POSITION PAPER

SMR PRE-APPLICATION ENGAGEMENT

January 2011

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1. Summary

With the advent of new, smaller reactor concepts, utilizing existing or unique active and passive systems, conventional or different fuels, and conventional or different coolants, the existing regulatory guidance is not completely applicable or complete. This leads to greater uncertainty and risk for licensing applicants expecting to deploy these new technologies if the content and acceptance criteria are only confirmed during the course of the regulatory review. This paper documents an approach to the licensing process that can be used to achieve an efficient regulatory review process.

The objective of this paper is to provide a generic mechanism for establishing a documented, clear delineation of NRC expectations for completeness and level of detail for new, unique small modular reactor design applications suitable for each design in those areas that are materially different from existing light water reactor guidance. This will provide assurance that there is a known and firm receipt acceptance and docketing basis; and there is a greater regulatory certainty for the application review process with fewer iterations with more predictable results.

In summary, this paper concludes that a well-planned approach to the licensing application process in the pre-application phase affords an efficient regulatory review process and provides regulatory certainty. Furthermore, the unique aspects of SMR technology require pre-application engagement to define how to utilize existing application guidance. Additionally, there are many lessons learned from near-term advanced LWR licensing processes that are applicable to the SMR licensing strategy.

2. Introduction

In order to assure an efficient design certification (DC), combined license (COL), manufacturing license (ML) application and review process, the expectations for application content, format, completeness, level of detail, and review criteria and timelines should be well-defined. The existing format and content guidance is principally contained in different parts of 10 CFR Parts 50, 51 and 52, Regulatory Guide 1.206, NUREG-800 and NUREG- 1555. These requirements are in many instances generic to all reactor types. In particular they are well aligned with specific large light water reactor technology features. With the advent of new, smaller reactor concepts, utilizing existing or unique active and passive systems, conventional or different fuels and conventional or different coolants, the existing application guidance is not completely applicable or complete. This leads to greater uncertainty and risk for applicants expecting to deploy these new technologies and extended regulatory reviews if the content and acceptance criteria are only confirmed during the course of the review. Additionally, given the range of different designs being developed, it would not be possible for the NRC to anticipate all of the unique conditions for each of these designs and establish appropriate requirements for individual design types in advance of some experience with each type.[1]

[1] NRC has explored technology neutral regulatory requirements under the proposed 10CFR53 regulation initiative. In the course of that program, it was recognized that this was a long term program that would benefit from pilot program activities involving real applicants with designs differing from the existing large LWR options. That

In the development of 10 CFR Part 52, it was recognized that prior to the submittal of an application, it was advisable for applicants to engage the NRC staff with respect to new or unique aspects of their design. This "pre-application" engagement would assure that the specific requirements applicable to the proposed design are understood so that the application will be high quality, complete and ready for review when received, and to provide the NRC staff with an opportunity to become familiar with unique design features or other long lead issues such as physical testing programs (applicant or NRC) that are envisioned and be prepared for an efficient review. Thus, the "pre-application" engagement is the prime opportunity to identify the areas of the existing review guidance that are not applicable, only partially applicable, or where appropriate guidance doesn't exist for a new design and to establish a design-specific set of agreements regarding what will likely constitute a complete application.

Specific topics that may require early or advance assessment such as acceptability of specific component design, analytical methods, models and techniques include, but are not limited to: fuel qualification issues, source term issues, design basis issues, defense-in-depth issues, approach to accident selection, classification of SSC's, regulatory treatment of non-safety systems, and evolving codes and standards.

This paper describes one mechanism for near-term design certification or COL applicants for small modular reactors (SMR) to maximize the value of pre-application by engaging the NRC staff to define how to utilize the existing application guidance and review criteria to a significant extent while adjusting the guidance where necessary to better align with the unique aspects of a new design. In developing this process, lessons learned from the reviews of current advanced LWR design certification and COL applications have been considered. The end product of this approach is a design-specific, modified application Format and Content Guide that serves as a repository of the agreements and revised expectations for a complete, high quality application and review criteria that resulted from the effective pre-application engagement.

Similar efforts associated with the manufacturing license processes should benefit by utilizing this same mechanism to achieve a similar result for a standard design approval and manufacturing license process that differs from that used for the current set of 10 CFR Part 52 plants.

Desired Outcome: A generic mechanism for establishing a documented, clear delineation of NRC expectations for completeness and level of detail for new, unique SMR design applications suitable for each given design in those areas that materially differ from existing LWR guidance.

This will provide sufficient assurance that:

- there is a known and firm receipt acceptance and docketing basis; and

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program was halted, amongst other reasons, since it would not be timely for a new wave of non-LWR designs that were just emerging. This leaves current prospective DC or COL applicants to propose alternate means for establishing and effective and efficient process for the review of new SMR reactor types using the existing regulatory framework. Whether individual issues need or are amenable to new rulemaking or other regulatory remedies are the subject of other industry papers being developed for consideration by NRC.

- there is greater regulatory certainty for the application review process with fewer iterations with more predictable results.

