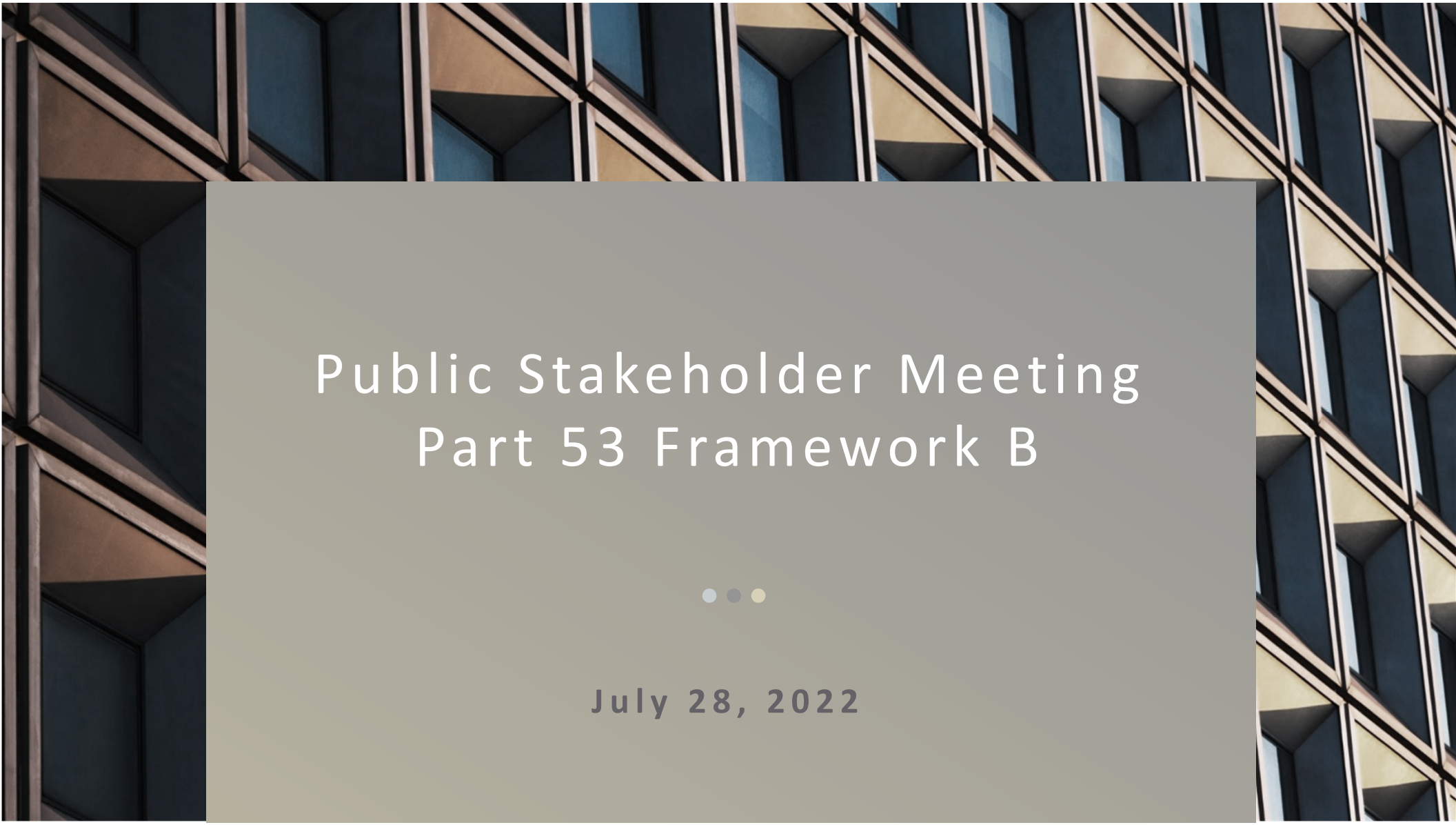


Public Stakeholder Meeting
Part 53 Framework B

July 28, 2022

Agenda

Time	Topic	Lead Participant
10:00 AM – 10:15 AM	Introductory Remarks	NRC/External Stakeholders
10:15 AM – 10:30 AM	Part 53 Introduction	NRC
10:30 AM – 10:45 AM	Framework B Introduction	NRC
10:45 AM – 11:45 AM	Open Discussion: Subparts N – Definitions Subpart O – Construction/Manufacturing Subpart P – Operations Subpart Q – Decommissioning	NRC/External Stakeholders
11:45 AM – 12:45 PM	Lunch Break	NRC/External Stakeholders
12:45 – 2:00 PM	Open Discussion: Subpart R – Application Requirements Subpart S – Licensing Maintenance Subpart T – Reporting Subpart U – Quality Assurance	NRC/External Stakeholders
2:00 – 3:00 PM	AERI Introduction and Open Discussion	NRC/External Stakeholders
3:00 – 3:15 PM	Break	NRC/External Stakeholders
3:15 – 4:50 PM	Open Discussion on Part 53	NRC/External Stakeholders
4:50 – 5:00 PM	Concluding Remarks	NRC/External Stakeholders

