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

10 CFR Part 26, Fitness for Duty

January 6, 2022

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Agenda

1:00pm – 1:15pm	Welcome / Introductions / Logistics / Goals
1:15pm – 3:30 pm	Overview and Discussion of Part 26, Sections Related to Fitness for Duty (FFD)
3:30pm – 3:45pm	Break
3:45pm – 4:45pm	Open Discussion of Other Part 53 Sections and Subparts
4:45pm – 5:00pm	Additional Public Comments, Questions, and Closing Remarks / Adjourn

Welcome/Introductions

Welcome:

- Sebrina Atack, Office of Nuclear Security and Incident Response (NSIR)

Speakers/Presenters:

- Bob, Beall, Office of Nuclear Materials Safety and Safeguards – Meeting Facilitator
- Paul Harris, NSIR
- Justin Vasquez, Office of Nuclear Reactor Regulation (NRR)

Public Meeting Slides: ADAMS Accession No. ML21295A259

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Purpose of Today's Meeting

- Review preliminary proposed rule language for 10 CFR Part 26, FFD Programs
- Open discussion of other Part 53 sections and subparts
- Today's meeting is a "Comment-Gathering" meeting, which means that public participation is actively sought in the discussion of the regulatory issues during the meeting.
  - This meeting is being held in a "workshop" format to facilitate the discussion of today's topics.
  - The meeting is being transcribed and the transcription will be available with the meeting summary by February 4, 2022.
- No regulatory decisions will be made at today's meeting.

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10 CFR Part 26, Fitness for Duty Programs

Presentation Approach

- Today's presentation will be in two parts:

- Part 1: Background and summary of the proposed FFD program presented during the NRC public meeting on June 10, 2021
  - including two specific requests for public input

- Part 2: A summary of the proposed FFD framework (section-by-section review)
  - including a discussion about fatigue management

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Part 1: Background, Summary of the June 10, 2021, Public Meeting, and Request for Public Input

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Summary from the June 10, 2021, NRC Public Meeting on Part 53

For the proposed FFD program, the staff presented:

1. Key Messages
2. Administrative requirements
3. The FFD criterion – staff requested public input on its proposal
4. The FFD Flow Chart – how do the FFD requirements apply
   - The June 10th iteration had two FFD-related criteria
   - The current staff iteration has one FFD-related criterion
5. Considerations for fatigue management
6. Proposed performance-based requirement – FFD Performance Monitoring and Review

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Key Messages - Summarized

1. The proposed approach leverages the existing requirements in 10 CFR Part 26, Subpart K, "FFD Programs for Construction," that have been implemented by power reactor licensees
   - Subpart K has been implemented by power reactor licensees for over 8 years
   - The proposal (Subpart M) uses objective- and performance-based requirements
2. The proposed approach is inclusive of all reactor technologies
   - Requirements are applied in a graded manner based on risk consequences
3. The proposal includes a "FFD performance monitoring and review" and an "FFD change control process"
4. The proposal includes:
   - Flexibilities in the conduct of drug and alcohol (D&A) testing
     - Allows oral fluid and urine drug testing
     - Allows the use of point of collection testing (POCT) and assessment devices for screening (random testing only)
   - Requirements that help ensure the facility integrates with the existing reactor community

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Administrative Requirements for all FFD Programs

Subpart A - Administrative Provisions

- § 26.1 Purpose.
- § 26.3 Scope.
- § 26.4 FFD program applicability to categories of individuals.
- § 26.5 Definitions.
- § 26.7 Interpretations.
- § 26.8 Information collection requirements: Office of Management and Budget approval.
- § 26.9 Specific exemptions.
- § 26.11 Communications.

Subpart O - Inspections, Violations, and Penalties

- § 26.821 Inspections.
- § 26.823 Violations.
- § 26.825 Criminal penalties.

