Study on Pre-Application Activities between Regulatory Bodies (NRC and CNSC) and Developers

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1. Introduction

Recently, demands for regulation of LWR (Light Water Reactor) type SMRs (Small Modular Reactor) and non-LWRs are increasing, but the regulatory framework for these types is lacking. The existing regulatory framework is based on large LWRs, making it challenging to apply to these types.

To address this issue, nuclear-advanced countries (USA, Canada, UK, ...) consider pre-application activities with developers as one of the essential solutions. Regulatory body aims to understand early the reactor designs of the developers through pre-application activities and establish safety criteria for that type, with the goal of conducting planned and systematic evaluations during the main review process such as SD (Standard Design), CP (Construction Permit) and OL (Operating License) [1]. More than 10 reactor designs are conducting pre-application activities with U.S. NRC (United State Nuclear Regulatory Commission) and CNSC (Canadian Nuclear Safety Commission) [2,3].

Pre-application activities for NuScale's Design is one of the best examples. NuScale submitted a preapplication request to NRC in 2008 and the preapplication activities have been conducted for 8 years (from 2008 to 2016) [4]. They discussed and reviewed the gap between the design and regulation criteria and derive not-applicable safety criteria [5]. NuScale suggested specified safety criteria for alternating the not-applicable safety criteria and technical methods for satisfying the specific safety criteria [6]. NRC reviewed NuScale's suggestion and responded to NuScale about their regulation position [7]. NuScale submitted DCA based on the results of the pre-application activities in 2016 and the DCA was published in 2023 (SDA was approved 2020) [8].

In South Korea, it is planned to have pre-application activities with i-SMR (innovative-SMR) developers for successful SDA until 2026. Regulatory body (NSSC, Nuclear Safety and Security Commission) and developers (i-SMR business group) object to identify regulation gap of the i-SMR and despite such a gap, they seek ways to demonstrate safety of the i-SMR.

The requests for such domestic pre-application activities are expected to continuously increase. The KAERI (Korea Atomic Energy Research Institute) is developing a molten salt reactor for actual commercialization [9]. GS Energy aims to build the NuScale design in Korea [10], and Seaborg targets to construct a test reactor of the CMSR (Compact Molten Salt Reactor) in Korea [11]. Therefore, it's evident that developers will engage in pre-application activities with regulatory body for a planned and efficient review.

Therefore, it's necessary to establish a systematic preapplication activity in Korea, referencing best practices from abroad. Given that the U.S. currently utilizes the most diverse reactor types globally, it would be beneficial to review the pre-application activities in the U.S. and Canada's VDR (Vender Design Review) process and incorporate their advantages into the domestic context.

2. Pre-Application Activities of NRC

NRC is currently working on systematizing preauthorization activities within the existing regulatory framework and developing a new regulatory system aimed for medium to long-term use, because NEIMA (Nuclear Energy Innovation and Modernization Act) requires NRC to urgently prepare a staged licensing that can be utilized even in conceptual design and to prepare a regulatory framework for new reactor types in the medium to long term [12]. Attention should be paid to the content of the former.

NRC conducts pre-application activities by combining activities they have already been carrying out. The NRC proposes suitable activities to be carried out during pre-application based on the topic in question, as presented in the following table [13].

Topical	Principal Design Criteria	
Report	Selection of licensing basis event	
	Classification and treatment of SSC	
	Fuel qualification and testing	
	Mechanistic or accident source	
	term	
	Quality assurance program	
	Safeguards information plan	
	Safety and accident analysis	
Meeting,	Probabilistic risk assessment	
audits, and	Regulatory gap analysis	
white papers	Policy issues	
	Novel design features or	
	approaches	
	Consensus codes and standards and	
	code cases	

Table I: Proposed Activities for New Reactor Design

White Papers (Environment)	 Unique or Novel Methodologies and Issues Alternatives to the Proposed Project Cooling Water Availability Status of Permits and Authorizations for the Proposes Project
Meeting (Environment)	 Socioeconomic characteristics of the community Aquatic or terrestrial ecology studies Potential impacts on Essential Fish Habitat
Pre- Application Readiness Assessment	 Evaluation of whether it's sufficient to proceed with the main reviews (SDA, CP, OL, COL)

It is shown that the NRC's activities are largely divided into two categories as Table I. Meetings, audits, and white paper are proposed to identify issues due to gap between regulation and reactor design. Then, Topical report is proposed for solutions of the issues identified during the former.