Meeting Format and Facilitation

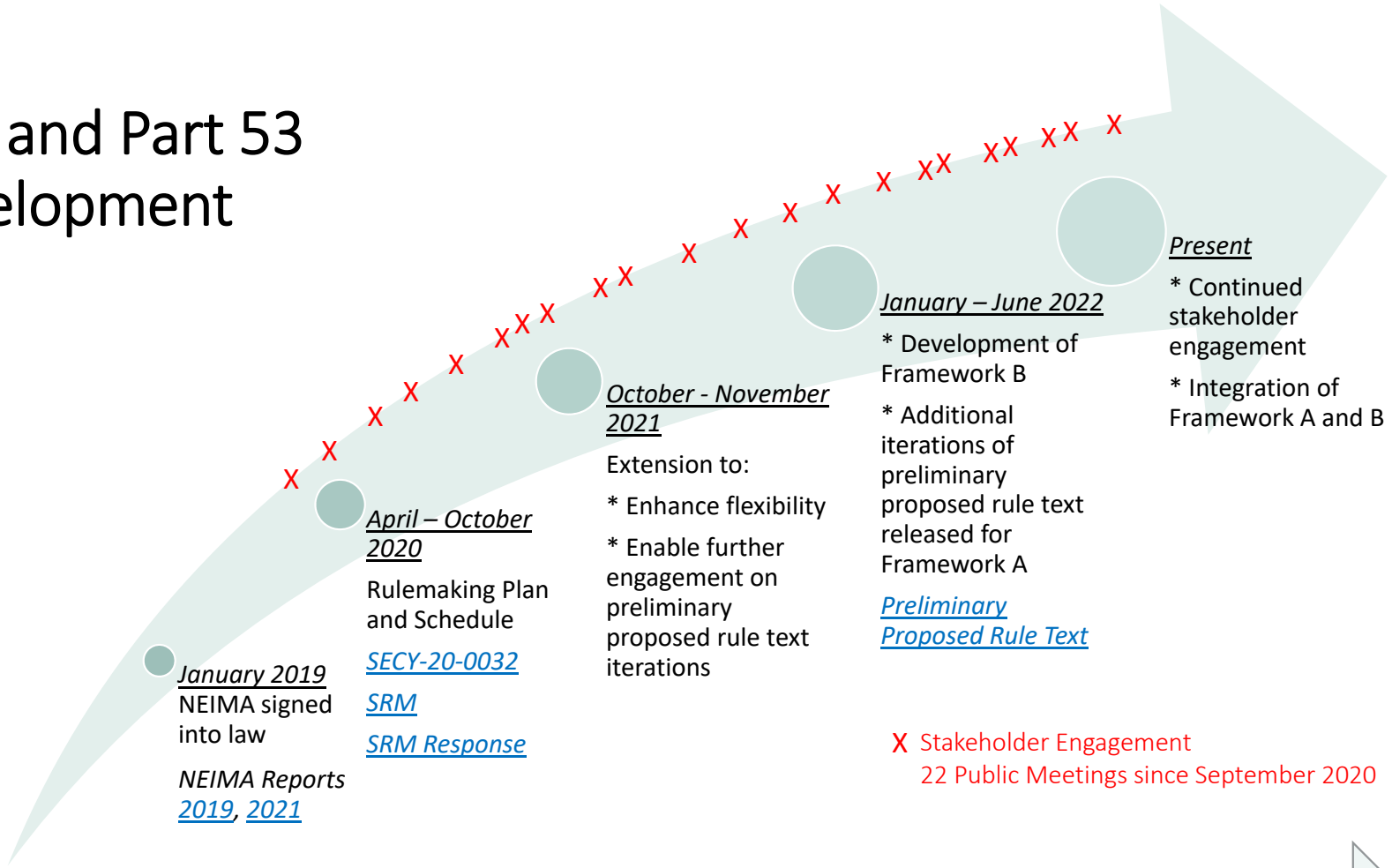

Part 53 Introduction

Nuclear Energy Innovation and Modernization Act

- NEIMA requires the NRC to complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use for commercial advanced nuclear reactors.

- The term “technology-inclusive regulatory framework” means a regulatory framework developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies, including, where appropriate, the use of risk-informed and performance-based techniques and other tools and methods.

NEIMA and Part 53 Development

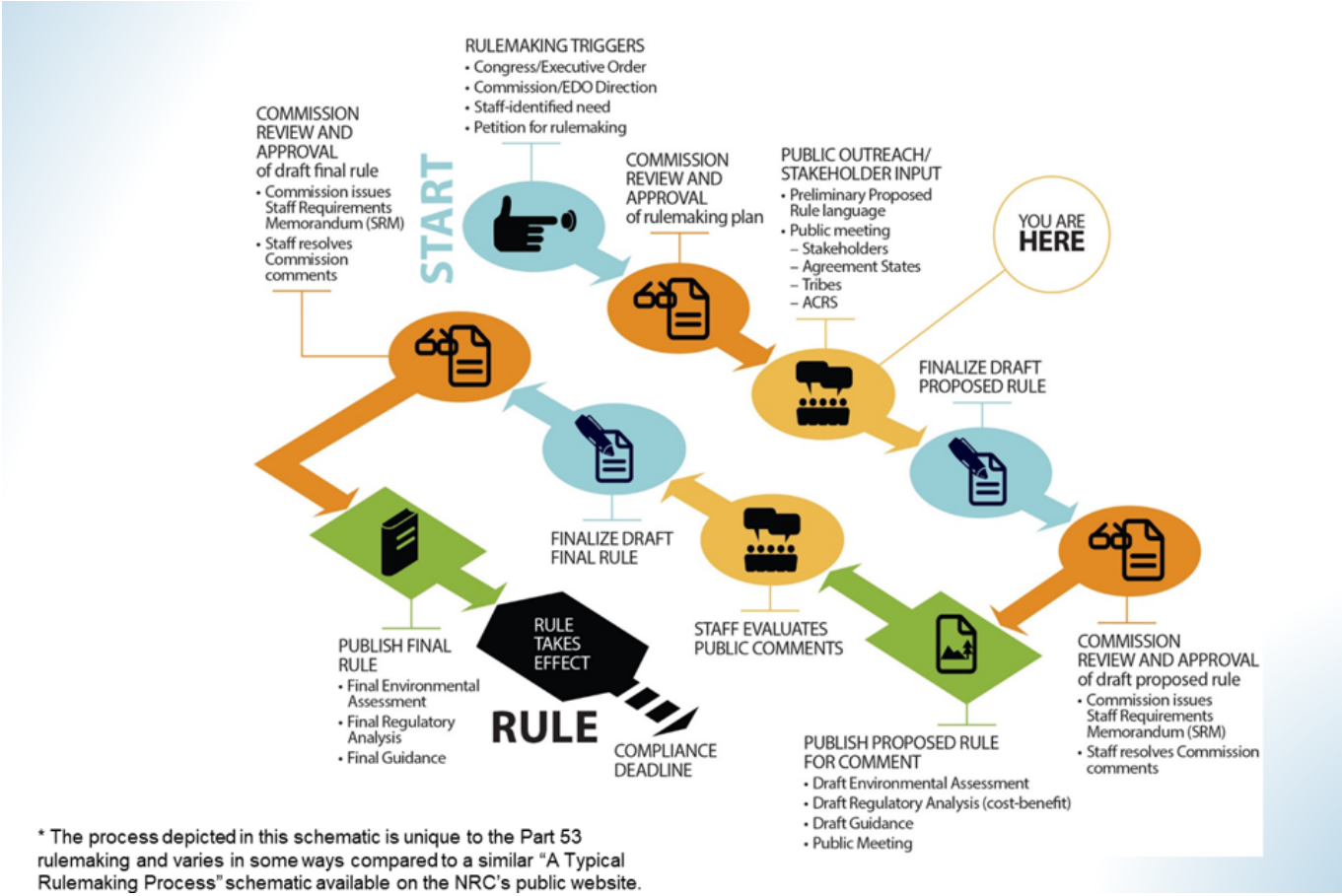


Example Initiatives
Vision and Strategy
LMP
Fuel Qualification
Codes and Standards
TICAP/ARCAP