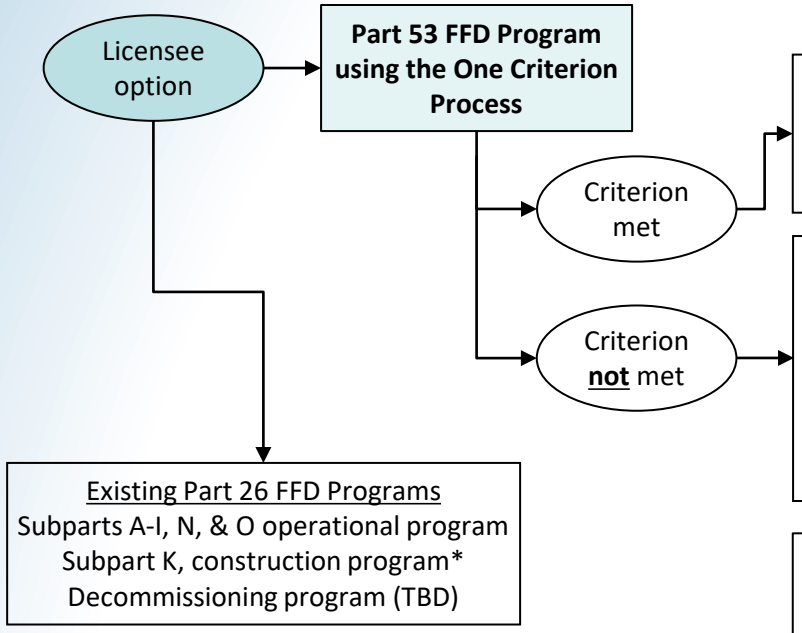
FFD Criterion

June 10th iteration (A & B) vs current iteration (A)

A. The criterion to be used for the analysis in § 26.603(c)(2) is proposed to be the criterion in 10 CFR 53.830(a)(2)(i), where:
   - The radiological consequences from a hypothetical, unmitigated event involving the loss of engineered systems for decay heat removal and possible breaches in physical structures surrounding the reactor, spent fuel, and other inventories of radioactive materials result in offsite doses below the values in § 53.210 of this chapter.
   - If the facility meets this criterion, drug and alcohol testing will not be required; however, a behavioral observation program will be required.

~~B. Plant technologies, engineered safety features, and controls provide reasonable assurance that without operator action the plant can achieve and maintain a safe stable condition and remove decay heat, and the radiological consequences resulting from design basis accidents and transients as described in the final safety analysis report do not exceed the dose limits in § 20.1301(a)(1) [100 mrem to member of the public in a year].~~
   - ~~Program will be tiered and based on current requirements in Part 26, Subpart K, FFD programs for construction of commercial power reactor facilities.~~

Preliminary Proposed FFD Requirements for Part 53 Licensees (rev. 1)



* Only by exemption

Part 26, Subpart M – § 26.604 FFD Program

1. Must have a behavioral observation program and implement administrative requirements
2. Enables, but does not require a D&A testing program

Part 26, Subpart M – § 26.605 FFD Program

1. Requires D&A testing and behavioral observation
2. Prior to reactor operation, the licensee or other entity must implement an FFD program that meets the Part 26 requirements in Subpart C, FFD authorization; Subpart D, management actions/sanctions; Subpart H, FFD policy violations and determining fitness; Subpart I, fatigue management; and, Subpart N, recordkeeping, and reportability

Both the § 26.604 and § 26.605 FFD programs must:

1. Be described to the NRC at the time of the Part 53 application
2. Annually report FFD performance data (e.g., individuals onsite and FFD policy violations) to the NRC
3. Implement a performance monitoring and review program (site- and industry-based measures and thresholds) and document its implementation biennially. This proposed requirement is based on current Part 26 requirements, § 50.47(c)(1)(iii)(B) emergency plan, § 50.48(c)(1) fire protection, and § 50.65 maintenance performance reviews
4. Implement a change control process. This proposed requirement is based on Part 53, § 50.48(f))(3), § 50.54(p), and § 50.54(q)(3), and § 50.59
5. Use urine or oral fluid if drug testing for any drug/alcohol test condition (e.g., pre-access testing) Licensees may use oral fluid or urine POCT devices only for random testing
6. Use forensic toxicology reviews and U.S. Department of Health and Human Services (HHS) certified laboratories, and implement the Medical Review Officer (MRO) reviews required by § 26.183 and § 26.185, if drug testing

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Seeking Public Input

1. Part 26 applicability to certain Holders of Manufacturing Licenses

2. Use of Hair Specimens for Drug Testing

FFD applicability to the Assembly and/or Fueling of a Reactor Module under an NRC Manufacturing License

