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Working Draft Rev 0M for NRC Discussion

Industry Guideline for Development of a Regulatory Engagement Plan

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NOTICE

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INDUSTRY GUIDELINE FOR DEVELOPMENT OF A REGULATORY ENGAGEMENT PLAN

PART I INTRODUCTION TO THIS GUIDANCE DOCUMENT

1 GENERAL

A Regulatory Engagement Plan (REP) can be a valuable tool for enhancing communication between a prospective applicant or pre-applicant[1] and the Nuclear Regulatory Commission (NRC) staff[2]. It can be used to document the agreement between the applicant and NRC staff regarding licensing approach, resolution of issues, schedule expectations, and other topics. The primary intent of such a document is to reduce regulatory uncertainty by establishing such agreements as early in the regulatory process as possible.

Information in an REP may include proprietary or sensitive information; see discussion elsewhere in this guidance regarding withholding of such information from public disclosure.

This document is not intended to substitute for a review of NRC regulations or regulatory guidance.

1.1 FORMAT AND CONTENT

This guideline provides suggested topics for a prospective NRC applicant to consider in developing an REP, and supporting information associated with the suggested REP topics. Part I contains information on the guidance document itself, along with general guidance for prospective pre-applicants and applicants. Part II discusses suggested topics for consideration.

1.2 NOTES ON USAGE AND OPTIONALITY

There is no regulatory requirement for developing an REP (sometimes referred to as Licensing Program [or Project] Plans). Both the concept of an REP and the specific content of any given REP are voluntary, and an REP is not part of a license application.

The intent of this guideline is to establish a suggested list of topics for possible inclusion in an applicant's REP. It is not intended to establish any minimum expectations for content, and it is not expected that any given applicant will use all the suggested content herein. Similarly, the grouping and order of presentation of suggested topics in Part II is not intended to prescribe a format. Certain reactor developers and other applicants established REPs prior to development of this industry guideline; they are under no obligation to modify prior REPs to conform to this guideline.

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[1] Prior to submittal of an application for an NRC permit, license, certification, etc., the party preparing for such a submittal may be referred to as a "pre-applicant." Prior to indicating an intent to prepare and submit an application, the party may be referred to as a "prospective" pre-applicant or applicant. For simplicity, the balance of this document will simply use the term "applicant" unless the distinction is important in the context of the applicable section.

[2] Most of the interface between an applicant and the NRC will be through the NRC staff. Interfaces with other NRC organizations (e.g., the Advisory Committee on Reactor Safeguards, the Commission itself, etc.) are discussed elsewhere in this guideline.

The list of topics in this guideline is not exhaustive. It is important for an applicant to communicate with its NRC staff project manager to identify the topics that are appropriate for inclusion in its REP.

1.3 RELATIONSHIP TO OTHER COMMUNICATIONS

The REP is not intended to fulfill any requirement or other obligation regarding formal communication with the NRC staff (e.g., under 10 CFR 50.4 or 52.3) . An REP should not be assumed to fulfill any formal reporting requirements under NRC regulations.

NRC staff periodically issue Regulatory Issue Summaries (RIS), requesting industry feedback. Historically, a new-reactor "scheduling RIS" has been issued approximately annually, requesting voluntary feedback from applicants to facilitate scheduling and prioritizing NRC staff resources. Generally, an REP should include most content requested via these RIS requests. When a new RIS is issued, the applicant should confirm with its NRC staff contact that no new information is being requested; otherwise, the applicant may consider supplementing its REP or providing discrete RIS responses.

Interactions between applicants and the NRC staff are governed by NRC rules, guidance,[3] policies, and practice that generally default to transparency and public access to documents. Information associated with project management and schedule management is not necessarily publicly accessible. fFr conservatism, an applicant should assume that all information provided to the NRC staff will be made public unless specifically designated otherwise. Guidance on requesting information be withheld from public disclosure under 10 CFR 2.390 is discussed in Part II.

2 COMMUNICATING WITH NRC

***NOTICE*:** Nothing in this guideline should be deemed to preclude either an individual or organization from reporting to the NRC a known or suspected safety concern, defect, or failure to comply with regulation and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. Anyone should feel free to communicate any safety concern to the NRC. It is the NRC's policy to encourage workers at NRC-regulated facilities to take safety concerns to their own management first, since the facility operator has the primary responsibility for, and is most able to ensure, safe nuclear operations. However, workers and other members of the public can bring safety concerns directly to the NRC at any time. It is the agency's responsibility to respond to those concerns in a timely manner and to protect the identity of the individual to the greatest degree possible. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. Refer to NUREG/BR-0240, *Reporting Safety Concerns to the NRC*, for additional information.

2.1 WRITTEN COMMUNICATION

Formal licensing submittals (e.g., application for license, permit, certification, etc., and submittal of associated reports, letters, and other documents) are governed by specific regulations such as 10 CFR

[3] The NRC conducts licensing activities through a combination of regulatory requirements and regulatory guidance. The applicable regulatory requirements are found in Title 10, "Energy," of the Code of Federal Regulations (CFR), Parts 1-199. Regulatory guidance is generally contained in regulatory guides, interim staff guidance, standard review plans, office instructions, and review standards. For detail, see https://www.nrc.gov/reactors/new-reactors/regs-guides-comm.html.

§§50.4 and 52.3. Guidance on electronic submittals can be found at https://www.nrc.gov/site-help/e-submittals.html.

Informal communication, e.g., via e-mail, may be appropriate, depending on the information being exchanged and subject to applicant internal policies and procedures. Applicants should be advised that any e-mail to the NRC staff may be included in a future hearing file or as a public document in the NRC's Agencywide Documents Access and Management System (ADAMS).

2.1 ORAL COMMUNICATION

Regular communication with the NRC staff (e.g., project manager) can be essential to successful interaction and progress of a project. Telephone calls may also be used routinely during NRC staff review in lieu of in-person meetings. Depending on the subject matter, notes from oral conversations may also be reflected in ADAMS.

2.2 COMMUNICATIONS PROTOCOLS

Many applicants will employ a "zipper plan" approach to communicating with the NRC staff, particularly as the licensing process progresses through issue resolution. Under such an approach, applicant and NRC staff points of contact are established, with counterparts established at the appropriate management levels to ensure predictable communications paths for escalation, if necessary (e.g., counterparts identified at the levels of Project Manager, Division and Office Directors, etc.). Such protocols vary in formality, and likely will change over time as a project progresses. It is advisable to establish and maintain a common understanding between applicant and NRC staff on how communications will be conducted.

2.3 APPLICANT/PRE-APPLICANT EXPECTATIONS

In establishing a schedule for project-related activities, it is important to understand general expectations that the NRC staff are likely to have as an applicant anticipates commencing a project. These issues should be discussed with the NRC staff as early in the process as practical to ensure common understanding of, or departures from, these expectations.

Public Participation

Except where excluded for commercially sensitive or security-related matters, most interactions between the applicant and NRC staff are conducted in public and/or documented in publicly-available records. Forums for public participation vary and include, but are not limited to:

- Participation in meetings (see https://www.nrc.gov/public-involve/public-meetings.html)
- Access to documents (see https://www.nrc.gov/public-involve/doc-comment.html and https://www.nrc.gov/reading-rm/adams.html)
- Participation in NRC-sponsored information sessions and scoping meetings
- Review of draft NRC safety evaluations, environmental impact statements, and design certification rulemaking-related documents
- Participation in hearings (see https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html)

Certain project management interactions between the applicant and NRC staff (e.g., associated solely with planning and scheduling) may not be open to the public; in these instances, it is the NRC staff's responsibility to ensure that such interactions do not "cross the line" into an area where they should be public.

Some applicants also choose to establish their own public outreach outside the licensing process, e.g., to inform nearby communities of impending site activities. Such efforts may provide useful means of public interaction and communication, they typically do not include NRC staff and will not meet NRC's criteria for "public participation."

Part II contains information about withholding information from public disclosure, as appropriate. (That discussion does not replace NRC regulatory guidance on that subject.)

Quality Assurance Program

Reactor license or design approval/certification applicants must establish and implement a quality assurance (QA) program pursuant to 10 CFR 50 Appendix B. Implementation guidance varies, but the most recent industry guidance endorsed by the NRC staff (as of the writing of this REP guideline) is found in NEI 11-04A [Revision 0], *Nuclear Generation Quality Assurance Program Description*. This NEI guidance reflects NRC endorsement of NQA-1-2008, *Quality Assurance Requirements for Nuclear Facility Applications*, and NQA-1a-2009 addenda.[4]

In terms of timing, the establishment of a QA program early in project development can be important, because it governs the conduct of safety-related activities including design; procurement; certain site characterization, testing, and fuel qualification activities (which may include qualification of legacy data); software development, validation, and verification; and associated training, records, and document control requirements. A QA program may not be submitted to or approved by the NRC staff for some time after project initiation, so the applicant incurs some regulatory risk in conducting safety-related activities prior to NRC staff approval of the QA program (e.g., risk of rework if NRC staff review indicates problems with the applicant's QA program).

Safeguards Information

10 CFR 73 governs physical protection of nuclear plants and materials. 10 CFR 73.21 applies to protection of safeguards information (SGI), a category of information associated with physical protection of reactors, spent fuel shipments, strategic special nuclear material, or other radioactive material. While SGI is not *classified* information, its handling and protection more closely resemble the handling of classified Confidential Information than other sensitive unclassified information. Establishing the capability to receive and store SGI may be important for a reactor developer or site licensee with respect to understanding certain design requirements such as protection from aircraft impact and the security design-basis threat.

Reporting of Defects

10 CFR 21 applies to individuals and organizations applying for or holding a license, permit, or certification, who discover that a facility, activity, or basic component fails to comply with NRC regulation or the Atomic Energy Act, or discover a defect, that could create a substantial safety hazard. The *reporting* requirements in 10 CFR 21 do not apply until an application has been docketed by the NRC. But such discovery could create a future reporting obligation if the related activities are relied upon after docketing. Additionally, 10 CFR 21 can play an important role in procurement of goods and

[4] A more recent version of NRC guidance was issued during preparation of this REP guideline. Regulatory Guide 1.28, *Quality Assurance Program Criteria (Design and Construction)*, Revision 5, endorses various versions of the ASME NQA-1 standard: NQA-1b-2011 Addenda to ASME NQA-1-2008, NQA-1-2012, and NQA-1-2015. At this writing, NEI 11-04A had not been updated to reflect the more recent version of Regulatory Guide 1.28.

services. Accordingly, prospective applicants may choose to implement a 10 CFR 21 (or "Part 21 like") reporting process early in the project.

Control of Non-Public Information

NRC records and documents generally are subject to public disclosure and available for inspection and copying at the NRC website, in ADAMS, and/or at the NRC Public Document Room. Exclusions to this policy include certain documents containing sensitive or commercially proprietary information, information withheld by statute, etc. Exclusions to public disclosure, including the requirements for requesting such withholding, are found in 10 CFR 2.390, and include information that is:

- Designated by Executive Order
- Related to NRC personnel rules and practices
- Exempted from disclosure by statute
- Trade secrets and commercial or confidential financial information
- Certain inter- or intra-agency correspondence
- Certain personnel and medical information
- Certain records compiled for law enforcement purposes
- Certain financial regulatory records
- Certain geologic and geophysical information and data, including maps , concerning wells
- Associated with physical protection, classified matter protection, or material control and accounting
- Submitted in confidence to the Commission by a foreign source.

An applicant has the burden of requesting and justifying such withholding (which the NRC staff may or may not grant). Certain special categories of information are exempt from public disclosure "by default," but in some cases require special handling. Because of the specific requirements applicable to such information, additional guidance is not provided here, but an applicant should confer with NRC staff and/or internal legal counsel, as appropriate, to determine/establish the proper handling procedures for:

- Safeguards Information
- Classified Information (e.g., Confidential National Security Information)
- Export Control Information
- Applied Technology
- Sensitive Unclassified Non-Safeguards Information (SUNSI)
- Privileged (e.g., attorney-client privileged) information

Part II contains information about withholding information from public disclosure, as appropriate.

3 PHASES OF ENGAGEMENT

An REP may be useful during pre-application interactions, in preparation of an application, and following submittal of an application. This guidance document discusses candidate topics during all phases of engagement, but there may be significant overlap in topics. Part II, Section 3 contains discussion topics.

One goal of an REP is to identify and resolve issues as early as practical during design development, so this guidance document suggests introducing many topics during the pre-application phase, described in Part II, Section 4. Guidance on discussion of those topics is not necessarily repeated in Part II, Sections 5 and 6, Application Process, and Post-Application Engagement. Those section focus more on process aspects of submittal and the NRC review process.

PART II REGULATORY ENGAGEMENT PLAN GUIDANCE

Part II discusses candidate topics for an applicant's REP and considerations for development of those topics. As Part II includes discussion/guidance that would not be expected to be included in an actual REP, this should not be considered a proposed REP outline.

The guidance includes supporting information, e.g., explanation, background, and/or pointers to external documents associated with the suggested topic. Applicants' selection of topics, and level of detail provided for each, should be based on the value of that information to establishing and maintaining effective communication with the NRC staff.

An applicant may choose to preface its REP with an Executive Summary that provides a high-level summary of the project, anticipated regulatory path, etc.

1 INTRODUCTION/PURPOSE OF REP

This category of information provides an introductory summary for the REP and reason for its development. It outlines basic information about the applicant, the structure of the applicant's company or project, the strategic approach an applicant expects to use, and the anticipated regulatory approach. There is also an opportunity to provide the NRC staff with summary-level information about the applicant's selected technology.

1.1 CONTACT INFORMATION

Contact information facilitates communication between the applicant and the NRC staff, and may include: the name of the applicant's organization; mailing and/or physical address, including office locations where appropriate; key telephone and e-mail addresses; any preferences the applicant may have regarding points of contact; and other information the applicant may wish to include regarding communication with the staff.

1.2 COMPANY/PROJECT STRUCTURE

To the extent useful in facilitating interaction with or understanding by the NRC staff, the applicant may choose to describe the structure of the applicant's company, organization, or project. The focus of this information should be on any aspects that could affect engagement with the NRC staff. Examples of this category of information could include:

- Applicant's relationship to an affiliate or parent company, particularly to the extent that the affiliate has existing applicant/licensee experience
- Applicant's ownership, e.g., if important with respect to questions regarding foreign ownership or control, export control, etc.
- Applicant's ability (for a site permit/license) to demonstrate financial qualification to carry out activities for which the permit or license is sought, and to provide for adequate decommissioning funding
- Project structure relative to affiliates' or contractors' prior experience under a regulated environment, quality assurance program, etc.
- Budgetary considerations with the potential to affect engagement schedules, applicant or NRC staff review resources, etc. (could include US government cost share, for example)
- Project's expected relationship, if any, to projects governed under a different regulatory authority (e.g., Department of Energy, another country's regulator, etc.)

1.3 SUMMARY STRATEGIC PROJECT APPROACH/GOALS

This category of information is intended to highlight, at a summary level, those aspects of the project's approach that could influence or impact the extent of pre-application engagement, the complexity of an application, NRC staff review schedule, or the need for NRC staff training and familiarity with the project. Considerations may include:

- Anticipated regulatory path(s), i.e., summary of expected application types (discussed later in more detail)
- Unique approaches with respect to compliance with NRC regulations or guidance
- The extent of first-of-a-kind design or unique implementation of previously demonstrated technology
- New or different implementation strategies, e.g., unconventional use of thermal power, novel fuel cycle considerations, unusual siting or emergency planning aspects, etc.
- Anticipated challenges or changes to existing NRC policy
- Unusual sequencing of licensing actions and deployment approach compared to prior, conventional commercial deployment (e.g., unconventional use of 10 CFR 50 construction permit, 10 CFR 52 combined license, untested 10 CFR provisions, use of research/test reactor provisions, etc.)