Stakeholder engagement on Part 53

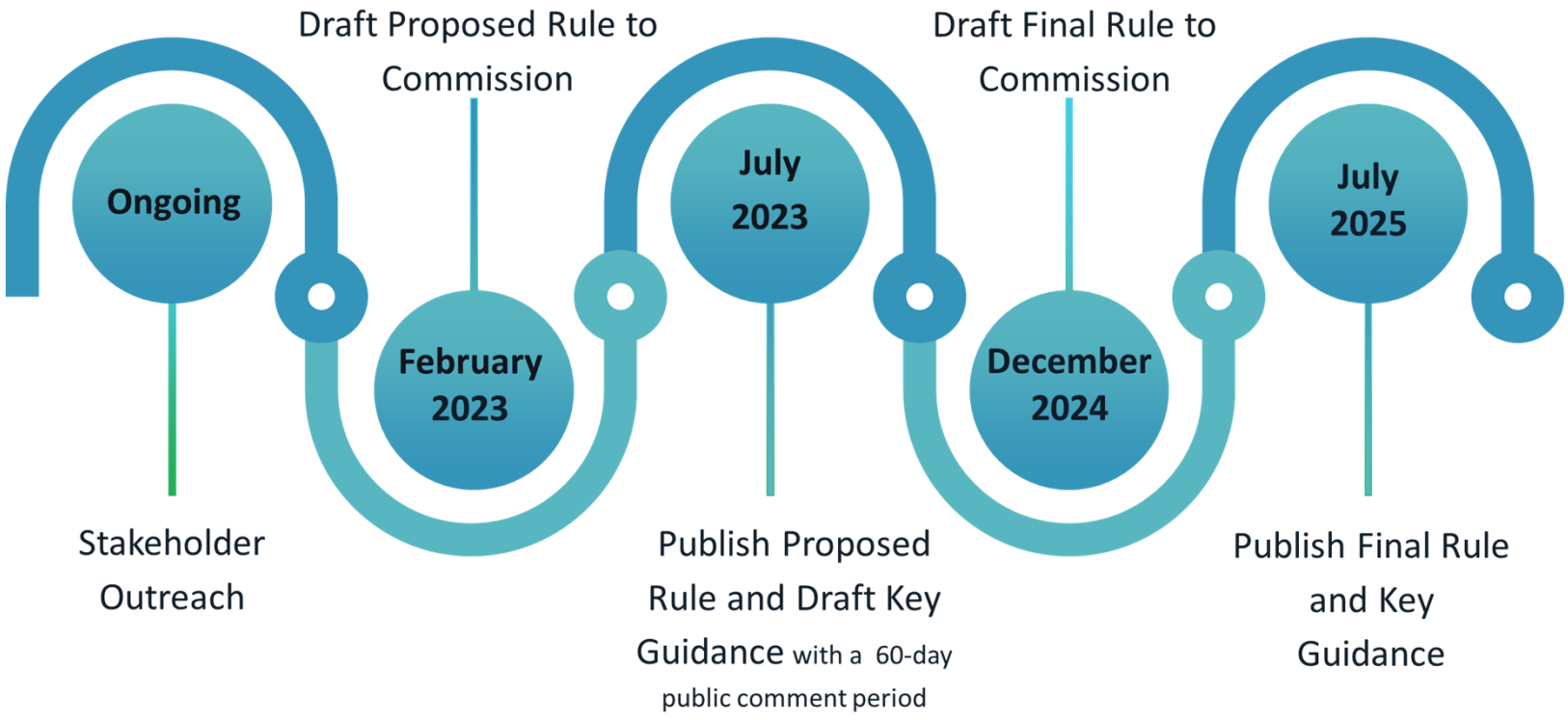
Stakeholder engagement on regulatory infrastructure for new commercial nuclear reactors

Part 53 Rulemaking Process



* The process depicted in this schematic is unique to the Part 53 rulemaking and varies in some ways compared to a similar "A Typical Rulemaking Process" schematic available on the NRC's public website.

Part 53 Rulemaking Schedule



Part 53 Licensing Frameworks

Subpart A - General Provisions

Subpart B - Safety Requirements
Subpart C - Design Requirements
Subpart D - Siting
Subpart E - Construction/Manufacturing
Subpart F - Operations
Subpart G - Decommissioning
Subpart H - Application Requirements
Subpart I - License Maintenance
Subpart J - Reporting
Subpart K - Quality Assurance

Framework A

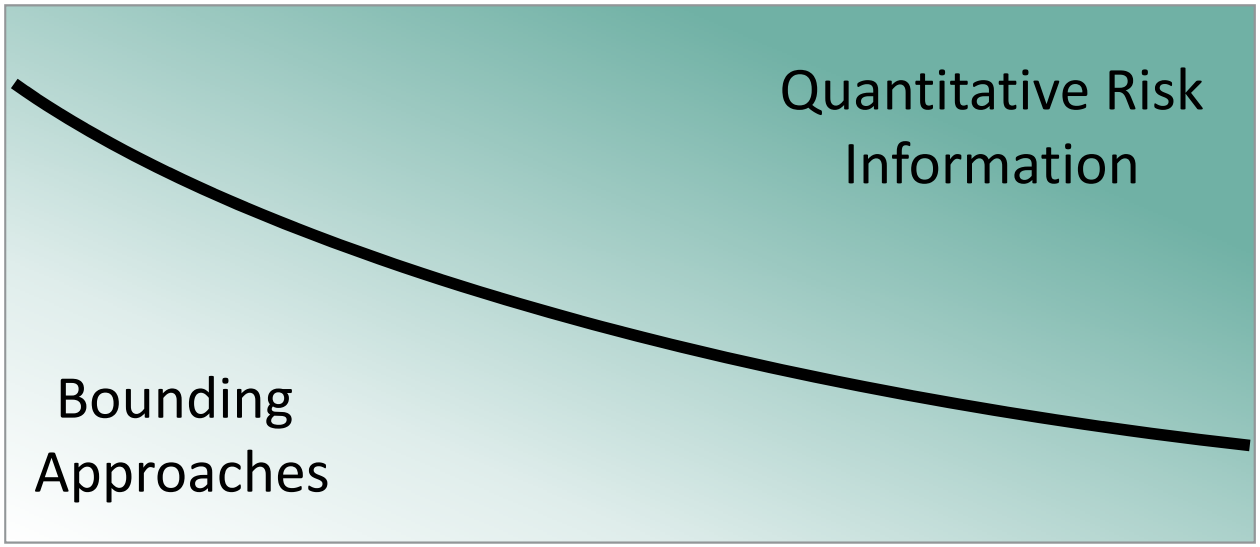
- PRA-led approach
- Functional design criteria
- Top-down approach for meeting high-level safety criteria and defining key safety functions

