U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Advisory Committee on Reactor Safeguards (ACRS)
Future Plant Designs Subcommittee

10 CFR Part 53
"Licensing and Regulation of Advanced Nuclear Reactors"

General Discussions and Subpart E Preliminary Proposed Rule Language

March 17, 2021

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United States Nuclear Regulatory Commission
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Agenda

9:30 am – 9:35 am	Opening Remarks
9:35 am – 9:40 am	Staff Introductions
9:40 am – 11:30 am	Stakeholder Insights
11:30 am – 1:00 pm	Continuing Dialogue on Structure and Logic of Part 53
1:00 pm – 2:00 pm	Lunch
2:00 pm – 3:00 pm	Key Guidance
3:00 pm – 4:00 pm	Subpart E: Construction and Manufacturing
4:00 pm – 5:30 pm	Upcoming Challenges
5:30 pm – 6:00 pm	Discussion

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Stakeholder Insights

Part 53 Rulemaking
NRC ACRS Meeting

Marc Nichol
Senior Director New Reactors

March 17, 2021

NUCLEAR ENERGY INSTITUTE

Areas where we agree with the NRC

Vision and Goals

- **Vision**: Licensing new reactors under the new rule will be the most efficient option for all new reactor applicants and will meet industry needs for schedule, cost and predictability, consistent with congressional directives, the NRC's own advanced reactor policies and initiatives, and the agency's Principles of Good Regulation.
- **Goals**:
  - **Safety-Focused**: Focus on reasonable assurance of adequate protection
  - **Technology-Inclusive:** All technologies, high-level requirements
  - **Efficient**: Schedule/cost targets integrated safety/security, commercial quality
  - **Flexible**: Variety of licensing approaches, reactor uses, interface with Part 50/52
  - **Informed**: Insights from previous efforts, near term activities, and other regulators
  - **Clear**: Nexus to adequate protection, interrelationship of requirements, concise

Fundamentals of Part 53

- Focus on safety in terms of radiological impacts
- NRC's "bow tie" diagram as the safety paradigm
- Scope of rule as identified by sub-parts (mostly)
- Allow for modern regulatory concepts (e.g., LMP/TICAP)
- Eliminating prescriptive and technology specific requirements
- Fundamental aspects to be addressed in requirements
  - Performance-based safety, security, siting and emergency preparedness
  - Radiological hazard
  - Characteristics of the site
  - Event sequences
  - Design features, human actions and programmatic controls

Areas where we recommend more efficient approaches to achieve NRC's intent

Purpose of NEI's discussion draft

- Provide example of how to meet vision and goals of rulemaking
  - High level rule language
  - Meeting high standards of safety more efficiently
- Focus on NRC's regulatory functions
  - Determine standards for reasonable assurance of adequate protection
  - Determine facility characteristics need to meet safety criteria
  - Determine how to provide reasonable assurance in design, construction, and operation
  - Determine types of licenses, permits and approvals and process to obtain

Subpart B – Safety

- Simplify and clarify the safety criteria
  - Adequate protection – 25 rem for events not expected during lifetime
  - Extra-adequate protection – 0.1 rem for normal operations, and beyond design basis
- Establish the facility characteristics needed for safety and security
  - Aligned with NRC's "bow tie" diagram
  - Performance-based safety, security, siting and emergency preparedness
  - Radiological hazard
  - Characteristics of the site
  - Required facility functions necessary and sufficient to meet safety criteria
  - Event sequences
  - Design features and human actions to perform required facility functions

Subpart C: Design and Analysis

- Simplify and clarify around updated safety criteria
  - Features that are necessary and sufficient to provide reasonable assurance that the design and analyses demonstrate that the facility is able to meet the safety and security criteria
- High level requirements that allow flexibility
  - Method for determining facility characteristics (required functions, events, design features)
  - Analysis of SSCs performance of required functions
  - Design requirements and performance criteria for SSCs
  - Method of evaluating risk
  - Measures to address design and analysis uncertainties
  - Qualification of SSCs
  - Categorization of SSCs

Areas where there are concerns with the NRC's proposed approach

Areas where more transformational approaches are needed

- Approach to high level rule language that is technology-inclusive and performance based
- Approach to evaluating potential requirements
  - Don’t add new requirements that weren’t needed in Part 50/52
  - Eliminate requirements that do not enhance safety – efficiency leads to improved safety
- Openness to reconsider all Part 50/52 requirements, Commission Policies and long-held staff positions
  - Determine whether what was developed based on LLWR technology is applicable to a technology-inclusive approach

Areas where more transformational approaches are needed

- ALARA – not appropriate as a requirement (wise practice)
  - Regulatory philosophy of “safe is safe”, not unending pursuit of safer
- Security – beyond current SMR Security rulemaking
  - Might be most prescriptive current NRC rule
  - Need performance based approach to physical barriers at minimum
- Siting
  - Defining safety criteria at site boundary eliminates need for LPZ and distance to population center
  - Event frequencies consistent with safety dose criteria
- Quality assurance
  - Commercial quality programs (e.g., ISO-9001) provide equivalent levels of quality as Part 50 Appendix B
  - Greater supply chain base can improve quality

Topics of Concern

- Probabilistic risk assessment
  - Agree that risk evaluation is necessary, but need flexible graded approach
  - Not all designs need a PRA, and not all PRAs need to be the same
  - The approach to risk evaluation should fit the safety profile of the design and licensing approach
- Defense in depth
  - Treat as a design philosophy similar to Part 50/52
  - Unnecessary as a requirement, and would create unintended consequences
  - Prescriptive “no single feature” requirement is unnecessary and not risk informed

Topics still under evaluation

- Quantitative health objectives
  - In the rule could create challenges and unintended consequences
  - In the policy statement works for Part 50/52
  - How to address beyond design basis events
- Quantitative frequencies
  - Treat as a design philosophy similar to Part 50/52
  - Unnecessary as a requirement, and would create unintended consequences
- Facility safety program
  - Need to see tangible benefits

More work on the horizon

- Many topics not yet evaluated – e.g., reporting, ITAAC,
- Higher-level requirements will rely more on guidance, potential needs for Part 53
  - Application scope/content – e.g., TICAP and NRC ARCAP
  - Safety paradigm / licensing approach – e.g., NEI 18-04 and alternatives
  - Quality Assurance
  - Graded approach to risk evaluations
  - Performance-based security (at least physical barriers)
  - Technology-specific (e.g., facility functions, events, design criteria)
  - NRC review
  - Oversight program
  - Transport of fueled micro-reactors

QUESTIONS?

U.S. Nuclear Industry Council
Comments for NRC ACRS Part 53 Meeting

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17 March 2021

Goals for Part 53

- Safety-Focused: Focus on reasonable assurance of adequate protection
- Technology-Inclusive: All technologies, high-level requirements
- Efficient: Schedule/cost targets, integrated safety, commercial quality
- Flexible: Variety of licensing approaches, reactor uses, interface with Part 50/52
- Informed: Insights from previous efforts, near term activities, and other regulators
- Clear: Nexus to adequate protection, interrelationship of requirements, concise

NEIMA Expectations and Objectives

- Expectations:
  - Technology inclusive (use by any fission reactor technology)
  - Risk-informed (focus on safety-significant elements of safety case)
  - Performance-based (clear, consistent, and understandable criteria)
- Success Criteria (Objectives):
  - Clear, effective regulatory framework and guidance resulting in significant improvements
  - Framework founded on demonstration of reasonable assurance of adequate protection of public health and safety
  - Regulatory burden should not be increased

Rulemaking Process

- USNIC comments/questions in multiple forums*
  - Transient & Accident Radiological Safety Criteria (25 rem total effective dose equivalent)
  - Postulated events in guidance (~1E-2 yr-1)
  - Use 10 CFR Part 20
  - Support but not require the LMP approach (additional guidance where needed)
- Comments to support NEIMA expectations

** ML20318A007*
ML21006A000
ML21032A045
ML21035A003

Topics for Consideration

- Adequate Protection Standard
- Dose Consequence-Based Performance
- Development and Application of Risk Insights
- Evaluating Defense in Depth Adequacy
- Quality Assurance

Adequate Protection Standard for Part 53

- Provide clarity for adequate protection (radiological foundation)
  - Requirements predicated by fundamental safety functions (53.210)
  - Requirements established in Part 53 should have a clear nexus to supporting the adequate protection standard
  - Adequate protection standard should be independent of technology, reactor size, or selected licensing process
- Avoid regulatory requirements that are not needed for adequate protection
  - Requirements need not exceed existing requirements under Part 50 (do not ratchet requirements compared to existing reactors)
  - Necessity of “second tier” has not been established
- Part 53 should establish the minimum criteria and supporting information necessary for demonstrating the safety case

Note: ALARA is important concept and good practice, but should not be included in Part 53

Dose Consequence-Based Performance

- Section 53.23 requires analysis of QHO
  - Need for new requirement not clear
  - QHO calculations would be required in addition to quantitative limits at site boundary
  - QHO method introduced in 1986 but deemed impractical and CDF and LERF surrogates were introduced instead (not applicable to non-LWRs); no QHO requirement in 10 CFR 20, 50, 52
  - QHOs virtually guarantee a specific analytical methodology (i.e., PRA) is required
  - Recommend removing (b)(2) from 53.23 in NRC preliminary Subpart B, Second Tier Safety Criteria, unless clear benefits shown
- Continue to have QHOs as NRC policy
- Quantitative frequencies could be included in guidance

Development and Application of Risk-Insights

- Risk tool (PRA today) insights complement the safety case
- Attributes of a useful Part 53 framework for the use of risk tools:
  - Provide flexibility without focusing on a specifically mandated analytical approach (like PRA)
  - Avoid prescriptive requirement for approach on defining LBEs, SSC classification, and DID determinations
  - Enable RG 1.233 implementation, but not require it
  - Enable combinations of risk-informed and deterministic approaches where appropriate (e.g., external hazards, seismic, bounding analyses, especially for designs with very small source terms such as microreactors)
  - Support international regulatory frameworks (e.g., IAEA SSR-2/1 and markets with dual-DSA/PSA requirements)
- PRA matures with plant design and site selection/characterization. Requiring extensive PRA with application submittal may not be feasible for all application types, especially for plants in early phases of application (e.g. CP)
  - Application content should be limited to information central to the safety case findings
  - Application content should be developed as part of ongoing regulatory guidance activities