- Currently, for facilities licensed under Parts 50 and 52, Part 26 does not apply to holders of a Manufacturing License
  - However, Part 26 does apply to licensees when assembling and fueling a reactor vessel at a reactor construction site licensed under Part 50 or 52
- The staff is proposing that select Part 26 requirements apply to holders of a Part 53 manufacturing license if they assemble and/or fuel a reactor module at the manufacture's site
- The staff proposal provides analogous treatment of assembly operations for safety-related structures, systems, and components, such as the reactor vessel and associated equipment
- See next slide

FFD applicability to the Assembly and/or Fueling of a Reactor Module under an NRC Manufacturing License

NRC is seeking input on whether to apply select FFD requirements to manufacturing licensees who assemble and/or load nuclear fuel in a reactor module at the manufacturer's site

<u>Questions</u>

1. Should the NRC consider the application of Part 26 to the assembly of the reactor module?
2. How should the NRC describe the milestone for when the FFD program should start?

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Use of Hair Specimens in the Current Part 26 requirements

- Currently, for facilities licensed and operating under Part 50 or 52, Part 26, Subparts A – I, N, and O, do not allow licensees or other entities to use hair specimens for drug testing
- However, for facilities that are being constructed under Part 50 or 52, Part 26, Subpart K, "FFD Programs for Construction," section 26.405(d) does not preclude the use of a hair specimen (or oral fluid specimens) for drug testing if:
  - The Part 26 panel of drugs and drug metabolites are used;
  - The cutoffs used are at "the cutoff levels specified in this part, or comparable cutoff levels if specimens other than urine are collected for drug testing;"
  - The initial drug test uses an immunoassay that meets the requirements of the U.S. Food and Drug Administration (FDA) for commercial distribution;
  - Privacy and quality controls are implemented;
  - "[P]ositive initial drug test results are subject to confirmatory testing by a laboratory that meets stringent quality control requirements that are comparable to those required for certification by the HHS"; and,
  - The Medical Review Officer (MRO) reviews the drug test results prior to issuance of an FFD policy violation.

Seeking Public Input on the Staff-proposed use of Hair Specimens in the Part 53 FFD framework

- NRC is seeking input on whether hair testing should be integrated into the FFD program to improve program effectiveness. For example:
  1. Should hair testing be used to supplement or used in lieu of urine or oral fluid drug testing?
  2. Should only HHS-certified laboratories be used, or should NRC enable laboratories, who may be certified by other organizations, to test hair specimens for drugs and drug metabolites?
  3. If the proposal enables (i.e., does not require) the use of hair specimens for drug testing, are current or future NRC licensees and other entities interested in voluntarily using hair specimens to improve FFD or access authorization program effectiveness?
  4. Are stakeholders aware of recent operating experience (e.g., studies of paired test results) demonstrating the effectiveness of hair testing?