Subpart N - Definitions
Subpart O - Construction/Manufacturing
Subpart P - Operations
Subpart Q - Decommissioning
Subpart R - Application Requirements
Subpart S - License Maintenance
Subpart T - Reporting
Subpart U - Quality Assurance

Framework B

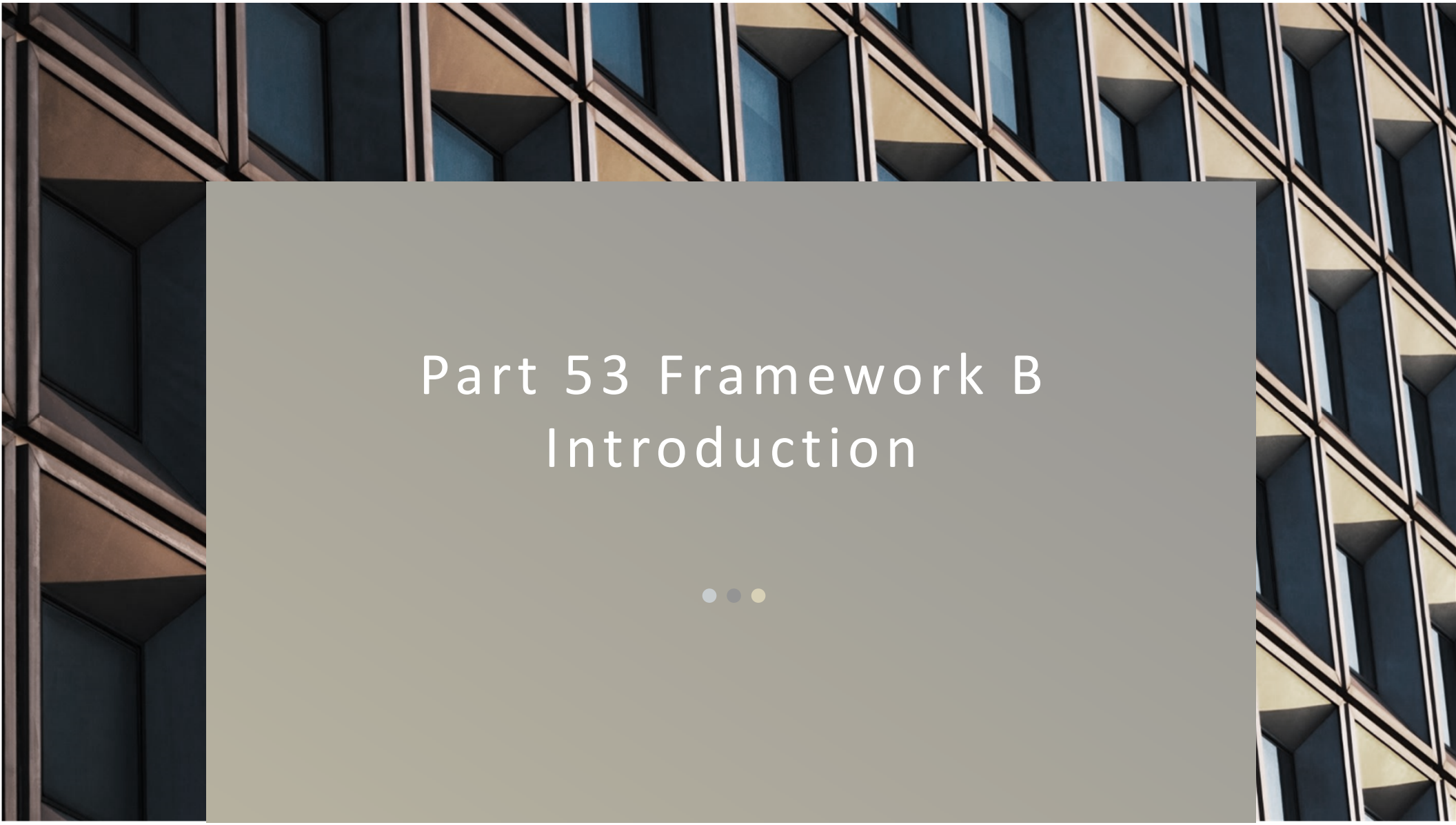
- Traditional use of risk insights
- Principal design criteria
- Bottom-up approach based on well-established safety functions
- Includes an Alternative Evaluation for Risk Insights (AERI) approach

Part 53 Licensing Frameworks



Traditional Use of PRA

Risk-Informed Continuum



Part 53 Framework B Introduction

Background

- Part 53 stakeholder feedback included consideration of international licensing approaches and flexibility in the use of probabilistic risk assessment (PRA)
- Previously released preliminary proposed rule text (“Part 5X”) outlined technology-inclusive, risk-informed alternatives for using the traditional technical requirements in Parts 50 and 52
- Including a traditional, technology-inclusive framework in Part 53 minimizes potential impact on existing requirements and centralizes alternatives for new commercial nuclear reactors