3. Current Regulatory Framework

3.A. Overview

Applications for new power reactors may be filed either under 10 CFR Part 50 or Part 52. Part 50 is the historical foundation by which the existing fleet of operating reactors has been licensed. It contains procedures for a "two step" licensing process in which an applicant first applies for a construction permit and later, following substantial completion of construction, files a second application for an operating license. Subpart C of 10 Part 52 allows for a "single step" licensing process in which an applicant files an application for a combined license that permits both construction and later, plant operations following verification that the facility has been constructed in accordance with the license. This latter process, in which a Combined License (COL) is granted, is the typical approach being taken by the advanced LWR applicants.[2]

Part 52 also contains provisions for optional licensing approaches that are designed to facilitate the review of a COL. These include the allowance for an Early Site Permit (ESP) under 10 CFR Part 52 Subpart A, and reactor Design Certification (DC) under 10 CFR Part 52 Subpart B. Other licensing processes included in 10 CFR Part 52 are the issuance of a Standard Design Approval (SDA) (under Subpart E), and a Manufacturing License (ML) (under Subpart F). Finally, Appendix N to 10 CFR Part 52 allows for applications for COLs to be filed by one or more applicants to construct and operate nuclear power reactors of identical design ("common design") to be located at multiple sites.

Each of the licensing processes within 10 CFR Part 52 requires that specific general and technical information be provided in the application. These requirements draw upon the detailed requirements contained in 10 CFR Part 50 as well as additional requirements detailed in other parts of 10 CFR, with the extent of the information required dependent upon the type of application filed.

3.B. Requirements on the Content of Applications

Each of the subparts within 10 CFR Part 52 details specific requirements on the information that is to be included in an application. For example, §§ 52.46 and 52.47 detail the specific general and technical requirements, respectively, that are to be met and are to be described in the application for a reactor design certification. Similarly, §§ 52.77, 52.79 and 52.80 detail the specific general, technical, and additional requirements, respectively, that are to be met and are to be described in a COL application.

[2] The 10 CFR Part 52 licensing processes are optional to those provided in Part 50 and offer potential advantages through the issuance of a single license. Part 50, however, remains in effect and may be used to pursue licensing under the two-step process.

In addition to these application content requirements that are to be met by all applicants, several additional requirements are included for particular applications. For example, should an applicant pursue a modular power plant design, § 52.47(c)(3) adds the requirement that[3]

"*An application for certification of a modular nuclear power reactor design must describe and analyze the possible operating configurations of the reactor modules with common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the configurations, including any restrictions that will be necessary during the construction and startup of a given module to ensure the safe operation of any module already operating.*"

As directed by §§ 52.46 and 52.47, other Parts of 10 CFR, notably Parts 20, 50, 51, 73 and 100, detail additional requirements that a design certification applicant must meet. For example, § 52.47(a)(6) directs the applicant to § 20.1406 which includes a requirement that an applicant "*shall describe in the application how facility design will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste*." Similarly, § 52.47(b)(2) includes a requirement that a design certification application include "*An environmental report as required by 10 CFR 51.55*."

For a COL applicant, § 52.80(b) includes the requirement that the application include an environmental report. Also, § 52.79(a)(35) directs that a COL applicant submit "*A physical security plan, describing how the applicant will meet the requirements of 10 CFR Part 73 (and 10 CFR Part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility)*."

3.C. Guidance on Application Format and Content

The primary format and content guidance for power reactor applications submitted in accordance with 10 CFR Part 50 is stated in Regulatory Guide (RG) 1.70, *Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)*, and for applications submitted under 10 CFR Part 52 is stated in RG 1.206, *Combined License Applications for Nuclear Power Plants (LWR Edition)*. RG 1.206 addresses the broader aspects, beyond just that of nuclear safety, of applications filed under 10 CFR Part 52. Additionally, RG 1.206 (completed in 2007) includes a more complete discussion of the elements of the safety analysis that are to be described in an applicant's Final Safety Analysis Report (FSAR) than that of RG 1.70 (last revised in 1978). As such, RG 1.206 is used here as the primary format and content guide from which this position paper derives the proposal for new SMR applications.

Additional guidance on application format and content is provided in other RGs related to specific content. These include RG 1.202, *Standard Format and Content of Decommissioning Cost Estimates for Nuclear Power Reactors*, RG 4.2, *Preparation of Environmental Reports for*

[3] Another requirement specific to a particular application is included in § 52.79(e) which details additional requirements for COL applications that reference the use of one or more manufactured nuclear power reactors licensed under subpart F of 10 CFR Part 52.

Nuclear Power Stations, and RG 5.54, *Standard Format and Content of Safeguards Contingency Plans for Nuclear Power Plants*.[4]

To these format and content guides must be added the litany of guidance on applicant content related to specialized assessments. For example, Appendix A to RG 5.71, *Cyber Security Programs for Nuclear Facilities*, provides a template for a generic cyber security plan which applicants may use to comply with the licensing requirements of § 73.54.

Not all safety assessments are required to be described in detail in an application. NRC's guidance allows an applicant to summarize results of a design-specific assessment in its application. For example, § 52.47(a)(27) states that a design certification shall include a *"description of the design-specific probabilistic risk assessment (PRA) and its results".* Another example resides in DG-1176, *Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts* (proposed revision 0 of a new RG), which states:

"Applicants are not required to submit the aircraft impact assessment to the NRC in their applications. However, the assessment will be subject to inspection by the NRC and, therefore, must be maintained by the applicant. Applicants are required to describe, in their preliminary or final safety analysis reports, the design features and functional capabilities that show that the facility can withstand the effects of the aircraft impact. Applicants must also include a concise description of how such design features and functional capabilities meet the acceptance criteria of the rule."

Regulatory Guides describe to applicants (and licensees) the methods that the NRC staff considers acceptable for use in implementing NRC's regulations. Other guidance exists, however, that can be used to clarify the format and content of applications. Standard Review Plans (SRPs) and Interim Staff Guidance (ISG) - prepared by the NRC as guidance for internal reviews of applications by the NRC staff - provide useful guidance to applicants. Standard Review Plans are comprehensive and integrated documents that provide the NRC staff reviewer with guidance that describes methods or approaches which the staff has found acceptable for meeting NRC's requirements. Adhering to the structure of the SRPs helps applicants ensure completeness of content in their applications.

