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Presentations for November 2, 2017 Public Meeting
Regulatory Improvements for Advanced Reactors

1) NRC Slides
   - Opening
   - Regulatory Roadmap / Testing Needs and Prototype Plant
   - Future Meetings

2) NEI Slides
   - Meeting Challenge of Providing Fuel for Advanced Reactors (Higher Assay Low Enriched Uranium)
   - Regulatory Engagement Plans (with excerpts from draft white paper)

3) American Nuclear Insurers Presentation

4) Advanced Reactor Design Criteria
   (ADAMS Accession No. ML17291A292)

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Public Meeting on Possible Regulatory Process Improvements for Advanced Reactor Designs

November 2, 2017

Telephone Bridge
(888) 793-9929
Passcode: 5862761

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Public Meeting

- Telephone Bridge

  (888) 793-9929

  Passcode: 5862761

- Opportunities for public comments and questions at designated times

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Outline

- Introductions
- Regulatory Roadmap
- Higher Assay LEU
- Regulatory Engagement Plans
- *Lunch*
- Financial Protection (Insurance)
- Advanced Reactor Design Criteria
- Licensing Modernization Project
- Functional Containment
- Other Topics
- Public Comment Period

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Regulatory Roadmap

- Design Processes (Critical Decisions, DOE model)
  - Preconceptual design process
  - Conceptual design process
  - Preliminary design process
  - Final design process
  - Construction
- Align with Technology Readiness
  - Research and development
  - Licensing project plans
- Other options available but desire to center around an approach to support common understandings

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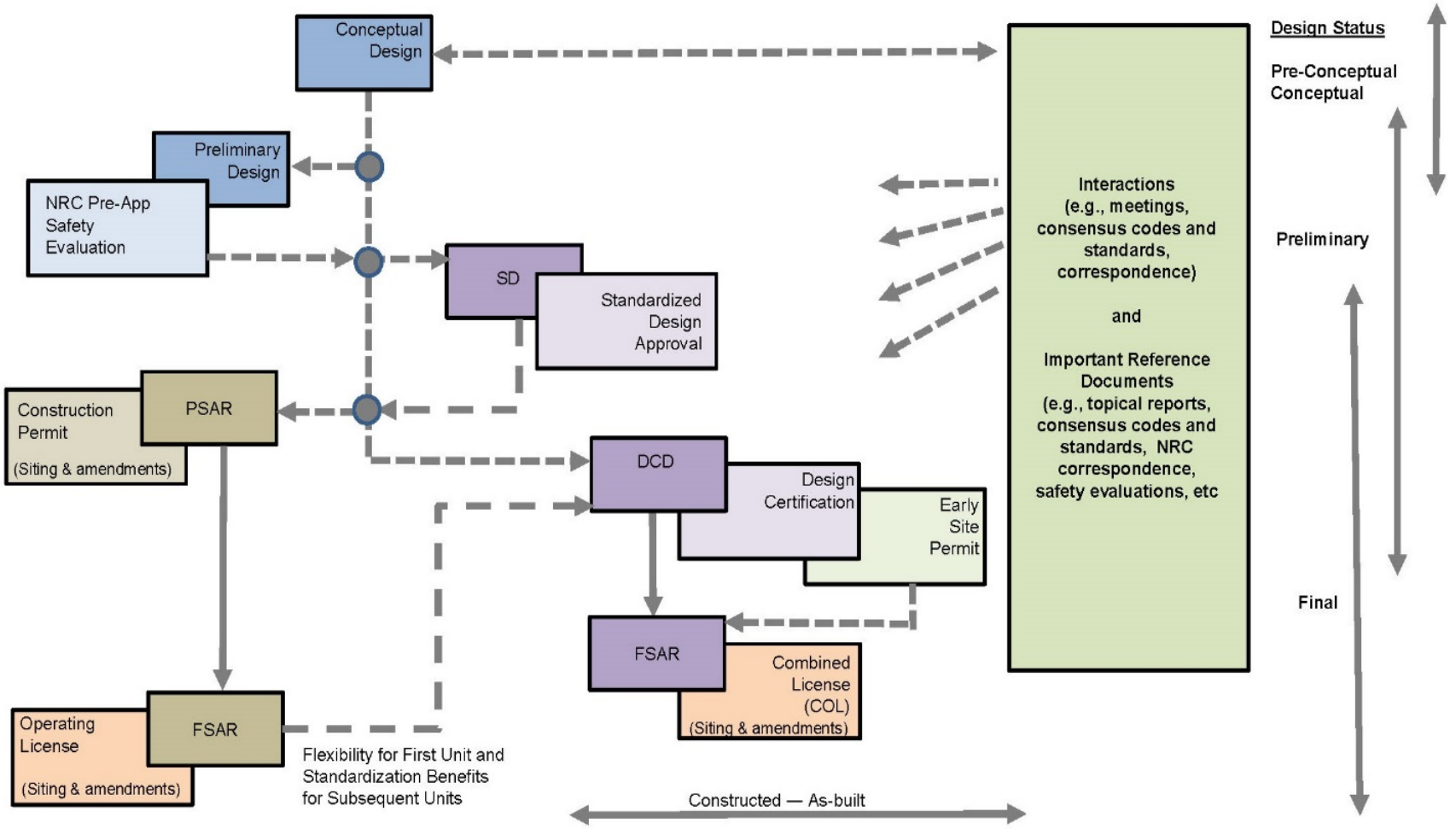
NRC Licensing-related processes



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Interactions/Outcomes

Non-Application Interactions

- Meetings
- Correspondence
- White papers
- Technical reports
- Topical Reports
- Consensus codes and standards
- Rulemaking and regulatory guidance
- Research plans
- Other supporting documents/programs

Outcomes

- Information exchange
- Initial feedback
- Conditional staff findings
- Conclusive staff findings
- Final agency position

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Pre-application & Applications

- **Conceptual Design**
- **Preliminary Design**

Feedback, white papers, topical reports, preliminary design assessment,

- **Standard Design Approval**
- **Construction Permit and Operating License**
- **Design Certification**
- **Combined License**
- Early Site Permit
- Manufacturing License
- Research/Test Reactor Licensing
- Fuel facility licensing
- Waste storage and transportation

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Revisions
Standard Design Approvals

Non-LWR developers considering seeking an SDA may find additional insights in the Nuclear Innovation Alliance report "Clarifying 'Major Portions' of a Reactor Design in Support of a Standard Design Approval" (ADAMS Accession No. ML17128A507). The NRC staff provided feedback on this report on July 20, 2017 (ADAMS Accession No. ML17201Q109).

with footnote

Subsequent to the development of the Nuclear Innovation Alliance white paper, the NRC identified an omission in 10 CFR 50.43(e) and is in the process of issuing a correction to include an SDA within the scope of that regulation. The requirement for an SDA application to meet the requirements of 10 CFR 50.43(e) is defined in 10 CFR 52.137(b). The use of an SDA within a staged process might include the need for the NRC staff to include in the safety evaluation report "conditional findings" versus "conclusive findings" if the associated test programs are not completed at the time of the application.