1.4 BACKGROUND

The applicant may choose to provide background information regarding the applicant, its design, or its regulatory or strategic approach, to the extent it helps establish useful context for regulatory engagement or review. Example topics might include:

- Extent to which the applicable reactor technology has been developed based on prior designs or technologies
- Extent to which development or deployment strategy is predicated on a specific need or strategic goal
- Discussion of technology or regulatory evolution to the extent it informs the regulatory review of the technology

1.5 REP APPROACH

This information can be used to describe the applicant's approach to use of the REP, including information such as:

- Extent to which the schedule for specific submittals, meetings, etc., will be projected in the REP
- Whether the REP will be updated periodically
- How/when the applicant will notify NRC staff of changes to information contained within the REP

2 TECHNOLOGY SUMMARY

Facilitating the NRC staff's understanding of a design, particularly to the extent the technology is novel or unfamiliar, could involve detailed discussions, presentations, and even formal training sessions. A summary description of the technology can provide a starting point for that familiarization. The applicant may provide varying levels of detail, depending on technology readiness/maturity, availability of information, and stability of the design. Importantly, the REP is not a design or licensing document; the developer should consider, however, the extent to which the design is likely to change and whether updates to that information should be provided (i.e., to avoid confusion over the status of the design). The developer also will want to ensure any proprietary information is appropriately controlled (see discussion later in this guidance regarding withholding of information from public disclosure).

For convenience, an applicant may wish to provide technology information in a separate appendix.

Candidate topics for technology description include (but are not limited to) the following. As with all the input to an REP, this information should be selected based on its relevance to informing the NRC review process.

- Size: this information could include reactor thermal energy output; gross and/or net electric output (if applicable); physical size of key components and/or structures; "footprint" of conceptual or actual site(s)
- Fuel: this information could include fuel type; key material and (if applicable) structural parameters; important design constraints (e.g., burnup, heat rate, etc.); discussion of the status of fuel qualification and/or existence or planned development of qualification data; and important or novel aspects of fuel handling
- Coolant: discussion here could focus on unique or novel aspects such as novel or unique materials, homogenous fuel/coolant combinations, and other unusual aspects compared to previous or conventional designs
- Moderation: this discussion may include a description of a design's moderation scheme, lack of or reduction in moderation for non-thermal designs, and/or any unusual material considerations
- Containment/Confinement: this information could include novel approaches to radionuclide retention, particularly for a design that expects to employ functional containment
- Usage (electric, process heat, etc.): this discussion could include the expected output of the plant, including variable functionality for a design intended to facilitate multiple uses such as cogeneration, desalination, or "plug-and-play" output options
- Technology Readiness: this information could include the extent to which a technology is proven, requires additional development and/or testing, and/or draws upon prior and/or existing knowledge
- Fuel Cycle Considerations: this discussion could include the extent to which the design takes advantage of existing fuel cycle infrastructure, relies on additional front-end fuel cycle development, and/or establishes novel approaches to front- or back-end fuel cycle aspects

3 REGULATORY STRATEGY

This category of information can be helpful in setting the stage for regulatory engagement, particularly with respect to establishment of the expected regulatory path. These topics may be applicable in pre- and post-application phases.

Establishing certainty around the regulatory strategy, particularly in terms of identifying key issues that need to be resolved early, can be the key to a predictable review schedule. That said, depending on technology readiness and other factors, an applicant may wish to emphasize the need for flexibility as strategies evolve. Meaningful pre-application engagement need not rely necessarily on a specific regulatory approach, and it is possible that such engagement will result in changes to strategies.

3.1 APPLICATION TYPE

When known by an applicant, the type of application(s) to be pursued is the foundation of engagement with the NRC staff. When not established as a final strategy, a description of possible or expected approaches nonetheless can be useful in framing interactions with the NRC staff.

Many of these approaches correspond to specific NRC guidance, references, and even expected review durations. Others do not; and past guidance and practice may be impacted by the introduction of novel technologies. Pre-application engagement regarding these approaches may significantly enhance regulatory predictability.

For many of the application types discussed below, no regulatory guidance specific to their format and content exists (e.g., Design Certification, Early Site Permit), so Regulatory Guide (RG) 1.206, *Combined License Applications for Nuclear Power Plants (LWR [Light Water Reactor] Edition)*, has been used as *de facto* guidance. (RG 1.206 currently applies to combined license applications.) RG 1.70, *Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants*, and NUREG-0800 also provide similar guidance. RG 1.206 is being revised as of the development of this document to reflect the application process for design certification, early site permit, and limited work authorization applications. In parallel, format and content guidance is being transitioned to NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition*. Equivalent guidance for non-LWRs has not been developed; adaptation of existing guidance for near-term applications could be a significant topic of pre-application discussion.

Staff acceptance, review, and approval of an application are conducted under guidance (NRO-REG-100, NUREG-0800, NUREG-1555, etc.) addressed within this document.

3.1.1 Early Site Permit (10 CFR 52 Subpart A)

The required content and applicable procedures for an early site permit (ESP) application are described in Subpart A of 10 CFR 52. Specifically, the general and technical content requirements are located in §§52.16 and 52.17. The regulation requires the application to contain a site safety analysis report; an environmental report as required by 10 CFR 51.50(b); and if emergency plan (EP) approval is sought by the applicant, a "major features" (i.e., partial) EP or complete and integrated EP, including applicable EP-related inspections, tests, analyses, and acceptance criteria (ITAAC).

An ESP may be design-specific (i.e., based on an identified design), or may be based on a specified "plant parameter envelope" (PPE), i.e., using a set of plant parameters that are expected to envelope the design of a reactor or reactors that might be later deployed at the site. NEI 10-01*, Industry Guideline for Developing a Plant Parameter Envelope in Support of an Early Site Permit*, Revision 1, provides guidance for development of such an application.

3.1.2 Standard Design Certification (10 CFR 52 Subpart B)

The required content and applicable procedures for a standard design certification (DC) application are described in Subpart B of 10 CFR Part 52. Specifically, the general and technical content requirements are in §§52.46 and 52.47 with additional specific requirements for designs that involve evolutionary changes or differ significantly from current light-water designs. The regulation requires the application contain a final safety analysis report; proposed ITAAC; and an environmental report as addressed in §51.55.

A DC application presents design information in two "tiers" in a single document called the design control document (DCD). Use of RG 1.206 for format and content guidance in developing the DCD facilitates subsequent integration with a COL application's FSAR.

3.1.3 Combined License (10 CFR 52 Subpart C)

The required content and applicable procedures for a combined construction and operating license (COL) application are described in Subpart C of 10 CFR Part 52. Specifically, the general and technical content requirements are in §§52.77, 52.79, and 52.80. The regulation requires that the application contain a final safety analysis report; proposed site-specific ITAAC; and an environmental report and emergency plan if not included as part of a prior ESP.

A COL application may reference a DC, an ESP, or both, or neither, and may also reference a Standard Design Approval (see Sectioon 3.1.5).

3.1.4 Standard Design Approval (10 CFR 52 Subpart E)

The required information content and applicable procedures for a standard design approval (SDA) application are described in Subpart E of 10 CFR Part 52. Specifically, the general and technical content requirements are in §§52.136 and 52.137 with additional specific requirements for designs that involve evolutionary changes or differ significantly from current light-water designs.

An SDA varies from a DC primarily in that an SDA does not result in a DC rulemaking. Additionally, an SDA may be prepared for a complete plant or for "major portions" of a plant. Additional discussion on a "major portions" SDA may be found in the Nuclear Innovation Alliance (NIA) paper, *Clarifying "Major Portions" of a Reactor Design in Support of a Standard Design Approval*, at http://www.nuclearinnovationalliance.org/standarddesignapproval, and also referenced in the NRC staff's *Regulatory Roadmap* (December 2017, ADAMS Accession Number ML17312B567).

3.1.5 Manufacturing License (10 CFR 52 Subpart F)

The required content and applicable procedures for a manufacturing license (ML) application are described in Subpart F of 10 CFR Part 52. The scope of this regulation is specific to the design and issuance of a license that authorizes manufacture of nuclear power reactors to be installed at sites that are not identified in the application. Specifically, the general and technical content requirements are located in §§52.156, 52.157 and 52.158.

The ML application regulation is considered largely "untested," so any plans for development of an ML application would benefit from significant early pre-application interaction with the NRC staff.

3.1.6 Construction Permit (10 CFR 50)

The required content and applicable procedures for a construction permit (CP) application are described in 10 CFR Part 50. The scope of the regulation is applicable to the licensing of production and utilization facilities in general. The general and technical information content requirements are located in §§50.33, 50.34(a), 50.34a, and 50.36b. Regulation requires the application contain a preliminary safety analysis report and an environmental report as addressed in §51.50.

RG 1.70 provides the guidance for format and content of a CP application for a power reactor. NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*, provides guidance for format and content of a CP application for non-power reactor.

3.1.7 Operating License (10 CFR 50)

The required content and applicable procedures for a operating license (OL) application are described in 10 CFR Part 50. The scope of the regulation is applicable to the licensing of production and utilization facilities in general. The general and technical information content requirements are located in §§50.33, 50.34, 50.34a, 50.36, and 50.36b. Regulation requires the application contain a final safety analysis report and an environmental report as addressed in §51.50.

RG 1.70 provides the guidance for format and content of a CP application for a power reactor. NUREG-1537 provides guidance for format and content of a CP application for non-power reactor.

3.1.8 Limited Work Authorization (10 CFR 50.10)

The required content and applicable procedures for a limited work authorization (LWA) application are described in 10 CFR Part 50. The LWA application content requirements are in §50.10; an LWA application must include a safety analysis report, an environmental report in accordance with §51.49, and a redress plan.

3.1.9 Research and Test Reactors

A *non-power reactor* refers to a research or test reactor licensed by the NRC pursuant to the provisions of 10 CFR 50.21(c) or 50.22 for research and development. Examples include a university research and teaching reactor licensed under Section 104c of the Atomic Energy Act (AEA) pursuant to10 CFR 50.21(c), and a commercial medical isotope production reactor licensed under AEA Section 103 pursuant to 10 CFR 50.22.

A *research reactor* refers to a reactor licensed under AEA Section 104c pursuant to §50.21(c) for operation at 10 MWth or less, and is not a *testing facility*. A *testing facility* is licensed under AEA Section 104c pursuant to 10 CFR 50.21(c) for operation:

- in excess of 10 MWth (e.g., NIST facility); or
- in excess of 1 MWth if the reactor is to contain:
    - a circulating loop through the core in which the applicant proposes to conduct fuel experiments; or
    - a liquid fuel loading; or
    - an experimental facility in the core in excess of 16 in^2 in cross-section

The AEA directs the NRC to impose under Section 104c "only such minimum amount of regulation of the licensee as the Commission finds will permit the Commission to fulfill its obligations." NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*, provides both format-and-content guidance for an application and NRC staff review guidance.

See https://www.nrc.gov/reactors/non-power.html and https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/research-reactors-bg.html.

3.1.10 Prototype Provisions

A *prototype plant* is defined in 10 CFR 50.2 as a reactor used to test design features, such as the testing required under §50.43(e). The prototype plant is similar to a first-of-a-kind or standard plant design in all features and size but may include additional safety features to protect the public and the plant staff from the possible consequences of accidents during the testing period.

There is not a separate licensing process for a prototype plant. 10 CFR 50.43(e) describes provisions for a design differing significantly from light-water designs licensed before 1997, and requires such designs to have demonstrated the performance of safety features through analysis, testing, experience, or a combination thereof, including sufficient test data, or the inclusion of additional requirements on siting, safety features, or operational conditions.

A prototype plant may be considered a non-power facility if less than 50 percent of the annual cost of owning and operating is devoted to sale of materials, products, energy, or services.

3.1.11 Other Considerations

a. "Phased Approach"

One goal of an REP is identification and resolution of key issues as early as practical in the development process. This consideration can be particularly important for a design that has little precedent with respect to applicable NRC guidance, or NRC staff review or familiarity. In response to suggestions that a review process analogous to the Canadian Nuclear Safety Commission's Pre-Licensing Vendor Design Review, the NRC staff initially discussed development of guidance regarding a "conceptual design assessment." After discussion, however, the NRC staff have observed that the existing US regulatory framework offers flexibility to conduct a similar review, albeit on a more ad hoc basis.

As examples, the NRC staff reviewed and generated preapplication safety evaluation reports (PSERs) for the General Electric (GE) Power Reactor Innovative Small Module (PRISM) sodium-cooled reactor and the DOE/General Atomic Standard Modular High-Temperature Gas-Cooled Reactor (HTGR). The review as conducted pursuant to the NRC's "Statement of Policy for the Regulation of Advanced Nuclear Power Plants" [51 FR 24643], described in NUREG-1226, "Development and Utilization of the NRC Policy Statement on the Regulation of Advanced Nuclear Power Plants." The goals of NUREG-1226 are to:

- encourage the earliest possible interaction of applicant, vendors, and government agencies, with NRC;
- provide all interested parties, including the public, with the Commission's views concerning the desired characteristics of advanced reactor designs, and;
- express the Commission's intent to issue timely comment on the implications of such designs for safety and the regulatory process.

The reviews were based on the submittal of a Preliminary Safety Information Document (PSID) for each design. NUREG-1226 provides that the NRC staff

> "[i]n general…will implement the Policy Statement by reviewing designs at the conceptual stage (before any formal application), developing guidance on the licensing criteria applicable to that design and making a preliminary assessment of the potential of that design to meet those criteria. This review will be done primarily by the staff (under the coordination and direction of the [Advanced Reactor Group] and will include the involvement of the [Advisory Committee on Reactor Safeguards]. Commission review will also be requested on those matters considered to have policy or other major implications. Once a design has reached the point at which a formal application for review is submitted (either a plant specific license application or an application for standard plant review), its review will use and build on the initial reviews done by the ARG at the conceptual design stage."

NUREG-1226 further indicates that, "[i]n general, it is desired that the scope of review of an advanced concept include review of the entire plant, [including] description of the plant design and its proposed design, safety and licensing criteria, including analysis of major accident scenarios demonstrating acceptable plant response; [p]robabilistic risk analysis; and [d]escription of those applicant sponsored [research and development] programs considered necessary to support development and licensing of the design.

More recently, however, NRC staff have expressed a willingness to review portions of a design in a similar manner. An applicant may wish, therefore, to propose specific topics that could be supported by this type of review. An REP could be used to establish agreement with the NRC staff on the type, extent, and format that such a review would take, and how the NRC staff would document their review.

An applicant should note that a PSER is a preliminary evaluation, and particularly to the extent it is based on a conceptual design, will not result in final approval of a design. It nonetheless may serve to identify key design and/or programmatic issues the developer may consider early in design.