Evaluating Defense in Depth (DID) Adequacy

- DID important design philosophy for LMP and “non-LMP” applications
  - Further discussion needed on adequate DID for license applications, accounting for the range of potential reactor designs and features that prevents and mitigates accidents
  - DID demonstration will vary across range of designs and features
  - LMP example level of detail (rule should enable, not require)
- Rule implies DID must include BDBE mitigation measures, which seems to expand existing requirements
- DID details should be described in guidance, not regulation
- Guidance should also clarify what DID is required when prevention/mitigation is physics or passive/inherent

Clarity in Quality Assurance Requirements

- Clarify QA requirements and facilitate application across industry (vendors, suppliers, and operators)
  - Opportunity for a fresh look at alternatives to Part 50 Appendix B and NQA-1
  - Commercially available components quality may meet/exceed “nuclear standards” with reduced artificial burden
  - Rule should require quality control program, but not specify approach
- Guidance should support broad standards, e.g., ISO 9000 series, IAEA, commercial dedication
  - Reduce barriers to commercial competition, and facilitate licensing abroad– recognizing greater supply chain base can improve quality
  - International acceptance of a single approval could be important in international marketability
  - Guidance should show ISO standards and IAEA approaches meet requirements
  - Guidance could address topic of universal acceptance of codes and standards (mechanical, electrical)

Conclusion

- Encourage ongoing participation and engagement of stakeholders
- Continue working to clarify more appropriate rulemaking objectives and implementation detail
- Achieve NEIMA goals without increase in regulatory burden for deployment of Advanced Reactors

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Part 53 Rulemaking
Southern Company Perspectives

Presented to ACRS Sub-Committee for Future Plants

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March 17, 2021

Southern Company

Current Part 53 Rulemaking History

- Energy Policy Act of 2005 (Rule-making activities terminated in 2011)
- Nuclear Energy Innovation and Modernization Act (NEIMA), signed Jan. 2019, directs NRC to “complete a rulemaking to establish a technology-inclusive regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications” by **12/31/2027**.
- Commission directed the Staff on **10/2/2020**, “to provide the Commission a schedule with milestones and resource requirements to achieve publication of the final rule by **October 2024** and inform the Commission of key uncertainties impacting publication of the final rule by that date.”
  - “Implement the development and intermittent release of preliminary draft rule language, followed by public outreach and dialogue, and then further iteration on the language until the staff has established the rudiments of its proposed rule for Commission consideration.”
  - “May need to develop requirements at a high level and utilize guidance documents to address details and technology-specific considerations; therefore, the staff should continue to work prospectively with stakeholders to identify and develop necessary regulatory guidance and technical bases.”

Southern Company's Perspective on Part 53

- Part 53 rulemaking offers an important opportunity **to set the foundation** for developing an integrated, technology inclusive **transformational** regulatory framework to achieve the following goals:
  1. Cohesive technical requirements and regulatory oversight programs set for all stages of a nuclear power plant life cycle (**Design, Licensing, Construction, Operation, and Decommissioning**)
  2. Coherent and consistent requirements and regulatory oversight programs for different designs based on design-specific safety margins, minimizing unbalanced regulatory requirements for different designs resulting in unfair competitive advantages
  3. Development and deployment of owner-controlled programs to improve efficiency and effectiveness of programmatic requirements and regulatory oversight programs.
- Southern Company believes achieving the above goals will result in commercially-viable designs that can be effectively and efficiently licensed, constructed, and operated.

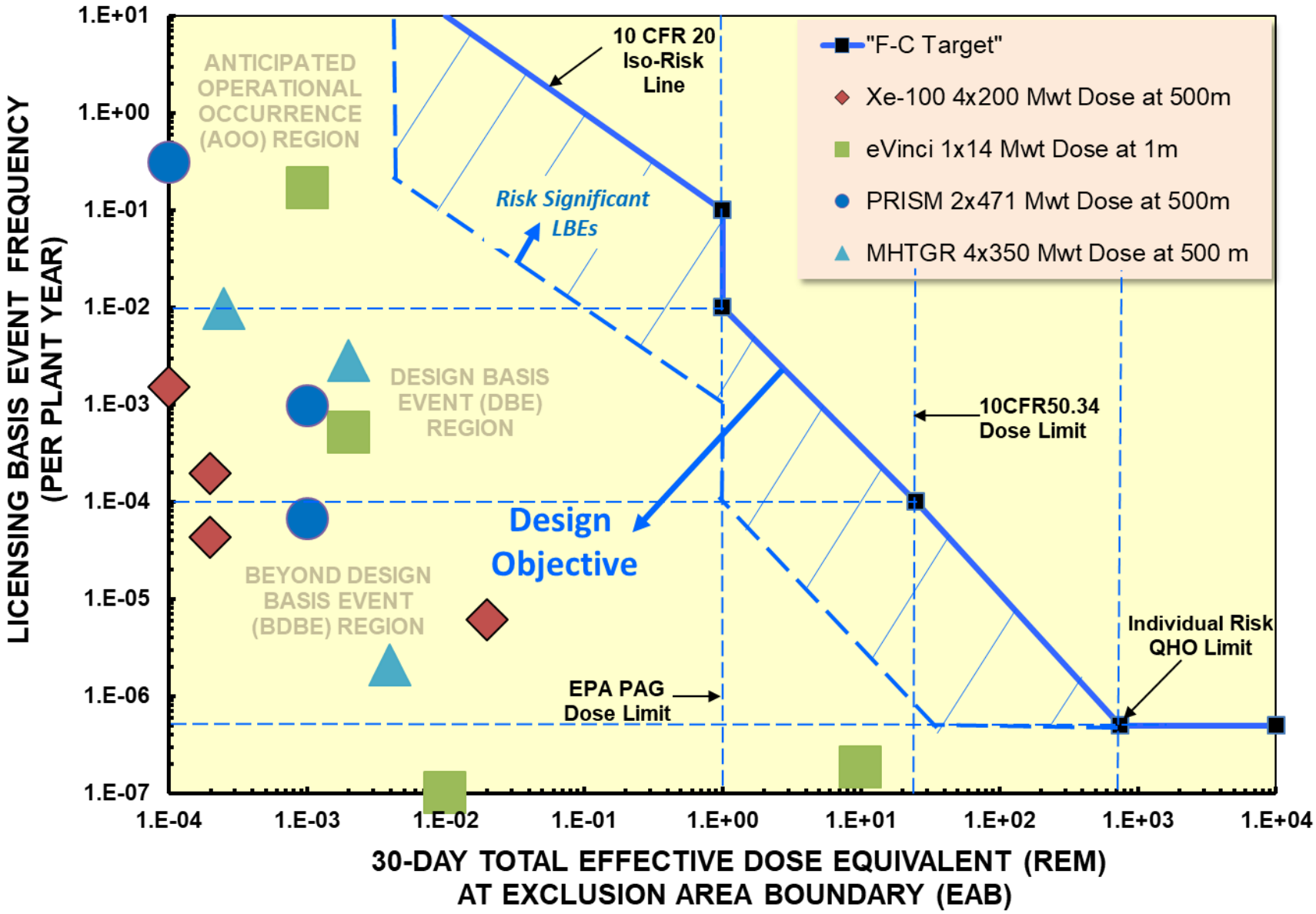
Southern Company's Perspective on Part 53

- Risk-Informed and Performance-Based (RIPB) Part 53 that includes the following will achieve the goals:
  - An alternative to the current qualitative Part 50 and Part 52 language to meet regulatory expectations. This will support Goals 1 and 2 by allowing coherent and consistent regulatory requirements and regulatory oversight programs to be established for a specific design and across different designs.
  - The foundation for regulatory oversight programs in which the regulatory body sets clear expectations and enforces them while the operator is primarily responsible for safety (consistent with the Canadian approach). This will make such programs more effective and efficient.
- The current Commission-directed deadline of 2024 for a new rule that facilitates achieving the above transformational goals is aggressive (making effectiveness of interim interactions more difficult and critical), but the timeline is justified and achievable because we have worked on RIPB for over 30 years.
- Similar to using any new language or structure, the concern that new rule may cause regulatory complications is real. Unforeseen licensing complications should be addressed through industry and NRC engagement.

Other Regulatory Modernization Needs

- Examples
  - Special Treatment Requirements (10 CFR Part 21 – Reporting of defects, 10 CFR 50.49 - Environmental qualification of electric equipment important to safety for nuclear power plants, inservice testing requirements in 10 CFR 50.55a, inservice inspection, etc.)
  - Emergency Planning Zone
  - Reactor Oversight Program
  - Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)
  - Maintenance Rule
- Needed because they impact:
  - Commercial viability through rightsizing the requirements
  - Balance treatment of different designs based on their design specific safety case
  - Regulatory oversight efficiency and effectiveness
  - Systematically, predictably and efficiently managing state of knowledge changes (even more crucial for new designs)

Example of Systematic, Transparent, and Coherent Treatment of Different Designs



Concluding Remarks

- Transformational and robust Part 53 is needed and can be deployed by 2024.
- The Rule language, as part of "... an integrated master plan" [1] should establish a firm foundation "... to help the agency achieve the Commission's goal of a holistic, risk-informed and performance-based regulatory structure." [1] This will result in a predictable, coherent, and transparent framework being available for efficient and effective establishment of technical requirements and regulatory oversight.
- Per Commission direction, the NRC staff should work collaboratively with the industry to manage potential implementation risks.