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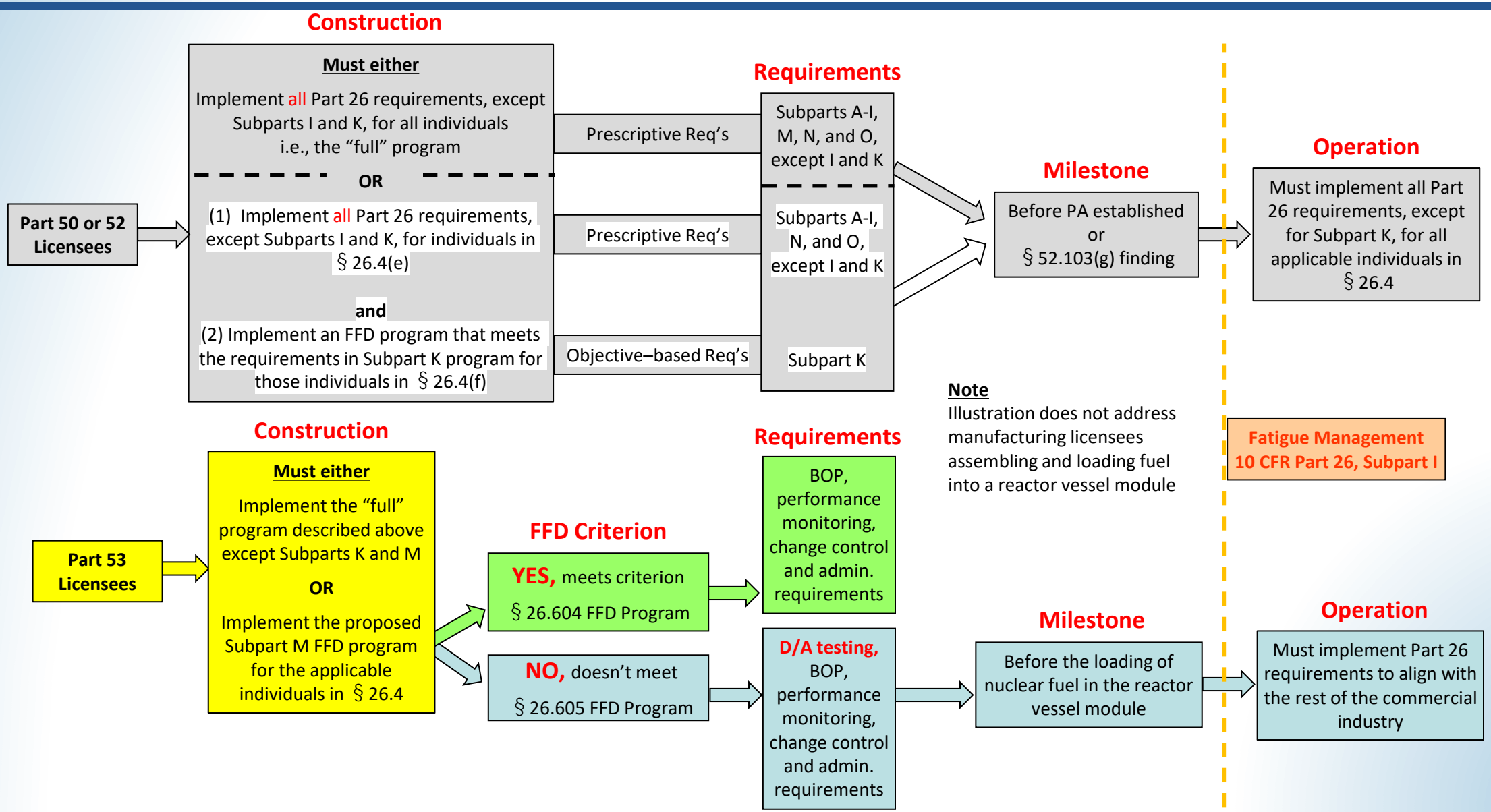
Part 2: Summarized FFD framework (section-by-section review)

Comparing the Current and Proposed FFD Frameworks



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Comparison of Principal FFD Requirements