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Revisions
Standard Design Approvals

A designer may submit a proposed preliminary or final standard design …. with footnote

The regulation at 10 CFR 52.135 states, "The submittal may consist of either the *final* design for the entire facility or the *final* design of major portions thereof" (emphasis added). The level of detail in an SDA application and use of the term "final" are based on the potential referencing of an SDA within a COL application. The level of detail in an SDA application for the subject major portions of the design might, therefore, be greater than the "preliminary" design and analysis information required to support an application for a CP. Nevertheless, the potential use of an SDA within the critical decision process (Figure 1) to reduce regulatory uncertainties before completing the design could be useful for a reactor developer in terms of the broader project plan. As discussed in the Nuclear Innovation Alliance report, "Clarifying 'Major Portions' of a Reactor Design in Support of a Standard Design Approval," the applicant bears all programmatic risk associated with changes in the design between an SDA and subsequent applications for a CP, DC, or COL.

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Regulatory Engagement Plans

- **Regulatory engagement plans** allow the designer and NRC staff to prioritize issues and optimize interactions to address design alternatives or address issues most important to the overall program
- Reflects the technology readiness level of the reactor design, including innovative features, and the related research and development activities
- Mutual agreement on the desired outcomes of defined interactions and estimated costs and schedules for defined reviews
- Particular attention to near-term activities needed to support the critical decision process (see DOE figure)

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Roadmap Examples

- Did not expand the paper to include examples

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Testing Needs and Prototype Plants

Comment	Resolution
Page 8 states: "In particular, test data for a commercial nuclear power plant must be shown to meet quality assurance criteria commensurate with those in Appendix B to 10 CFR Part 50." Comment This provision is not necessary and could prove difficult, if not impossible, to satisfy in practice. Instead, NRC should accept the use of operating experience and test data from non-NRC licensed plants, provided that the applicant demonstrates that the information is reliable.	~~In particular, test data~~In particular, the capabilities and reliability of SSCs will need to be demonstrated using appropriate combinations of testing, operating experience, and operational programs. Test data used to support the qualification of safety-related SSCs for a commercial nuclear power plant must be shown to meet quality assurance criteria commensurate with those in Appendix B to 10 CFR Part 50.

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Testing Needs and Prototype Plants

Comment	Resolution
Page 11 states: "In accordance with 10 CFR 50.43(e)(1), testing is required to demonstrate that new safety systems function satisfactorily in accordance with the safety analysis." <u>Comment</u> This statement does not recognize the full range of described options, e.g., "analysis, appropriate test programs, experience, or a combination thereof". For example, NUREG-1226 provides an extensive discussion on NRC expectations for the use of prior experience from NRC licensed and non-licensed (international) operating plants.	In accordance with 10 CFR 50.43(e)(1), ~~testing~~ <u>analysis, testing, experience, or a combination thereof</u> is required to demonstrate that new safety systems function satisfactorily in accordance with the safety analysis.

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Testing Needs and Prototype Plants

Comment	Resolution
Page 12 and 13 states: "The simplified prototype licensing process is depicted in Figure 1 below… Because of the variety of approval, licensing, and certification options presented in 10 CFR Part 52 and the combinations within that part and with those of 10 CFR Part 50, numerous possible approaches are available." Comment Figure 1 presents a notional depiction of ONE licensing approach. Some refinement is needed to ensure the figure and associated text are not taken as the ONLY licensing approach.	~~The simplified~~. Figure 1 below gives a notional depiction of the prototype licensing process ~~is depicted in Figure 1 below~~.

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Testing Needs and Prototype Plants

Comment	Resolution
Page 13 states: "[T]he prototype plant testing period may need to continue through equilibrium core conditions." Comment Waiting for equilibrium core conditions is not necessary. As the scope of testing is dependent on the sufficiency of data to demonstrate the performance of the intended safety feature(s), the availability of data at an earlier date would obviate the need for a long test period.	For this reason, for the purpose of certain tests, the prototype plant testing period may need to continue through equilibrium core conditions. Equilibrium core conditions may be necessary to demonstrate important fuel and core safety characteristics, such as nuclear reactivity feedback effects and the performance of fuel fission product barriers, and their variation over the reactor's operating lifetime.

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NEI Higher Assay LEU

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NEI Regulatory Engagement Plan

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Financial Protection / Insurance

- SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs"
- SECY-11-0178, "Insurance and Liability Regulatory Requirements for Small Modular Reactor Facilities"
  - Thermal Power vs Electrical Power
  - Multi-module with reactors < 100 Mwe
    - Comparative Analysis
- NEI Position Paper / ANS Special Committee / Other Assessments
- Periodic Report to Congress

  The Commission and the Secretary shall submit to the Congress by December 31, 2021, detailed reports concerning the need for continuation or modification of the provisions of this section, taking into account the condition of the nuclear industry, availability of private insurance, and the state of knowledge concerning nuclear safety at that time, among other relevant factors, and shall include recommendations as to the repeal or modification of any of the provisions of this section.

Advanced Reactor Program

Financial Protection / Insurance

Problem Statement

Interactions between the NRC staff and stakeholders are intended to identify potential issues associated with requirements for financial protection to cover public liability claims for advanced reactor designs, and to subsequently identify relevant information or needed research/studies to resolve those issues. These activities will support developing recommendations for possible modifications, if warranted, to the Price-Anderson Act, NRC regulations or both.