If a given design or design aspect has progressed to the point of supporting more final reviews, the applicant may consider other types of submittals (e.g., topical reports).

b. Partial Application Submittals

Provisions for submittal of partial applications are addressed in regulation as follows:

- An applicant for a construction permit (under 10 CFR 50) or combined license (under 10 CFR 52) may submit an application in two parts pursuant to 10 CFR 2.101(a)(5). One part must include an environmental report under §50.30(f) or §52.80(b), as applicable. The other part must include a PSAR or FSAR (under §50.34(a) or §52.79, respectively). One part may precede or follow the other by no more than six months.
- An applicant seeking limited work authorization under 10 CFR 50.10 may submit that application as part of a complete application for a construction permit or combined license or as a partial application pursuant to 10 CFR 2.101(a)(9). In the latter case, the second part of the application must be submitted within 18 months of submittal of the first part. (An ESP applicant seeking LWA must include the LWA application with the ESP application.)
- 10 CFR 2.101(a-1) allows an applicant for a construction permit or combined license to submit an application in parts to allow for early consideration and a "partial initial decision" on site suitability matters. An application may be submitted in three parts, with the first part containing information on site suitability. The second and third parts, which constitute the remainder of the application as described in §§2.101(a–1)(1)(ii) and (iii) and 2.101(a–1)(2)(ii) and (iii), must be submitted within five years [10 CFR §§2.606 and 2.627].

As these are comparatively unusual provisions, an applicant may choose to ensure alignment on use of such a strategy in an REP, including early engagement with NRC staff.

c. International Considerations

Refer to Section 8.6 below. Significant overlap with another regulator or use of international standards, etc., may be a useful topic for inclusion in an REP.

3.2 NATIONAL ENVIRONMENTAL POLICY ACT

The NRC staff's obligations under the National Environmental Policy Act (NEPA) are described in 10 CFR 51. An applicant provides input, e.g., in the form of an environmental report, to the NRC staff for their review and preparation of the NRC staff's NEPA documentation. Content requirements in support of NEPA are described in the various parts of regulation associated with the application types discussed in 3.1 above.

Actions requiring NEPA documentation (e.g., an environmental impact statement [EIS] or supplement to an EIS) are listed in 10 CFR 51.20. Regulatory actions not given categorical exclusion and not specifically identified in 10 CFR 51.20(b) as requiring an EIS are evaluated by the NRC on an individual basis to determine whether an EIS or environmental assessment (EA) should be prepared. An environmental report (ER) provided by the applicant supplies the environmental input to support the NEPA documentation.

The general requirements for an applicant's ER are addressed in 10 CFR 51.45 with specific requirements for the various application types provided in 10 CFR §§51.50 through 51.55. Regulatory Guide (RG) 4.2, *Preparation of Environmental Reports for Nuclear Power Plants*, describes an acceptable method to satisfy ER requirements. RG 4.7, *General Site Suitability Criteria for Nuclear Power Stations*, describes an acceptable method to implement site suitability requirements and provides guidelines for determining the suitability of a candidate site for nuclear power stations. NUREG-1555, *Standard Review Plans for Environmental Reviews for Nuclear Power Plants* (ESRP), contains guidance for NRC staff review of an ER.

An applicant may reflect the approach to preparation of an ER in an REP, particularly where such an approach deviates from prior NRC staff experience.

3.2.1 Site-Related Environmental Input and Review

For an ESPA, COLA, CPA, OLA, and LWA, requirements for preparation of an ER are similar. This guidance is not intended to replicate existing guidance for preparation and review of an ER, or NRC staff preparation of an EIS. But an applicant may choose to capture certain aspects of the NEPA process in an REP, particularly if the applicant anticipates novel approaches to be employed. Potential topics for discussion in an REP are discussed below.

a. ER Introduction

- Status of reviews and consultations
- Novel methodologies
- Purpose and need

b. Environmental Description

- Novel considerations with respect to land, water, ecology, socioeconomics, geology, meteorology, noise, or related federal actions
- Approach to site data collection, particularly with respect to application schedule

c. Plant Description

- Novel aspects of plant design relative to environmental impact
- Use of cooling water

- Use of power (e.g., non-electric, still need offsite power connection, etc.)
- Novel approaches to construction, including modular construction, factory-built, etc.

d. Environmental Impacts of Construction

- Novel aspects of construction in impact areas described in 3.2.1.b (land, water, etc.)
- Radiological impacts to construction workers, particularly with respect to modular construction

e. Environmental Impacts of Operation

- Novel aspects of operation in impact areas described in 3.2.1.b
- Atypical approaches/impacts for water use (e.g., cooling), transmission systems, and fuel cycle considerations
- Decommissioning

f. Environmental Measurements and Monitoring

- Unusual measurements or monitoring, e.g., chemical

g. Environmental Impacts from Postulated Accidents Involving Radioactive Material

- Reflection of design's safety basis (as reflected in safety analysis report)
- Alternative approaches to defining severe accidents

h. Need for Power

- Approach to defining non-baseload need for electricity
- Approach to defining non-electric need for power
- Approaches unique to smaller plants

i. Alternatives

- Characterization of no-action alternative in context of purpose and need statement
- Siting alternatives, particularly for siting near population centers
- Plans for use of, or significant deviation from, site evaluation guidance found in EPRI's Site Selection and Evaluation Criteria for New Nuclear Power Generation Facilities (Siting Guide Report 3002005435)
- USACE jurisdiction, if applicable (see Section 4.5.2.b below)

j. Environmental Consequences of Proposed Action

- Identification of adverse environmental impacts of construction and operation for which no mitigation may be available
- Identification of irreversible and irretrievable commitments of materials used in project construction and operation
- Environmental impacts of postulated accidents

3.2.2 Research/Test Reactors

Refer to Section 3.1.9 above for discussion of research and test reactors. Research and test reactors often are discussed together but the information necessary to comply with NEPA requirements may be different. Applicants for a research reactor permit or license are subject to an environmental assessment

pursuant to 10 CFR 51.21, while test reactor applicants are subject to an EIS per §51.20(b)(1). Applicants should be prepared to supply the required supporting environmental information to the Commission in the form of an environmental report. ER content is addressed in §51.45 with additional content guidance provided in NUREG-1537, Part 1 (review criteria are addressed in Part 2).

Given the unique treatment of research/test reactors within the regulatory process, research/test reactor applicants may benefit from discussing strategy with the NRC staff and documenting any agreements or implications in an REP.

3.2.3 Non-Site-Related Environmental Input and Review

10 CFR 51.55 requires a design certification applicant to submit an "Applicant's Environmental Report—Standard Design Certification"; 10 CFR 51.54 contains similar requirements for a manufacturing license applicant.

Unlike an ER for a site permit or license (early site permit, construction permit, operating license, or combined license), a non-site ER is limited to addressing the costs and benefits of severe accident mitigation design alternatives (SAMDA), and the bases for not incorporating severe accident mitigation design alternatives in the design to be reviewed. Guidance for SAMDA analysis is provided in NUREG/BR-0184, *Regulatory Analysis Technical Evaluation Handbook*. NUREG-1555 provides guidance for NRC review of an ER's SAMDA analysis.

A standard design approval (SDA) application does not require the inclusion of an environmental report [see 10 CFR §§52.136 and 52.137], and §51.22(c)(22) identifies SDA issuance as a categorical exclusion. An SDA may be referenced subsequently in an application for a construction permit, combined license, design certification, or manufacturing license, which would be subject to an EIS or EA.

As with a site-related ER, the REP may be used to document novel approaches to be employed in the context of establishing common understanding with the NRC staff, particularly where early resolution of issues is anticipated to be important.

3.3 PRINCIPAL DESIGN CRITERIA

3.3.1 10 CFR 50 Appendix A, General Design Criteria

10 CFR §§50.34, 52.47, 52.79, 52.137, and 52.157 require an application to contain principal design criteria (PDC) for a construction permit, design certification, combined license, design approval, and manufacturing license, respectively. 10 CFR 50 Appendix A establishes the general design criteria (GDC) that are considered the "minimum requirements for principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which construction permits have been issued by the Commission." PDC establish the "necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety, i.e., structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public."

Pursuant to Appendix A, the GDC are not necessarily sufficient for all light-water designs, and additional criteria may be needed "in the interest of public safety." Similarly, not all GDC may be necessary or appropriate for a given design, in which case "departures" from the GDC must be identified and justified. In past practice, such departures sometimes have required an exemption.

An applicant who intends to deviate significantly from the GDC for a light-water design may consider discussing such deviations in pre-application interactions.

3.3.2 Non-LWR Design Criteria

NRC staff issued Draft Regulatory Guide (DG-)1330, Guidance for Developing Principal Design Criteria for Non-Light Water Reactors, in February 2017. This guidance (to be issued as Regulatory Guide 1.232) establishes guidance that non-LWR reactor designers, applicants, and licensees may use to develop PDC in support of the regulatory requirements cited above. The DG also describes guidance for modifying and supplementing these criteria to develop PDC that address non-LWR design concepts in three categories: sodium-cooled fast reactors (SFR-DC), modular high temperature gas-cooled reactors (mHTGR-DC), and a design-neutral category, advanced reactors (ARDC). The RG enables developers to establish PDC without documenting specific departures/exemptions from the GDC in 10 CFR 50 Appendix A.

3.3.3 Establishment of Design-Specific Principal Design Criteria

As with light-water reactor deviations from the GDC, exceptions to the ARDC, SFR-DC, or mHTGR-DC may require justification in order to attain NRC approval. Analyses such as risk-informed, performance-based assessments of licensing basis events may prove helpful in establishing these justifications.

Particularly where PDC are being developed for novel designs or modified in ways the NRC staff have not evaluated previously, the establishment of the PDC may warrant pre-application discussions with the staff.

3.4 SELECTION OF APPLICABLE GUIDANCE

3.4.1 NUREG-0800

NUREG-0800, *Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition* (SRP), provides the guidance used by NRC staff to perform safety reviews of construction permit or operating license applications under 10 CFR Part 50 and early site permit (ESP), standard design certification (DC), combined license (COL), standard design approval (SDA), or manufacturing license (ML) applications under Part 52. (As discussed in Section 3.1 above, the NRC staff also plan to transition format-and-content guidance from RG 1.70 to NUREG-0800 over time.)

While the SRP is not a substitute for the regulations, and compliance is not a requirement, for most application types, the regulation requires an assessment of the facility/design against the SRP in effect six months prior to docketing of the application. In most cases, this provision applies to "applications for light-water reactors" (or, in the case of an ESP, evaluation of the site against "applicable sections" of the SRP).

The SRP describes review criteria and procedures/methods used by NRC staff to conduct the review. Areas where the review standards are not anticipated to be relevant (e.g., exceptions to review and/or acceptance criteria) to the specific application may be especially important for early engagement and discussion. The absence of a non-light-water review standard may serve to make this an area of significant interaction and discussion in an REP.

3.4.2 NUREG-1555

NUREG-1555 (referenced in Section 3.2 above) provides guidance for the NRC staff for environmental reviews. Application types that require an applicant's environmental input (an ER) are identified in Section 3.2.1. The ESRP guides staff environmental review for a range of applications that include "green field" reviews of construction permit and operating license applications (Part 50), early site permits (Part 52), and combined licenses (Part 52).

Each licensing action (e.g., application type) reviewed by staff requires a specific type of environmental review for generation of the EIS. Appendix A of the ESRP provides a guide to the information needs that are relevant and required for specific application types. Where limited scope environmental reviews are concerned (i.e., LWAs, Early Partial Decisions on Site Suitability, and Pre-application Early Review of Site Suitability) engagement with NRC staff can be important to establish alignment on information content and level of detail. Similarly, areas where the review standards are not anticipated to be relevant (e.g., exceptions to the review and/or acceptance criteria) can be especially important for early agreement.

3.4.3 NUREG-1537

NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors*, provides guidance on all aspects of non-power reactor licensing provided in two parts. Part 1 contains acceptable safety analysis report format and content guidance and Part 2 contains the standard review plan and acceptance criteria used by the NRC staff reviewers.

Most of the design, operation, and safety considerations for non-power reactors apply to both test and research type reactors. The NUREG guidance for staff review and the criteria for acceptability should be followed for all non-power reactors. The differences for test reactors are discussed in the review criteria for each chapter. Overall, test reactors must conform to additional requirements beyond research reactors, i.e., conformance to accident dose requirements of 10 CFR 100.11, preparation of an EIS, and ACRS review.

The NRC recognizes in NUREG-1537 that not all guidance contained therein will be applicable to every design and suggests applicants review and carefully consider what guidance is applicable. The applicant should be able to justify deletion of any suggested content upon request.

Review of Parts 1 and 2 of the NUREG may identify areas that could benefit from engagement with NRC staff for clarification and/or agreement of a strategy and expectations prior to submittal.

3.4.4 NUREG-0933/Generic Issue Management Control System

The NRC has identified certain issues in the Generic Issues Program (GIP); the GIP routinely reports generic issue status and resolutions. Historically, NUREG-0933 was periodically updated through supplements that incorporated updated information on the generic issues. After Supplement 34, the Generic Issue Management Control System (GIMCS) is maintained exclusively online and generic issues identified since the previous publication of NUREG-0933 are identified in quarterly GIMCS reports. (See https://www.nrc.gov/about-nrc/regulatory/gen-issues.html.)

Design certification and combined license applications are required (10 CFR §§52.47(a)(21) and 52.797(a)(20), respectively) to contain proposed technical resolutions of unresolved safety issues and medium and high-priority generic safety issues identified and technically relevant to the design in the NUREG-0933 version that is current up to six months before the application docket date. Information on the GIP can be found in NRC Management Directive 6.4, *Generic Issues Program*.

Although the application content requirements in Part 50 do not specifically address the inclusion of resolutions to unresolved generic safety issues like Part 52, certain Part 50 information requirements are related to issues discussed in GIP.

Identification of potential issues related to the GIP and issues addressed in the GIMCS could be useful to capture in an REP.

3.4.5 Regulatory Guide 4.2

Regulatory Guide 4.2, *Preparation of Environmental Reports for Nuclear Power Stations*, is discussed in Section 3.2 above. An applicant may choose to capture certain aspects of ER preparation in an REP, particularly if the applicant anticipates novel approaches or significant deviation from such guidance.

3.4.6 Regulatory Guide 4.7

Regulatory Guide (RG) 4.7, *General Site Suitability Criteria for Nuclear Power Stations*, also is discussed in Section 3.2 above. Acceptability of a site is based on a detailed evaluation of the proposed site-plant combination and a cost-benefit analysis comparing it with alternative site-plant combinations. RG 4.7 describes the information necessary to demonstrate compliance with the applicable requirements in 10 CFR Parts 50, 51, 52, and 100. Particularly in the context of evaluation of alternative sites under 10 CFR Part 51, evaluation guidance found in EPRI's *Site Selection and Evaluation Criteria for New Nuclear Power Generation Facilities (Siting Guide Report 3002005435)* is generally accepted by the NRC staff. As above, an applicant may choose to include discussion of siting in an REP, particularly if the applicant anticipates novel approaches or significant deviation from such guidance.

3.4.7 Regulatory Guide 2.5

Regulatory Guide 2.5, *Quality Assurance Program Requirements for Research and Test Reactors*, describes a method acceptable to NRC staff for compliance with the overall quality assurance program requirements for research and test reactors. 10 CFR 50.34(a)(7) requires applicants for a construction permit to include a description of the quality assurance program applied to the design and construction of the structures, systems and components (SSCs) of the facility and 10 CFR 50.34(b)(6) requires operating license applicants to include the managerial and administrative controls in the final safety analysis report.

RG 2.5 recognizes ANSI/ANS-15.8-1995 as an acceptable method for complying with the program requirements of 10 CFR 50.34 for research and test reactors.

3.4.8 Regulatory Guide 1.70

Regulatory Guide 1.70, *Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants*, describes a standard format and the required content of safety analysis reports for light-water cooled nuclear power reactors acceptable to NRC staff under 10 CFR 50. As discussed in Section 3.1 above, this content is being transitioned to NUREG-0800 over time.