	Part 50 and 52 Licensees		Part 53 Licensees - Proposed FFD Program		
	Operating	Construction Subpart K	26.604 (meets the FFD criterion)	26.605(a) construction	26.605(b) operations
Describe FFD program during application stage	yes	yes, 52.79(a)(44)	yes, 26.603(a)	yes, 26.603(a)	yes, 26.603(a)
Subpart A – Administration Requirements	yes	yes 26.413, Review process (appeals)	yes 26.613, Review process (appeals)	yes 26.613	yes 26.613
Subpart B – Program Elements	yes	NA	no	no	no
26.21, Fitness-for-duty (FFD) program		26.401 General	- -	- -	- -
26.23, Performance objectives		- -	yes	yes	yes
- -		- -	- -	- -	- -
26.27, Written policy and procedures		26.403, Written policy & procedures	26.606, Written policy & procedures	26.606	26.606
26.29, Training		- -	26.608, FFD program training	26.608	26.608
26.31, Drug and alcohol testing		26.405, Drug and alcohol testing	26.607, Drug & alcohol testing, based on performance	26.607	26.607
- -		- -	- -	- -	- -
- -		26.406, Fitness monitoring	NA	NA	NA
26.33, Behavioral observation		26.407, Behavioral observation	26.609, Behavioral observation	26.609	26.609
- -		- -	- -	- -	- -
26.35, Employee assistance programs		- -	- -	- -	- -
26.37, Protection of information		26.411, Protection of information	26.611, Protection of information	26.611	26.611
26.39, Review process for FFD policy violations		26.409, Sanctions	26.610, Sanctions	26.610	26.610
26.41, Audits and corrective action		26.415, Audits	- -	26.615, Audits	26.615
			26.603(d) FFD Performance Monitoring	26.603(d)	26.603(d)
			26.603(e) FFD Change Control Process	26.603(e)	26.603(e)
Subpart C – FFD Authorization	yes	no	no	no	yes
Subpart D – Management Actions and Sanctions	yes	no	no	no	yes
Subpart E – Collecting Specimens (urine)	yes	no	no	no	no
Subpart F – Licensee Testing Facilities	yes	yes	no	no	no
Subpart G – HHS-Certified Labs	yes	yes	yes	yes	yes
Subpart H – FFD Policy Violations & Fitness Determinations	yes	no 26.419 Suitability & Fit Evals	no 26.619, Suitability & Fit Det	no 26.619	yes
Subpart I – Managing Fatigue	yes	no	no (yes for RVM, with fuel, fabrication)	no	yes
Subpart K – FFD for Construction	no	yes - option	no	no	no
Subpart M – FFD program for Part 53 Facilities	no	no	yes -option	yes - option	yes - option
Subpart N – Reporting & Records	yes	no 26.417 Recordkeeping& Reporting.	no 26.617, Recordkeeping & Reporting	no 26.617	yes
Subpart O – Inspection. Violations & Penalties	yes	yes	yes	yes	yes

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.3, Scope**
  - Amended to include Part 53 licensees
- **26.4, FFD program applicability to categories of individuals**
  - Amended to include individuals working at the Part 53 facility
- **26.5, Definitions**
  - Amended to apply to an FFD program at a Part 53 facility

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **Subpart M, FFD Program for Commercial Power Plants Licensed under Part 53**

- **26.601, Applicability statement**

- **26.602, FFD program applicability to categories of individuals**

- **26.603, General provisions**
  a. FFD Program Description – provided to the NRC during the Part 53 license application phase
  b. FFD Program Implementation and Availability.
  c. FFD Criterion and Analysis

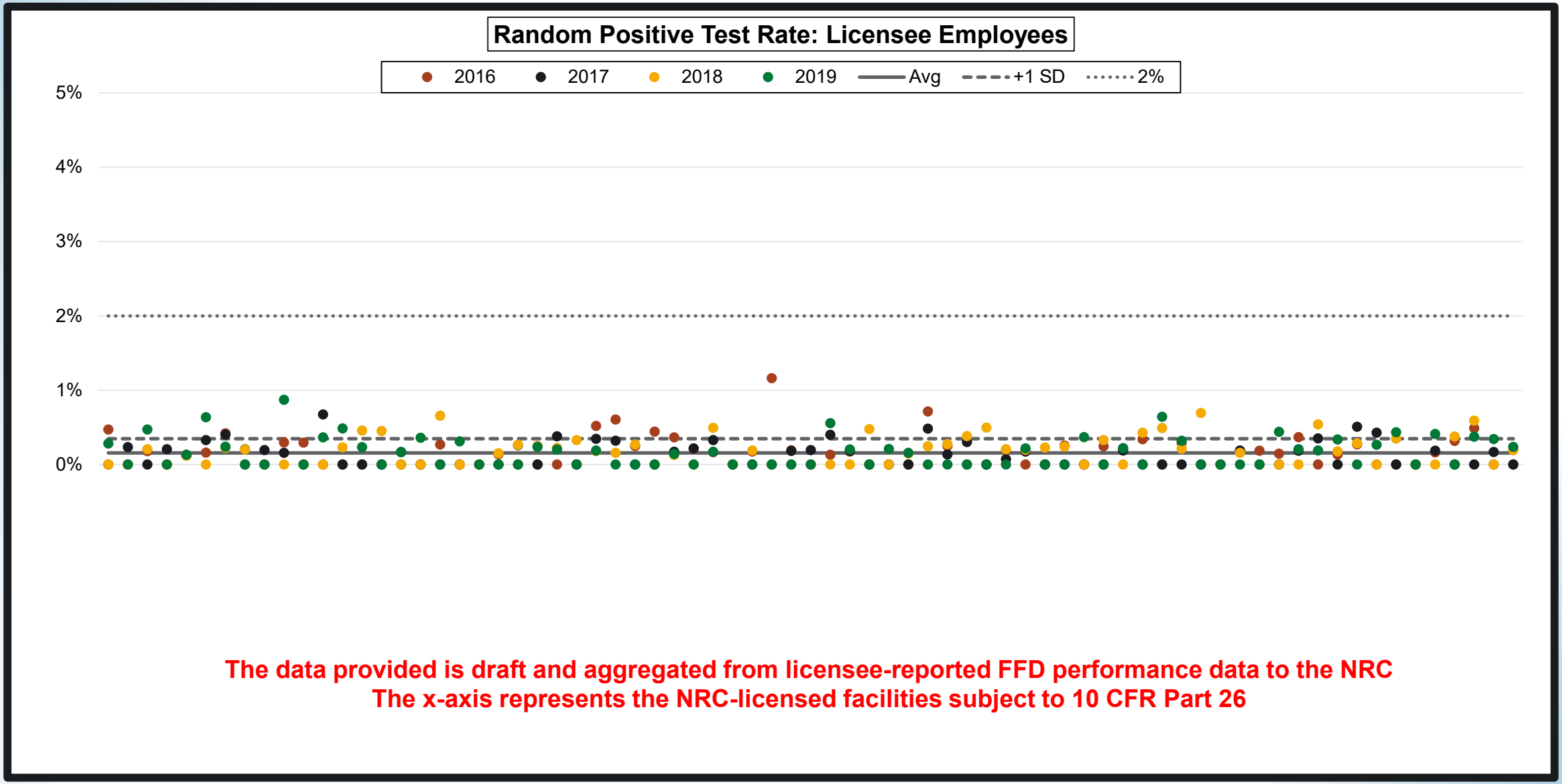
Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.603, General provisions**