An example of a previous report to Congress is NUREG/BR-6617, "The Price-Anderson Act – Crossing the Bridge to the Next Century: A Report to Congress"

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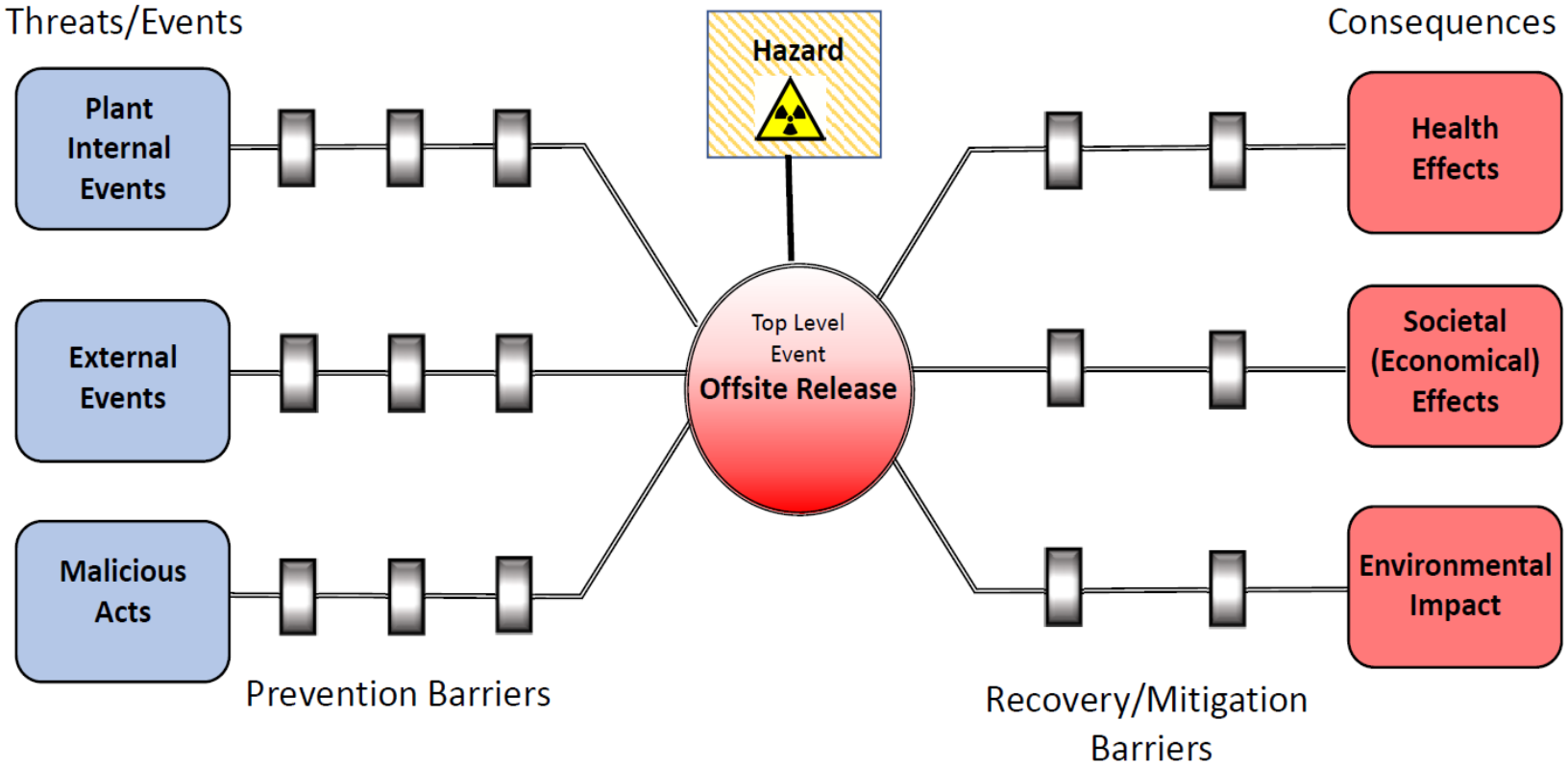
Integrating Activities



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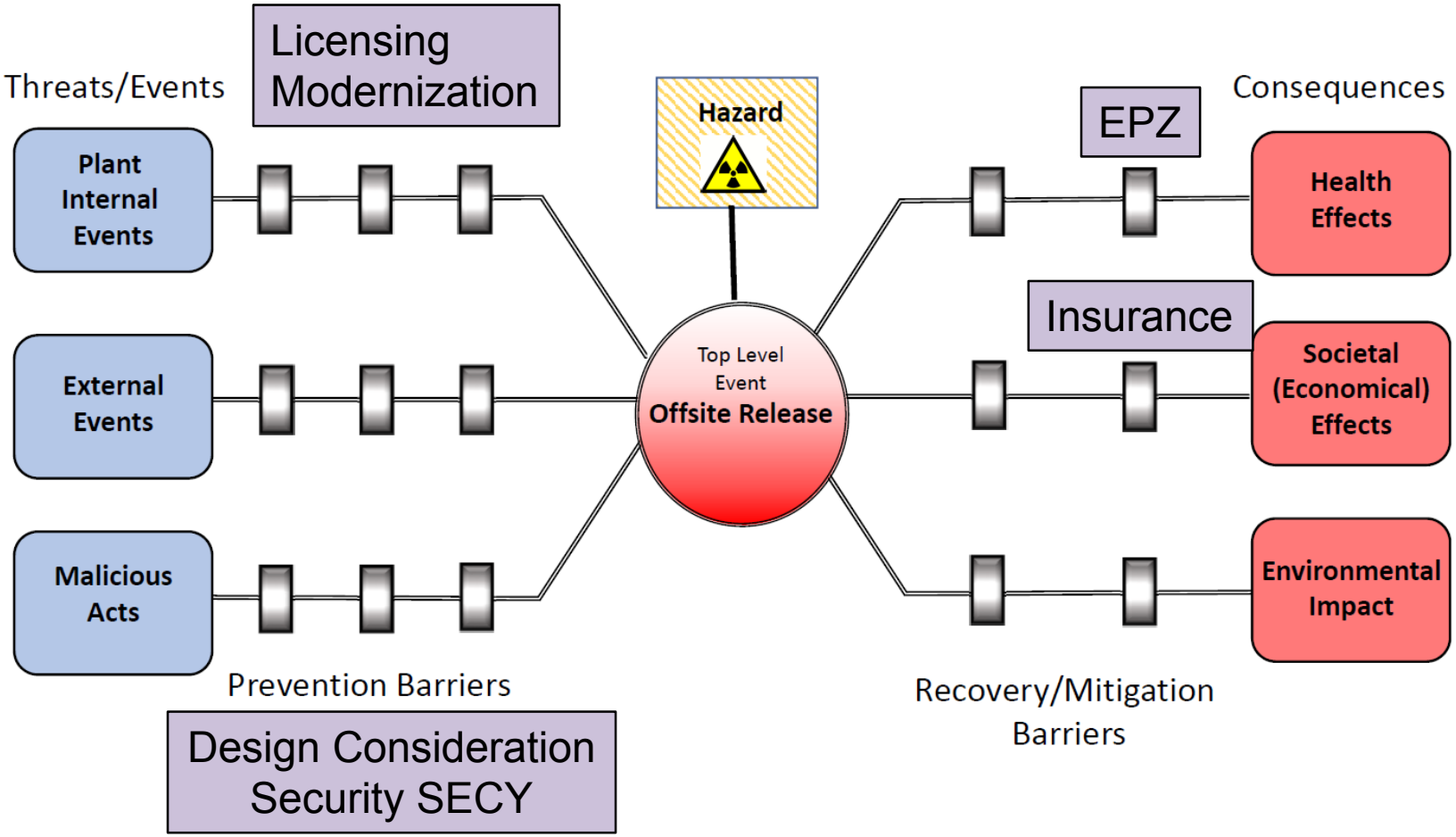
Integrating Activities