3.4.9 Regulatory Guide 1.206

Regulatory Guide (RG) 1.206, *Combined License Applications for Nuclear Power Plants*, provides guidance regarding information to be submitted in a combined license application and addresses many of the Part 52 application options. RG 1.206 is based primarily on the guidance provided in RG 1.70 that has been updated to reflect the information requirements for combined license applications and includes additional information guidance not provided in RG 1.70. Although prepared to provide guidance on combined license applicants, use of the format and content descriptions for design certification and early site permit applicants facilitates their subsequent integration with combined license applications.

As discussed in Section 3.2 above, guidance specific to many Part 52 applications does not exist, so RG 1.206 has been used as *de facto* guidance, in concert with RG 1.70 and NUREG-0800. RG 1.206 is being revised as of the development of this document to reflect the application process for design certification, early site permit, and limited work authorization applications.

3.5 USE OF STANDARDS AND INDUSTRY GUIDANCE

An application is likely to invoke several industry standards in describing various aspects of a plant's design, methodology for design and analysis, siting, etc. Particularly to the extent a given standard has not been endorsed by the NRC staff, or is being used in a novel way, an applicant may wish to present information in its REP to establish dialog with the NRC staff.

3.5.1 Consensus Standards

Consensus standards refer to those developed by standards development organizations (SDOs) such as American Nuclear Society, American Society of Mechanical Engineers, and American Society for Testing and Materials, among others, accredited by the American National Standards Institute (ANSI). Other international organizations such as the International Atomic Energy Agency or the International Organization for Standardization (ISO), also develop standards (which may or may not be considered "consensus standards," depending on one's definition).

NRC staff may endorse certain consensus standards, typically via regulatory guidance, which may, in turn, take exception to or supplement a standard via regulatory positions within that guidance. Federal law stipulates that agencies use standards developed or adopted by voluntary consensus standards bodies rather than developing unique standards unless such use is inconsistent with applicable law or is otherwise impractical. Other standards are incorporated into regulation by reference (e.g., as found in 10 CFR 50.55a). Additional detail on consensus standards in use by NRC staff can be found at https://www.nrc.gov/about-nrc/regulatory/standards-dev/consensus.html.

3.5.2 NEI Guidance

The Nuclear Energy Institute (NEI) develops various guidance documents and industry templates that are frequently endorsed by NRC staff and provide approaches and even pre-approved language for various topics such as Quality Assurance, Radiation Protection, Emergency Preparedness, and Risk-Informed Engineering, among others. Available NEI guidance documents may be found at https://www.nei.org/member-center/technical-reports (requires NEI member login),

3.5.3 EPRI Guidance

T Research Institute (EPRI) also develops various documents that can provide guidance in development of an application, such as the EPRI Siting Guide; other documents may provide support in other areas that underlie various aspects of an application, such as configuration management programs, ageing management (for license renewal and life extension), and the Utility Requirements Document (and Advanced Reactor Requirements Document under development). Topical areas within EPRI may be found at https://www.epri.com/#/portfolio/en/2018/programs/044648.

3.6 ASSESSING ALIGNMENTS/GAPS

An applicant may find that assessing its alignment with regulatory requirements (i.e., regulation and key guidance) is productive in establishing regulatory strategy, and that discussing significant "gaps" or novel approaches to meeting regulatory requirements can be useful in minimizing downstream programmatic risks. Specific engagement (via meetings, submittals, etc.) can be important in establishing alignment regarding the results of such assessments; however, there is no regulatory requirement for any formal assessment such as this (outside of the regulatory requirements to demonstrate compliance in the application itself). Assessments, if conducted, may take several forms.

3.6.1 Principal Design Criteria

Assessments of conformance with 10 CFR 50 Appendix A, or development of Principal Design Criteria (PDC) based on DG-1330 (RG 1.232) and associated departures, may include discussion of key issues worthy of early interaction. Establishment of PDC is discussed in Section 3.3 above.

3.6.2 Design Specific Review Standard and Risk-Informed Review

A Design-Specific Review Standard (DSRS) is intended to be a design-specific augmentation of the standard review plan (SRP, NUREG-0800), adding review criteria where the SRP does not adequately cover the design, or taking exception to SRP criteria where they do not apply to the design. There was a DSRS developed for each of the mPower and NuScale small modular reactors. The general consensus is that the DSRS effort is a useful concept but is limited in its value because of the natural tension between the need for early identification/resolution of issues and the availability of sufficiently detailed design information to enable the NRC staff to draw final conclusions early enough in pre-application interactions to make binding conclusions in a DSRS. An applicant may wish to consider this or similar approaches to assessing the availability and applicability of existing review guidance.

More generically, the concept of the DSRS derived from Commission direction to establish design-specific, risk-informed review approaches to new reactor designs. To facilitate a safety-focused review of a new design, it can be important to achieve a common understanding with NRC staff regarding those SSCs that are the most important to the safety basis of the design. This understanding will provide the planning basis for the safety-focused review and for establishing an appropriate review schedule, as discussed in Section 3.9.To the extent an applicant wishes to employ such an approach to focus NRC staff review on safety-significant aspects of an application, this could be a particularly useful pre-application topic.

3.6.3 Ad Hoc Assessments

Various approaches have been used in the past to establish mutual understanding between applicants and NRC staff; it may be helpful to an applicant to evaluate those past practices in determining whether to seek such engagement and what tools could provide value in such discussions. Examples include:

- The development and discussion of Regulatory Framework Documents by the Tennessee Valley Authority during initial development of a construction permit application for the Clinch River site (see https://www.nrc.gov/reactors/new-reactors/esp/clinch-river/pre-app.html)
- Development of regulatory gap analyses by NuScale Power, LLC as part of pre-application activities, including detailed reconciliation of existing light-water reactor regulatory requirements and guidance with the characteristics of the NuScale reactor plant design
- The Regulatory Gap Analysis for Modular HTGRs for the Next Generation Nuclear Plant (NGNP) project (see https://www.nrc.gov/reactors/new-reactors/advanced/ngnp/documents.html); this and other white papers submitted and reviewed under the NGNP program provided insights for acceptability of key HTGR licensing issues (these white papers also are being used to develop industry risk-informed, performance-based licensing guidance)

3.7 DESIGN-CENTERED REVIEW APPROACH

During the c. 2006 preapplication activities associated with large LWR applications, industry and the NRC staff established the "design-centered" review approach, whereby combined license (COL) applicants for the same reactor design (e.g., AP1000, ESBWR, EPR) cooperated in development of "standard content." Under this approach, a "reference" COL application (R-COLA) would be used for

review of standard content, and each "subsequent" application (S-COLA) would contain identical (or virtually identical) content. Under this approach – which was employed successfully for several COLA reviews – most standard content was reviewed only in the R-COLA, and S-COLA reviews were not subject to re-review of standard content, thus resulting in significant efficiency gains.

A design-centered work group (DCWG) also may be useful for a developer in terms of collaboration with applicants intending to incorporate the developer's design, site owner/operator input to the development and review of the design, and cooperation with applicants during the NRC staff review of the design.

An applicant wishing to participate in a Design-Centered Work Group (DCWG) may choose to include discussions with the NRC staff regarding the conduct of DCWG interactions, approaches for DCWG reviews, etc.

3.8 KEY ISSUES

Possible issues for discussion in an REP include but are not limited to those discussed below. The intent of such discussions would be early identification of issues, proposed approaches for resolution of such issues, and common understanding (between applicant and NRC staff) on how resolution will be reflected in the application.

3.8.1 Generic Issues

Refer to Section 3.4.4 for discussion of the NRC's generic issues program (GIP). Associated insights may be particularly helpful with respect to new technology and first-of-a-kind designs where an identified issue may not be initially considered as generic.

When potential issues are identified, clarification, agreement and documentation of the issue's technical relevance to a proposed design may be of particular value during a pre-application engagement.

3.8.2 New Reactor Issues

NRC staff and industry (via NEI) typically will track generic issues related to new reactors and periodically update progress in addressing/resolving such issues. At the time of this writing, NRC policy issues may be found at https://www.nrc.gov/reactors/new-reactors/smr.html for SMRs and at https://www.nrc.gov/reactors/new-reactors/advanced/policy-issues.html for advanced non-LWRs. NEI maintains similar lists, which may be accessed via communications with the NEI SMR Working Group and Advanced Reactor Working Group. Many of the representative issues discussed below are included in the NRC staff and/or NEI lists.

3.8.3 Selected Specific Issues

This is a representative list only; issues will vary with design and with time. The approach to engagement – e.g., the types of engagement/interaction as discussed in Section 4.2 below – will also vary depending on maturity of design, complexity of the issue, and other factors.

a. Staffing

- Minimum control room staffing (per regulation) vs. number of staff required to operate advanced designs (e.g., per task analysis)
- Shift complement – staff needed to perform non-control-room tasks

b. Safeguards and Security

- Design considerations for physical security
- Detection, assessment, and notification vs interdiction and neutralization
- Security staffing
- Material control and accounting for "unconventional" fuel

c. Emergency Planning

- Alternative approaches to establishing emergency planning zones
- Dose consequence criteria and analytical methods
- Exemptions and EP rulemaking

d. Fuel Qualification

- Planned approach to fuel qualification
- Use of historic/legacy data, including quality assurance implications
- Testing and analytical approaches
- Novel fuel forms

e. Seismic

- Anticipated challenges (e.g., high site seismicity, changing seismic characterizations)
- Consideration of seismic isolators
- Beyond-design-basis considerations

f. Flooding

- Anticipated challenges (e.g., site-specific analysis, tsunami evaluations)
- Susceptibility of design (or lack thereof) to flooding impacts
- Beyond-design-basis considerations

g. Aircraft Impact and "Loss of Large Area" Requirements

- 10 CFR 50.150 aircraft impact assessment
- 10 CFR 50.54(hh) aircraft impact threat and loss-of-large-area response

h. I&C, Digital I&C

- Common cause failure due to software failure, inter-channel communication, communication between safety and non-safety systems
- Cyber security

i. Accident Analysis Methodology

- Use of phenomena identification and ranking tables
- Development of codes and models
- Consideration/use of test data
- Applicability/application of Regulatory Guide 1.203, *Transient and Accident Analysis Methods*
- Interface with risk-informed framework
- Basis for SSC classification

j. Probabilistic Risk Assessment and Risk-Informed, Performance-Based Regulatory Framework

- PRA requirements for 10 CFR 50 applications
- Use of risk-informed, performance-based regulatory framework for establishment of non-LWR safety basis
- Potential use of 10 CFR 50.69

k. Human Factors

- Use of NUREG-0700, *Human-System Interface Design Review Guidelines*, and NUREG-0711, *Human Factors Engineering Program Review Model*
- Timing of Human Factors Engineering activities

l. Quality Assurance

- Use of NEI 11-04 and Regulatory Guide 1.28
- Alternative QA programs and consideration of international standards
- Timing of QA program approval and implementation, particularly for early development
- QA program applicability to testing
- Dedication of legacy data
- Software validation and verification requirements

m. Concept of Operations

- Fuel cycle length
- Refueling and other maintenance/outage approaches
- Other drivers for operational regimes, surveillance/inspection frequencies, etc.

n. ITAAC and Design Acceptance Criteria

- Incorporation of DC ITAAC and timing of closure
- Plant-specific ITAAC
- Physical Security ITAAC
- Emergency Planning ITAAC
- Use of Design Acceptance Criteria
    - I&C
    - HFE
    - Piping
- SECY-05-0197 Operational Programs

o. Nuclear Insurance and Disaster Relief

- Offsite liability insurance (Price-Anderson), including scaling for small reactors
- Onsite insurance (10 CFR 50.54(w))
- (See also https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/nuclear-insurance.html)

p. Ownership and Financial Assurance

- Financial qualification (proposed rule in progress at this writing; see also NUREG-1577 and DG-9004)

- Decommissioning funding (see https://www.nrc.gov/waste/decommissioning/finan-assur.html)
- Foreign Ownership, Control, or Domination (see https://www.nrc.gov/reactors/focd.html)

3.9 NRC REVIEW TIMEFRAMES

Pending review for completeness and acceptability for docketing, applications submitted for a limited work authorization, construction permit, operating license, early site permit, design certification, standard design approval, combined license, or manufacturing license are assigned a docket number but initially treated as a "tendered application." (See Section 5.3 below for additional discussion.)

Prior to submittal of an application, NRC staff may prepare a pre-baseline review schedule based on the anticipated scope of the review. During the acceptance review the pre-baseline schedule is adjusted as necessary based on the technical content of the application to develop an adjusted baseline review schedule. The baseline or adjusted baseline schedule determined by the complexity or uniqueness of the application content is transmitted with or subsequent to the application acceptance letter. Acceptance and docketing of the application does not guarantee a fixed review schedule. Deficiencies or complexities identified during the subsequent detailed technical review, or changes to the application during the review, can impact the review schedule.

The most recent NRC baseline schedule (in public meetings in 2014) for design certification review (for an SMR) is 39 months, including the design certification rulemaking. For a combined license, the nominal review schedule is 30 months, assuming reference to a design certification. These timeframes are subject to adjustment based on a variety of factors, including the level of design complexity, the number of safety systems, new safety features, alternatives to standard review acceptance criteria, departures or exemptions from design certification or combined licenses referencing a design certification, or variances from an early site permit included in a specific application. NRC staff engagement and identification of issues in an REP can facilitate alignment on such issues that have the potential to impact a review schedule.

Similarly, Topical Report applications (see Section 4.2.5) are subject to an acceptance review with a detailed review timeframe that can typically span 12 to 18 months for review and approval. Early engagement may provide significant benefit in support of alignment on a review schedule.

In addition to the submittals addressed above, availability of information in the form of responses to requests for additional information (RAIs) or requests for supplemental information (RSIs), and supporting information in the form of technical reports, calculations, and analyses can influence the review timeline. For example, applicant response to an RAI is typically expected within 30 days unless a different expectation is agreed upon.

Staff reviews but does not typically approve technical reports, calculations, or analyses. Such information is typically reviewed on a sample basis during the application review to determine if it is sufficient and adequate to support the information that is to be approved within the application. Such information may be reviewed in an audit environment (i.e., NRC staff conducting in-office reviews, during onsite audits, or via an "electronic reading room") or may be submitted formally (i.e., "on the docket"). Notably, NRC staff expectations have increased over time regarding the amount of information requested to be submitted formally, particularly with the advent of electronic means of facilitating significantly easier transfer of such information. Examples include plant/site implementing procedures, detailed calculations, and data files that, if printed, could constitute tens of thousands of pages of additional "docketed" content. Early engagement with NRC staff and management may be important in meeting the projected

timeframes for review by establishing expectations, mutual understanding of staff information needs, regulatory basis for those information needs, acceptability of auditable versus docketed information, and agreements with regard to content, level of detail, and regulatory treatment of the information.

NRC staff early engagement may prove beneficial in establishing common expectations in this regard.

4 PRE-APPLICATION ENGAGEMENT

This section provides guidance and candidate topics regarding engagement with the NRC staff prior to submittal of an application for NRC review and approval. An applicant should consider overlaps between this guidance and the topics discussed in Section 3 above. This section provides context and considerations for how that information can be addressed in the REP for the pre-application phase.

4.1 IDENTIFICATION OF TOPICS

The topics identified in Section 3 above are representative and not exhaustive. Early identification of topics to be discussed in pre-application interactions can be important to allocation of NRC and applicant resources, timely engagement and resolution of issues, and minimization of licensing risk.