NRC has significantly expanded the scope of the topical report to use it as a central component in the pre-application process [14]. While the topical report was originally limited to specific safety-related topics, it has been revised to cover any subject. Additionally, it has been amended to allow for the review of topical reports that have not yet been finalized. Therefore, while the original use of the topical report was limited to obtaining approval for specific safety-related analysis methodologies or codes, after the revision, it is possible to obtain preliminary approval during the pre-authorization process for specific safety standards and licensing considerations for the new reactor types being developed, through the topical report.

The cost for pre-licensing activities is borne by the applicant. The cost is calculated based on 10CFR170.20, and the NRC estimates that the pre-licensing cost will be around 45 to 70 million dollars [15]. Currently, the United States is supporting many new reactor development programs through the DOE or other government programs, and these developers are using their budgets to carry out pre-licensing activities with the NRC [16, 17].

3. Vendor Design Review (VDR) of CNSC

CNSC operates a system called VDR, which is a procedure to provide CNSC feedback during the initial design phase before the official licensing application. Although it's not part of the licensing process and does not have binding power during the official licensing phase, the technical review results from this process are extensively utilized. VDR is divided into three phases. Fundamentally, all phases address the 19 safety areas reviewed by the CNSC, and as the phase progresses, a more detailed review is conducted. The result reports from each phase are commercially sensitive and are not disclosed to the public, only summarized results are made public. The following table summarizes the focus points at each VDR phase[18].

	Table II: Focusing Area of VDR Phases		
	Phase 1: Intent	➤ Understanding design of	
to comply with regulatory requirements (8~12 months)		applicants	
		Novel and Unique characteristics	
		and knowledge basis for the	
		characteristics	
		Regulation Gap and Alternative	
		criteria of applicants	
	Phase 2: Pre-	Same with Phase 1, but more	
licensing		detailed	
assessment		Potential barrier for licensing	
(12~18 months)			
	Phase 3: Pre-	Follow-up process regarding	
construction		actions and solutions for the	
follow-up		results of the VDR Phase 2	

Unlike the U.S. case (Topical Report), the VDR explicitly states that the results derived from the prelicensing activity process have no legal binding force. However, like the licensing review, the cost is charged to the applicant [19].

4. Discussion and Conclusion

The core objectives of pre-authorization are 1) to identify differences between the new design and existing regulations at an early stage, 2) to find solutions to address them early on, and 3) to complete a systematic and timely licensing review through this process. The pre-application activities of NRC and CNSC are summarized as follows:

	NRC	CNSC	
Outline	Combination of	Additional process	
	existing activities		
	Categorized by	Categorized by	
	Topics	detail of review	
Range	Understanding new reactor design		
	Regulatory Gap Analysis		
	Applicants' design specific safety		
	criteria		
	Follow-up applicants' solution		
Legal	Partially	None	
binding	(Topical Report)		
Mandatory	Not (Optional)	Not (Optional)	
Cost	Applicants	Applicants	
burden			

Table III: Summary of Pre-Application Activities

Currently, South Korea seems to be in a position to permit the licensing of new reactor types through some amendments in its laws. The regulations concerning safety standards applied to power plants are structured to allow alternative requirements, and similar to the United States, there is a procedure to independently approve specific topics through the topical report.

Therefore, it is considered that the pre-application activities approach similar to that of the United States is a good method that can be timely introduced in Korea. Existing activities, such as the topical report which needs some revisions (expanding its scope similar to the U.S.), the cost billing procedure for pre-application activities, and the supportive programs, should be organized in a way that allows both regulators and developers to utilize the system without it being mandatory.

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