[1] Staff Requirements Memorandum M060503B, "Briefing on Status of Risk-Informed and Performance-Based Reactor Regulation," June 2006.

Back-Up
LMP/TICAP and Part 53

Southern Company

Risk-Informed Ground Rules

Rule 1: There is no practical “Zero” risk option

Rule 2: All options do not have equal significance level

Rule 3: The required confidence level is dependent on the significance level

Rule 4: Conservative decision making is best achieved through realistic and integrated risk assessment.

Rule 5: Using systematic uncertainty analysis is best option for managing it (“*If a man will begin with certainties he shall end in doubts, but if he will be content to begin with doubts, he shall end in certainties. Francis Bacon The Advancement of Learning, 1605.*”

Rule 6: Risk-informed decision making provide a useful tool for dealing with uncertainty and complexity, but it does not make the problem simple or difficult. It allows for rightsizing.

Context for Southern Company Perspective
Southern Company RIPB Regulatory Framework

- Mission

  To facilitate the generation of safe, reliable, and affordable energy through a risk-informed operational-focused framework that incentivizes continuous performance improvements through state-of-knowledge advancements and plant-specific margin enhancements.

- Guiding Values
  - Conservative decision-making based on realistic analysis
  - Utility ownership of safety, resulting in effective plant-specific safety improvements
  - Incentivizing an environment of continuous knowledge improvement, resulting in innovative solutions

- Strategy
  - Transitioning to advanced risk-informed programs (see Slide 5 for more information)
  - Providing industry-wide support of risk-informed initiatives such as piloting risk-informed applications for NRC and industry (e.g., 4b and 50.69 pilots), developing industry-leading tools (e.g., FPRA and SPRA), and assisting NRC with its research program (NRC L3 PRA)
  - Investing in the modernized RIPB AR regulatory framework (e.g., NEI 18-04)

LMP/TICAP and Part 53

- Modernizing the “What”
  - » Change the regulatory dose limits to the public based on new scientific evidence
    - Not part of the LMP
    - Not recommended as a priority by Southern Company
  - » Frequency boundaries of meeting these dose limits
    - Establishing frequency boundaries—Highly recommended and it is part of LMP
    - Establishing new frequencies —Not recommended; not a priority for Southern Company
- Modernizing “When”
  - » Eliminating elements of “When” such as AOOs —Not recommended as a priority by Southern Company
  - » Establishing a transparent, RIPB approach for selecting “When” constituents—Recommended and part of LMP
- Modernizing “How”
  - » RIPB approach for SSCs classification —Recommended and is part of the LMP
  - » RIPB base for establishing technical requirements of the SSCs (e.g., functional containment) — Recommended; not part of LMP, but LMP products can be used for this purpose.

LMP/TICAP and Part 53

- Modernizing “How Well” (need for diversity, redundancy, external events treatments, etc.) and programmatic features (inspections, monitoring, Tech Spec., analytical tools verification, etc.)
  - » Modernized RIPB process for setting high level performance objectives —Recommended and is part of the LMP-based safety case
  - » Modernized RIPB programmatic elements (RIPB ISI, RIPB Fire Protection Program, RI technical specification, RIPB surveillance frequency, Maintenance Rule, regulatory framework, etc.) — Not part of the LMP, but the framework (e.g., the C-F curve) can be used to modernize all the RIPB programs. It is highly recommended to be developed.
  - » Modernized RIPB External Events Requirements (e.g., establishing RIPB methods for establishing seismic design basis) —Not part of the LMP, but the framework (e.g., the F-C curve) can be used to modernize all the RIPB programs. It is highly recommended to be developed.

Comments on Proposed 10 CFR Part 53

American Nuclear Society

American Nuclear Society

N. Prasad Kadambi
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March 17, 2021

American Nuclear Society

Purpose of ANS Input to Part 53

ANS members have a great deal of interest in advanced reactors. It is important for ANS to offer them opportunities to participate in formulating the “rules of the road” in this vital rulemaking

- The NRC staff has been holding stakeholder meetings regularly at which a lot of information is presented
  - The ANS letter of March 3, 2021 offers our interpretation of certain key points with the expectation that there will be further discussion and clarification
- The ANS letter contained eight bullet points covering a variety of the areas for which rule language and staff explanation have been provided
  - This presentation provides a separate slide for each of the bulleted points to reiterate our understanding of provisions that have been made available so far

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Part 53 Should Support Endorsed Consensus Standards

The first bullet addresses current ANS efforts to modernize our standards

- We want to take full advantage of national and NRC initiatives promoting modernization of safety standards
  - NEIMA has incorporated risk-informed and performance-based (RIPB) methods in statute and calls for consensus standards
  - NRC incorporated RIPB into regulatory policy 20 years ago
    - NRC implementation of RIPB has been ad hoc
    - ANS has pursued a more systematic approach
- We point out that Subpart D is unnecessarily prescriptive in part
  - Proposed Part 53.530(c) imposes a population center distance over which a licensee may not have any control
  - Subpart D is important for ANS standards that address population distribution, environmental effects, and socio-economic factors

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Integrated Decision Making for Safety Findings

The proposed Part 53 construct is supportive of structured performance objectives with integrated decision-making to ensure defense-in-depth

- A hierarchical decomposition of performance factors appears to be part of Subpart B
  - One category of factors requires accomplishment of safety functions to support adequate protection
  - Another category appears to cover cost-justified safety enhancements purportedly for consistency with current practice
    - It appears that ALARA is used as an analog for including cost-benefit analysis requirements. This deserves further discussion
    - A later slide deals with ALARA in more detail
- A properly constructed structure of performance objectives may reveal unnecessarily prescriptive elements

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Design, Construction and Operation in Continuum

Part 53 offers the opportunity to depart from fragmented consideration of design, construction and operation

- The inefficiencies of the current practice of disjointed consideration of the major phases of project accomplishment are well known
- In addition to correcting for these inefficiencies, additional benefit of effectiveness is possible by managing requirements hierarchically
  - Large margins included at the component level may offer little benefit at the system or function levels
  - NRC's Standards Forum showed need for harmonization of standards that impose margins in isolation
- Part 53 should be combined with a systems engineering framework that holistically considers the phases on a life-cycle basis

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Implementation of Parts 50 and 52 Offer Valuable Lessons

While 10 CFR Parts 50 and 52 have been successful in assuring adequate protection currently, experience indicates lessons to be learned

- Part 52 has not been consistently implemented with RIPB methods being applied in safety decisions
  - A prominent example relates to rebar issues in AP-1000 plants under construction
  - Potential benefits of RIPB in Part 52 relate to how ITAACs may be improved using performance-based approaches
- Implementation of Part 50 has accommodated RIPB methods successfully
  - Promulgation of 10 CFR Part 50.69 has provided much benefit
  - The application of RIPB concepts in the Reactor Oversight Process offers valuable lessons that should fully inform Part 53 development
- Part 53 can benefit from RIPB not having to be “bolted on” afterwards

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Build on Success of the Licensing Modernization Project

The LMP has resulted in production of industry reports and RG-1.233 which should facilitate licensing applications that are easier to review and establish more effective licensing bases for oversight

- Part 53 should support application of RIPB methods in all aspects of the licensing basis
- The regulatory structure should support development of coherent and consistent requirements and regulatory oversight programs for different designs based on design specific safety margins, minimizing unbalanced regulatory requirements for different designs resulting in unfair competitive advantage
- It should also enable development of owners-controlled programs to improve efficiency and effectiveness of programmatic requirements and regulatory oversight programs (example of such programs currently in place include RIPB surveillance frequency program and 10CFR 50.69)

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Build on NUREG/BR-0303, "Guidance for Performance-Based Regulation"

NUREG/BR-0303 offers the structure of the Reactor Oversight Process to support adequate protection findings. Part 53 should provide for construction of such objectives' hierarchies whereby logically decomposed performance objectives and their associated decision criteria are part of managing requirements.

- Transparency and predictability would be enhanced with discrete objectives being successfully accomplished
- Performance elements identified in this way can incentivize improved outcomes while providing flexibility for innovation
  - The interdependence between flexibility and margins needs to be deliberately incorporated into the integrated decision-making processes of the regulator as well as the licensee

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Consistency with ANS Position Statement 46

ANS PS-46 anticipated the need for a rulemaking of the type now underway

- It recognized the flexibility available in the existing regulatory structure even without RIPB methods
  - Flexibility by itself, without other necessary elements, was recognized to be insufficient for new reactor designs
  - Achieving observable outcome attributes is superior to mere compliance with prescribed processes
- It is now entirely possible to envision broadly similar beneficial outcomes from implementing a wide range of technologies

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Careful Deployment of ALARA Principles

Success of ALARA principles for radiation protection does not necessarily translate to other areas

- Experience with implementation of ALARA offers plentiful evidence of suboptimal and counterproductive results
  - Being risk-informed does not by itself produce sound outcomes
- The proposed Subpart F lacks clarity on defining desired outcomes and the use of ALARA principles and cost-benefit analysis to achieve them
  - Subpart F may work better if oriented toward margins optimization over the different phases of the plant life-cycle

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Summary

ANS is convinced that the aspirations of the Commission's White Paper on RIPB (SRM-SECY-98-0144) can and should be realized in practice through the advent of 10 CFR Part 53

- Five outcome attributes of risk-informed approaches (including logically prioritized challenges, consideration of a broad set of resources to defend against them, and better decision-making that considers sensitivity to assumptions);
- Four outcome attributes of performance-based approaches (including flexibility with incentives for improved outcomes);
- Five outcome attributes of RIPB approaches (including focusing attention on the most important activities, objective decision criteria for evaluating performance, identifying parameters for monitoring system and licensee performance, and focusing on results for regulatory decision-making).