4.1.1 Regulatory Strategy

a. Application Type(s)

- Anticipated Application Type (see Section 3.1 above)
- Novel regulatory approaches, if any

b. Deviations from Regulation and Key Guidance

- Exemptions (from regulation)
- Departures (from certified design)
- Exceptions and Clarifications (from/to guidance)

4.1.2 Applicable Generic and Industry Issues

Refer to Sections 3.8.1 and 3.8.2 above. Applicants should coordinate with NEI when issues have generic applicability or potential generic impact.

4.1.3 Applicable Design-Specific Issues

Refer to Section 3.8.3 above. Applicants may collaborate with NRC staff to identify any additional issues where early identification and resolution is warranted in the interest of minimizing regulatory risk. Applicants should coordinate with other members of the applicable DCWG and/or NEI when issues have generic applicability of potential generic impact.

4.1.4 Applicable Site-Specific Issues

Refer to Section 3.2.1 and elsewhere in this document for identification of site-related issues. Consideration of site-specific hazards such as flooding and seismic behavior, site meteorology, nearby industrial facilities/hazards, emergency planning, site-related physical security attributes, site hydrology, 10 CFR 100 siting criteria, and other site-specific items could be identified as pre-application topics for early resolution. Site interfaces also should be evaluated for potential early interaction when incorporating a certified design into a site license. Siting near collocated industrial facilities, on or near existing licensed reactors, or on or near US Department of Energy sites may be useful topics as well.

4.1.5 Prioritization of Topics

As described previously, a primary benefit of pre-application engagement is early identification and resolution of issues that otherwise might adversely impact licensing. Accordingly, topics for pre-application interaction may be prioritized based on complexity, anticipated lead time as regards development and licensing timelines, and applicant/NRC staff resource availability. Early interaction with NRC staff and management can contribute significantly to the selection of appropriate topics.

Priority might be considered for topics with potentially broad programmatic impact, such as QA program and procedure development; securing approval for receipt, handling, and storage of Safeguards Information; issues that could impact long-lead material and equipment procurement; fuel qualification; and testing, particularly for novel designs. (This is not an exhaustive list.)

An applicant may choose to document topic-based interactions and submittals in periodic communications (as part of, or supplemental to, an REP).

4.2 TYPES AND FREQUENCY OF INTERACTIONS

Various engagement types are available for different issues; the type and frequency of interaction will vary depending on where an applicant is in the development/application cycle, the level of complexity and "novelty" of a design, desire on the part of the applicant (including funding capability), and availability of NRC staff resources.

4.2.1 Routine Project Management Discussions

Prior to and following submittal of an application, routine and frequent interaction with the assigned NRC staff project manager(s) is a key to maintaining consistent understanding of the status of issue identification resolution. It is not unusual for an applicant to be in touch by phone several times a week during peak interaction periods. E-mail interactions are also common, although the applicant is advised of the potential for any written communication to become subject to public disclosure.

It is also common for the NRC staff to assign more than one project manager to an active site-related application – one for the safety review and a second for the environmental review. Coordination between multiple project managers is the responsibility of the "lead," although it is also not unusual for more than one individual to be assigned for each role, or for project managers to rotate through assignments. Project staffing for multi-year projects and maintaining continuity during staff rotations can be important topics for discussion with NRC management. (See also Sections 9.1 and 9.2 for discussion of NRC schedule information, fees, and estimates.)

4.2.2 Project Management "Drop-Ins"

"Drop-in" visits are periodic, non-public meetings between the applicant and project management team, which may include participation by various levels of NRC staff management as well. Such meetings typically are for general exchange of information on non-technical topics such as planning for future interactions, schedule discussions, etc., and not directly related to a regulatory action or decision. Limited discussion of technical issues can occur, but typically it will be in the context of status of review or identification of topics for separate discussion (see below). Accordingly, these meetings usually are closed to the public. The process is discussed in NRC Management Directive MD 3.5, *Attendance at NRC Staff-Sponsored Meetings*.

Many applicants also will schedule drop-in visits with the NRC Commissioners. Predictably, such discussions typically will focus on higher-level (e.g., policy) issues. It is also common practice to include

senior NRC staff management (e.g., Office Directors, Executive Director of Operations) in Commission drop-in visits.

4.2.3 Technical Discussions

Technical discussions with the NRC staff provide the opportunity for direct engagement with NRC staff reviewers in specific subject areas, and frequently will include reviewers and management. NRC staff typically will schedule one or more introductory meetings with an applicant before beginning to bill the applicant for staff time.

Meetings may be focused on individual topics or several topics can be combined, which may serve to make applicant travel more efficient. Meetings may be in person at NRC offices, at the applicant's office or site, conducted via telephone or video/web conference, or a combination. Such meetings typically will be open to the public and publicly "noticed" by NRC staff ten working days in advance. If the subject matter of a meeting is proprietary or otherwise sensitive, the applicant may request the meeting be closed to the public; in such cases, the NRC staff typically will produce a publicly-available summary of the meeting.

A site license will consist of a safety review and an environmental review. Each review includes a number of technical topics, with some overlap between the safety and environmental review. Coordination with the appropriate project manager is intended to provide for attendance appropriate to the subject(s) to be discussed.

4.2.4 NRC Staff Familiarization

Another goal of pre-application interactions is to maximize the NRC staff familiarity with the application and related technology in advance of submittal of the application. An applicant may wish to provide background information via meetings, conferences, visits to the applicant's site, visits to other locales, and even formal training. Coordination with the project manager(s) is important to ensure the appropriate NRC staff are available, and to ensure common expectation regarding whether NRC staff will bill the applicant for this time.

4.2.5 Written Submittals

Written submittals may take various forms, ranging from formal Topical Reports to less formal technical reports and white papers.

a. Topical Reports

Topical reports are stand-alone documents with an associated safety evaluation report (refer to Section 4.3.1) available for referencing by other applicants and licensees as appropriate. A topical report typically addresses a technical issue, methodology, or process submitted for review and approval for when approved is useable by other licensees in the licensing process. The report allows for a single NRC review and approval of a topic that is applicable to multiple applications.

Topical reports are reviewed independently of an application and, depending on the complexity of the review, may take 12-18 months or more for approval. When referenced within an application, topical reports are considered part of the application and are considered part of the licensing basis.

An applicant may wish to include in an REP its plans for developing and/or referencing other topical reports, including engagement with the NRC staff areas requiring additional discussion or review, potential technical issues, applicability of existing topical reports, proposed topical reports, strategy and scheduling considerations.

Topical report reviews are conducted using LIC-500, *Topical Report Process*.

b. Technical Reports

Technical reports generated by an industry group or applicant in support of an application typically are reviewed by NRC staff and considered only in support of information formally submitted for review and approval in an application. The NRC staff does not provide a safety evaluation for most technical reports, with some exception (e.g., certain NEI reports). The information in a technical report typically is reviewed in the context of support for and clarification of information in an application; when referenced in an application, the technical report typically is reviewed prior to or with the submitted application but the report itself is not "approved" and is not considered part of the application.

Because expectations may vary with respect to the review a technical report will receive – particularly when submitted in advance of an application – and the form of NRC staff feedback on a technical report, discussion of an applicant's plans for development and use of technical reports may be particularly useful in an REP.

c. White Papers

"White paper" is a generalized term describing a report that presents information or describes a position on a specific issue with the objective of increasing understanding, solving a problem or making a decision. A white paper during pre-application engagement may be used to describe a business case or present a topic or issue to seek applicant or industry alignment with NRC staff. White papers are typically employed and useful in the pre-application timeframe to address issues on a high level, summarize a proposed approach, or seek clarification on methodologies, guidance, policy, or technical issues. Because there is no specific requirement or guidance on development or review of a "white paper," an REP and NRC staff engagement can be important in ensuring common expectations for their use and review.

d. Other Approaches

The PRISM and HTGR Preliminary Safety Information Documents (PSIDs) are discussed in Section 3.1.11.a above. These examples provide insight into processes that can be proposed by an applicant for significant pre-application engagement with documented NRC staff feedback. An REP may be useful in establishing alignment on processes such as these.

4.2.6 Early ACRS engagement

The Advisory Committee on Reactor Safeguards (ACRS) is statutorily mandated by the Atomic Energy Act with four main purposes: to review and report on safety studies and reactor facility license and license renewal applications; to advise the Commission on the hazards of proposed and existing production and utilization facilities and the adequacy of proposed safety standards; to initiate reviews of specific generic matters or nuclear facility safety-related items; and to provide advice in the areas of health physics and radiation protection. The ACRS is independent of the NRC staff and reports directly to the Commission.

Regulations require that most application types discussed in this guidance are referred to the ACRS for review of those portions of the application that concern safety. NRC staff engagement of the ACRS typically will begin early within the regulatory process and will include ACRS review of the NRC staff's safety conclusions. (See https://www.nrc.gov/about-nrc/regulatory/advisory/acrs.html.)

Staff engagement to establish alignment on strategy and timing of ACRS discussions and review can be useful, particularly with regard to the timing and information needs associated with specific issues for ACRS discussion.

4.2.7 Escalation of Issues

During pre-application interaction on key issues – and particularly during review of the submitted application – disagreements or misalignments between the applicant and NRC staff may occur. Early identification and appropriate escalation of such issues can be very useful in timely resolution. The concept of a tiered interaction model (i.e., "zipper plan") as discussed in Section 2.3 of Part I can provide for a predictable escalation path. While escalation may seem confrontational, past practice and feedback from senior NRC staff management have indicated that early recognition of the need for escalation is much more productive than numerous iterations of questions. Establishment of an escalation approach with the NRC project manager can be a particularly useful early discussion.

4.3 NRC FEEDBACK

Particularly during pre-application engagement, it can be especially important to establish a common understanding of how NRC staff feedback will be provided.

4.3.1 Feedback as a Function of Submittal Type

NRC staff feedback mechanisms vary depending on the type of applicant input and applicant request for what level of NRC staff concurrence/approval is being sought. Approval of a Topical Report, for example, typically is provided via a Safety Evaluation Report (SER). Feedback on technical reports or white papers may be provided via NRC staff correspondence to the applicant (or NEI, for instance, in the case of a submittal on behalf of industry). Not all technical reports will be approved by NRC staff outside of an application; it is important that the applicant identify where there is benefit from prior concurrence/ approval, and establish agreement with the NRC staff on the form of that approval. Depending on the formality of the applicant submittal, NRC staff also may issue formal requests for supplemental information or RAIs.

Conclusions from meetings or other interactions may be provided via an NRC staff trip report, audit report, etc. When the subject of an interaction is proprietary or otherwise sensitive, NRC staff often will summarize discussions in a form appropriate for public disclosure but that does not divulge the sensitive information.

Establishing agreement in advance with NRC staff on the requested and expected type and extent of feedback can be essential to ensuring a predictable level of issue resolution.

4.3.2 "Finality"

When pre-application approval is sought, in addition to seeking alignment with the NRC staff on the form of that approval, it also can be important to understand and anticipate the degree of "finality" associated with it. Finality may vary as a function of any of the following factors:

a. Design maturity and future changes in design: for example, pre-conceptual information in pre-application discussions are unlikely to result in binding NRC staff conclusions; findings issued on a design may be subject to change if aspects of the design significant to those findings change during design development

b. Policy issues: preliminary NRC staff conclusions in advance of resolution of related policy issues could be affected if such policy issues are later addressed/resolved in a way contrary to those findings

c. Form of submittal: as indicated in 4.3.1 above, the form of NRC approval varies in part based on the type of request being made; formal Topical Reports approved via an NRC staff SER carry "more weight" in terms of a final decision than informal feedback on a white paper

d. Relationship to a docketed application: information directly tied to an application under review – such as an RAI – typically should result in a conclusion consistent with the findings ultimately to be made on the application itself

While not desired or expected as a matter of NRC staff practice, it also happens occasionally that NRC staff positions will evolve as a result of a change in reviewing personnel. For this reason, clear communication on the expected timing, form, and formality of NRC feedback can be an essential component of engagement.

4.4 SCHEDULE CONSIDERATIONS

The extent of pre-application interaction is a function of availability of information, interest in the applicant, and resource availability. Having a mutual understanding of the timing of such interactions can be critical, and conferring with the NRC staff (e.g., assigned project manager) on the following considerations can facilitate that understanding:

- **Scheduling of meetings and submittals:** scheduling discrete meetings, agreeing on frequency/timing of routine meetings, timing of planned submittals
- **Consideration of NRC staff and applicant resources:** establishing schedules based on availability of the key resources for specific subject areas
- **Agreement on timing/duration of NRC staff reviews:** for planned submittals, understanding not only submittal timing but also when NRC staff review is expected to occur and anticipated length of review
- **Communication of changes in schedule and scope:** understanding that schedules and priorities will change, maintaining clear and frequent communication, including early notification, when schedules change or scope of submittals/meetings evolves or changes

4.5 RELATION TO OTHER PROCEEDINGS/REVIEWS

4.5.1 Related NRC Reviews

It can be useful to ensure alignment on the relationship of an application to other ongoing or expected NRC activities. Often these relationships are obvious, such as a COL application submitted for review while the associated DC application is under review and has yet to be approved. Establishing "ground rules" for how such a review will be conducted can help support predictability during the common reviews. For example, COL application RAIs that are associated with a portion of the design that will be certified, or contentions related to such content, may be deferred pending resolution of related issues as part of the DC application review.

Similarly, when participating in a design-centered review approach, ensuring alignment between members of the design center and the NRC staff can be important when, for example, an RAI on "standard content" is preferred to be addressed in the R-COL application. Likewise, agreements on endorsement of adoption of R-COL RAI responses for S-COL applicants (i.e., "me too" letters) can improve efficiency of a design-centered review.

Sometimes connections between reviews may not be as obvious. For instance, as a result of the 2012 remand of the Waste Confidence Decision and Temporary Storage Rule, numerous licensing decisions were suspended pending resolution, and several new contentions were similarly held in abeyance. Following issuance of the final Continued Storage Rule in 2014, those suspensions were lifted. Conferring with NRC staff can help anticipate potential impacts of which an applicant may not be aware.

4.5.2 Other Review Bodies

Reviews by other agencies may occur in addition to, or as part of, an NRC application review. Anticipating requirements from and interactions with those other agencies can be important to predictability. This aspect of application development and review planning can be particularly important when/if another agency is acting in a cooperating review role or providing other collaboration with NRC staff.

a. US Department of Energy

The Department of Energy (DOE) usually will not have a regulatory role in commercial reactors. But as a function of siting, DOE may be involved in certain "landlord" considerations when siting a reactor on or near a DOE site, such as facility collocation with other facilities; memoranda of understanding regarding site access, site security, power distribution, etc.; training for site personnel; and emergency planning.

b. US Army Corps of Engineers

A memorandum of understanding between NRC staff and the USA Army Corps of Engineers (USACE) establishes a framework for coordination and participation between the two agencies associated with the review of proposed nuclear power plant applications. Like NRC, the USACE has responsibilities under the National Environmental Policy Act (NEPA), specifically associated with aquatic resources, including wetlands, under Section 10 of the Rivers and Harbors Act of 1899 and Section 404 of the Clean Water Act. Many nuclear plants licensed by the NRC also require USACE permits. The USACE typically will act as a cooperating agency. (See https://www.nrc.gov/docs/ML0825/ML082540354.pdf.) Applicants may wish to confer with the USACE district with jurisdiction over the associated site, similar to NRC staff pre-application reviews. While the USACE scope of evaluation is usually narrower than that of NRC, applicants may also wish to discuss with USACE and NRC staff the implications of differences and overlaps between USACE and NRC reviews, including the differences between evaluation criteria (for example, a key USACE site evaluation criterion is associated with "least environmentally damaging preferred alternative," while NRC's overarching site selection criterion is assurance that no clearly superior sites have been overlooked).

c. Federal Emergency Management Agency

44 CFR 353 Appendix A includes a memorandum of understanding between the Federal Emergency Management Agency (FEMA) and NRC with respect to FEMA participation in NRC

reviews and offsite emergency planning. Consultation with FEMA can support predictability in the emergency preparedness component of an application review.