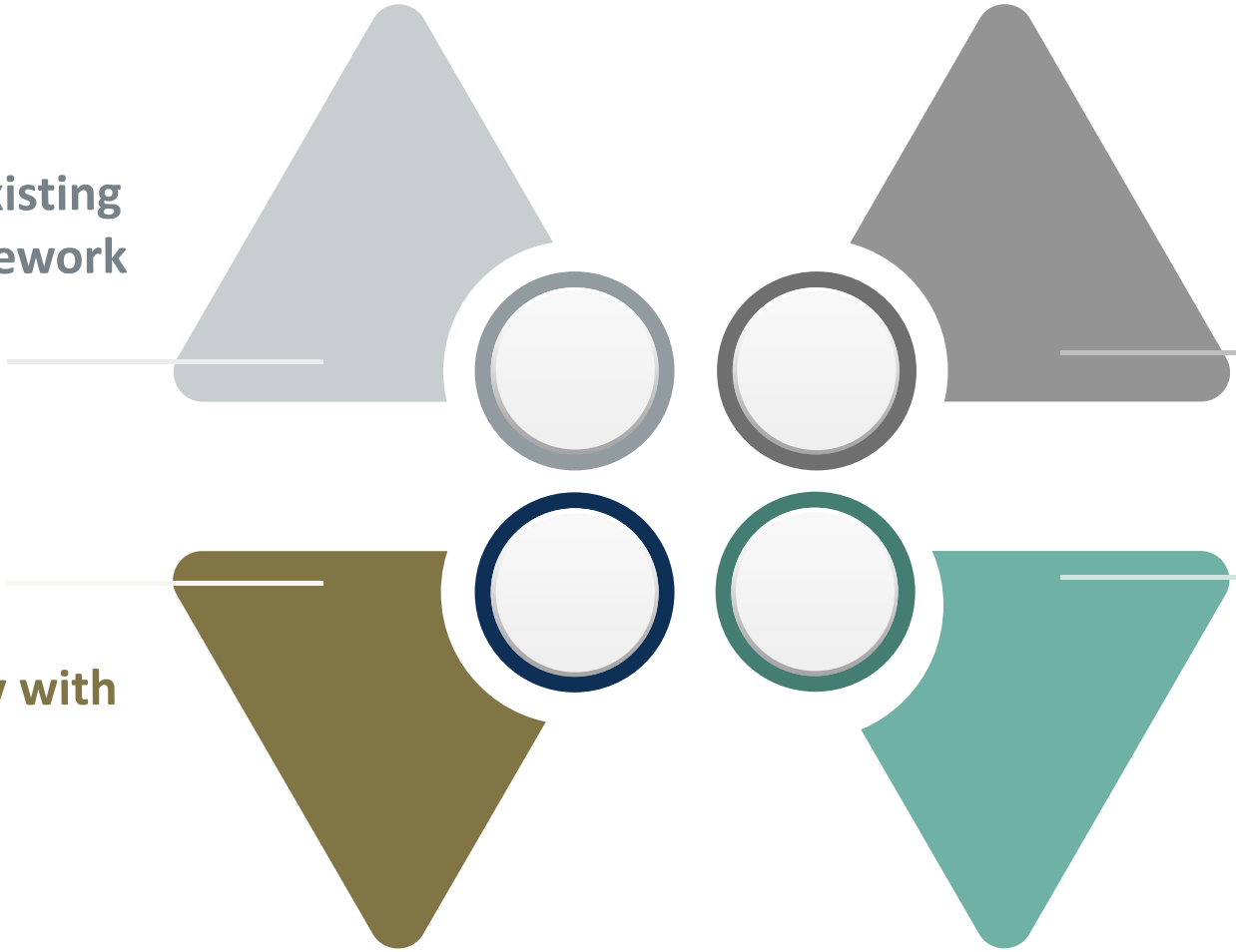
Part 53 Subpart Comparison

Subpart Title	Framework A Subpart	Framework B Subpart
General Provisions	Subpart A (Common)	
Technology-Inclusive Safety Requirements	Subpart B	(Subpart R)
Design and Analysis Requirements	Subpart C	
Siting Requirements	Subpart D	(Part 100)
Definitions	-	Subpart N
Construction and Manufacturing Requirements	Subpart E	Subpart O
Requirements for Operation	Subpart F	Subpart P
Decommissioning Requirements	Subpart G	Subpart Q
Licenses, Certifications, and Approvals	Subpart H	Subpart R
Maintaining and Revising Licensing Basis Information	Subpart I	Subpart S
Reporting and Other Administrative Requirements	Subpart J	Subpart T
Quality Assurance Criteria	Subpart K	Subpart U

Framework B Development Approach

Incorporate Applicable Existing Part 53 Framework Innovations

Leverage Part 50 and 52 Rule Language



Consider Compatibility with International Standards

Develop Unique Rule Language

Consider state-of-practice research and experience with other improvements to regulatory structure and licensing processes

Framework B Guidance Development

Many Framework A and B guidance development activities are linked

May involve updates or supplements to existing guidance covering existing regulatory frameworks

Guidance for technical content of application requirements now part of Advanced Reactor Content of Application Project effort

Areas of Focus
Integration of Frameworks A and B

Ensure consistency between parallel provisions

Evaluate other provisions for potential alignment

- Siting
- Seismic Design Criteria
- Requirements for Operation

Commonalities in Subpart A

- Definitions
- General Provisions

Continue consideration of stakeholder feedback

Part 53 Framework B
Open Discussion

Subpart N – Definitions

- Subpart N contains terms that are specific to Framework B
- Common definitions remain in Subpart A (§ 53.020)

Subpart N – Definitions

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart O – Construction and Manufacturing Requirements

- Parallel structure and content to Framework A Subpart E

- Variations largely limited to conforming changes needed to adapt Framework A provisions to Framework B

Subpart O – Construction and Manufacturing Requirements

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart P – Requirements for Operation

- Structured similar to Subpart F in Framework A
- Programmatic requirements for security, emergency preparedness, and radiation protection aligned with those in Framework A
- Provisions for staffing, training, personnel qualifications, and human factors are largely equivalent between frameworks with the exception of GLROs
- Other requirements for operation informed by existing requirements applicable to applicants and licensees under Parts 50 and 52
  - Maintenance, repair, and inspection programs
  - Technical specifications
  - Fire protection
  - Primary containment leakage
  - Environmental qualification of electrical equipment

Subpart P – Requirements for Operation

§ 53.4210	Maintenance, repair, and inspection programs.
§ 53.4213	Technical specifications.
§§ 53.4220 - 53.4299	General staffing, training, personnel qualifications, and human factors requirements.
§ 53.4300	Programs.
§ 53.4310	Programs: Radiation protection.
§ 53.4320	Programs: Emergency preparedness.
§ 53.4330	Programs: Security programs.
§ 53.4340	Programs: Quality assurance.
§ 53.4350	Programs: Fire protection.
§ 53.4360	Programs: Inservice inspection/inservice testing.
§ 53.4380	Programs: Environmental qualification of electric equipment
§ 53.4390	Programs: Procedures and guidelines.
§ 53.4400	Programs: Integrity assessment program.
§ 53.4410	Programs: Primary containment leakage rate testing program.

