequately reflect advanced reactor characteristics or may create regulatory gaps.

As the world's first nuclear reactor developer, the U.S. has long played a leading role in establishing global technical and regulatory standards. The U.S. Nuclear Regulatory Commission (NRC), operating under Title 10 of the Code of Federal Regulations (CFR), is developing 10 CFR Part 53 as a dedicated licensing framework for advanced reactors. Regulatory innovation in major nuclear states can shape international norms and influence global governance standards.

This paper examines the evolution of the U.S. regulatory framework for advanced reactors, tracing its development from early policy foundations to legislative acceleration under the Nuclear Energy Innovation and Modernization Act (NEIMA), and analyzing the structural and philosophical foundations of 10 CFR Part 53. Understanding this transformation requires a systematic examination of official regulatory records.

To systematically investigate this transformation, the present study conducts a qualitative policy-tracing analysis of official U.S. government documents, including NRC policy statements, commission papers (SECY), Federal Register notices, regulatory guidance documents, and the NEIMA. By chronologically examining these materials, the present study identifies critical turning points in the regulatory evolution process and analyzes how regulatory philosophy shifted from prescriptive large LWRs–based frameworks toward a technology-inclusive, risk-informed, and performance-based (RIPB) model. This approach enables a structured examination of the continuity and transformation of regulatory philosophy throughout the development of Part 53.

2. Evolution of U.S. Regulatory Policy for Advanced Reactors

2.1 Early Policy Foundations: The 1985 Policy Statement

During the expansion of commercial nuclear power in the late 1960s and early 1970s, the U.S. regulatory system was designed primarily for large LWRs. However, technological diversification and the emergence of new reactor concepts gradually exposed the need for a more adaptable regulatory approach.

In response, the NRC issued the 1985 'Policy Statement on the Regulation of Advanced Reactors' [1]. Rather than imposing detailed prescriptive requirements, the statement articulated guiding regulatory principles emphasizing flexibility, predictability, and early engagement with applicants. Subsequent revisions incorporated institutional learning, international alignment, and expanded regulatory scope, including security considerations [2–4].

2.2 Institutionalization through NRC Vision and Strategy

In 2016, in response to the U.S. Department of Energy (DOE)'s objective of deploying at least two non-LWRs by the early 2030s, the NRC announced its 'Vision and Strategy' [5]. Building upon accumulated policy evolution since the 1980s, this initiative formally institutionalized advanced reactor regulation and provided a structured framework for subsequent legislative and regulatory initiatives. The strategy prioritized regulatory preparedness, technological readiness, and improved stakeholder communication, presenting a phased roadmap for advanced reactor regulation. By formally recognizing advanced reactor regulation as a strategic priority, the NRC established an institutional basis for proactive regulatory adaptation. This initiative reflected not only domestic regulatory needs but also the strategic intent to lead global safety and non-proliferation standards. The Vision and Strategy directly contributed to the enactment of the NEIMA, which provided statutory direction for regulatory modernization.

2.3 Legislative Acceleration: The Enactment of NEIMA

The NEIMA responded to concerns that the existing regulatory framework lacked sufficient flexibility and that regulatory inefficiencies were weakening U.S. nuclear competitiveness [6]. The Act mandated the development of a new licensing framework for advanced reactors within seven to eight years, moving beyond the large LWRs focused regulatory model. It also restructured the NRC's fee recovery system to reduce licensing costs and improve accessibility. While earlier efforts had relied on policy evolution and strategic planning, the NEIMA provided a clear legislative mandate and timeline, accelerating the development of Part 53 and transforming regulatory modernization into a statutory obligation.

3. New Regulatory Approaches for Advanced Reactors

3.1 Evolution of Regulatory Philosophy: Risk-Informed and Performance-Based Approaches

A central element of Part 53 is the RIPB regulatory approach. This philosophy is the result of decades of NRC efforts to refine nuclear safety regulation [7].

A risk-informed approach evaluates regulatory priorities based on quantitative risk assessment rather than uniform prescriptive rules [8]. Using probabilistic risk assessment (PRA), regulators identify and prioritize significant accident scenarios, allocating regulatory attention proportionally to risk significance.

A performance-based approach structures regulatory requirements around measurable safety outcomes instead of mandating specific design solutions [8]. For example, rather than requiring a particular cooling system configuration, regulations may require that core temperature remain below a defined threshold under accident conditions. The integrated RIPB framework combines these principles. Compliance is demonstrated through evidence that overall risk has been reduced to acceptable levels, rather than through adherence to prescriptive technological mandates. This enables quantitative risk management while maintaining technological neutrality within a technology-inclusive regulatory framework.

3.2 Development of Methodological Foundations: Licensing Modernization and Regulatory Guidance

The NRC's 1995 policy statement on probabilistic risk assessment formally incorporated PRA into regulatory activities [9]. Subsequent stakeholder discussions throughout the 2000s explored technology-inclusive frameworks for non-LWRs [10–12]. The 2016 Licensing Modernization Project, supported by the DOE and led by industry, translated RIPB principles into systematic methodologies applicable to licensing [13]. The Nuclear Energy Institute (NEI)'s 2019 report, NEI 18-04, and the NRC's 2020 Regulatory Guide (RG) 1.233 further institutionalized technology-inclusive RIPB guidance [14]. Collectively, these initiatives established the methodological and philosophical foundation for 10 CFR Part 53.