Applicants should be mindful that site-specific support may result in FEMA levying fees to the applicant. Certain of these fees may be in advance of FEMA conducting an application review.

d. NEPA Consultations

During preparation of a site environmental report, an applicant will be expected to describe consultations with certain Federal, State, and local authorities. Such consultations may be associated with issuance of collateral permits, or with agency input to assessment of environmental impact. Typical consultations include US Fish and Wildlife Agency, State environmental agencies, and American Indian Tribes.

4.6 PRE-APPLICATION SITE VISITS, AUDITS, AND INSPECTIONS

Prior to submittal of an application, various audits and inspections can occur. NRC staff pre-application reviews can include various topics. Coordination with NRC staff (e.g., project manager) facilitates scheduling and alignment on the scope of any pre-application audits, including establishment of audit/inspection plans.

4.6.1 Quality Assurance

NRC staff may audit QA program implementation during application development, in the interest of identifying issues that should be addressed prior to completion of the application. Such an audit also may be in tandem with a review of site investigation or application development activities

Sometimes an applicant will submit its quality assurance program (QA) description in advance of the application. This may be in the form of a Quality Assurance Topical Report or similar stand-alone document. Once submitted – either prior to or as part of the application – NRC QA review is likely to take the form of a formal inspection.

See https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/qual-assure-license.html#report for additional details.

4.6.2 Testing

When development of an application includes or relies on testing, those test activities may be reviewed by NRC staff during pre-application interactions. Such reviews may take the form of simple site visits – e.g., for NRC staff familiarization of the test facilities and methods – or may be the subject of a pre-application audit, particularly where testing is being used to demonstrate or qualify first-of-a-kind technologies.

4.6.3 Site Selection and Site Characterization

It is common for NRC staff to visit the location proposed for siting a new reactor, as well as the alternative sites considered during the site selection process. Such visits inform the NRC staff's generation of the portion of an EIS associated with siting and site alternatives. The NRC staff also may perform one or more audits of site characterization activities such as subsurface exploration, seismic and geotechnical evaluation, hydrologic testing, cultural resource investigations, etc. Such audits inform not only EIS preparation but also facilitate familiarization in preparation for the safety review and identification of any issues that may need to be addressed prior to submittal of the application. Such audits may be combined with site visits.

4.6.4 Security/Critical Infrastructure

A site visit may include evaluation/assessment by the US Department of Homeland Security (DHS) of the site's protection from (or vulnerability to) terrorist attack in the context of critical infrastructure protection. An applicant should coordinate such a visit with the NRC staff project manager (NRC facilitates the DHS review), including any applicant role in the evaluation and the applicant's access to the results of the review.

4.6.5 Vendors/Suppliers/Supply Chain

Depending on the status of application development, testing, and fabrication of SSCs, the NRC staff also may conduct audits or inspection of key suppliers. An applicant may choose, for example, to conduct a portion of its pre-application audits in concert with (or in the offices of) a contractor providing related services. Similarly, a supplier providing key safety-related services as part of the facility's design may be subject to an NRC inspection.

5 APPLICATION PROCESS

This section provides guidance to the applicant in managing the transition from pre-application engagement to submittal of an application and commencement of "post-application" engagement (i.e., interaction during conduct of NRC staff review).

5.1 READINESS ASSESSMENT AUDIT

NRC staff may conduct one or a series of pre-application audits or inspections, as discussed in Section 4 above. Prior to the submittal of an application, the applicant may choose to request the NRC staff to conduct a readiness assessment audit of the completed (or near-complete) application. Historically, this audit has been a comprehensive review of the draft application over several days, involving a number of NRC staff and contractors. The conclusion of the audit is a series of observations by the NRC staff, focusing on issues that might preclude the acceptance of the application if left unresolved or uncorrected.

This audit can be very resource-intensive, but also can be valuable to the applicant in establishing the readiness of the application and providing insight into the likelihood of acceptance of the application.

As NRC staff findings during this audit are not binding, the conduct of the audit is not without risk: the NRC staff is not bound by the findings in the audit, and has no obligation to accept the application even if no significant findings were documented during the audit. Similarly, the NRC staff may conclude at a later date, including at the time of submittal of the application, that a shortfall in the application results in it not being suitable for acceptance.

Timing of the audit can be complex. The application should be close enough to being complete that the audit is meaningful and does not result in significant findings simply because of the lack of completeness of the draft application. Yet the audit should occur with sufficient time to resolve any identified issues prior to submittal of the application. Historically, readiness assessment audits have occurred approximately six months prior to the scheduled submittal of the application.

Additional details regarding the readiness assessment audit may be found in NRO-REG-104*, Pre-Application Readiness Assessment*.

An applicant may choose to document expectations regarding the scope, schedule, and outcome of a readiness assessment audit in the REP at the appropriate time.

At this writing, there is growing interest in enhancing the linkage of the readiness review assessment to the acceptance review process (see Section 5.3), in order to improve the relevance and value of the readiness review and the overall efficiency of the acceptance review process. Applicants should monitor developments in this area.

5.2 APPLICATION SUBMITTAL

An REP may establish the expected schedule for submittal of an application. Depending on the complexity and results of the various pre-application reviews discussed above, the schedule for submittal may change. Such a change may warrant an update to the REP, or may be communicated through more routine discussions between the applicant and NRC staff.

An REP may be helpful in establishing certain logistics around the application submittal, such as applicant expectations regarding hard-copy or electronic submittal tools. In the case of electronic submittals (which also can be useful for submittals besides applications), coordination in advance with the NRC staff can be particularly useful; see https://www.nrc.gov/site-help/e-submittals.html.

An REP also may be useful in seeking alignment on access to documents supporting the application. It is common for the NRC staff review to include review of supporting documents such as internal calculations and analyses, procedures, and reports. Such documents frequently are not at a level that would be appropriate for inclusion in the application itself or "on the docket," but facilitate NRC staff review, e.g., on a sample basis in support of the NRC staff's reasonable assurance finding. Access to such documents may occur during in-office reviews, site audits, etc., or may be provided by the applicant via a read-only online "electronic reading room" (e.g., see https://www.nrc.gov/docs/ML1514/ML15149A397.pdf).

5.3 ACCEPTANCE REVIEW AND DOCKETING

Following submittal of an application, the NRC staff will acknowledge receipt of the application, then conduct an acceptance review prior to formally docketing the application, developing a review schedule, and commencing the official application review (see, for example, 10 CFR §§2.101 and 2.815). Information regarding the acceptance review for an Early Site Permit, Design Certification, or Combined License application is found in NRO-REG-100 (see https://www.nrc.gov/docs/ML1407/ML14078A152.pdf). The NRC staff expectation for what constitutes a sufficiently complete application has evolved over the years, and the 2014 revision to NRO-REG-100 included a change to the standard for accepting an application from "enough information to 'begin' the review" to "enough information to 'conduct' the review." Additional focus also has been established around achieving a "high level of certainty" in the application review schedule as a condition of docketing the application.

As a result of the (nominally) 30- or 60-day acceptance review, the application may be (a) accepted for docketing, (b) deemed unacceptable for docketing, resulting either in the application being rejected or withdrawn by the applicant, or (c) considered "tendered but not docketed," if the NRC staff determines that the applicant can provide sufficient supplementary information within six months.

While the REP likely would not be amended "in real time" to reflect the results of the acceptance review, an applicant may choose to seek alignment with the NRC staff regarding communication during the critical period leading up to and during the acceptance review, in the interest of avoiding surprises.

5.4 NRC PROCESSES

Various NRC staff actions are initiated based on the anticipation of submittal of an application, and later based on acceptance and docketing of an application. The applicant may choose to capture agreement with the NRC staff on certain actions with the potential to involve/impact the applicant.

Typically, for example, at some point prior to the planned submittal of an application for a specific site, the NRC staff may conduct one or more public information sessions near the site, to inform the nearby public on the process that will be followed for NRC staff review. The applicant does not have a role in this session, but may be offered the opportunity to establish a presence, along with other stakeholders such as public interest or intervenor groups, during an "open house" preceding the session.

Once an application is accepted for review (as discussed above), the NRC staff will develop a review schedule, which the applicant may choose to reflect in the REP or may choose to reference via the NRC staff website.

Similarly, upon acceptance of an application that includes an opportunity for public hearing, a notice to that effect will be published in the Federal Register by the NRC staff. Such a Notice of Opportunity will establish a schedule by which a request for hearing must be filed, and describe the requirements for making such a request. (See https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing-license-applications.html.)

The NRC staff also will advise the public of the staff's intent to gather information necessary to prepare an EIS, and inviting the public to participate in the scoping process. One or more public scoping meetings typically will be convened and announced in the Notice of Intent.

While the majority of actions discussed above are the responsibility of the NRC staff, they include impacts to, interactions with, or opportunities for involvement by, the applicant. Accordingly, the applicant may wish to include discussion of these and related NRC staff actions in conferring with the NRC staff.

6 POST-APPLICATION ENGAGEMENT

Upon commencement of the formal NRC staff review, many processes are established as part of regulation, guidance, or NRC procedure, such that discussion within an REP may be of limited value. The applicant may choose, however, to use an REP to establish and maintain alignment regarding:

- Resolution of issues not directly addressed as part of review of the application
- Relationship of an application and its review to other proceedings
- Changes in the application content and/or scope
- Schedule, particularly with respect to NRC review and applicant response to RAIs

6.1 TECHNICAL MEETINGS

While pre-application interactions may have included technical meetings with the NRC staff, an applicant can expect numerous such meetings during the conduct of the review. Unless the subject matter is proprietary, security-related, or otherwise sensitive, such meetings typically will be open to the public and noticed by the NRC staff ten working days in advance. Such meetings may be at NRC offices, or held by phone or web conference. Meetings may also be held at the associated site or applicant office or a contractor office, provided they are closed to the public or provisions otherwise are made for public access.

During the course of the review, the need for such meetings frequently will occur such that maintaining a meeting schedule in an REP is not practical. The applicant may choose, however, to establish in the REP agreement on how such meetings will be scheduled, as well as a process for periodic review of the schedule for such meetings with the NRC staff project manager, and periodic review of schedule performance with NRC staff management. (Such schedule reviews typically can be considered non-public, as they do not involve regulatory actions or NRC staff decisionmaking.)

6.2 AUDITS AND INSPECTIONS

As discussed in terms of pre-application engagement, audits and inspections likely will continue during review of the application. As with technical meetings, the lead time on a given audit or inspection may not lend itself to capturing in an REP; but an REP may be useful in establishing agreement on how such interactions are scheduled, as well as establishing in advance known topics that will be the subject of an audit or inspection.

6.3 SUBMITTAL OF ADDITIONAL INFORMATION

6.3.1 Supplemental Information

During NRC staff review of the application, an applicant may establish from time to time the need to update information in the application. Such a need may arise, for example, from:

- Changes in information contained in the application (e.g., applicant organization information, changes in design information)
- Information identified during NRC staff interactions but not yet identified in formal requests for information (see below)
- Periodic mandated updates to the application (see below)

Routine communication with the NRC staff project manager(s) should include notification of pending supplemental information. An applicant may wish to include schedule information for known, major updates (e.g., scheduled periodic revisions to the application).

6.3.2 Requests for Additional Information

Requests for additional information (RAIs) are one of the primary means the NRC staff will use to collect additional information in support of the application review.

a. eRAI Process

The typical RAI is processed in accordance with NRO-REG-101, *Processing Requests for Additional Information*. Usually the NRC staff project manager will apprise the applicant during routine interactions that a question has arisen that may require an RAI. Using the NRC staff's "eRAI" database, the staff will issue a draft RAI via email, providing the applicant with an opportunity to request a clarification discussion (usually by phone), and to identify any proprietary information. Following such a discussion, the RAI may be withdrawn, or amended or confirmed, and then issued; the applicant may also identify during clarification discussions that an RAI will require longer than the standard assumed response time (see below).

b. Response Timing

The typical assumption made by NRC staff in scheduling a review is a 30-day applicant response to RAIs. In some cases – e.g., in the event of a complex topic, or an issue requiring consultation

among multiple applicants or a design center – a longer response time may be appropriate. An REP can be a useful tool to establish planning assumptions regarding RAI responses; an applicant also should notify the NRC staff project manager promptly if an RAI response is expected to be delayed or take longer than planned.

c. Application Changes

In addition to the answer to the NRC staff's questions, an RAI response also may identify impacts, if any, to the content of the application. Typically, an applicant can include a description of the impact and/or "markups" of the affected application text.

6.3.3 Application Revisions/Updates

Some content in certain application types requires periodic revision on a fixed frequency. For example, a COL application's FSAR requires updating annually while the application is under review, pursuant to 10 CFR 50.71(e)(3)(iii). When no minimum update frequency is specified in regulation, an applicant nonetheless is likely to update the application periodically, including any changes resulting from RAIs up through some preestablished point preceding the formal revision. An REP can capture expectations regarding the frequency of update, including coordination with other key schedule milestones.

6.4 FREQUENCY OF INTERACTIONS

As discussed in terms of pre-application engagement, an REP may be used to establish a routine interaction schedule with the NRC staff. While technical interactions will occur on an ongoing basis, and may not warrant schedule management at an REP level, an applicant may choose to use an REP to ensure alignment on a process for periodic review of the schedule for such meetings with the NRC staff project manager, and periodic review of schedule performance with NRC staff management.

6.5 REVIEW PHASES AND SCHEDULE

Following acceptance and docketing, the NRC staff will issue a review schedule for the application. The review typically is described in review phases, including a milestone date for the conclusion of each phase. NRO-REG-100 establishes baseline assumptions for a DCA review schedule of 42 months and for a COL application of 30 months.

Schedules will vary as a result of design, NRC staff resource availability, etc. Additionally, the NRC staff's convention for definitions of review "phases" changes over time, but as an example, a recent DCA review schedule was established based on the following phases:

Task	Task Name	Milestone
Submittal	Application Submittal	Jan 2017
Docketing	Application Accepted/Docketed	Mar 2017
Phase 1	Preliminary Safety Evaluation Report (SER) and Request for Additional Information	Apr 2018
Phase 2	SER with Open Items	May 2019
Phase 3	ACRS Review of SER with Open Items	Aug 2019
Phase 4	Advanced SER with No Open Items	Dec 2019
Phase 5	ACRS Review of Advanced SER with No Open Items	Jun 2020
Phase 6	Final SER with No Open Items	Sep 2020*

*This schedule does not include a schedule for finalizing the DC rule for this design.