American Nuclear Insurers

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Insurance

Discussion

Advanced Reactor Design Criteria

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Licensing Modernization

- Safety Classification and Performance Criteria for Structures, Systems, and Components
  - ADAMS Accession No. ML17290A463
  - Preliminary Comments and Questions

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Functional Containment

- SECY Paper for FY 2018
- Identified in previous stakeholder meeting as a high-priority issue
- Outline
  - Background/history
  - Proposed Approach
    - Safety Function
    - Physical Building

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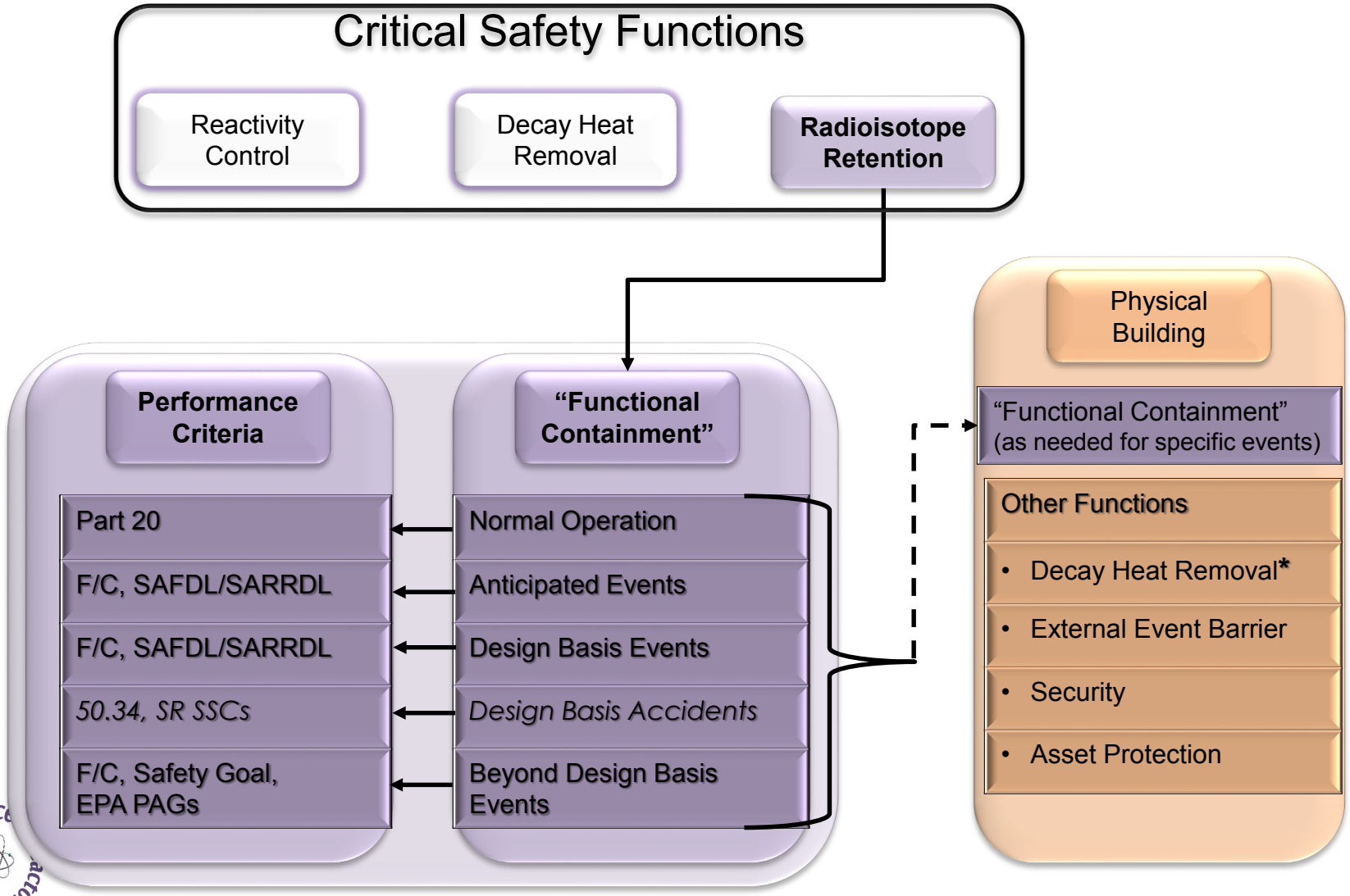
Functional Containment