Two SRPs, NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)*, and NUREG-1555, *Standard Review Plans for Environmental Reviews For Nuclear Power Plants*, have received the greatest amount of attention and undergo continuous revision to ensure their relevance to new applications.

The NRC also drafts ISGs as a means to providing timely updated guidance information to stakeholders, until such time as the SRP or other guidance documents are updated.[5]

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[4] As a replacement for RG 5.54 (issued for comment in March 1978), the NRC has recently prepared draft guide DG-5016, *Format and Content for Contingency Plan at Nuclear Reactors*, for assisting applicants in meeting the requirements of § 73.55.

[5] *See* NRC Office of New Reactors Office Instruction NRO-REG-301, *Development and Issuance of Interim Staff Guidance for the Office of New Reactors*, Revision 1, September 29, 2010.

Finally, NEI has also helped the development of selected application guidance and templates for new reactors. These industry prepared guidance are reviewed by the NRC and, if found acceptable, are endorsed for use. Examples include generic FSAR template guidance on: *Radiation Protection Program Description* (NEI 07-03A), *Ensuring That Occupational Radiation Exposures Are Low As Reasonably Achievable* (ALARA) (NEI 07-08A), *Offsite Dose Calculation Manual (ODCM) Program Description* (NEI 07-09A), and *Process Control Program (PCP)* (NEI 07-10A).

4. Scope of Issues

4.A. Background

The purpose of this section is to present the licensing approach for evaluating the regulatory framework for a specific SMR design to support development, submission and acceptance of a complete licensing application. This is primarily a pre-application activity that is essential to establishing the format and content of an SMR Design Certification Application (DCA) or an SMR Combined License Application (COLA). The licensing methodology presented allows an SMR design to be licensed within the current regulatory framework, utilizing current regulations, and incorporating risk-informed elements and insights.

Existing design-related regulations are used as guidance to the extent that they relate to the design functions of the SMR technology. Some regulations may not be relevant and others may only be partially applicable to the design. Additionally, other aspects of the SMR design may not be addressed by existing regulations, and there will be a need to develop criteria to control the design in those areas. A risk-informed licensing approach is recommended to help identify the extent to which LWR-based regulations should be applied to the SMR design as guidance and to develop new criteria for the SMR design where existing regulations are insufficient.

The NRC staff has previously endorsed this licensing approach which was utilized for the Exelon PBMR project, and determined that, if adequately implemented, is a reasonable process for ensuring that the applicable NRC regulations are met and for identifying SMR design-specific regulatory requirements (Reference 1). This licensing approach has been further developed by the Idaho National Laboratory (INL) Next Generation Nuclear Plant (NGNP) Licensing Plan documented in Reference 2. The licensing approach outlined herein integrates the Exelon/NRC PBMR licensing approach and the INL NGNP project's Licensing Plan referenced above.

This licensing approach has three guiding principles: (1) to conform with the current regulations while recognizing that many of the current regulatory requirements are based on large light-water reactor technology; (2) to use a systematic decision-making process that determines the applicability of existing regulations; (3) to use a risk-informed process to supplement existing regulations; and, (4) to provide a documented set of revised application requirements summarized in a design-specific format and content guide based on RG 1.206.

4.A.1. Adapting LWR Regulations

The current set of regulations and guidance must be reviewed for applicability to the SMR design. Updated regulatory guidance (or framework) derived from existing LWR regulations must be proposed and agreed upon during pre-application activities with the NRC to guide development of a complete DC or COL application, and to guide NRC staff in reviewing the application.
The proposed approach supports the use of probabilistic risk assessment (PRA) information to establish the application basis for the specific SMR design.

A combination of deterministic and probabilistic analysis is also appropriate to use in defining SMR safety functions and success criteria, prediction of plant response to initiating events, and development of mechanistic source terms and therefore also guides the changes in the information needed in an application for a specific SMR design type.

Using a risk-informed and performance-based approach that adapts existing NRC licensing requirements in establishing SMR design-specific technical licensing requirements is justified on the basis that:

- Using a PRA to aid in the development of events that are included in the licensing basis maximizes the probability of establishing a comprehensive safety basis. (PRA development is a rigorous process that considers the comprehensive performance of the facility design, uncertainties and safety margins.)
- Integrating PRA insights into the application provides a more structured means for assuring a complete description of a design that may differ from existing large LWR designs.
- Using PRA provides a rational method for identifying new or unique design features that need to be adequately described in the application
- Using PRA insights can assist in focusing both applicant and NRC staff resources on specific features that are significant in SMR designs and aid in reducing or eliminating detailed reviews of less important design features.

4.B. Review of 10 CFR Parts 50 and 52 Application Requirements

The detailed requirements for contents and technical information for Design Certification applications are defined in 10 CFR 52.47. The regulations specified in 10 CFR 52.47c)(2) and (3) contain the following requirements applicable to SMR designs.