Similarly, a recent ESP application review schedule was established as follows:

Task	Task Name	Milestone
Submittal	Application Submittal	May 2016
Docketing	Application Accepted/Docketed	Dec 2016
Safety Review		
Phase A	Preliminary Safety Evaluation Report (SER) and Requests for Additional Information	Aug 2017
Phase B	Advanced SER with No Open Items	Oct 2018
Phase C	ACRS Review of Advanced SER with No Open Items	Mar 2019
Phase D	Final SER Issued	Aug 2019
Environmental Review		
Phase 1	Scoping Summary Report	Oct 2017
Phase 2	Draft Environmental Impact Statement (EIS) Issued to EPA	Jun 2018
Phase 3	Responses to DEIS Completed	Jan 2019
Phase 4	Final EIS Issued to EPA	Jun 2019
Hearing		
	Mandatory Hearing by Atomic Safety and Licensing Board	**
Permit		
	Commission Decision on Early Site Permit	**

**This schedule does not include an estimate for the duration of a mandatory hearing or a contest hearing, if applicable.

6.6 RELATION TO OTHER PROCEEDINGS/REVIEWS

As discussed in Section 4.5 above, alignment on the relationship of an application to other NRC reviews or licensing proceedings can be important. This aspect of an REP can be particularly critical during the review itself; for example, a COL application that incorporates a DC application under review in parallel may have certain RAIs deferred pending resolution of issues as part of the DC application review. And an RAI on "standard content" may be deferred for an S-COL application pending resolution in the R-COL application.

7 WITHHELD INFORMATION

Certain information is not suitable for disclosure to the public. This information may be controlled by the applicant or by the NRC staff. Guidance on defining/categorizing this information is summarized below. An applicant may choose to discuss in the REP the types of withheld information that it expects to produce, and any specific controls or constraints expected to be applicable to that information.

An applicant may choose to seek withholding from public disclosure of the REP itself to the extent it contains commercially sensitive or proprietary information. An REP, however, may not contain security-sensitive information (e.g., Safeguards Information or Classified Information) unless the document itself is appropriately controlled.

7.1 CLASSIFIED INFORMATION

Historically, it is rare for NRC applicants to handle National Security Information or Restricted Data. Certain applicants, however, may require such access, such as may apply to those seeking to receive or use Category I special nuclear material (SNM). Access to classified information requires a personnel security clearance (NRC "Q" or "L") equal to or higher than the level of information and a need-to-know determination. Because the requirements for access to such information (see 10 CFR 95, *Facility Security Clearance and Safeguarding of National Security Information and Restricted Data*) can be considerably

more onerous than for other levels of sensitive information, an applicant should seek alignment with the NRC staff as early as possible on the applicability of such provisions.

7.2 SAFEGUARDS INFORMATION

Safeguards Information (SGI) is a category of sensitive, unclassified information concerning physical protection of reactors, spent fuel, strategic SNM, or other radioactive material. SGI requirements will apply to most reactor applicants, and are described in 10 CFR 73, *Physical Protection of Plants and Materials*. Additional information may be found in Regulatory Guide 5.79, *Protection of Safeguards Information* and to https://www.nrc.gov/security/info-security.html#safe, which in turn points to NRC's *Guide to Marking Safeguards Information*.

Requirements and guidance for implementing SGI controls are well established, so an REP need not elaborate on them necessarily, but an REP may be useful in establishing when an SGI program will be established, in the interest of applicant access to certain information that can be useful early in design (such as design-basis threat information).

7.3 SUNSI AND SRI

Sensitive unclassified non-safeguards information (SUNSI) is information that is generally not publicly available and encompasses a wide variety of categories (e.g., personnel privacy, attorney-client privilege, confidential source, etc.). Information about a licensee's or applicant's physical protection or material control and accounting program for special nuclear material not otherwise designated as Safeguards Information or classified as National Security Information or Restricted Data is required by 10 CFR 2.390 to be protected in the same manner as commercial or financial information (i.e., they are exempt from public disclosure).

"Security Related Information" (SRI) or "Security Related Sensitive Information" is a less commonly used term that describes that subset of SUNSI that is specifically related to security matters. As with other SUNSI, SRI is protected from disclosure under 10 CFR 2.390, except that, pursuant to 2.390(d)(1) and SECYs 2005-26 and -31, an affidavit is not required for SRI (see Section 7.4).

See also https://www.nrc.gov/reading-rm/sensitive-info/reactors.html, https://www.nrc.gov/reading-rm/sensitive-info/materials.html, and https://www.nrc.gov/reading-rm/sensitive-info/faq.html#q7.

As with SGI, early alignment with the NRC staff can be useful in establishing requirements for control of SUNSI.

7.4 10 CFR 2.390 AND WITHHOLDING INFORMATION FROM PUBLIC DISCLOSURE

10 CFR 2.390 sets forth the provisions for public access to information and the requirements for requesting withholding of information from public disclosure, including identification, labeling, and justification of information requested to be withheld, and requirements for submittal of an affidavit substantiating such a request. The applicability and use of §2.390 is well established and detailed discussion in an REP is not expected to be necessary. In the event of the need for clarification between the applicant and NRC staff, however, such clarification could be documented in an REP.

7.5 OTHER INFORMATION CONTROL REQUIREMENTS

Certain other requirements may apply to an applicant's control of information. In some cases, information controlled as a result of other (non-NRC) requirements may constitute a basis for requesting

NRC withholding of such information from public disclosure under 10 CFR 2.390. The following list is not exhaustive and is provided for reference information only.

7.5.1 EXPORT CONTROL

Applicability of and requirements associated with US Department of Energy 10 CFR 810, *Assistance to Foreign Atomic Energy Activities*, are beyond the scope of this document. NRC staff do not have a role in implementing or enforcing 10 CFR 810, except in limited areas of overlap described below:

- 10 CFR 810 applies to, among other things, transfer of technology for certain nuclear development activities, including certain illustrative items described in 10 CFR 110, *Export and Import of Nuclear Equipment and Material*, Appendices A-K and O [10 CFR 810.2(b)(9)]. 10 CFR 810 does not apply to exports authorized by NRC [10 CFR 810.2(c)(1)].
- Generally-authorized activities under 10 CFR 810.6 include transfer of technology to a citizen or national of countries listed in 10 CFR 810 Appendix A and working at an NRC-licensed facility; and certain activities at an NRC-licensed facility.
- Certain decisions under 10 CFR 810 require concurrence by NRC.

Accordingly, an REP associated with applicant-NRC interaction may not be expected to include significant discussion of Export Control requirements. To the extent an applicant's plans include significant aspects of import or export pursuant to 10 CFR 110, discussion of such plans in an REP could be useful.

7.5.2 APPLIED TECHNOLOGY

Applied Technology (AT) refers to a category of unclassified information established by DOE's Office of Nuclear Energy, Science, and Technology (NE) to preserve the foreign trade value of certain NE-funded information. Such designation is indicated through contractual requirements or in the task orders under which such information is developed. In October 2016, the DOE Acting Assistant Secretary for Nuclear Energy (NE) signed a memo ceasing the use of the AT label on new NE-sponsored work, but existing AT information is still controlled. While AT information may be unclassified, it may be subject to Export Control requirements. Approval for release may be very time consuming and could impact an applicant's access to legacy information.

NRC staff have no role in defining or controlling Applied Technology information.

7.5.3 OFFICIAL USE ONLY

Official Use Only (OUO) information is sensitive unclassified information, generated by a US Government Agency, that (1) may fall under Freedom of Information Act exemptions and (2) has the potential to damage government, commercial, or private interests if disseminated to persons who do not need the information to perform official activities. Generally, NRC staff will not publicly disclose this information except as required by law.

8 PARTNERSHIPS AND INDUSTRY PARTICIPATION

Establishing the extent to which an applicant is working in cooperation with various other organizations can be useful, particularly when the relationship has influence or impact on interaction between the applicant and NRC staff.

8.1 DESIGN-CENTERED WORK GROUP

See discussion in Section 3.7 above.

8.2 NUCLEAR ENERGY INSTITUTE

The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified nuclear industry policy on matters affecting its members, including the regulatory aspects of generic operational and technical issues. NEI's members include utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry. Applicants becoming aware of issues that have the potential to impact other applicants/licensees are urged to bring those matters to NEI's attention, and to work through NEI work groups and task forces to maximize the opportunities to address issues generically where applicable.

NEI often will interact with NRC staff on behalf of its members, and utilizes member experts to provide support for such engagements. NEI documents (such as this guidance document) also provide a platform for consistent guidance to applicants and – where appropriate – seeking NRC staff concurrence in resolution of issues.

An applicant may choose to cite NEI documents where applicable to address identification and resolution of issues. Use of pre-approved NEI templates may be helpful in addressing various topics (e.g., NEI template for a QA program description) with minimal regulatory risk.

8.3 STANDARD DEVELOPMENT ORGANIZATIONS

Standards Development Organizations (SDOs) are those bodies who produce technical consensus standards; SDOs in the US typically are organized under the American National Standards Institute (ANSI). ANSI does not produce consensus standards, but oversees SDOs and administers the process for accreditation of SDOs. Common SDOs associated with nuclear development include the American Nuclear Society, American Society of Mechanical Engineers, Institute of Electrical and Electronics Engineers, and many others. See Section 3.5.1 for information regarding selection and use of consensus standards.

An applicant may choose to document plans for use of such standards in an REP.

8.4 DEPARTMENT OF ENERGY

An applicant's relationship with the US Department of Energy (DOE) may have bearing on siting (e.g., where an applicant plans to site a plant on or near a DOE reservation), budget and schedule (e.g., where an applicant takes advantage of DOE cost-share agreements), or other aspects of an applicant's development plan. Such an applicant may elect to capture associated aspects of the applicant-DOE relationship in an REP where it influences NRC-applicant interactions.

8.5 OTHER ORGANIZATIONS

Other organizations may provide opportunities for collaboration or participation in ways that could influence NRC interactions. The Nuclear Innovation Alliance, Nuclear Infrastructure Council, and American Nuclear Society (apart from its SDO role) often address industry-level issues in a way similar to NEI, and may address technical or policy issues in a way an applicant might find useful to address in an REP.

8.6 INTERNATIONAL CONSIDERATIONS

8.6.1 Non-US Regulators

To the extent a developer intends to seek regulatory approval outside the US in addition to NRC review, an REP may be useful to establish common understanding with the NRC staff regarding sequencing of regulatory reviews (e.g., whether the NRC or another regulator will be "first" to review the design), expectations regarding reliance on one regulator's conclusions for meeting another regulator's requirements, and/or any expectations regarding cooperation or collaboration between two regulatory bodies.

8.6.2 Multinational Design Evaluation Programme

The Multinational Design Evaluation Programme (MDEP) is a multinational initiative for collaboration between national regulatory authorities over new reactor designs. As of 2017, 15 countries participate in MDEP, including five design-specific working groups and three issue-specific working groups. The Nuclear Energy Agency (NEA) facilitates MDEP and provides its technical secretariat services. See https://www.oecd-nea.org/mdep/. An applicant wishing to avail itself of MDEP processes may choose to include such plans in REP discussions.

8.6.3 International Atomic Energy Agency

The International Atomic Energy Agency (IAEA) conducts a broad range of functions including information exchange and collaboration among nuclear power developers, providing assistance to member states in developing nuclear infrastructure (including regulatory infrastructure), and supporting nuclear innovation. An applicant's participation in IAEA efforts that could impact interactions with NRC staff could include, for example, use of IAEA standards (similar to ANSI-based consensus standards), or participation in IAEA working groups that could impact resolution of technical issues of concern to NRC.

9 OTHER TOPICS

9.1 SCHEDULE

An REP may be used to establish a schedule for pre-application interactions, applicant submittals, and planned application submittal. It may also provide for periodic reviews of the schedule, including management-level review of schedule performance following submittal and docketing of an application. The topics that can be considered for inclusion in such a schedule are discussed in the sections above, and may be summarized as:

- Pre-application
    - Project kickoff and notification of intent to prepare an application
    - Routine project management drop-in meetings
    - Technical exchanges, including issue identification and resolution meetings and NRC staff familiarization sessions
    - Establishment of long-lead programmatic items such as QA program, SGI access, etc.
    - Submittal of Topical Reports, technical reports, white papers, etc.
    - Pre-application site visits, audits, and inspections
    - Pre-application readiness assessment

- Application
    - Resolution of readiness assessment issues
    - Finalization and submittal of application
    - Acceptance review
- Post-application
    - Docketing and NRC notifications
    - Establishment of review schedule, including ACRS interactions
    - Audits and inspections
    - Periodic management reviews of schedule performance

Certain of these topics may be particularly useful to discuss in an REP.

For example, an REP can be useful in establishing a specific schedule for planned pre-application submittals such as Topical and technical reports. The applicant and NRC staff can use the REP to establish alignment on that schedule, to communicate changes to the scope or schedule of such submittals, and to agree on prioritization of applicant and NRC staff resources in development and review of the submittals.

Similarly, an REP can establish the applicant's strategic plan for submittal of an application and resulting issuance of the applicable license(s), permit(s), and/or approval(s). While the NRC-issued review schedule will govern a proceeding after an application is docketed, and REP still can be useful in maintaining awareness of the applicant's strategic goals and facilitating mutual understanding between the applicant and NRC staff regarding impacts of issues and reviews on the overall plan.

9.2 BUDGET

Project funding may or may not be of concern to the NRC staff: specific sources of funding for a given project may not have any bearing on the NRC review, yet budgetary considerations can play a significant role in establishing a project's schedule. Establishing a dialog between the applicant and NRC staff can be essential to ensuring alignment on expectations in areas such as:

- Estimated NRC staff review fees, including review hours, use of contractors, etc., including assumptions for NRC site visits, travel costs, etc.
- Applicant limitations on funding during any particular phase of NRC interaction and review
- Resulting constraints on the extent of review being requested
- Cost-share agreements, e.g., with DOE
- Applicability/availability of fee waiver opportunities

Capturing agreements for such expectations in an REP can be helpful in assessing project management performance.

From: Peter Hastings
To: Segala, John; Reckley, William; Cubbage, Amy
Cc: TSCHILTZ, Michael; AUSTGEN, Kati
Subject: [External_Sender] REP Guidance Rev 0M for NRC discussion
Date: Tuesday, March 13, 2018 9:21:38 PM
Attachments: REP Guidance Rev 0M for NRC discussion.pdf

John, Bill, and Amy:

On behalf of Kati Austgen, please find attached draft Rev 0M of the NEI Industry Guideline for Development of a Regulatory Engagement Plan (REP) for NRC staff feedback. As you'll recall, NEI is not seeking formal NRC endorsement of this document; but to maximize the benefit of applicant-staff collaboration of an applicant-specific REP, NEI is interested in any staff feedback or questions.

Kati and I will be at the RIC the remainder of this week; if it would benefit your review for us to provide an overview of the document, please feel free to seek us out for a brief discussion.

Sincerely,
Peter Hastings
for NEI

From:	Reckley, William
To:	"Peter Hastings"; "AUSTGEN, Kati"; "TSCHILTZ, Michael"
Cc:	Cubbage, Amy; Segala, John
Subject:	Regulatory Engagement Plan Guidance
Date:	Thursday, April 19, 2018 10:06:00 AM
Attachments:	NRC Staff comments-suggestions on REP guidance.docx

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Sorry for the delays .. attached are some comments and suggestions from the NRC staff (several contributors) on the REP guidance. Since not provided for endorsement, we don't plan anything more formal than this email – and our commetnts/suggestions are just for your consideration. I think the primary one is given first – and that is to reinforce early in the document the usefulness for developers in the conceptual design stages. Our fear is that the completeness of the guidance might lead to the perception that a developer needs to have a handle on all of the material before engaging with us (and that would be overwhelming for some developers). One of the purposes of early engagement can be to educate the developer and identify key issues to take on first – and then the REP guidance and other documents can help formulate how that is done. Please give me a call if you have any questions and thanks for giving us an opportunity to review.