d. FFD Performance Monitoring and Review

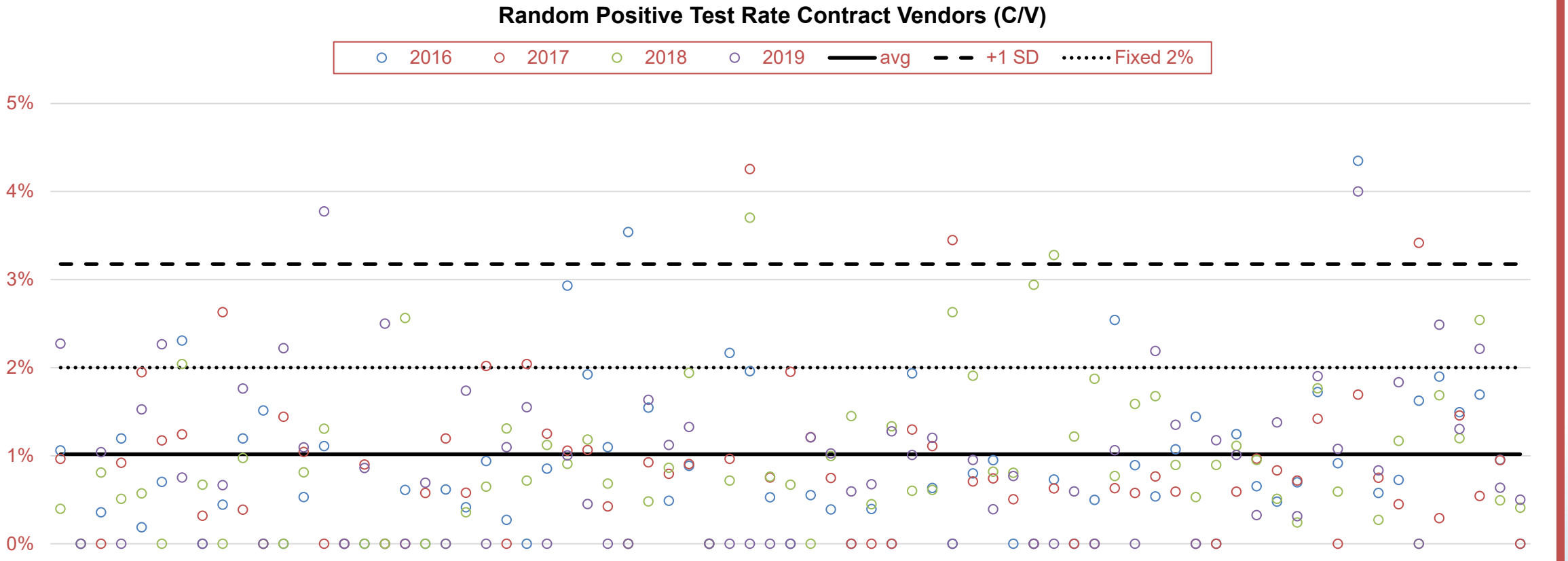
1. The program must be documented, justified, and maintained and include the following elements:
   - i. Performance measures for FFD policy violations and program weaknesses
     - A. If not performing D&A testing, must monitor the behavioral observation program
     - B. If D&A testing, must monitor pre-access, random, and subversion attempts
   - ii. Trending – year-to-year comparisons, timely conducted as data is received
   - iii. Thresholds – developed prior to program implementation, using comparable FFD data, including FFD programs (multiple sites in the same program) and industry-wide data
2. Qualitative Measures
   - i. Appeals process
   - ii. Laboratory Test Results and MRO performance
   - iii. Change control process
3. Corrective Actions – timely implemented to address adverse trends, designed to restore performance
4. Program Review Periodicity – biennial, documented by Nov 15 of every even year
5. Regulatory guidance will be issued