10 CFR 52.47(c)(2) states that an application for certification of a nuclear power reactor design that differs significantly from an LWR design must provide an essentially complete nuclear power reactor design except for site-specific elements, and meet the requirements of 10 CFR 50.43(e). 10 CFR 50.43(e) requires that such reactor designs will be approved only if:

- The performance of each safety feature of the design has been demonstrated through either analysis, test programs, experience, or a combination thereof, and

- Interdependent effects among the safety features of the design have been demonstrated by analysis, test programs, experience, or a combination thereof, to be acceptable, and

- Sufficient data exist on the safety features of the design to assess the analytical tools used for safety analyses over a sufficient range of normal operating, transient conditions, and specified accident sequences, including equilibrium core conditions, or

- In lieu of the above, there has been acceptable testing of a prototype plant over a sufficient range of normal operating conditions, transient conditions, and specified accident sequences, including equilibrium core conditions.

10 CFR 52.47(c)(3) applies to an application for certification of a modular nuclear power reactor design, and specifies that the application must describe and analyze the possible operating configurations of the reactor modules with common systems, and interface requirements, and include any restrictions that will be necessary during construction and startup of a given module to ensure the safe operation of any module already operating.

The pre-application program interactions with the NRC staff should address how each of these regulatory requirements will be satisfied and documented in the FSAR. It is also important that agreements are reached on physical testing programs since these programs are often very extensive, long lead activities that, if only identified after application submission, can be highly disruptive to the review schedule and potentially fatal to commercialization. The DC or COL application specification document will capture these SMR specific design commitments, including any associated schedule commitments or requirements that are supportive of an efficient review.

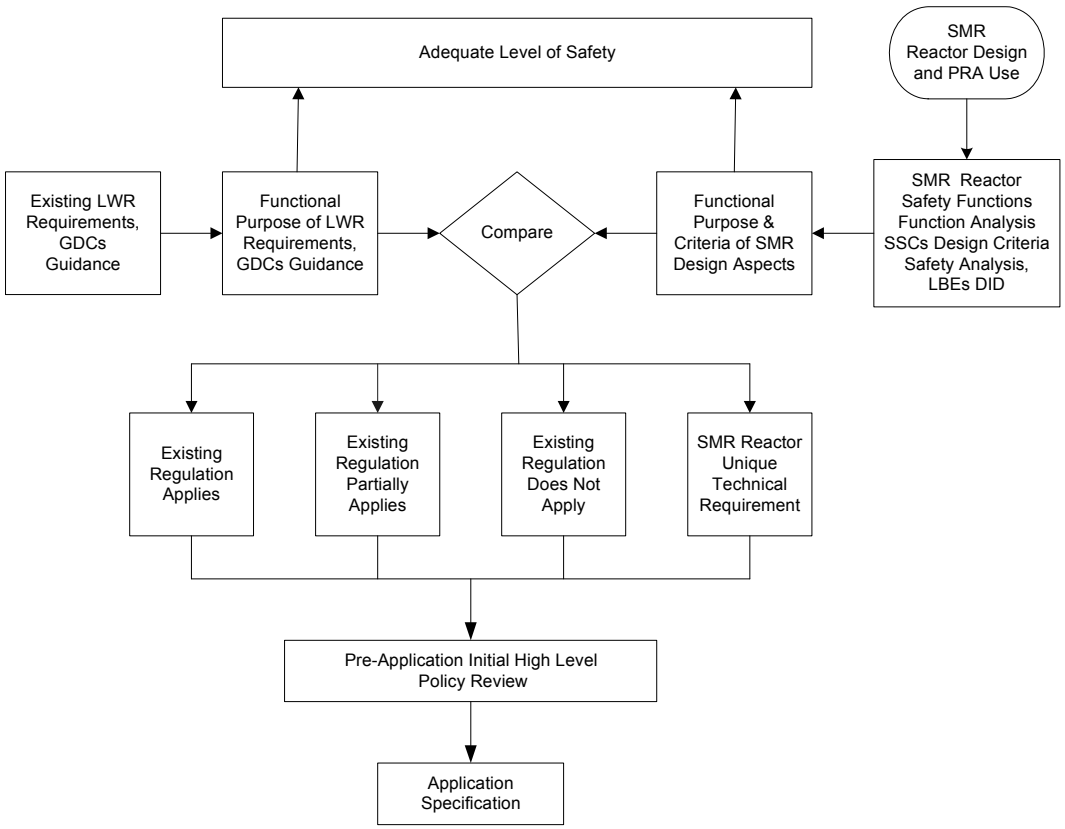
4.B.1 Regulatory Gap Analysis

Application development will require a detailed reconciliation of existing LWR regulatory requirements with the characteristics of the specific SMR design. The list of regulatory requirements to be considered includes 10 CFR Part 50, 10 CFR Part 50 Appendix A (General Design Criteria), 10 CFR Part 51, 10 CFR Part 52, 10 CFR Part 100, and applicable Regulatory Guides, Standard Review Plans (SRPs), NUREGs, and NRC generic guidance such as Interim Staff Guidance (ISGs).

A detailed review of the Standard Review Plan (NUREG-0800) criteria (Reference 4) must be performed since this guidance most directly impacts preparation of the application. This review will identify current design-related regulations that are fully applicable to the SMR design, the current design-related regulations that are not applicable to the SMR design, and the current design-related regulations that are partially applicable to the SMR design. This review will also identify features of the SMR design that cannot be addressed by any regulatory criterion, thus requiring new guidance criteria or agreements to be developed during the licensing process. This reconciliation should demonstrate that the SRP remains a strong foundation for preparation of Part 2 (FSAR) of the DC or COL application.