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Stakeholder Insights

Discussion

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Continuing Dialogue on Structure and Logic of Part 53

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Key Messages

- The staff is committed to developing a technology-inclusive, risk-informed regulatory framework in accordance with the Commission-approved schedule.
- The staff is implementing a novel approach of releasing preliminary rule language to facilitate discussion and recognizes this requires an iterative dialogue as language is refined.
- The staff is committed to a framework that achieves the goals of the Commission Advanced Reactor Policy Statement and NRC's Principles of Good Regulation.
- The staff recognizes the importance of developing a regulatory framework that provides predictability and stability while accommodating various technologies.
- The staff is ensuring that it collects input from numerous stakeholders including industry, trade groups, nongovernmental organizations (NGOs), the public, and ACRS, as it evaluates changes to the preliminary language.
    - The rule language will remain open for discussion as the staff works toward providing the Commission a proposed rule.

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Rulemaking Objectives

1) Provide reasonable assurance of adequate protection of the public health and safety and common defense and security at reactor sites at which advanced nuclear reactor designs are deployed, to at least the same degree of protection as required for current-generation light water reactors;
2) Protect health and minimize danger to life or property to at least the same degree of protection as required for current-generation light water reactors;
3) Provide greater operational flexibilities where supported by enhanced margins of safety that may be provided in advanced nuclear reactor designs;
4) Ensure that the requirements for licensing and regulating advanced nuclear reactors are clear and appropriate; and
5) Identify, define, and resolve additional areas of concern related to the licensing and regulation of advanced nuclear reactors.

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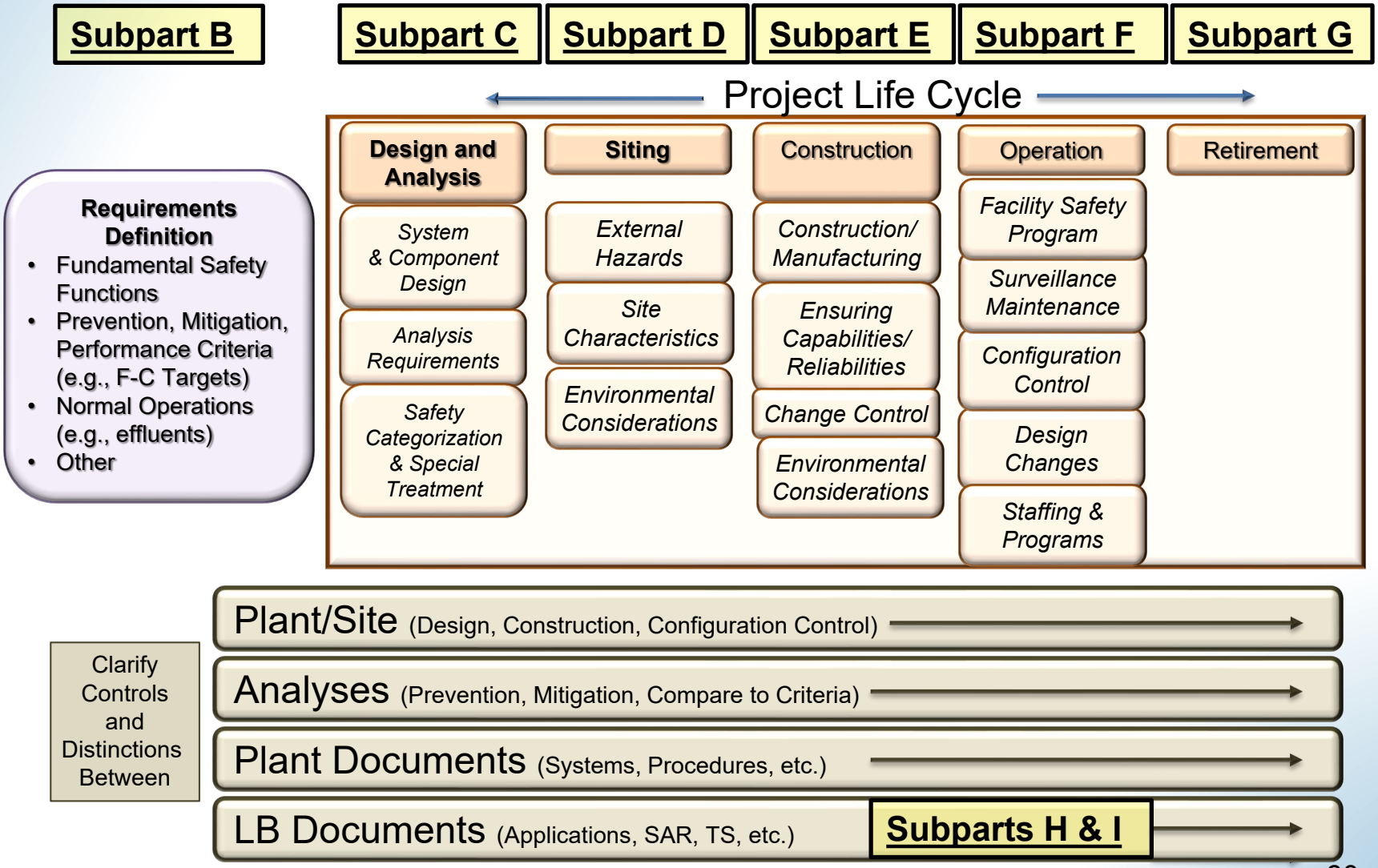
NRC Staff Plan to Develop Part 53



NRC Staff Engagement Plan

ACRS Interactions

Stakeholder Interactions									
	Framework	Safety Criteria	Design	Siting	Construction	Operations	Decommission	Licensing	General/Admin
Sept 20									
Nov 20									
Dec 20									
Jan 21									
Feb 21									
Mar 21									
Apr 21									
May 21									
Jun 21									
Jul 21	Consolidated Technical Sections								
Aug 21	Consolidated Technical Sections								
Sept 21									
Oct 21									
Nov 21	Consolidated Rulemaking Package								
Dec 21									
Jan 22	ACRS Full Committee								
Feb 22									
Mar 22									
Apr 22									
May 22	**Draft Proposed Rulemaking Package to the Commission**								
Jun 22									
Jul 22									
Aug 22									
Sept 22									
Oct 22									

	Concept/Introduction
	Discussion
	Interim Staff Resolution

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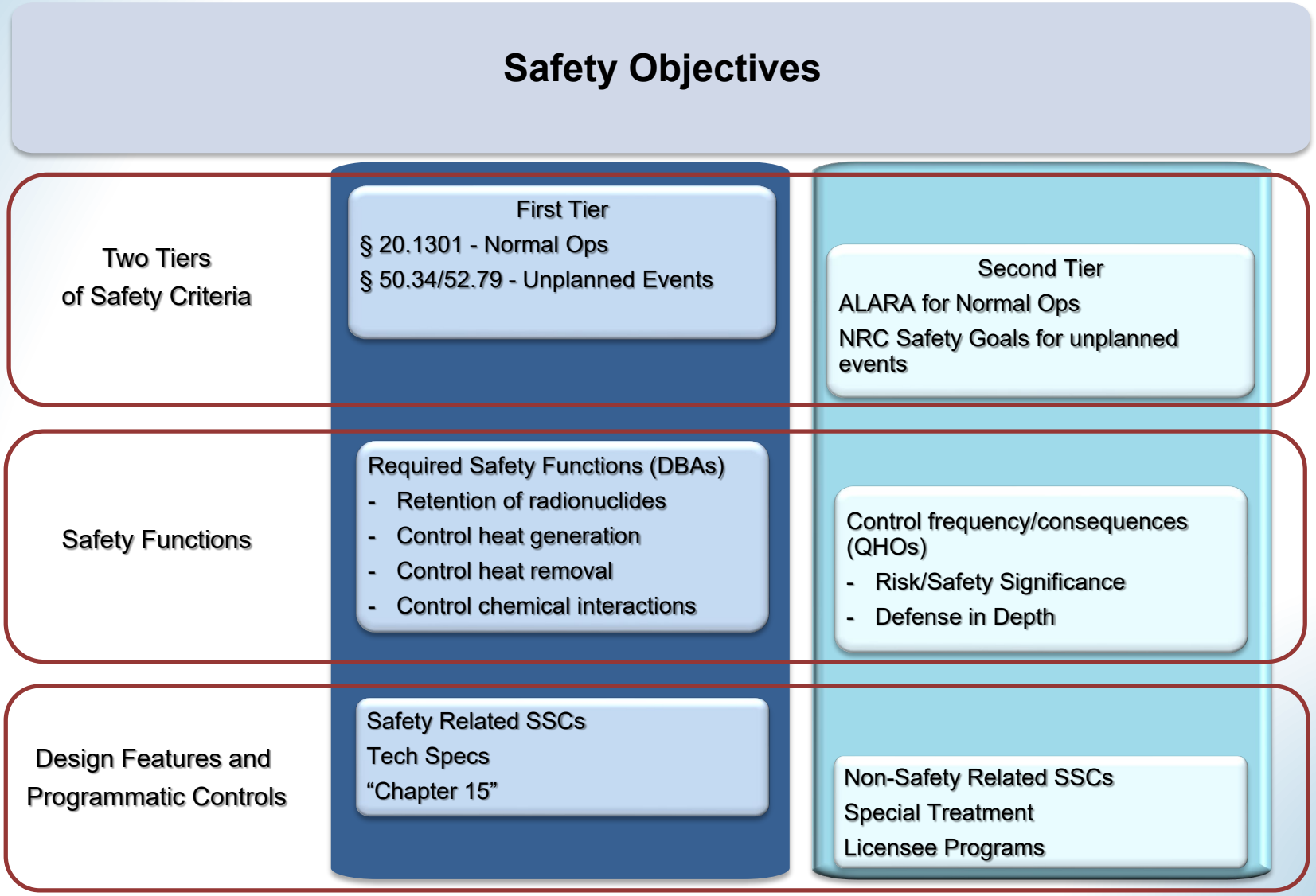
Subpart B Flowchart