4. Development and Structural Evolution of 10 CFR Part 53

4.1 Initial Design and Regulatory Framework Development

Following the NEIMA's enactment, the NRC released the '10 CFR Part 53 Development Plan' in 2020 [15]. The plan proposed a technology-inclusive, RIPB regulatory framework while seeking to minimize overlap with existing regulations. road stakeholder engagement was emphasized to enhance transparency and regulatory predictability.

4.2 Stakeholder Feedback and Structural Refinement

During drafting and public consultation, stakeholders raised concerns regarding the strong reliance on probabilistic methods. In response, the NRC introduced a dual-framework structure consisting of:

- System A: A top-down, probabilistic, RIPB-based approach
- System B: A bottom-up framework incorporating deterministic principles

The initial draft approved in 2023 contained both systems, resulting in a complex structure with extensive provisions [16]. Industry stakeholders argued that duplication and structural complexity could undermine clarity and efficiency. Reflecting this feedback, the NRC reorganized Part 53 into a unified regulatory structure centered primarily on the RIPB-based System A, simplifying the framework while preserving flexibility [17].

The final promulgation date was set for April 2027, ahead of the statutory deadline as depicted in Fig. 1. Through this restructuring, the advanced reactor licensing framework was consolidated into a more coherent and consistent system.

5. Conclusions

The fundamental philosophy of 10 CFR Part 53 is grounded in a RIPB approach. This regulatory philosophy evolved over decades through policy development, institutional learning, and adaptation to changes in nuclear energy technology in the U.S. The development of Part 53 demonstrates how RIPB principles were refined and embedded in a technology-inclusive licensing framework. Both the substance of Part 53 and its rulemaking reflect this institutional consolidation.

Although the U.S. had long recognized the need for a regulatory framework tailored to advanced reactors, the transition from conceptual discussion to rulemaking proceeded gradually. For decades, reform efforts

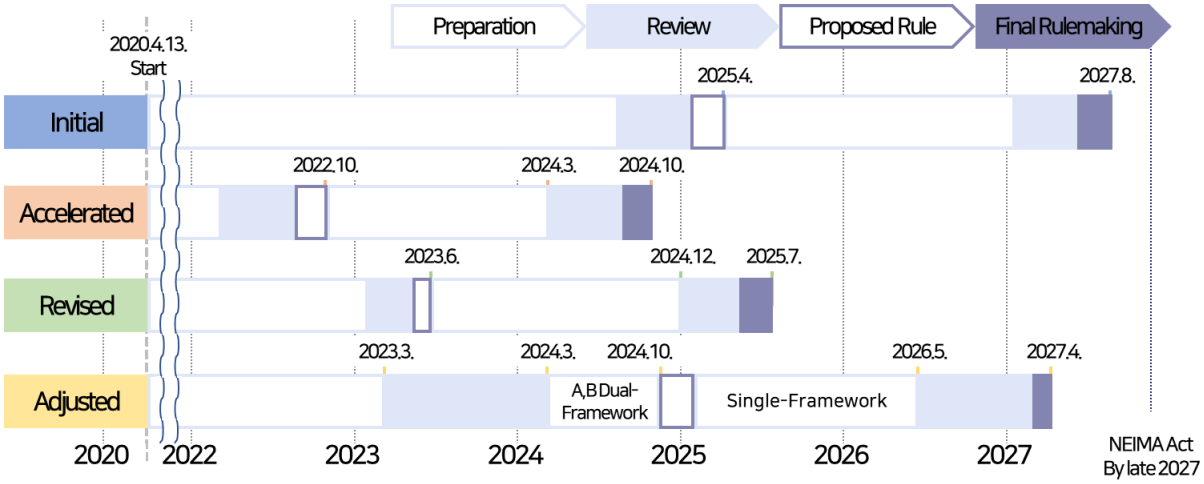

Fig. 1. Confirmed schedule for 10 CFR Part 53

remained within policy evolution and strategic planning. The enactment of the NEIMA marked a turning point. Supported by bipartisan legislation, the NEIMA established a statutory mandate and timeline—under which Part 53 is expected to be promulgated by 2027—thereby accelerating the development of a new licensing framework. In this respect, Part 53 represents not merely an administrative revision, but a regulatory transformation aligned with the national energy strategy.

The U.S. case indicates that regulatory clarity and predictability can reduce investment risk, facilitate private-sector participation, and shorten licensing timelines for advanced reactor projects. A licensing framework can also strengthen a country's position in the global market for advanced nuclear technologies. These implications may be relevant to other countries pursuing advanced reactor deployment.

In this regard, Korea is advancing legislation to enact the Special Act on the Promotion of Development and Support for Small Modular Reactors. Regulatory modernization is also urgent in Korea. Waiting for the promulgation of 10 CFR Part 53 before benchmarking the U.S. regulatory framework may result in delay. Rather than observing the outcome, it is necessary to monitor U.S. rulemaking deliberations and public consultation processes, while conducting analysis of Korea's regulatory and industrial conditions. Such an approach could facilitate the development of a Korean-tailored regulatory framework, thereby supporting regulatory modernization and industrial competitiveness.

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