William D. Reckley
Advanced Reactor Program
william.reckley@nrc.gov
(301) 415-7490

General observations, comments, and suggestions:

- The length of the document could cause some developers who are in early design stages to get lost in details or be unclear of first steps. The staff wants to encourage regulatory engagement plans early in process to set objectives for effective pre-application engagement. A bit more discussion at the beginning, under General or as a Preface might help. Could begin with more explanation of purpose and benefits of developing a regulatory engagement plan.
    - Could move some of the regulatory 101 to an appendix to explain what DC, COL, CP, OL, SDA, ESP, LWA, and provide more emphasis on REPs and pre-application engagement in the body of document.
    - Could provide more explanation of regulatory engagement plan purpose and benefits. For example, these are some thoughts from the roadmap for consideration to be included in NEI guidance:
        - Non-LWR developers should prepare a regulatory engagement plan as an early step in the overall program to develop and deploy a new reactor technology. The regulatory engagement plan will reflect the technology readiness level of the reactor design, including innovative features, and the related R&D activities. The development of the regulatory engagement plan will include interactions with the NRC staff to reach mutual agreement on the desired outcomes of defined interactions and estimated costs and schedules for defined reviews. The regulatory engagement plan should pay particular attention to near-term activities needed to support the critical decision process and the development of submittals and NRC review plans.
        - The regulatory engagement plan and the associated NRC review plan should define the expected outcomes from early interactions (e.g., initial, conditional, conclusive, or final) and related matters such as costs and schedules.
        - To the degree that a particular outcome (e.g., conditional staff finding) is needed to support the development of design, research, or business plans, the regulatory engagement plan and associated staff review plan should be developed with that outcome in mind. The plans will also need to reflect the resource and schedule limitations facing all parties and appropriately prioritize, and in some cases adjust, the expected outcomes from interactions on a variety of topics.
        - A regulatory engagement plan could include numerous possible plans and combinations of interactions and submittals during the conceptual or preliminary design processes. Interactions with the NRC staff on proposed regulatory engagement plans would include consideration of the agency's capabilities and resource availability, recognizing the allocations for supporting non-LWR activities and the potential need to support multiple non-LWR technologies. The development of a regulatory engagement plan allows the designer and the NRC staff to prioritize issues and optimize interactions to address design alternatives or those issues most important to the overall project plan.
        - The regulatory engagement plan and associated NRC review plans should establish expectations in terms of outcomes, resources, and schedules. The NRC will work with a designer to establish a mutually agreeable review plan that includes a defined scope and level of review, desired outcome in terms of regulatory observations, particular areas of focus, review costs, and review schedules. The NRC staff will arrange meetings during the process to support the review, ensure the goals of the review plan are being met, and monitor costs and schedules. The scope and level of detail of preapplication submittals that will be necessary to achieve the desired regulatory outcomes should be determined as part of a regulatory engagement plan.
    - Could provide more examples of flexible preapplication engagement and discussed in item 1 below.
    - Could refer to advanced reactor policy statement to further encourage preapplication engagement: "To provide for more timely and effective regulation of advanced reactors, the Commission encourages the earliest possible interaction of applicants, vendors, other government agencies, and the NRC to provide for early identification of regulatory

requirements for advanced reactors and to provide all interested parties, including the public, with a timely, independent assessment of the safety and security characteristics of advanced reactor designs. Such licensing interaction and guidance early in the design process will contribute towards minimizing complexity and adding stability and predictability in the licensing and regulation of advanced reactors."

- Note that the document appears to focus more on licensing and the phase close to licensing rather than early engagement on pre-conceptual, conceptual and preliminary designs. The staff encourages early interactions and don't want people to wait until close to the licensing stage.

- Could explain that the REP is expected to be a living document and that it will be updated and expanded as plans evolve.

Specific Comments/Suggestions

1) Does not explain the full range of flexible regulatory review options (topicals, informal engagement, etc.). For preapplication it only focusses on PRISM-like review whereas regulatory engagement plans allow us to customize flexible preapp engagement to meet business needs and level of design completion. Could explain the full range of flexible pre-app engagements available and provide more examples of what could be done with topical report reviews, etc. Could also explain more about finality/conclusions the staff can make under various processes. The following discussion makes the point that the staff likes to see emphasized)

• Page 10 last paragraph, "Establishing certainty around the regulatory strategy, particularly in terms of identifying key issues that need to be resolved early, can be the key to a predictable review schedule. That said, depending on technology readiness and other factors, an applicant may wish to emphasize the need for flexibility as strategies evolve. Meaningful pre-application engagement need not rely necessarily on a specific regulatory approach, and it is possible that such engagement will result in changes to strategies."

• Page 14, 3.1.11a, Other Considerations – Phased Approach. "In response to suggestions that a review process analogous to the Canadian Nuclear Safety Commission's Pre-Licensing Vendor Design Review, the NRC staff initially discussed development of guidance regarding a "conceptual design assessment." After discussion, however, the NRC staff have observed that the existing US regulatory framework offers flexibility to conduct a similar review, albeit on a more ~~ad hoc~~ flexible and customizable basis." The section goes on to discuss the SFR and MHTGR PSERs and NUREG-1226. Could show more examples of prior preapplication engagements. ACR-700 Pre-Application Safety Assessment Report? NGNP? ESBWR with focus on testing, scaling and models? Or NuScale "gap letters"

2) Page 4, Section 1.3, it is not clear whether the paper suggests that the user should consider both an RIS response and a REP. The staff prefers both. The RIS for high level planning and budgeting, and the REP for detailed plans and objectives. Also typo in 3rd paragraph of section 1.3 Should be "For" instead of "fFr".

3) Page 4, Section 1.3 third paragraph suggest change, "Interactions between applicants and the NRC staff are governed by NRC ~~rules~~regulatory requirements, guidance, and policies ~~and practice~~…"

4) Page 6, QA Program, should reference NRC reg guide (more recent than the NQA version cited in NEI guidance). Also suggest adding that the QA Topical Report can/should be submitted early in the design process. See edit below

"In terms of timing, the establishment of a QA program early in project development can be important, because it governs the conduct of safety-related activities including design; procurement; certain site characterization, testing, and fuel qualification activities (which may include qualification of legacy data); software development, validation, and verification; and associated training, records, and document control requirements. The NRC staff encourages applicants to develop a QA program early in the design process, If a QA program is not ~~may not be~~ submitted to or approved by the NRC staff until after ~~for some time after~~ project initiation, ~~so~~ the applicant incurs some regulatory risk in conducting safety-related activities prior to NRC staff approval of the QA program (e.g., risk of rework if NRC staff review indicates problems with the applicant's QA program)."

5) Page 12, section 3.1.4 on SDAs says "An SDA varies from a DC primarily in that an SDA does not result in a DC rulemaking." The two significant differences are 1) that an SDA is an NRC staff approval versus a DC being a Commission approval via rulemaking, and 2) that the DC as a result has a greater level of issue finality than the SDA.

6) Page 12, last paragraph mentions RG 1.70. This is out of date (it is from 1978) and was largely superseded by RG 1.206. The staff also has non-LWR editions of RG 1.70. Reference to RG 1.70 may be better in a limited respect for CPs than RG 1.206 for part 50 applicants but is outdated and would not include any of the improvements currently being developed by industry initiatives (e.g., licensing modernization) and the NRC staff.

7) Page 13, Prototype Provisions, section should reference the "Regulatory Roadmap" document, which is where the NRC staff's white paper was provided as an enclosure.

8) Free meetings are mentioned in Page 30, Section 4.2.3, "NRC staff typically will schedule one or more introductory meetings with an applicant before beginning to bill the applicant for staff time." And, "Coordination with the project manager(s) is important to ensure the appropriate NRC staff are available, and to ensure common expectation regarding whether NRC staff will bill the applicant for this time." Some clarification might be useful:

- Technical discussions with the NRC staff provide the opportunity for direct engagement with NRC staff reviewers in specific subject areas, and frequently will include reviewers and management. Initial interactions between the NRC and developers will occur before the NRC formally assigns a project number and makes arrangements for sending invoices. The developers are effectively treated as members of the public during these initial interactions. These meetings and other interactions can be especially valuable to developers in learning about NRC processes, developing an REP, and introducing the NRC staff to a new reactor concept and associated development and deployment plans. After the opening of a project number, the NRC staff typically will schedule one or more introductory meetings with an applicant before beginning to bill the applicant for staff time.

9) Suggest section 4.3 also reference the regulatory roadmap paper as the staff described the various levels of staff approval in greater detail than described here.

10) Suggest adding PRA audits to Section 4.6

11) Consider adding a section on electronic submittals since there is a process that needs to be followed for these and early consideration of items such as links and packing slip could improve efficiency of longer-term preparation of submittals.

12) page 5 Section 2.1 “Written communications” add something to end of the sentence convey subject to release unless the applicant request withholding under 2.390 or the information is otherwise determined to be sensitive/non-public.

13) page 5 there are two section 2.1’s so the numbering needs to be fixed. The last sentence of the second section 2.1 “Oral communications” could sound chilling with respect to limiting communications. Perhaps wording such as below:

- Although not the usual practice, notes from oral conversations may, depending on the subject matter, also be reflected in ADAMS. If sensitive or proprietary information is shared during an oral conversation, a developer should convey that sensitivity such that the information is handled appropriately by the NRC staff, including any potential written records generated as a result of the conversation.

14) section 2.3, page 5, last line on the page reads awkwardly. Rather than “cross the line” the staff suggests saying that the project manager “ensures that communications are conducted in accordance within NRC’s policies and guidance.”

15) Safeguards Information, Page 6. At the end of the paragraph consider adding additional sentence – “Prospective applicants should contact the NRC for information about the process for obtaining access to SGI information and to discuss the appropriate timing of such interactions.”

16) Section 3, Regulatory Engagement, first sentence, suggested edit - An REP ~~may be useful~~ is highly encouraged during pre-application interactions, in preparation of an application, and following submittal of an application. An REP is very important in establishing the scope, schedule and expected outcomes for pre-application engagement.

17) first sentence on top of page 8.. suggested edit - For convenience, an applicant may wish to provide technology information in a separate appendix or a separate document.

18) middle of Page 1, Possible edit

> ~~Containment/Confinement~~Means of radionuclide retention: this information could include novel approaches to radionuclide retention, particularly for a design that expects to employ functional containment rather than a traditional pressure retaining containment structure

19) page 10 – bullet on technical readiness – Could refer to pre-conceptual, conceptual, preliminary, final design so the staff has a somewhat clear understanding of the design phase.

20) 3.1 application type – The last sentence of paragraph 3 on page 11 needs to be changed to match NEI’s recent transformation letter. Rather than “adaption of SRP,” discuss need for new guidance based on high level principles. Is the audience for this document supposed to be non-LWRs? If so, you need to be careful about how the SRP is referenced and possibly add references to ongoing activities (e.g., licensing modernization). Likewise, in paragraph 4. – NUREG-0800 SRP is LWR edition. The staff does not want to emphasize NUREG-0800 with respect to application content for acceptance review for non-LWRs. (see also other references to NUREG-0800 and RG 2.206 throughout the document)

21) Top of page 12 . “A DC application typically presents design information in two “tiers” in a single document called the design control document (DCD). Use of RG 1.206 for format and content guidance in developing the DCD facilitates subsequent integration with a COL application’s FSAR.” [Tiered submittals are not required but are expected based on precedence

and policy, but the Tiering could be revisited if desired] Also RG 1.206 has limited applicability to non-LWRs so this could be couched (again possibly reference ongoing activities to better define the scope and level of detail for non-LWR applications).

22) sections 3.3 and 3.3.3 and 3.6.1 on PDCs - Might need to clarify this in regard to light water SMRs and non-LWRs. LWRs would need to follow GDC or get exemptions. However, for non-LWRs the GDC don't apply so the statements about identifying and justifying departures from GDC is not relevant nor is the suggestion that exemptions may be required. Last sentence of section 3.3.3 rather than "may" warrant – suggest that establishment of the PDC for a specific design SHOULD be discussed before application is submitted. And refer to RG 1.232 as guidance for developing PDCs.

23) section 3.6.2 talked about DSRS – the staff does not want to set expectation that DSRSs will necessarily be developed for future designs.

24) section 3.6.3 – "ad hoc" assessments – "Gap Analyses" or another tem would be a preferred title for this section rather than ad-hoc assessments.

25) pages 40/21 presumes that the process will maintain a 6 phase review schedule concept. This may not be the case if the staff finds more efficient strategies (e.g., keeping a core team approach throughout the review). It also assumes a DCA review in 42 months and a COL in 30 months. This may not be the case depending on the technology, size, complexity, etc., and applicant performance.

26) Editorial - In many places a regulatory part is not cited properly. For example, 10 CFR 52 should instead be cited as 10 CFR Part 52. Sections of the regulation (e.g., 10 CFR 52.63) and paragraphs (e.g., 10 CFR 50.43(e)) are cited correctly.

27) page 35 section 4.6.2 should also refer to the appendix to the regulatory roadmap paper which described in greater detail the process for determining testing needs.

From: Reckley, William
To: "Peter Hastings"; "AUSTGEN, Kati"
Cc: Segala, John; Cubbage, Amy
Subject: Regulatory Engagement Plans
Date: Thursday, April 26, 2018 3:07:00 PM

Sorry for the delay .. you had asked about a couple specific phrases within the REP guidance and I'll offer my view below;

1. In Section 2, "Technology Summary," I don't see a major issue with the phrase "even formal training sessions." We did these in the past – sometimes using DOE as a vehicle to avoid any perceived conflict. In other cases, vendors have provided the equivalent of training sessions to the staff. Just like in other areas, the designer should ensure that the outcome and estimated costs of an interaction are understood – for example whether the staff (and how many staff) will be charging against their project number for the training.

2. In Section 4.6.2, you asked for our guidance or an example of a pre-application audit plan.
    - Pre-application Audit Plan for NuScale Risk Insights Drawn from PRA (ML16126A176)
    - Pre-application Audit Plan for NuScale Human Factors Engineering (ML16195A178)

    The NRO office instruction providing guidance is NRO-REG-108 (ML081910260) –which I am not sure is kept up to date but the processes do not change that much so while I might caution against a reference to it, it nevertheless gives one a good idea of how audits are conducted

3. In Section 4.2.5, I think the terms from the roadmap are OK but as stated, we are not always consistent. It is probably not worth the effort to try to force a terminology since some vendors are already established in what they call reports. As with everything else, the REP and subsequent interactions need to make clear that there is a common understanding of the reports being submitted and the desired outcomes.

4. In regard to drop-ins and pre-application meetings are being charged (pages 29-30), we did offer some language about pre-application meetings occurring before our opening of a project number. I am cautious about adding language about the charging for drop-ins and some pre-application meetings (other than those occurring before a project number) because NRC policy could change. However, at the current time, many drop-ins will involve managers (branch chiefs and above) and these hours are not charged to a project or applicant – there may be some charges depending on the role of a project manager or other staff. Some drop-ins may also involve discussions of generic activities or matters not directly related to a pending or future application and these discussions are also usually not charged against a project or docket number. It might be easier to just include a sentence under the higher level 4.2 interactions that reinforces that a designer should make sure they define the expected outcome and costs or any interaction.

Feel free to give me a call or email if you wish to discuss. Thanks..

William D. Reckley
Advanced Reactor Program
william.reckley@nrc.gov
(301) 415-7490