Also required, is the review of all regulations (addressing administrative as well as design-related regulations) and sub-tier guidance provided or referenced in the SRP such as Branch Technical Positions, ISG's, various NUREG reports, Unresolved and Generic Safety Issues, and Bulletins and Generic Letters. The results of the gap analysis, especially those regulations judged to be not applicable, will form a part of the regulatory issues that need to be resolved with the NRC staff during the pre-application program. The mechanism for capturing the gap analysis and the agreements regarding application format and content for unique design and operating features of a specific SMR design will be to produce an amended format and content guide for a given design. An approach for conducting the gap analysis is provided in Figure 1.

Figure 1 – Gap Analysis Process



4.B.1.a. Identification of Applicable Regulations

Creating a focused list of regulatory documents for any SMR design is a two-step process. The first step is a preliminary screening of documents for applicability, and the second step is to refine the focus of the applicable regulations using available design and risk-informed insights to develop the proposed set of regulatory requirements.

The initial screening of regulatory documents can be performed by a panel of subject matter experts (i.e., expert panel) with diverse industry backgrounds. This process provides a preliminary view on the applicability of each of the regulations in 10 CFR 50 plus a partial set of other rules that could be used to shape the application and review requirements for the SMR design.

It is important to obtain agreement with the NRC during the pre-application period on the process, logic, and needed definitions in order to prepare a high quality application. This will enable a properly focused application that can be efficiently and effectively reviewed and address the necessary and sufficient requirements to provide reasonable assurance of public safety and security for the SMR design.

Once agreement is reached with the NRC on the process and logic to be used, the entire set of NRC power reactor or manufacturing license regulations should be screened to determine applicability, partial applicability, and non-applicability. The results should be documented in a modified format and content guide that will serve as the repository of application requirements and applicable review topics. This document will be the basis for completing the application and subjecting the application to acceptance review for completeness.

It is the intent of the process that the applicant and the NRC will use the pre-application period to assure that the full set of regulatory documents that must be considered in whole or part for the SMR design are identified in advance of completing the application. It may be that both the design and identification of applicable regulations may evolve over time, with finality achieved once a license is issued.

The screening of existing LWR regulations for applicability to the SMR design requires specific SMR design information and the PRA for the SMR design. The SMR design and PRA are used to establish the Licensing Basis Events (LBEs) and associated technical requirements. The LBEs determine the specific design functions and design functional capabilities that will be required for prevention and mitigation of each LBE. These design functions and capabilities are then compared against the regulatory requirements and criteria of the existing LWR regulations. This approach for adapting existing LWR regulations was proposed for the Exelon PBMR project pre-application review activities, and was recognized by the NRC as sufficiently comprehensive to permit an effective screening of regulations, and also to develop considerations that may serve as a basis for appropriate exemption requests (Reference 1).

This licensing approach is fully consistent with the NRC's regulations and Policy on Advanced Reactors. The complete implementation of these processes will provide a firm foundation for the NRC staff to prepare for and conduct an efficient and effective review of the SMR application.

4.B.2. Pre-application Review Activities

An effective pre-application program must be a critical part of the SMR licensing strategy and overall project plan because the early establishment of the approach to resolution of issues can significantly impact the preparation of acceptable DC and COL applications, subsequent application review schedule, and ultimate deployment of the plant.

Frequent, focused, and coordinated interactions with the NRC staff during the pre-application period are critical to the success of this licensing approach. It is expected that NRC will participate in the project pre-application review by gathering information, identifying and developing proposals for resolution of key design, safety, and licensing issues; and identifying programmatic, regulatory, and key technical issues with recommendations for consideration and approval by the Commission.

The results of these pre-application activities will be utilized when revising or developing the format and/or content of the COL or ESP applications, so that early and ongoing alignment with the NRC is developed. This minimizes the potential for significant mismatches in content expectations when the applications undergo acceptance reviews. The conduct of the pre-application program as outlined in this document will significantly reduce the schedule risk in the preparation and review of the DC or COL application.

Successful implementation of this approach supports development of the DC or COL application to be submitted to the NRC. Implementation of this approach requires that the applicant and the NRC agree on a set of DC or COL application development requirements and guidance documents suitable to the SMR-specific design. Since the existing LWR regulatory framework may only apply in part to the SMR-specific design, development of an agreed upon set of application content requirements that parallel existing LWR requirements is essential in order to ensure a technically complete application with sufficient level of detail to meet NRC staff review requirements in all areas.

For any information required by regulation that is not included in the DC or COL application, the applicant should provide a request for exemption in accordance with 10 CFR 52.7. In this respect, the pre-application determination of information required by regulation that is "not applicable" is an important step since this eliminates the development of unnecessary exemption request documentation.

4.C. Expectations for Small Reactor Applications

4.C.1. Licensing Topical Reports, Technical Reports and White Papers

The SMR DC or COL application content is expected to be supplemented by various licensing topical reports or technical reports incorporated by reference. Topical reports can be used as a supplemental mechanism to document technical nuclear plant safety topics that are submitted to the NRC for review and approval either in advance of the DC or COL application, in parallel with, or even after submittal of the application. These reports include information that is not suitable for inclusion in the application that often contain proprietary information, and/or

establishes standard approved references that can be used for multiple applications. These reports become part of the formal licensing basis upon issuance of the DC or COL.

Topical reports are submitted individually to the NRC for formal review and approval, and form part of the overall application. These reports are typically incorporated into the application by reference. Each topical report will be subject to the NRC acceptance review process in accordance with NRC Office Instruction LIC-500, "Processing Requests for Reviews of Topical Report," (Reference 9). A topical report should contain complete and detailed information on the specific subject presented. Topical reports are used to protect intellectual property, establish standard approved references for future applications, compartmentalize highly specialized information that needs to be reviewed, and can be submitted and reviewed independent of the overall FSAR thus mitigating the risks of long review periods.