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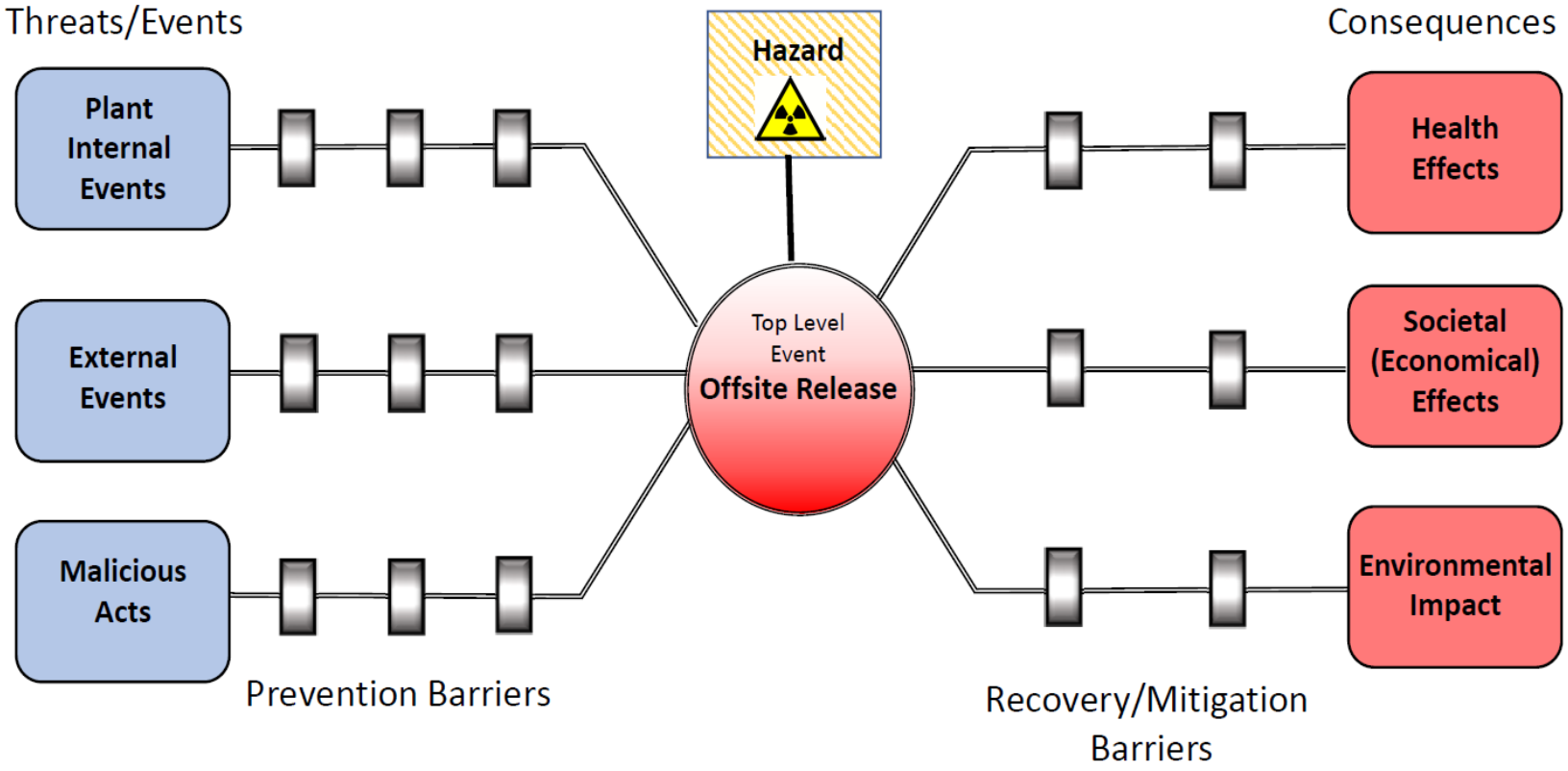
Integrating Activities



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Future Stakeholder Meetings

Dec 13	Physical Security (NRC White Paper)
Dec 14	Licensing Modernization Project White Papers
	Siting (populations)
	"Functional Containment" (NRC White Paper)
	ASME Section III Division V
Feb 1	Advanced Reactor Fuel Cycle (NIC)
Mar 22	NEI (Consolidated) RIPB Guidance
May 3	
Jun 14	

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ACRS Schedule (tentative)

Date	Committee	Topic
Feb 7	Sub	ARDC
Feb 23	Sub	Functional Containment
Mar	Full	ARDC
Apr	Full	Functional Containment
Apr 19	Sub	RIPB Guidance
Oct 30	Sub	RIPB Guidance

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Public Comments / Questions

NUCLEAR ENERGY INSTITUTE

Mike Tschiltz
Senior Director New Plant, SMR and Advanced Reactors

November 2, 2017

Meeting The Challenge Providing Fuel For Advanced Reactors

NRC Advanced Reactors Public Meeting

BACKGROUND

- Current generation of light water reactors (LWRs) uses fuel enriched to less than 5% uranium-235
- Most advanced non-LWR designs and an advanced fuel design for the existing fleet will require enrichments between 5% and 20%, high assay low enriched uranium (HALEU) fuel
- No current capability in US to manufacture commercial HALEU fuel

NEI

PURPOSES OF NEI WHITE PAPER

- This presentation focuses on the technical and regulatory issues that need to be addressed to facilitate the manufacturing and utilization of HALEU fuels in the United States

- In addition the white paper also covers the role of government in establishing a domestic HALEU fuel supply

    - Identify technical and regulatory

PRESENTATION TOPICS

- Criticality Issues for HALEU Facilities
- Enrichment Facilities Licensing
- HALEU Fuel Fabrication Facilities Licensing
- Transportation of HALEU Fuel
- Material Control and Accounting for HALEU Fuel
- Physical Protection of HALEU Plants and Materials
- Projected Timeline

CRITICALITY ISSUES FOR HALEU FACILITIES

- The most significant technical issue in the licensing of any HALEU facility or equipment is **criticality**
- To facilitate the safe and effective use of HALEU fuels, criticality **benchmark data for material between 11% and 20% needs to be developed**
- The data should be developed by the Department of Energy or the private sector (with DOE funding) in cooperation with the NRC

NEI

ENRICHMENT FACILITIES LICENSING

- The licensing of a facility to enrich uranium is a single step process with one license issued pursuant to 10 CFR Parts 30, 40 and 70
  - Approval of modifying an existing plant to enrich uranium to HALEU levels is expected to take about as long as getting a license for a new facility
  - Most significant factor affecting the licensing of a HALEU enrichment facility - criticality safety
  - Licensing facilities for enrichments of 5-20% would not require revisions or changes to the existing regulations

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HALEU FUEL
FABRICATION FACILITIES LICENSING

- Will be licensed under 10 CFR Part 70 and NUREG-1520 as a Category II facility
- NRC has licensed three Category III fuel fabrication facilities that are operating now, using low enriched uranium
- Amending current licenses to produce HALEU fuel possible (complex)

NEI

HALEU FUEL
FABRICATION FACILITIES LICENSING

- Two Category I fuel fabrication plants are currently licensed by the NRC to use high enriched uranium
  - Produce fuel containing both high and low enriched uranium, for use in the U. S. Naval Reactors program
  - Down-blend HEU to lower enrichments, which can be used for applications such as non-power reactors
- Potential to produce fuel for HALEU reactors

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TRANSPORTATION OF HALEU FUEL