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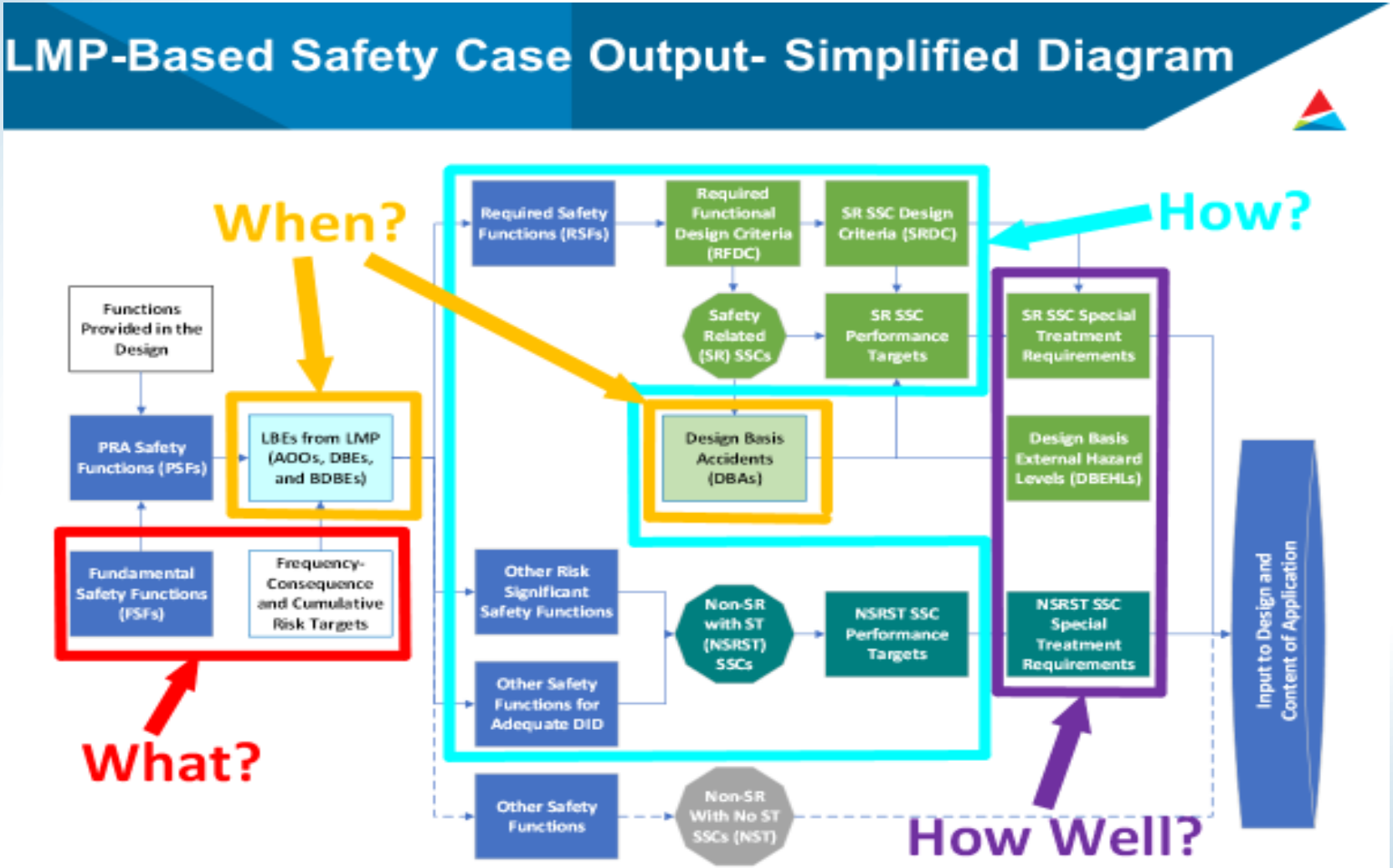
Additional Discussion



Taken from Technology-Inclusive Content of Applications Project (TICAP) Presentation

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Part 50 and Part 53 Licensing Frameworks

- Safety criteria
  - Same safety criteria in Parts 50 and 53
  - QHOs used in guidance under Part 50
- Design and Analyses
  - DBAs
    - Part 50: Assessed using prescriptive, highly conservative analyses
    - Part 53: Assessed methodically using event frequencies and assuming only safety-related structures, systems, and components (SSCs) are available
  - BDBEs
    - Part 50: Identified & assessed by largely ad-hoc, prescriptive approach with uncertainties addressed through conservatisms
    - Part 53: Derived methodically using event frequencies with explicit consideration for uncertainties
- Special Treatment for Non-Safety-Related but Risk-Significant SSCs
  - Part 50: Ad-hoc (e.g., § 50.69 programs, Reliability Assurance Programs)
  - Part 53: Systematic approach to control frequencies and consequences of the LBEs in relation to safety criteria

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Additional Discussion – First Tier

- Possible Applications of First Tier Safety Criteria
  - Minimally acceptable level of safety
  - Defines required safety functions
  - Defines safety classification (safety-related SSCs)
  - Supported by analyses DBA
  - Defines SSCs for protection against external events up to the design basis external hazard levels
  - Defines appropriate content of technical specifications
    - Reserved for the most significant safety requirements
    - Necessary to obviate the possibility of an abnormal situation or event giving rise to an immediate threat to the public health and safety
  - May support staffing and operator licensing decisions
  - Greatest level of detail for information in licensing documents

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Additional Discussion – Second Tier

- Possible Applications of Second Tier Safety Criteria
  - With first tier, ensures appropriate level of safety for long-term, risk-informed operations
  - Supported by systematic analyses
  - Defines additional risk-informed requirements
  - Enables appropriate special treatment for non-safety related SSCs
  - Enables risk management approach to operations
  - May enable staffing and operator licensing decisions
  - Enables appropriate level of detail in licensing basis documentation based on a risk-informed, function-oriented and performance-based approach

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Continuing Dialogue on Structure and Logic of Part 53

Discussion

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MEETING BREAK

Meeting to resume in 1 hour

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Key Guidance

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Key Guidance by Subpart

Subpart A: General Provisions	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	
Subpart B: Safety Criteria	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ Further explanation of criteria and two-tier structure in the Statements of Consideration
Subpart C: Design and Analysis	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ NEI 18-04 & RG 1.233, LMP ▪ ANS/ASME-RA-S-1.4 (Non-LWR PRA Standard) ▪ ANS/ASME Standards ▪ Fuel Qualification ▪ RG 1.232, Advanced Reactor Design Criteria (ARDC)	▪ Application of Analytical Margins ▪ Treatment of Chemical Hazards
Subpart D: Siting Requirements	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ SECY-20-0045/RG 4.7, Siting ▪ External Hazard Updates ▪ Risk-Informed Seismic Design (RES); ANS 2.26	N/A

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Key Guidance by Subpart

Subpart E: Construction and Manufacturing	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ Manufacturing Guidance ▪ QA Alternatives
Subpart F: Operations	
SSCs	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ NEI 18-04 & RG 1.233, LMP	▪ Technical Specifications ▪ Special Treatment (possible industry initiative) ▪ Maintenance, Repair & Inspection
Personnel	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ Division of Reactor Oversight (DRO) Paper/preliminary Interim Staff Guidance (ISG)	▪ Concept of Operations
Programs	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ EP for Small Modular Reactors (SMRs)/Other New Technologies (ONTs) Final Rule, RG 1.242 ▪ Radiation Protection	▪ Emergency Preparedness ▪ Security Programs ▪ Facility Safety Program

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Key Guidance by Subpart

Subpart G: Decommissioning	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	N/A
Subpart H: Licensing	
Existing Guidance or Guidance Under Development	Additional Guidance
▪ TICAP ▪ ARCAP	▪ Manufacturing Licenses ▪ Possibly Conceptual Design
Subpart I: Maintaining Licensing Basis	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ 50.59 Equivalent ▪ Final Safety Analysis Report (FSAR)/PRA Updates
Subpart J: Administrative/Misc.	
Existing Guidance or Guidance Under Development	Additional Guidance
N/A	▪ Reporting Requirements ▪ Financial/Liability

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TICAP / ARCAP

- Advanced Reactor Content of Application Project (ARCAP)
  - Purpose is to develop technology-inclusive, risk-informed and performance based application guidance
  - Being developed to support 10 CFR Part 50, Part 52, and Part 53 applications
    - Near-term need to develop guidance to support expected advanced reactor Part 50/52 applications using the LMP process endorsed in RG 1.233
    - Guidance will be updated as Part 53 rulemaking language is adjusted
  - Encompasses TICAP
- TICAP
  - Scope is governed by the LMP-based safety case
    - LMP process uses risk-informed, performance based approach to select licensing basis events, develop SSC categorization and ensures defense-in-depth is considered
  - Industry developing key portions of TICAP guidance
  - Industry guidance will be supplemented by NRC staff-developed guidance as appropriate

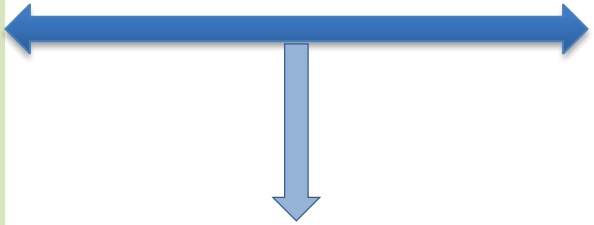
ARCAP

Outline Safety Analysis Report (SAR) – Based on TICAP Guidance

1. General Plant Information, Site Description, and Overview of the Safety Case
2. Generic Analyses
3. Licensing Basis Event (LBE) Analysis
4. Integrated Plant Analysis
5. Safety Functions, Design Criteria, and SSC Categorization
6. Safety Related SSC Criteria and Capabilities
7. Non-safety related with special treatment SSC Criteria and Capabilities
8. Plant Programs

Additional SAR Content –Outside the Scope of TICAP

9. Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste
10. Control of Occupational Doses
11. Organization
12. Initial Startup Programs