Subpart P – Requirements for Operation

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart Q – Decommissioning Requirements

- Parallel structure and content to Framework A Subpart G
- Variations largely limited to conforming changes needed to adapt Framework A provisions to Framework B

Subpart Q – Decommissioning Requirements

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart R – Licenses, Certifications, and Approvals

- Structured similar to Subpart H in Framework A
- Process-related requirements in Subpart R are identical between the frameworks
- Technical requirements informed by existing regulatory frameworks
  - Requirements captured in content of application sections
  - Technical content of application requirements consolidated in § 53.4730
  - Many requirements from Parts 50 and 52 translated to Framework B with select updates and modifications for technology-inclusiveness
- Initiating event and accident analyses requirements evolved from initial “Part 5X” effort
  - Requirements in § 53.4730(a)(5) cover AOOs, DBAs, BDBEs, severe accidents and chemical hazards
  - Generally aligned with current requirements and, as appropriate, incorporates international concepts on DID
- Requirements for containment address the need for functional containment alternatives that may be employed by non-LWRs

Subpart R – Licenses, Certifications, and Approvals

§ 53.4700	General Provisions.
§ 53.4725	Standards for review.
§ 53.4730	**General technical requirements.**
§ 53.4731	Risk-informed classification of structures, systems, and components.
§ 53.4740	Limited work authorizations.
§ 53.4750	Early site permits.
§ 53.4800	Standard design approvals
§ 53.4830	Standard design certifications.
§ 53.4870	Manufacturing licenses.
§ 53.4900	Construction permits.
§ 53.4960	Operating licenses.
§ 53.5010	Combined licenses.

Subpart R – Licenses, Certifications, and Approvals

§ 53.4730: General Technical Requirements

- Technical content of application requirements consolidated in § 53.4730
  - Reduces rule length
  - Minimizes the potential for requirements to diverge between application types

Application Type

§ 53.4730(a) Requirement	COL	OL	CP	ML	DC	SDA	ESP
(1)	X	X	X	X	X	X	X
(2)	X	X	X	X	X	X	X
(3)	X	X		X	X	X	
…							
(37)	X	X	X	X	X	X	X

Subpart R – Licenses, Certifications, and Approvals

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart S – Maintaining and Revising Licensing Basis Information

- Parallel structure and content to Framework A Subpart I
- Notable differentials
  - § 53.6010, *Application for amendment of license*
  - § 53.6040, *Updating licensing basis information and determining the need for NRC approval*
  - § 53.6045, *Updating final safety analysis reports*
  - § 53.6050, *Evaluating changes to facility as described in final safety analysis reports*
  - § 53.6052, *Maintenance of risk evaluations*
- Remaining variations largely limited to conforming changes to adapt Framework A provisions to Framework B

Subpart S – Maintaining and Revising Licensing Basis Information

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart T – Reporting and Other Administrative Requirements

- Parallel structure and content to Framework A Subpart J
- Notable differentials
  - § 53.6320(e) added to align with state-of-practice policy initiative on reporting requirement for fee purposes
  - § 53.6330, *Immediate notification requirements for operating commercial nuclear plants*, aligned with § 50.72
  - § 53.6340, *Licensee event report system*, aligned with § 50.73
- Remaining variations largely limited to conforming changes to adapt Framework A provisions to Framework B

Subpart T – Reporting and Other Administrative Requirements

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Subpart U – Quality Assurance

- Subpart U parallels structure and content of Framework A Subpart K
- Closely aligned with 10 CFR Part 50 Appendix B (18 criteria)
- Exception: § 53.6635, *Control of Purchased Material, Equipment and Services* (10 CFR Part 50 Appendix B Criterion VII)
  - “Commercial nuclear plant” used in lieu of “nuclear power plant”
  - Ensures consistency with terminology throughout Part 53

Subpart U – Quality Assurance

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Part 53 Framework B Alternative Evaluation for Risk Insights (AERI)

Evolution of the AERI Alternative Approach

- Evolution of the AERI approach is an example of modern risk-informed regulation:
  - Achieves the underlying purposes of Commission policy statements:
    - Policy Statement on the Regulation of Advanced Reactors (73 FR 60612; October 14, 2008)
    - Safety Goals for the Operation of Nuclear Power Plants (51 FR 28044; August 4, 1986 as corrected and republished at 51 FR 30028; August 21, 1986)
    - Severe Reactor Accidents Regarding Future Designs and Existing Plants (50 FR 32138; August 8, 1985)
    - Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities (60 FR 42622; August 16, 1995)
  - Provides sufficient risk information to inform licensing decisions
  - Right-sizes the effort required to evaluate risk

Uses risk insights to enhance regulatory efficiency.

- Two pre-decisional draft regulatory guides (PDGs) have been developed to:
  - Clarify for potential applicants the logic and the expectations of the NRC staff
  - Address related ACRS recommendations to "start with a blank sheet of paper" (10/7/2019, 10/21/2020, 5/30/2021, and 10/26/2021)