- Transporting the uranium hexafluoride (UF6) from the enrichment plant to the HALEU fuel fabrication facility is a **challenge**
- Existing cylinders licensed above 5% are too small to be commercially viable
- No **commercially viable cylinder** or packaging for UF6 that is enriched to greater than 5% uranium-235
- Need to design and manufacture, test and certify new shipping package (DOT 49 CFR 173.420, NRC 10 CFR Part 71)
- Alternative approaches

MATERIAL CONTROL AND ACCOUNTING (MC&A) FOR HALEU FUEL

- 10 CFR Part 70.22(b) - requires an MC&A program for a commercial HALEU facility
- HALEU = Category II SNM of moderate strategic significance
  - MC&A for special nuclear material of moderate strategic significance is described in 10 CFR Part 74.41
- Gap in the safeguards guidance for Cat II SNM
  - NRC guidance for high enriched uranium are published in NUREG-1280, Rev. 1
  - NRC guidance for low enriched facilities is contained in NUREG-1065
  - No specific guidance for facilities utilizing uranium of moderate strategic significance (Cat II)
- Need to develop NRC guidance for an MC&A program including the FNMC plan for Cat II facilities licensed under 10 CFR Part 70.22(b)

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PHYSICAL PROTECTION OF HALEU PLANTS AND MATERIALS

- Cat II SNM requires a physical security plan that meets the requirements of 10 CFR Part 73.67(d)
- No U.S. facilities have been licensed to possess Cat II material for several decades.
- Over time, the perceived threat has changed and the planned protective measures will likely need to change.
- Need to develop industry guidance for Physical Security Plans for facilities licensed under 10 CFR 70.22(k) for Cat II material
- Would need NRC review and endorsement

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PROJECTED TIMELINE

CONCLUSIONS

- Developing the needed fuel cycle infrastructure will require government involvement and funding in cooperation with the U. S. nuclear industry
- DOE and the U.S. nuclear industry, in cooperation with the NRC, should develop the necessary criticality benchmark data, to allow efficient and cost effective licensing of a new generation of HALEU fuel facilities
- DOE, NRC, and DOT involvement along with government funding will be necessary to support the certification of packages that can used to economically transport enriched UF6 for HALEU fuels
- NRC working in conjunction with DOE, industry and other stakeholders, should develop the needed regulatory guidance to implement an acceptable MC&A program and an acceptable Physical Security plan to facilitate the licensing of HALEU facilities
- No changes to existing regulations are needed to license the facilities needed to produce and utilize HALEU fuel for the next generation of nuclear reactors in the U.S.

NEI

NUCLEAR ENERGY INSTITUTE

Peter Hastings

November 02, 2017

Update on Regulatory Engagement Plan Guidance Development

NRC Advanced Reactors Public Meeting

REGULATORY ENGAGEMENT PLAN (REP)
INTRODUCTION

- Project scope: develop draft of REP template for industry and NRC review
- Approach
  - Informed by prior licensing project plans, annual new reactor planning Reg Issue Summaries
  - Guidance: FAQ-like descriptions of underlying elements of template, including options
- Overarching assumptions
  - Optional product
  - Flexible content & format

REGULATORY ENGAGEMENT PLAN (REP) OUTLINE

Part I: Introduction to Guidance Document

1. General (e.g., format & content, notes on usage, etc.)
2. Communicating with NRC (i.e., general information re: written/oral communication
3. Phases of Engagement

Part II: REP Guidance

1. Introduction/Purpose of REP (applicant contact info, project info, summary of approach)
2. Technology Summary
3. Regulatory Strategy (application type/approach, NEPA considerations, PDCs, selection of guidance & standards, identification of key issues)

REGULATORY ENGAGEMENT PLAN (REP) OUTLINE (continued)

Part II: REP Guidance (continued)

4. Pre-Application Engagement (identification of pre-app topics, types of interactions, NRC feedback, schedule considerations)
5. Application Process (including readiness assessment, acceptance review)
6. Post-Application Engagement (including overview of NRC processes, review expectations, audits and inspections, RAIs)

Miscellaneous

- Withheld Information
- Partnerships and Industry Participation
- References

GUIDANCE DOCUMENT
Discussion of Excerpts

QUESTIONS/COMMENTS

NEI18-XX

Industry Guideline for Development of a Regulatory Engagement Plan

[Month] 2018

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.

1.1 FORMAT AND CONTENT

This guideline provides suggested topics for a prospective NRC applicant to consider in developing an REP, and supporting information that includes explanation, background, and/or pointers to external documents 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 contains suggested topics for consideration, along with supporting information.

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 is 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 expected that any given applicant will not use all the suggested content contained herein. Similarly, the grouping and order of presentation of suggested topics in Part II is not intended to prescribe an expected 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.

Importantly, the list of topics in this guideline are 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 the REP.

[1] Prior to submittal of an application for and 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.

PART II REGULATORY ENGAGEMENT PLAN GUIDANCE

Part II discusses both 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.

[develop pointer(s) to NRC roadmap and IAPs]

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 structure. 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.
- 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: [expand with examples]
- The extent of first-of-a-kind design or unique implementation of previously demonstrated technology: [expand]
- New or different implementation strategies, e.g., unconventional use of thermal power, novel fuel cycle considerations, unusual siting or emergency planning aspects, etc.: [expand]
- Anticipated challenges or changes to existing NRC policy: [expand]
- 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.): [expand]

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 obviously 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: [expand]

- Moderation: [expand]

- Containment/Confinement: [expand]

- Usage (electric, process heat, etc.): [expand]

- Active/Passive: [expand]

- Risk informed: [expand]

- Technology Readiness: [expand – include discussion of potential high-level strategy to describe extent to which planned application draws upon prior and/or existing knowledge, whether reactor plants or technologies having influential value to the application]

- Fuel Cycle Considerations: [expand to include discussion of front- and back-end 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.

3.1.1 Early Site Permit (10 CFR 52 Subpart A)

[content requirements citation – note that the discussion under each of the "conventional' license types will be limited with pointers to external sources such at 10 CFR 50/52, RG-1.206, etc.]

3.1.1.1 Design-specific

3.1.1.2 Plant Parameter Envelope

3.1.2 Standard Design Certification (10 CFR 52 Subpart B)

[content requirements citation]

3.1.3 Combined License (10 CFR 52 Subpart C)

[content requirements citation]

3.1.4 Standard Design Approval (10 CFR 52 Subpart E)

[content requirements citation; pointer to NIA SDA paper]

3.1.11 Other Considerations

3.1.11.1 “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 are considering development of guidance regarding a “conceptual design assessment.” In the meantime, 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 an example, the NRC staff reviewed and generated a preapplication safety evaluation report (PSER) for the General Electric (GE) Power Reactor Innovative Small Module (PRISM) sodium-cooled reactor. 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 PRISM review was based on the submittal of a Preliminary Safety Information Document (PSID). 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).