An applicant should develop a proposed listing of the topical reports anticipated for technical support of the FSAR/COL application that is shared with the NRC. In addition, overall licensing effort should be developed and reviewed with the NRC staff during the pre-application program interactions. Topical reports will typically support FSAR Chapters 3, 4, and 7 to establish equipment design characteristics and design verification, and in support of FSAR Chapter 15 accident analysis code requirements.

Topics typically addressed in topical reports include:

- System and plant assessment reports – usually prepared in preliminary (when sufficient design information is available) and final (when plant programmatic information becomes available) versions. Examples include:
  - Security assessment
  - Fire protection assessment
  - Aircraft impact assessment

- Safety analysis code reports needed for complete description of the evaluation models used in the safety analyses. For each unique safety analysis code, a series of reports may be submitted that address:
  - Evaluation model description
  - Individual safety analysis code description
  - Code Validation &Verification process description
  - Test data adequacy
  - Scaling analyses
  - Analysis of code applicability to specific design application

- Analyses or documentation of select design aspects. These topical reports may be prepared in preliminary and final versions, especially in areas that require early submittal to the NRC of a descriptive process and (later) submittal of an as-built reconciliation report. Examples include:
  - Materials code selection
  - Component integrity analyses such as piping and structural analyses

  - Specialized design requirements such as Control Room Human Reliability Analyses (HRA)
  - Equipment qualification methods such as Seismic and Environmental Qualification
  - Digital I&C Software Management and Development Plans

- Vendor data reports (proprietary)

In regard to the timing of topical report submittals, the earliest topical reports – submitted prior to the application – are those that have not been previously evaluated by NRC and which are intended to address long-lead items. These can embrace the application's use of unique or new safety analysis codes, confirmation of the adequacy of test data collection needed to support code V & V, or the need for additional test programs not currently planned. These early topical reports have their greatest benefit when they are available in advance of the license application and when their review and approval is completed in a time frame that helps support preparation of the application.

Technical reference reports may also be utilized during the pre-application or application period. These documents are similar in nature to a topical report but normally do not receive a separate NRC safety evaluation report (SER). These reports, like topical reports, are incorporated by reference into the application and listed in section 1.x. The safety evaluation for these technical reference reports are incorporated into the SER for the DC or COL. The choice of which is appropriate for a given design should be established as part of the pre-application engagement.

Topical reports typically have broad applicability, whereas technical reports are related specifically to the action under review. For example, a technical report only applicable to a design being reviewed for a certification would not be a topical report. Whereas, a report for a COLA that would be later related to a subsequent COLA's would be more appropriate as a topical report.

White papers are a form of pre-application documentation used to describe an issue on a high level, summarize any existing regulatory requirements or guidance that help contextualize the issue (e.g., regulations, policy statements, precedents, etc.), describe the approach proposed to address the issue and define the outcome objectives desired to achieve applicant/NRC or industry/NRC alignment on the topic or approach. They suggest strategic approaches that have the potential to influence commercial deployment.

The choice of which type of pre-application submittal is appropriate for a given topic should be established as part of the pre-application engagement.

4.C.2. Additional Interactions

During the development of the DC or COL application specification documents (writer's guides and topical reports list) there will be significant interaction between the SMR applicant and the NRC staff to ensure NRC agreement and endorsement of those guidance documents ultimately

used as guidance to develop the application. Additional interactions will occur between the SMR applicant and the NRC staff following the application submittal through public meetings, written requests for additional information by the NRC staff, NRC audits, and NRC public workshops. RG 1.206, Position C.IV.7 provides additional guidance regarding applicant pre-application activities supporting both the NRC safety and environmental reviews.

A post-submittal orientation meeting with the NRC staff (normally conducted early during the NRC acceptance review) is recommended to reinforce pre-application interaction agreements on any design-specific issues, to present the overall format and content of the application, and to share schedule expectations. This practice is recommended during pre-application as well for significant topical reports, technical reports, or white paper submissions. The orientation meeting is also an opportunity to address any initial NRC staff acceptance review or subject matter questions. The individualized SMR format and content guide specification established in pre-application should serve to guide acceptance review activities.

The NRC/industry Design Centered Working Group (DCWG) process should be implemented where multiple COL applications are contemplated for a specific SMR design. The DCWG process enhances the review schedule by providing a generic forum to address and resolve issues that affect all applicable applications and facilitates the NRC's "one issue, one review, one position" approach to licensing.

The pre-applicant should be clear to request the desired feedback mechanism expected. The options for NRC feedback are dependent on the type of issue being addressed and are based on the one that provides reasonable stability and predictability during application review. It is generally expected in the following forms:

- NRC status review letter, providing staff inputs and insights related to the position(s) being proposed, including the staff's acceptance of portions of the position, and recommendations/requests for further work on particular topics. These agreements or insights should be incorporated into the individualized format and content guide so that the results of the pre-application engagement are consolidated within a familiar framework.
- ISG based on NRC staff review of a particular topic unique to an SMR design, ISG will later be incorporated into appropriate NRC guidance documents.
- NRC staff Safety Evaluations for material presented in a Topical Report format that is intended to be directly referenced and credited in the DC or COL application.
- Commission SRM for those matters that are submitted by the NRC staff to the Commission seeking resolution of a policy issue.