Audit/inspection of Applicant Records

- Calculations
- Analyses
- P&IDs
- System Descriptions
- Design Drawings
- Design Specs
- Procurement Specs

Additional Portions of Application

- Technical Specifications
- Technical Requirements Manual
- Quality Assurance Plan (design)
- Fire Protection Program (design)
- PRA
- Quality Assurance Plan (construction and operations)
- Emergency Plan
- Physical Security Plan
- Special Nuclear Material (SNM) physical protection program
- SNM material control and accounting plan
- Cyber Security Plan
- Fire Protection Program (operational)
- Radiation Protection Program
- Offsite Dose Calculation Manual
- Inservice inspection/Inservice testing (ISI/IST) Program
- Environmental Report
- Site Redress Plan
- Exemptions, Departures, and Variances
- Facility Safety Program (under consideration for Part 53 applications)

- Safety Analysis Report (SAR) structure based on clean sheet approach

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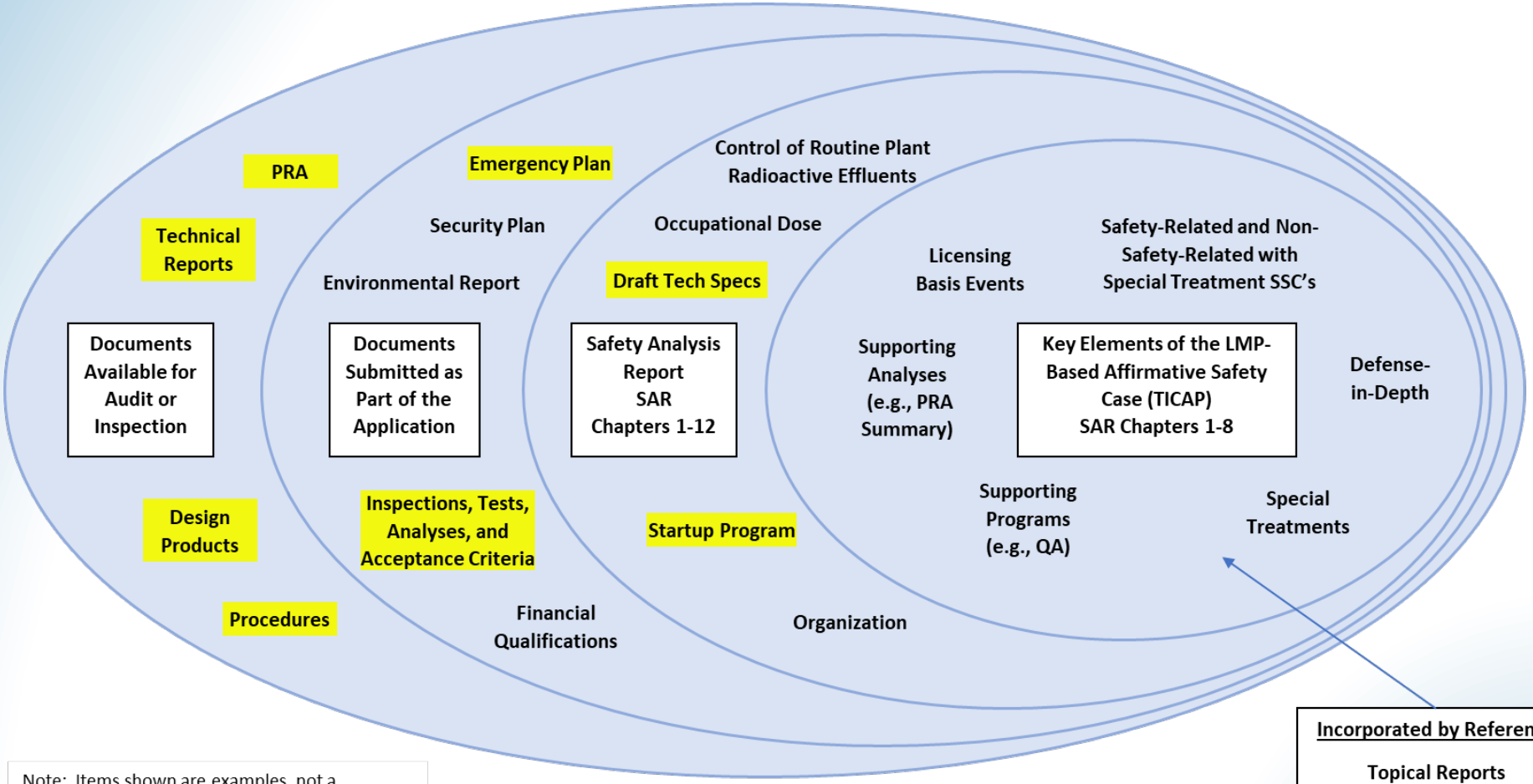
Visual Depiction of TICAP Guidance in Context of an Advanced Reactor Application (Taken from Industry TICAP presentation)



Note: Items shown are examples, not a complete list. Highlighted items may also support the LMP-Based Affirmative Safety Case even though they are not inside the TICAP area.

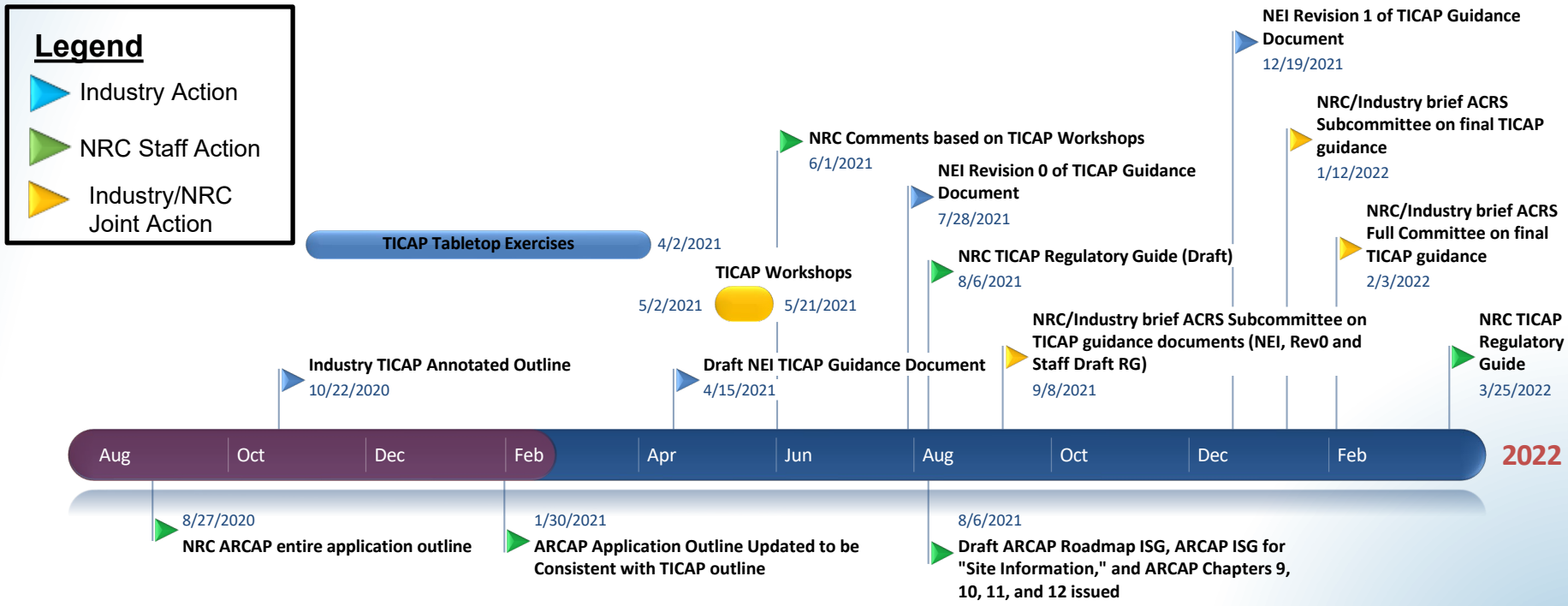
* Special treatments include quality assurance, reliability assurance, protection against design basis external events, equipment qualification, in-service inspection, etc., as described in NEI 18-04 Table 4-1.

Tentative Schedule

- TICAP
  - 4/15/21: Draft NEI Guidance Document to NRC
    - Will factor in lessons-learned from TICAP tabletop exercises on 4 different technologies that are being performed in the February-March 2021 time frame
  - May 2021: Workshops with NRC on draft guidance document
  - Late July: NEI Guidance Document Rev. 0 provided to the NRC
  - Early August: NRC TICAP draft regulatory guide issued
- ARCAP
  - Several ARCAP draft documents discussed in public meetings including:
    - "Site Information"
    - Chapter 9, "Control of Routine Plant Radioactive Effluents, Plant Contamination, and Solid Waste"
    - Chapter 10, "Control of Occupational Doses"
    - Chapter 11, "Organization"
    - Chapter 12, "Initial Startup Program"
  - Staff developing ARCAP Roadmap ISG
  - Early August: NRC draft interim staff guidance to be issued for above document
- Tentative plan to brief ACRS Subcommittee on the above document in Fall of 2021

Tentative Schedule

Notes:
- TICAP portion of the application based on applying LMP process to appropriate portions of an application. TICAP milestones shown above the timeline
- ARCAP broader than TICAP. Provides roadmap for all portions of an application and encompasses TICAP
- Timeline does not reflect TICAP and ARCAP efforts that started in December of 2019. These early efforts led to the development of the industry-led TICAP Annotated Outline discussed in an October 22, 2020, public meeting and the NRC-led ARCAP outline plan discussed in a August 27, 2020, public meeting



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Key Guidance

Discussion

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Subpart E – Construction and Manufacturing

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NRC Staff Plan to Develop Part 53

Subpart B | **Subpart C** | **Subpart D** | **Subpart E** | **Subpart F** | **Subpart G**