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.

For each suggestion of an ER [cite format and content source], potential topics for discussion in an REP are discussed below.

3.2.1.1 ER Introduction

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

3.2.1.2 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

3.2.1.3 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.

3.2.1.4 Environmental Impacts of Construction

- Novel aspects of construction in impact areas described in 3.2.1.2 (land, water, etc.)
- Radiological impacts to construction workers, particularly with respect to modular construction

3.2.1.5 Environmental Impacts of Operation

- Novel aspects of operation in impact areas described in 3.2.1.2
- Atypical approaches/impacts for water use (e.g, cooling), transmission systems, and fuel cycle considerations
- Decommissioning

3.2.1.6 Environmental Measurements and Monitoring

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

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.

Unfortunately, the NRC staff findings during this audit are not binding, so 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 three months - TBV] prior to the scheduled submittal of the application.

Additional details regarding the readiness assessment audit may be found at [cross-ref NRC guidance].

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.

American Nuclear Insurers Presentation to NRC New Reactor Working Group

November 2, 2017

Michael P. Cass
Senior Vice President & General Counsel

Presentation Topics

I. Price-Anderson Act & Financial Protection Requirements for Licensees

II. American Nuclear Insurers: Meeting Financial Protection Needs & More

III. Application of PAA and 10 CFR 140 to New Reactor Designs

IV. Considerations/Takeaways

V. Questions

Price-Anderson Act

PAA codified at 42 USC § 2210 (AEA Sec. 170)

- Liability & indemnification program for protection of the public in the event of a nuclear incident
- Financial Protection required to cover "Public Liability"
- Public Liability = "any legal liability arising out of or resulting from a nuclear incident or precautionary evacuation…"
- Public Liability Action = "any suit asserting public liability." Federal court jurisdiction over all Public Liability Actions
- Financial Protection = "ability to respond in damages for public liability and to meet the costs of investigating and defending claims and settling suits for such damages"

Price-Anderson Act

Other PAA features:

- Economic channeling of liability – all liability channeled to operator
- Limitation on liability – liability "capped"
- Government Indemnity:
  - Reactors with < $560 million in required financial protection, government indemnity of $500 million (reduced where FP > $60 million) 42 USC 2210 (c)
- Two layers of Financial Protection: Primary and Secondary

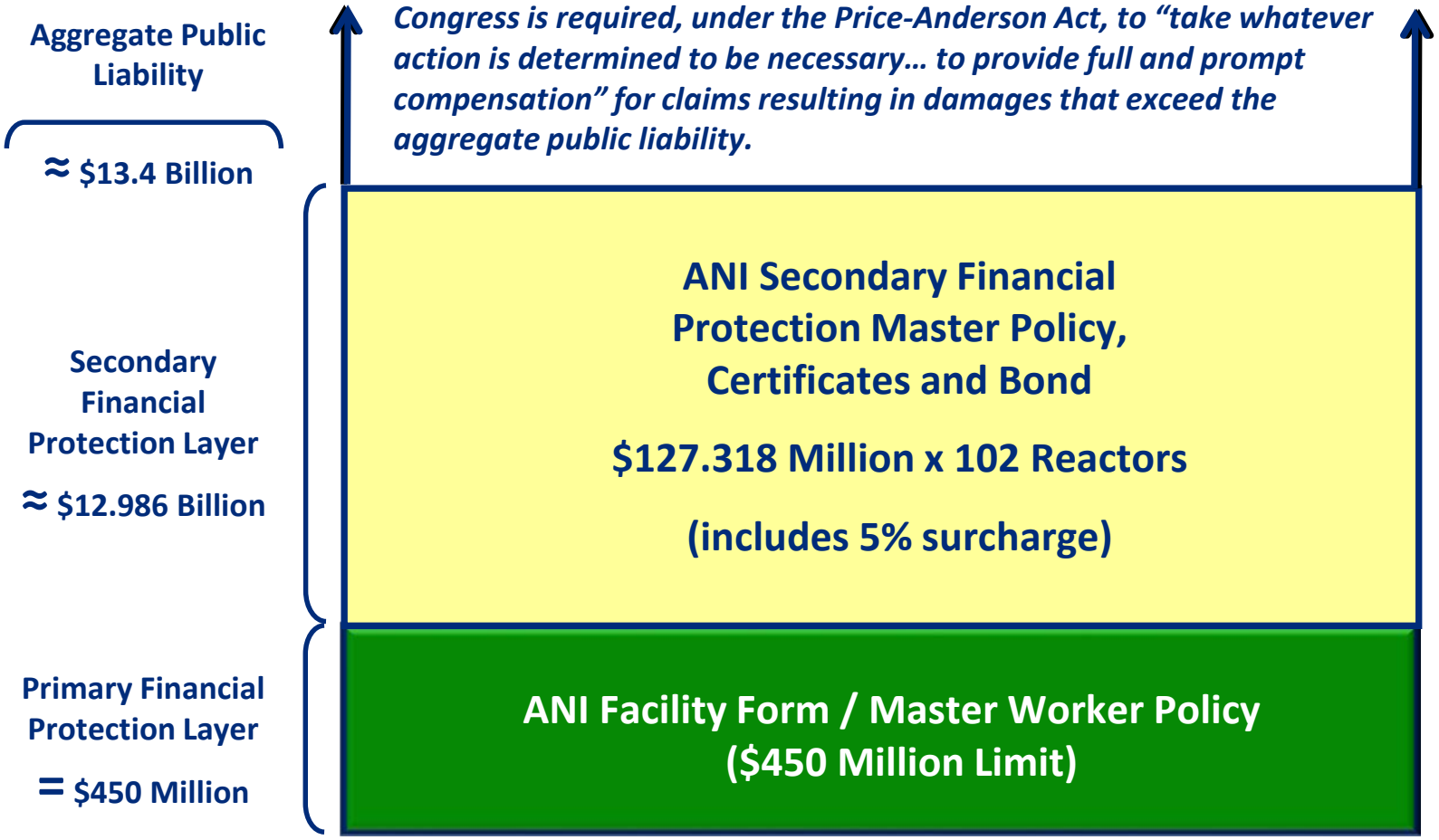
Primary Financial Protection

- Amount required shall be the amount of liability insurance available from private sources.
- NRC may establish lesser required amounts in consideration of factors such as type, size and location of licensed activity
- Rated capacity ≥ 100 MWe required to maintain maximum amount available from private sources (currently $450 million, see 10 CFR 140.11(a)(4))
- May be satisfied in different ways, but all operating power reactors utilize insurance