4.C.3. Application Content Changes

Compliance deviations from NRC SRPs, RGs, ISGs, and regulatory requirements must be documented in the DC and COL application FSAR. Based on precedent from the large LWR DC and COL applications, FSAR Section 1.9 typically provides a set of conformance evaluation

tables. These tables should document compliance with the NRC regulations and guidance documents in effect 6 months before submittal of the DC or COL application, which includes:

- NRC regulations (e.g., 10 CFR 50 and 10 CFR 52)
- SRP and Branch Technical Positions (NUREG-0800)
- Applicable Division 1, 4, 5, and 8 RGs
- Conformance with the FSAR content guidance in RG 1.206, including RG 1.206, Section C.III.1, "Information Needed for a Combined License Application Referencing a Certified Design," if applicable
- Industrial Codes and Standards
- Applicability of Experience Information

Any differences from regulatory requirements, SRP acceptance criteria, or RG positions are identified and justified, with references to the applicable FSAR or DCD section(s) that address the difference, as necessary. For a COL application, these tables need not readdress conformance and/or compliance with regulations, SRPs, RGs, codes and standards, and experience information for those portions of the facility design included in the referenced DCD.

NRC ISG documents associated with DC and COL applications for new reactors are additional guidance documents, available on the NRC website, which provide supplemental NRC review guidance beyond RG 1.206. Where applicable, ISG guidance should be addressed in the appropriate section of the application.

NRC could issue additional ISG documents in order to provide guidance in technical areas where the existing regulatory guidance does not adequately address certain features or aspects specific to the SMR design. This may be the appropriate approach for issues that are applicable to more than one SMR design, i.e., generic. Issues specific to a single design should be incorporated into the design specific format and content guide.

4.C.4. Format Considerations

The overall format and content of the FSAR for a DC or COL application is governed by NRC RG 1.206 (Reference 5) and NUREG-0800(Reference 4). Similar guidance for the Environmental Report is provided in RG 4.2 (Reference 6) and NUREG-1555, (Reference 7). The DC and COL application FSAR chapter numbering should be consistent with the SRP section and subsection numbering in NUREG-0800 and RG 1.206, Section C, Part I Standard Format and Content. The DC and COL application ER chapter numbering should be consistent with NUREG-1555. Guidance document sections that are not applicable should be noted as such in the FSAR and/or ER so that the numbering sequence remains consistent with the guidance document. Maintaining the FSAR and ER section numbering consistent with the respective format and content guidance documents supports incorporation by reference (IBR), facilitates the DCWG Reference COL (RCOL) and Subsequent COL (SCOL) process, and provides a consistent overall structure to the DC/COL application.

The COL applicant should consider use of the following tools when formatting the COL application:

- Use of IBR for DCD text and for ESP SSAR text (the ESP SSAR text can be IBR as well as DCD text) , where applicable
- Use of electronic links to DCD or other parts of the COL application
- Use of left margin annotations (LMA) for identification of standard content, site specific information, departures, supplemental information, and COL items
- Use of precedent should be included where appropriate and clearly identified

COL information requirements should be clearly identified and summarized at the end of each FSAR chapter. Conceptual design elements should be clearly defined. Clear criteria for what constitutes an ITAAC should be specified.

4.C.5. Level of Detail and Acceptable Standards

The DC and COL applicant should ensure that structure, system, and component interactions, such as support systems, and reliability assurance program and maintenance rule program requirements, are clearly identified and described, and reference is provided to the associated sections to supports efficient NRC staff reviews. Electronic links built into the FSAR, ER, and other parts of the application can be used to provide efficient access to referenced sections, subsections, tables, and figures.

A DC or COL application must contain sufficient technical information in scope and depth for the NRC staff to begin its detailed technical review and complete it within a predictable time frame. For example, detailed radionuclide source term information must be presented to support design basis accident atmospheric release dose analyses (FSAR Chapter 15), and normal liquid and gaseous radiological effluent release dose analyses (FSAR Chapter 11), and to support development of emergency preparedness and emergency plan considerations. Refer to NRC Office Instruction NRO-REG-100, "Acceptance Review Process for Design Certification and Combined License Application," (Reference 8).

The requirements of 10 CFR 52.80(a) specify that the contents of a COL application must include the proposed ITAAC, including those applicable to emergency planning, that the licensee shall perform, and the acceptance criteria that if met will provide assurance that the facility has been constructed and will operate in accordance with regulations. COL applicants should incorporate-by-reference the ITAAC included in the reactor vendor DCD. Only plant-specific ITAAC needs to be described in detail in the COL application. RG 1.206, Section C.III.7 provides guidance on possible COL application variations with respect to ITAAC.

Design Acceptance Criteria (DAC) has been used by design certification applicants in a limited number of design areas in lieu of detailed design information. The NRC expects that the COL applicant will include detailed design information in the areas where DAC were used during the design certification. RG 1.206, Section C.III.5 provides guidance for addressing the information

necessary to verify completion of instrumentation and controls design, human factors engineering design, piping design, and radiation protection design.

4.D. Implications of Manufacturing License Approach on COL Format and Content

SMR vendors may choose to utilize the NRC Manufacturing License (ML) process under 10 CFR 52 Subpart F, with or without a Standard Design Approval (SDA). Utilizing the ML process, the SMR customer is responsible for addressing all environmental, site, construction, and operation issues in connection with the COL application. ML licensees may only transport manufactured reactors to licensed sites with either a construction permit (CP) or COL. NRC approval for siting and construction will be the responsibility of the SMR customer upon its submission of either an ESP, CP, or COL application as such the license application content should address all site-specific issues, including environmental issues. COL applicants are permitted to reference the ML in the same manner in which standard design certifications are referenced, as stated in 10 CFR 52.73. In doing so, the COL application referencing an ML approved design must contain information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the FSAR or in the ESP for the site.