Project Life Cycle

Requirements Definition
- Fundamental Safety Functions
- Prevention, Mitigation, Performance Criteria (e.g., F-C Targets)
- Normal Operations (e.g., effluents)
- Other

Design and Analysis	Siting	**Construction**	Operation	Retirement
System & Component Design	*External Hazards*	*Construction/ Manufacturing*	*Facility Safety Plan*	
Analysis Requirements	*Site Characteristics*	*Ensuring Capabilities/ Reliabilities*	*Surveillance Maintenance*	
Safety Categorization & Special Treatment	*Environmental Considerations*	*Change Control*	*Configuration Control*	
		Environmental Considerations	*Design Changes*	
			Staffing & Programs	

Clarify Controls and Distinctions Between

- Plant/Site (Design, Construction, Configuration Control) →
- Analyses (Prevention, Mitigation, Compare to Criteria) →
- Plant Documents (Systems, Procedures, etc.) →
- LB Documents (Applications, SAR, TS, etc.) **Subparts H & I** →

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Part 53 General Layout

- Subpart A, General Provisions
- Subpart B, Technology-Inclusive Safety Objectives
- Subpart C, Design and Analysis
- Subpart D, Siting Requirements
- Subpart E, Construction and Manufacturing
- Subpart F, Requirements for Operation
  - Facility Safety Program
- Subpart G, Decommissioning Requirements
- Subpart H, Applications for Licenses, Certifications and Approvals
- Subpart I, Maintaining and Revising Licensing Basis Information
- Subpart J, Reporting and Administrative Requirements

Subpart E – Construction and Manufacturing

- Scope and Purpose
- Part 1 - Construction
  - (a) Management and Control
  - (b) Construction Activities
  - (c) Inspection and Acceptance
  - (d) Communication
- Part 2 – Manufacturing
  - (a) Management and Control
  - (b) Manufacturing Activities
  - (c) Fuel Loading
  - (d) Communication
  - (e) Transportation
  - (f) Acceptance and Installation at the Site

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§ 53.600 – Scope and Purpose

- Subpart applicable to construction and manufacturing activities authorized by Construction Permit (CP), Combined License (COL), Manufacturing License (ML), or a Limited Work Authorization (LWA)

§ 53.610 – Construction

- Management and Control
  - Design and analyses conform with subpart C
  - Organization and procedures describing qualifications, responsibilities, and interfaces
  - Program to evaluate construction experience
  - Preliminary emergency plan for site, fitness-for-duty program
  - Quality Assurance conforms to generally accepted codes and standards
  - Radiation protection, information security, and cyber security programs, as applicable

§ 53.610 – Construction

- Construction Activities
  - Procedures in place to appropriately handle special nuclear material, multi-unit site hazards, control of design, redress plan
  - Requirements for fresh fuel storage, fire protection
- Inspection and Acceptance
  - Inspect and test SSCs prior to acceptance
- Communication
  - Procedures for coordinating with other units and NRC

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§ 53.620 – Manufacturing

- Management and Control
  - Design and analyses conform with subpart C
  - Organization and, procedures describing qualifications, responsibilities, and interfaces
  - Program to evaluate manufacturing experience
  - Fitness-for-duty program
  - Quality Assurance conforms to generally accepted codes and standards
  - Radiation protection, information security, and cyber security programs, as applicable

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§ 53.620 – Manufacturing

- Manufacturing Activities
  - Adhere to manufacturing license, conform to generally accepted codes and standards
  - Procedures in place to appropriately handle SNM, fresh fuel, fire protection, emergency planning, radiation protection, minimizing contamination
- Fuel Loading – Develop further, if pursued

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§ 53.620 – Manufacturing

- Communication – Stay in contact with NRC
- Transportation
  - Interface with 10 CFR Part 71
  - Procedures for movement, transfer only to accepted license holders
  - Supports fixed siting of manufactured reactors
  - Not currently planning to address mobile reactors
- Acceptance and Installation
  - Reactor must be certified in compliance with ML prior to installation
- Consideration of transport and disposal post operation in subsequent subparts

Subpart E: Construction and Manufacturing

Discussion

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Upcoming Challenges: Operations, Manufacturing, and Licensing

Upcoming Challenges: Use of Analytical Safety Margins

- Subpart C, Design and Analysis Requirements

Preliminary Language
§ 53.470 Application of Analytical Safety Margins to Operational Flexibilities
Where an applicant or licensee so chooses, design criteria more restrictive than those defined in § 53.230(b) may be adopted to support operational flexibilities (e.g., emergency planning requirements under Subpart F of this part). In such cases, applicants and licensees must ensure that the functional design criteria of § 53.420(b), the analysis requirements of § 53.450, and identification of special treatment of SSCs and human actions under § 53.460 reflect and support the use of alternative design criteria to obtain additional analytical safety margins. Licensees must ensure that measures taken to provide the analytical margins supporting operational flexibilities are incorporated into design features and programmatic controls and are maintained within programs required in other Subparts.

- Possible applications to operating flexibilities beyond siting and EPZs
- Establishing appropriate design criteria (e.g., offsite dose limits) to justify possible flexibilities

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Upcoming Challenges: Operations, Staffing (Subpart F)

- Subpart F: Establishing and Maintaining Appropriate Staffing
  - Concept for Operations
    - Identifying Role of Personnel in Meeting First Tier Safety Criteria
    - Identifying Role of Personnel in Meeting Second Tier Safety Criteria
- White Paper to be released on Staffing Considerations:
  - "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors"

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Upcoming Challenges: Licensing (Subpart H)

- Manufacturing Licenses
  - Manufacturing, Transportation, Deployment
- Conceptual Design Reviews *(if needed)*
- PRA and Other Submittal Requirements
- License Renewal
- Process for Conversion of Part 50 or 52 application to Part 53 application *(if needed)*
- Interplay with Parts 50 and 52 Lessons Learned Rulemaking

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Upcoming Challenges: Maintaining Licensing Basis (Subpart I)

- Amendments to a license
  - Application (review?)
  - Public notice and consultations
  - Issuance
- Updating FSAR
  - Including PRA
- Change control
  - Changes during construction

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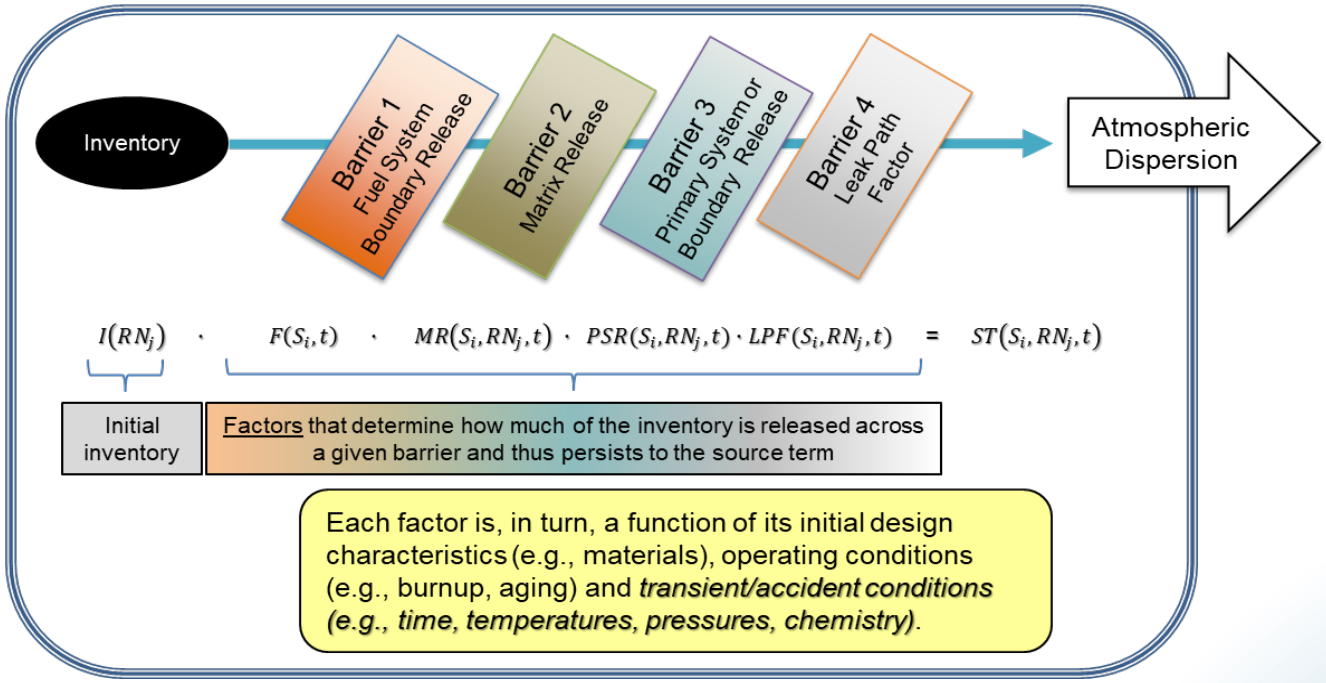
Upcoming Challenges: Misc Requirements (Subpart J)

- Reporting
- Notifications (§§ 50.72, 50.73)
- Financial Qualifications
- Property insurance (§ 50.54(w))
- Liability / Price Anderson

First Principles

Recent NRC activities related to advanced reactors (e.g., functional containment performance criteria, possible changes to emergency planning & security, and DG-1353) recognize the limitations of existing LWR-related guidance, which requires a return to first principles such as fundamental safety functions supporting the retention of radionuclides



See: SECY-18-0096, "Functional Containment Performance Criteria for Non-Light-Water-Reactors," and INL/EXT-20-58717, "Technology-Inclusive Determination of Mechanistic Source Terms for Offsite Dose-Related Assessments for Advanced Nuclear Reactor Facilities"

Unmitigated Consequences & Inherent Characteristics

ANS 2.26

… unmitigated consequence analysis shall be performed considering only the inherent physical or chemical characteristics of the hazardous material and the energy sources for dispersing the material …