Secondary Financial Protection

- Licensees required to maintain maximum primary financial protection must also participate in secondary program
- Private liability insurance under an industry retrospective rating plan with premiums deferred until public liability exceeds (or appears likely to exceed) primary layer
- NRC establishes maximum retrospective/deferred premium charged (10 CFR 140.11(a)(4)), adjusted every 5 years for inflation
  - Annual maximum = $18.963 million/reactor/incident
  - Total maximum = $121.255 million/reactor/incident (plus 5% surcharge set forth in PAA)
- Multi-reactor sites where each reactor is between 100-300 MWe and total capacity <1300 MWe, considered a single reactor for purposes of SFP

Financial Protection Overview



ANI Nuclear Liability Insurance

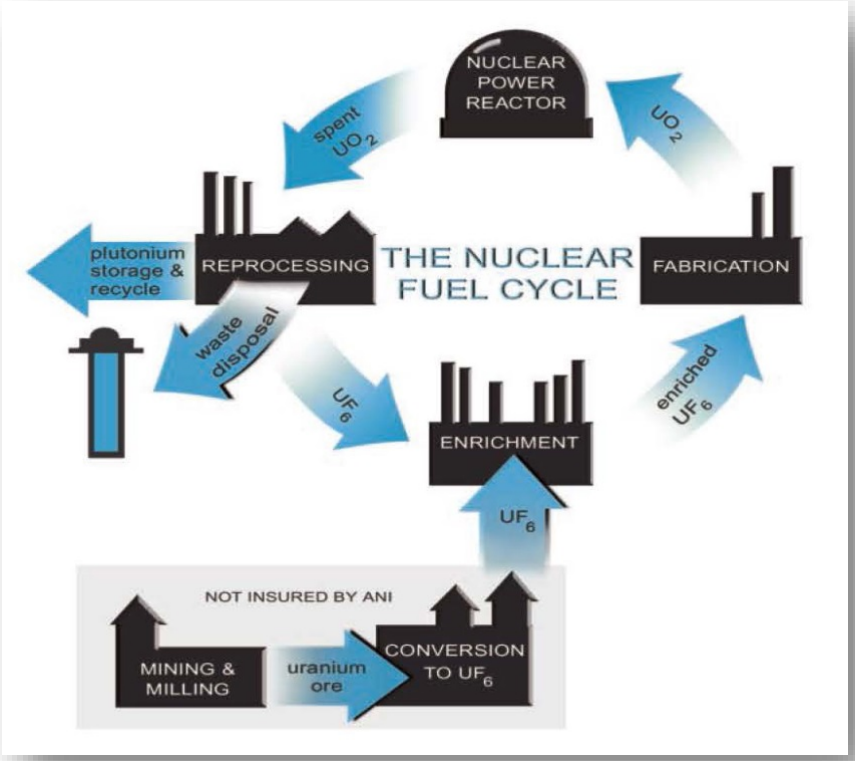
ANI Background

- Formed in 1956
- Unincorporated voluntary Joint Underwriting Association
  - Currently 23 member companies
  - All U.S. domiciled
  - All AM Best rated “A” or better
  - Aggregate surplus of approximately $279 billion
- Supports broad form nuclear exclusion
- Represents insurance industry’s support of commercial nuclear power industry
- ANI operates pools comprised of member companies

ANI Domestic Program

ANI insures risks that are associated with the commercial nuclear fuel cycle, including:

- all U.S. commercial nuclear power plants
- uranium enrichment facilities
- fuel fabrication facilities
- waste reduction and disposal facilities
- shippers and transporters of nuclear material
- suppliers of nuclear-related products and services
- academic and research reactors



November 2, 2017

ANI Nuclear Liability Insurance

ANI Policies

- Facility Form Policy
  - Source of primary financial protection for all operating power reactors
  - $450 million available limit (per site)
- Master Worker Policy
  - Insures against injuries to nuclear workers (not employees of insured – not workers comp)
  - Single industry aggregate ($450 million)
- Secondary Financial Protection Master Policy
  - Master policy held by NRC
  - Licensees subscribe per reactor via Certificates and Bond
  - ANI administers retrospective premium collection and claims
- Suppliers and Transporters Policy

ANI's Liability Program Features

- Satisfies PAA financial protection requirements
- Covers evacuation costs and BI/PD caused by the nuclear energy hazard
- Economic Channeling - omnibus insured clause
- Lifetime aggregate policy limit
- Continuous policy until cancelled
- Defense costs within limits
- Public Liability claims expertise
- ANI Emergency Response role
- Secondary Financial Protection (SFP) administration

PAA and New Reactor Designs

Price-Anderson Act:

- Price-Anderson Act establishes financial protection requirements based on the size and operating status of a nuclear reactor
- PAA distinguishes between reactors with rated capacity ≥ 100 MWe and those with lower rated capacities.
- PAA also addresses siting of multiple units, each with rated capacities between 100 and 300 MWe but with total rated capacity ≤ 1,300 MWe

NRC Regulations

- Implementing regulations (10 CFR 140.11-12) provide requirements for reactors with lower rated capacities and non-electricity generating reactors
  - Ranges from $4.5-74 million based on formula
  - <100 MWe not required to participate in SFP
  - required FP < $560 million has gov't indemnification

ANI Underwriting Considerations

Siting of reactors

- Greenfield v. pre-existing/legacy liabilities
- Population density

Nuclear Liability risk

- Program designed to respond to catastrophic nuclear incident
- Claims often brought alleging injury resulting from normal operations
- Occupational exposure, effluents, chemistry

Engineering review

- ANI Engineers review design criteria and develop recommendations to underwriting and ANI members regarding insurability of the risk
- Engineers perform regular loss control inspections at reactor sites
- Focus on insurance risk

Considerations/Takeaways

- ANI recognizes that the technology, application and regulations applicable to new reactor designs will continue to evolve
- Price-Anderson Act provides financial protection framework and affords NRC flexibility under its regulatory authority to adapt requirements as designs evolve
- Collaborate early with a qualified nuclear liability insurance broker
- Provide ANI with adequate time to consider your requests
- Consider ANI as a stakeholder

Questions?