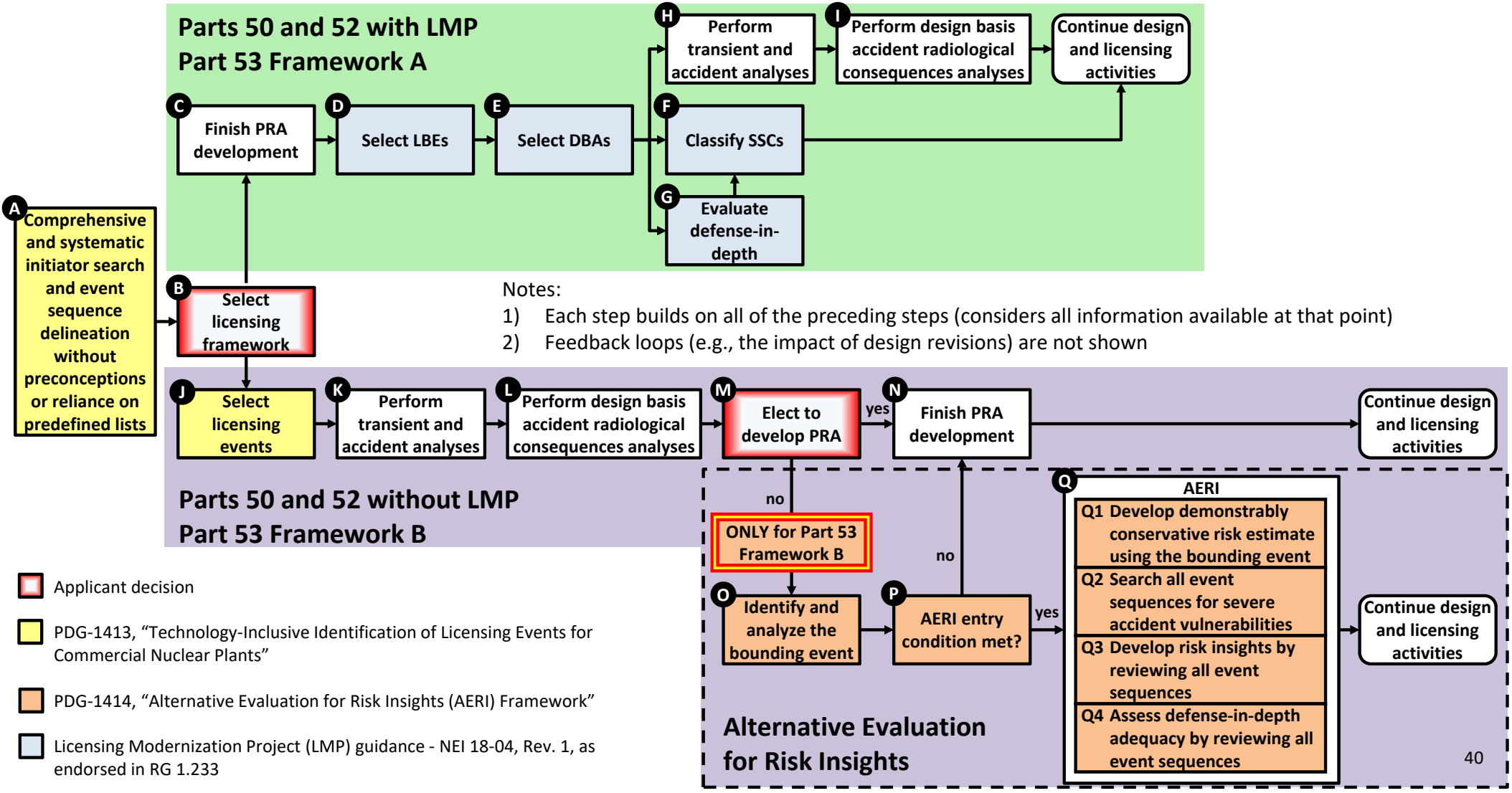
Assessing Risk in Framework B

- Risk insights support or complement deterministic analyses, consistent with traditional approach
- Includes requirement to provide a description of the plant-specific PRA and its results translated to Framework B

  § 52.79(a)(44) → § 53.4730(a)(34)(i)

- Optional alternate risk evaluation for applicants that meet the criteria in § 53.4730(a)(34)(ii)
  - No PRA required
  - Implicitly demonstrates that quantitative health objectives (QHOs) are met, searches for severe accident vulnerabilities, and provides risk insights without a requirement for a PRA
  - Inherently addresses the mitigation of beyond-design-basis events requirements when AERI entry criteria are met
  - Cannot implement risk-informed applications if AERI approach is used
- Risk evaluations (PRA or AERI) must be maintained consistent with requirements in Subpart S (§ 53.6052, informed by § 50.71(h))

Licensing Frameworks – Risk Evaluation Perspective



Notes:

1) Each step builds on all of the preceding steps (considers all information available at that point)
2) Feedback loops (e.g., the impact of design revisions) are not shown

- Applicant decision
- PDG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants"
- PDG-1414, "Alternative Evaluation for Risk Insights (AERI) Framework"
- Licensing Modernization Project (LMP) guidance - NEI 18-04, Rev. 1, as endorsed in RG 1.233

Proposed AERI Entry Condition

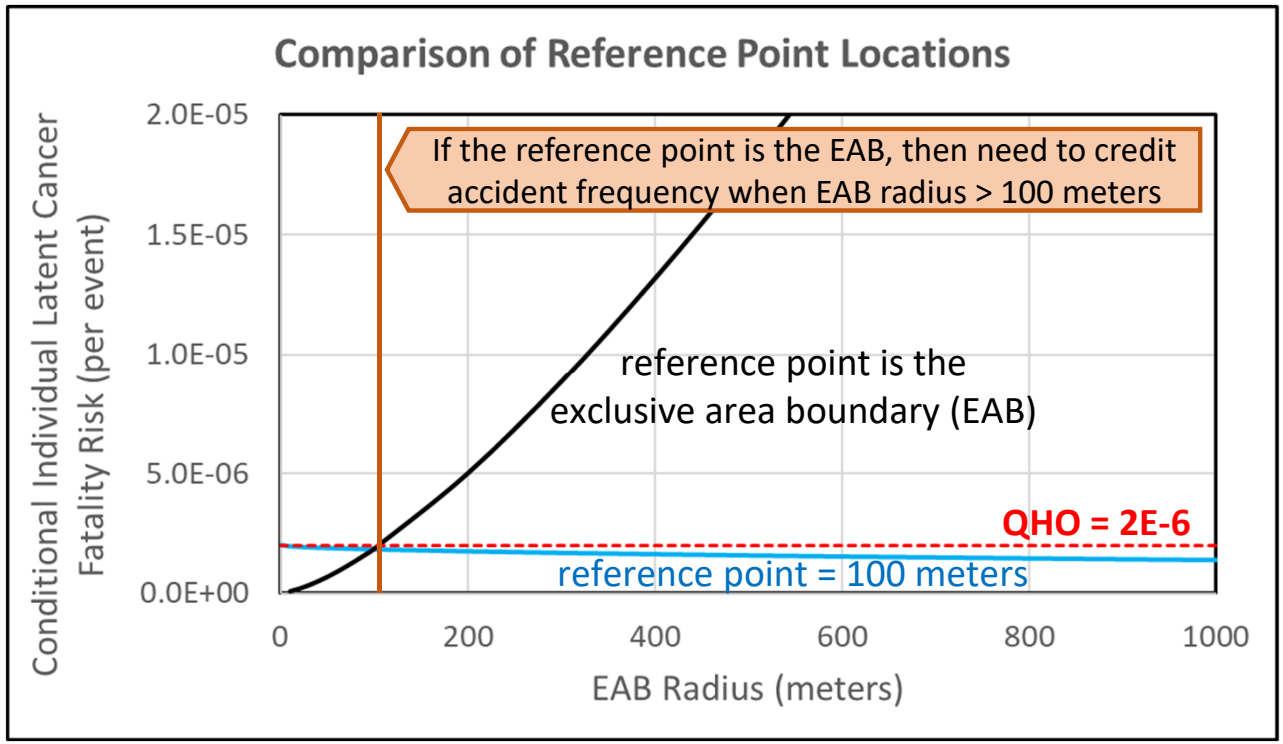
53.4730(a)(34) *Description of risk evaluation*.
A description of the risk evaluation developed for the commercial nuclear plant and its results. The risk evaluation must be based on:

(i) A PRA, or

(ii) An AERI, provided that the dose from a postulated bounding event to an individual located 100 meters (328 feet) away from the commercial nuclear plant does not exceed 1 rem total effective dose equivalent (TEDE) over the first four days following a release, an additional 2 rem TEDE in the first year, and 0.5 rem TEDE per year in the second and subsequent years.

The AERI entry condition is not a safety or siting criterion!!!

Development of the AERI Entry Condition



- **Premise:** It is feasible to identify a bounding event such that the consequence of <u>any</u> event sequence is less than or equal to the consequence of the bounding event.
- **Implication:** Risk is less than or equal to the product of the sum of event sequence frequencies and the consequence of the bounding event.
- **Note:** It is only necessary to estimate the sum of the event sequence frequencies; <u>it is not necessary to estimate each individual event sequence frequency using a PRA.</u>

"Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants" (PDG-1413)

- Formatted like a regulatory guide; currently a pre-decisional draft regulatory guide
- Section A: Applies to LWRs and non-LWRs licensed under Parts 50, 52, and 53 (Frameworks A and B)
- Section B (Discussion):
  - Identifies licensing events for each licensing framework
  - Provides historical perspectives (early licensing, development of the standard review plan (SRP))
  - Addresses ACRS recommendations to "start with a blank sheet of paper" (10/7/2019, 10/21/2020, 5/30/2021, and 10/26/2021)
- Section C (Staff Guidance) provides an integrated approach for:
  - Conducting a systematic and comprehensive search for initiating events
  - Delineating a systematic and comprehensive sets of event sequences
  - Grouping the lists of initiating events and event sequences into licensing events
- Appendix A (Comprehensive Search for Initiating Events):
  - Reviews techniques for searching for initiating events and points the user to helpful references
  - Does not endorse or recommend any specific technique

“Alternative Evaluation for Risk Insights (AERI) Framework” (PDG-1414)

- Formatted like a regulatory guide; currently a pre-decisional draft regulatory guide
- Section A (Introduction): Only applies to LWRs and non-LWRs licensed under Part 53 Framework B
- Sections B (Discussion) & C (Staff Guidance) - Components of the AERI approach:
  - Identification and characterization of the bounding event
    - Definition of a bounding event
    - Multiple events may need to be considered as bounding events
  - Determination of a consequence estimate for the bounding event to confirm that the reactor design meets the AERI entry condition
  - Determination of a demonstrably conservative risk estimate for the bounding event to demonstrate that the QHOs are met
    - Assumed frequency of 1/yr consistent with frequency of all event sequences for LWRs
    - Applicant may use a lower frequency with justification
  - Search for severe accident vulnerabilities for the entire set of licensing events
    - Definitions of severe accident and severe accident vulnerability
  - Identification of risk insights for the entire set of licensing events
  - Assessment of defense-in-depth adequacy for the entire set of licensing events

Alternative Evaluation for Risk Insights (AERI)

- Discussion of Stakeholder Feedback Received
- Stakeholder Open Discussion

Open Discussion

- Discussion of Other Stakeholder Feedback
- Stakeholder Open Discussion

Concluding Remarks

Additional Information

- Additional information on the 10 CFR Part 53 rulemaking is available at https://www.nrc.gov/reactors/new-reactors/advanced/rulemaking-and-guidance/part-53.html
- For information on how to submit comments go to https://www.regulations.gov and search for Docket ID NRC-2019-0062
- For further information, contact Robert Beall, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3874; email: Robert.Beall@nrc.gov

Acronyms

ACRS	Advisory Committee on Reactor Safeguards
AEC	Atomic Energy Commission
AERI	Alternative evaluation for risk insights
AOO	Anticipated operational occurrence
ARCAP	Advanced Reactor Content of Application Project
ATWS	Anticipated transient without scram
BDBE	Beyond design basis event
BE	Bounding event
CFR	Code of Federal Regulations
COL	Combined license
CP	Construction permit
DANU	Division of Advanced Reactors and Non-Power Production and Utilization Facilities
EAB	Exclusion area boundary
DBA	Design basis accident
DBE	Design basis event
DC	Design certification
DG	Draft regulatory guide
DRA	Division of Risk Assessment
ESP	Early site permit
FR	*Federal Register*
GLRO	Generally licensed reactor operator
HFE	Human factors engineering
IAEA	International Atomic Energy Agency
IEFR	Individual early fatality risk
ILCFR	Individual latent cancer fatality risk
LBE	Licensing basis event

Acronyms

LCO	Limiting condition for operation
LMP	Licensing Modernization Project
LNT	Linear no-threshold
LWR	Light water reactor
ML	Manufacturing license
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NUREG	U.S. Nuclear Regulatory Commission technical report designation
OL	Operating license
PDG	Pre-decisional draft regulatory guide
PRA	Probabilistic risk assessment
QA	Quality assurance
RO	Reactor operator
QHO	Quantitative health objective
RES	Office of Nuclear Regulatory Research
RG	Regulatory guide
SBO	Station black out
SDA	Standard design approval
SRO	Senior reactor operator
SRP	Standard review plan
SSCs	Structures, systems, and components
STA	Shift technical advisor
TEDE	Total effective dose equivalent
TICAP	Technology Inclusive Content of Application Project