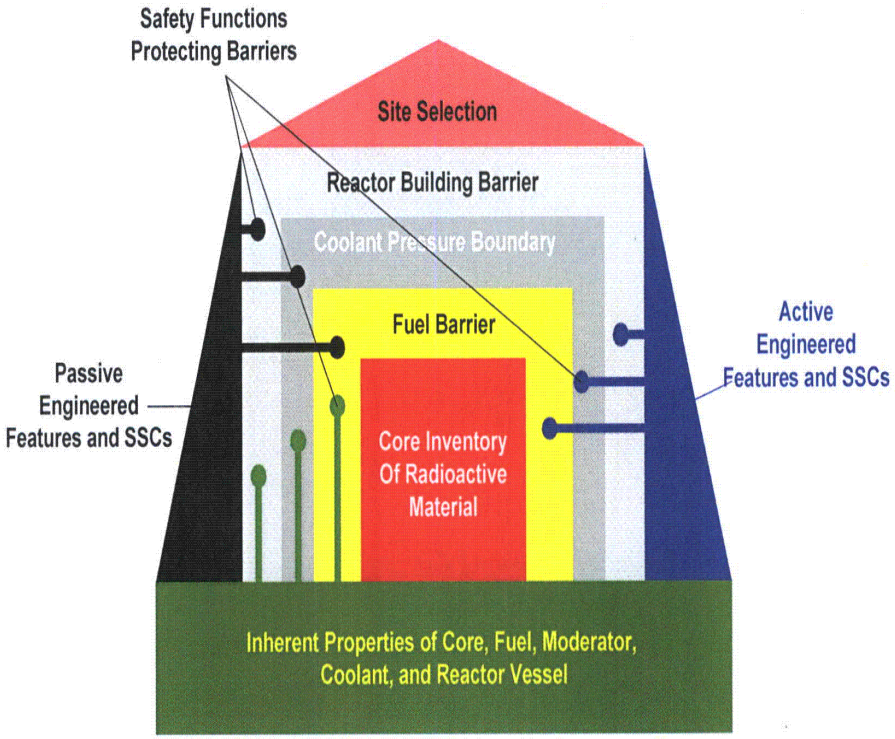
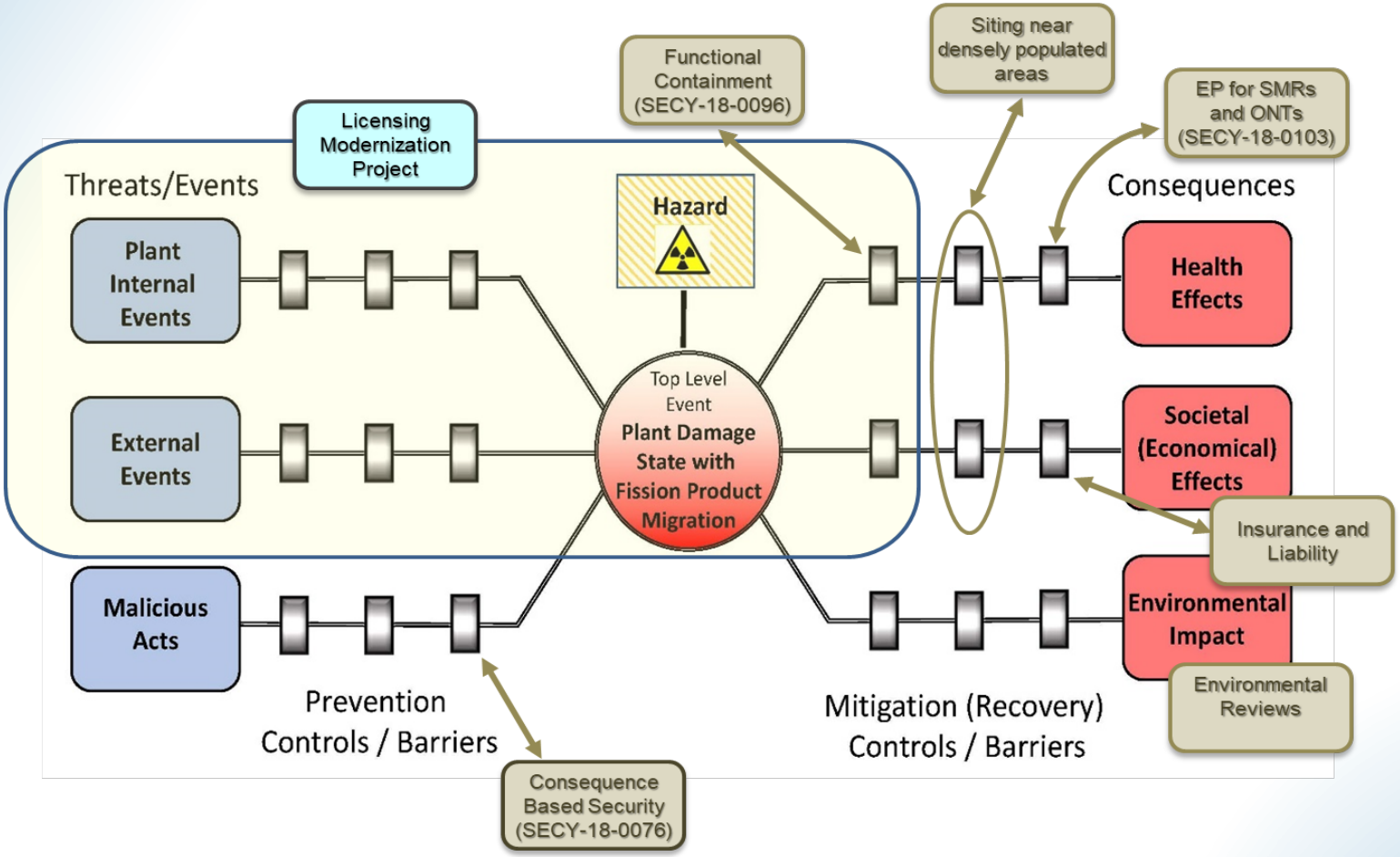


Figure 3-6. Elements of safety design approach incorporated into *Plant Capability Defense-in-Depth*.

Integrated Approach (NRC Activities)



Note that a goal of the current effort is to build from the LMP and have that guidance (NEI 18-04, RG 1.233) be one acceptable way of meeting the requirements to be developed and incorporated into Part 53

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Upcoming Challenges: Operations, Manufacturing, and Licensing

Discussion

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Part 53 Rulemaking Schedule

Milestone Schedule	
Major Rulemaking Activities/Milestones	Schedule
Public Outreach, ACRS Interactions and Generation of Proposed Rule Package	Present to April 2022 (13 months)
Submit Draft Proposed Rule Package to Commission	May 2022
Publish Proposed Rule and Draft Key Guidance	October 2022
Public Comment Period – 60 days	November and December 2022
Public Outreach and Generation of Final Rule Package	January 2023 to February 2024 (14 months)
Submit Draft Final Rule Package to Commission	March 2024
Office of Management and Budget and Office of the Federal Register Processing	July 2024 to September 2024
Publish Final Rule and Key Guidance	October 2024

Final Discussion and Questions

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Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
ALARA	As low as reasonably achievable
ANS	American Nuclear Society
AOO	Anticipated operational occurrence
AR	Advanced reactor
ARCAP	Advanced Reactor Content of Applications Project
ARDC	Advanced Reactor Design Criteria
ASME	American Society of Mechanical Engineers
BDBE	Beyond design-basis event
CDF	Core damage frequency
CFR	Code of Federal Regulations
COL	Combined License

CP	Construction Permit
DBA	Design-basis accident
DBE	Design-basis event
DBEHL	Design-basis External Hazard Level
DG	Draft regulatory guide
DID	Defense in Depth
DRO	Division of Reactor Oversight
DSA	Deterministic Safety Analysis
EAB	Exclusion Area Boundary
EP	Emergency preparedness
EPA	U.S. Environmental Protection Agency
EPZ	Emergency Planning Zone

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Acronyms and Abbreviations

F-C	Frequency – Consequence
FPRA	Fire Probabilistic Risk Assessment
FSAR	Final Safety Analysis Report
FSF	Fundamental Safety Function
IAEA	International Atomic Energy Agency
ISG	Interim staff guidance
ISI	Inservice Inspection
ISO	International Organization for Standardization
IST	Inservice Testing
ITAAC	Inspections, Tests, Analyses, and Acceptance Criteria
LB	Licensing basis
LBE	Licensing basis event
LERF	Large Early Release Frequency
LLWR	Large Light-water Reactor
LMP	Licensing Modernization Project
LPZ	Low population zone
LWA	Limited Work Authorization
LWR	Light-water Reactor
ML	Manufacturing License
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NGO	Nongovernmental organizations
NQA	Nuclear quality assurance
NRC	U.S. Nuclear Regulatory Commission
NSRST	Non-safety related with Special Treatment
NST	Non-safety related with no Special Treatment
ONT	Other new technologies

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Acronyms and Abbreviations

P&ID	Piping and instrumentation diagrams
PAG	Protective action guide
PRA	Probabilistic risk assessment
PSA	Probabilistic safety assessment
PSF	PRA Safety Function
QA	Quality assurance
QHO	Quantitative health objective
rem	Roentgen equivalent man
RES	Risk-informed seismic design
RFDC	Required Functional Design Criteria
RG	Regulatory guide
RI	Risk-Informed
RIPB	Risk-Informed and Performance-Based
RSF	Required Safety Function
SAR	Safety Analysis Report
SECY	Office of the Secretary
SMR	Small modular reactor
SNM	Special nuclear material
SPRA	Seismic probabilistic risk assessment
SR	Safety-related
SRDC	Safety-related SSC Design Criteria
SRM	Staff requirements memorandum
SSCs	Structures, systems, and components
TICAP	Technology Inclusive Content of Application Project
TS	Technical specifications
USNIC	U.S. Nuclear Industry Council