4.E. Consideration of SMR Generic Industry Issues

NEI is preparing a series of industry position papers for NRC endorsement that address generic SMR positions on various regulatory requirements. These include SMR regulatory positions on Decommissioning Funding, Emergency Preparedness, Physical Security and Security Force Staffing, Modularity, Control Room Staffing and Layout, Plant and Site Staffing, Defense-in-Depth, and Risk Metrics. Each of these areas impact the content of various parts of the DC or COL application, such as General Information (Part 1), FSAR (Part 2), Security Plan (Part 8), and Emergency Plan (Part 45), and should be consulted in the preparation of the associated application content. Upon endorsement by the NRC, these position papers will provide generic SMR guidelines for adequately addressing each issue. It is recommended that the applicable sections of the application specific Format and Content guide be amended so that a complete reference guide is available for application receipt review.

SMR license applications can accommodate single module or multi-module configurations. The license application should clearly define the scope of the application in terms of how many modules are to be licensed. Multi-module configurations should be clearly described in the application. Pre-application discussions with the NRC should agree on common section(s) that need to address multi-module configurations, as well as, any SMR unique and integrated design features, any departures from conventional reactor designs, and concurrent operations and construction for multi-module configurations.

SMR unique design features should also be considered in developing emergency preparedness provisions to be included in Part 4 of the application (e.g., source term, and release timing).

10 CFR 52.79 (a)(20) requires COL applicants to include in the FSAR address safety matters that must be resolved before issuance of a COL. The list of topics to be addressed within the FSAR includes the proposed resolution of Unresolved Safety Issues and Generic Safety Issues as well as insights from operating experience. Applicants for a design certification have a similar requirement in 10 CFR 52.47(a)(21). These safety issues include TMI Action Plan Items, Task Action Plan Items, New Generic Items, Human Factors Issues, and Chernobyl Issues. NUREG-0933 lists additional generic issues that are applicable to future reactor plants, and should be addressed in the FSAR. RG 1.206, Section C.IV.8 provides guidance for addressing these issues.

NEI Document 10-01, "Industry Guideline for Developing a Plant Parameter Envelope in Support of an Early Site Permit," provides guidance for the development of a plant parameter envelope in support of an ESP application, including aspects unique to SMRs.

5. Conclusion

Conclusion #1: Unique aspects of SMR technology require individualized pre-application engagement to define how to utilize existing application guidance.
Recommendations:

- Perform gap analysis of all regulations to identify regulatory issues to be resolved during pre-application program.
- Use risk-informed licensing approach to identify the extent to which LWR-based regulations should be applied to SMR designs.
- Use risk-informed licensing approach to supplement existing regulations.
- Use risk-informed licensing approach to develop new criteria where existing regulations are silent.
- Address scalable modular application topics to define what it means for a specific SMR technology.
- Incorporate all of the lessons learned and insights from pre-application engagement with the NRC into a consolidated location to guide the development of the application.

Conclusion #2: A well-planned approach to the licensing application process, including specification of the application format and content in the pre-application phase, is essential for a complete application and development and supports an efficient regulatory review process with regulatory certainty for designs that differ from near-term advance LWRs.
Recommendations:

- Make the most out of the pre-application period.
- Develop full set of regulatory documents that must be considered for the application.
- Obtain NRC endorsement of the documented set of revised application requirements to be summarized in a design-specific format and content guide.
- Obtain NRC endorsement of the Format and Content Guide for a specific SMR technology.
- Agree on long-lead physical test program.
- Agree on application section requirements that need to address multi-modular configurations.

- Agree on topical reports and technical reports to be submitted prior to application.
- Conduct an orientation meeting after application submittal to reinforce pre-application interaction agreements.

Conclusion #3: There are many lessons learned from advanced LWR that are applicable to the SMR licensing strategy.
Recommendations:

- Conform to current regulations to maximize familiarity to a known process.
- Use a systematic decision making process to the determine applicability of existing regulations.
- Capture and document agreements regarding the application format and content for unique design and operating features.
- Create a design-specific list of applicable regulatory documents.
- Establish a numbering system for the application consistent with SRP sections and subsections.
- Distinguish between technical reports and topical reports requiring separate SERs and type of response requested, e.g., agree, review, approve, endorse.

6. References

1. USNRC letter to Exelon Generation, dated March 26, 2002, "NRC Staff's Preliminary Findings Regarding Exelon Generation's (Exelon) Proposed Licensing Approach For The Pebble Bed Modular Reactor (PBMR)."

2. PLN-3202, "NGNP Licensing Plan," Idaho National Laboratory, June 26, 2009

3. SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements," Nuclear Regulatory Commission, July 16, 1993.

4. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," Nuclear Regulatory Commission, March 2007.

5. R.G. 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants (LWR Edition) 1978.

6. R.G. 1.206, "Combined License Applications for Nuclear Power Plants (LWR) Edition" Rev. 0, June 20, 2007.

7. R.G. 4.2, "Preparation of Environmental Reports for Nuclear Power Stations" Rev. 2, July 1976.

8. NUREG-1555, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants,” Nuclear Regulatory Commission, March 2000 and August 2007.

9. NRO-REG-100, “Acceptance Review Process for Design Certification and Combined License Applications,” Nuclear Regulatory Commission, January 2008.

10. LIC-500, “Processing Requests for Reviews of Topical Reports” Rev. 4, Nuclear Regulatory Commission, April 2008.