FFD Performance Monitoring and Review – Illustration 1 of 2



The data provided is draft and aggregated from licensee-reported FFD performance data to the NRC
The x-axis represents the NRC-licensed facilities subject to 10 CFR Part 26

FFD Performance Monitoring and Review – Illustration 2 of 2



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Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.603, General provisions**

e. FFD Program Change Control

1. Changes not requiring NRC approval
   - Changes that do not reduce FFD program effectiveness (i.e., performance)

     Examples: Changes caused by a change to Part 26
     Changes caused by a change to DHS' Mandatory Guidelines for Federal Workplace Drug Testing
2. Changes requiring NRC approval
   - Changes that cause or may cause a reduction in program effectiveness (i.e., performance)
   - Must obtain NRC approval prior to implementation

     Examples: Increasing cutoffs or removing drugs to be tested
     Changing when random testing is to be conducted
     Reducing management/supervisory oversight of plant staff (behavioral observation)
3. Changes to the credited technical analysis used to justify meeting the FFD criterion
4. Substantial changes must be provided in the annual FFD performance report submitted to the NRC
5. D&A program changes must have a Forensic Toxicologist review
6. Changes must be documented, justified, and maintained

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

Why? **To maintain FFD program effectiveness if licensee implements program changes**

Based on: **Existing change control processes in Sections 50.48(f)(3), 50.54(p) and (q)(3), the change control processes for fire protection, security and emergency plans, § 50.59, and that proposed in Part 53**

Program Flexibilities

- May use either urine or oral fluid
- May use of POCT and assessment devices – if certain requirements are met
- May use of offsite collection facilities – must be audited
- Specimen collection, storage, shipping are per manufacturer's instructions
- The framework will require Forensic Toxicologist review for D&A program changes
- Nothing in Subpart M prohibits a Part 53 licensee or other entity specified from subjecting all individuals to an FFD program that meets:
  - Subpart M
  - All the requirements in this part, except Subparts K and M
  - A drug testing program described in the HHS Guidelines

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.604, FFD program for Part 53 facilities <u>that meet</u> the FFD criterion**
  a. The FFD program:
     1. Applies to the individuals in § 26.602
     2. Implements the program elements in § 26.603
     3. Implements the following subparts and requirements:
        i. Subpart A—Administrative Provisions
        ii. Subpart O—Inspections, Violations, and Penalties
        iii. § 26.23, Performance objectives
        iv. § 26.606, Written policies and procedures
        v. § 26.608, FFD program training
        vi. § 26.609, Behavioral observation
        vii. § 26.610, Sanctions
        viii. § 26.611, Protection of information
        ix. § 26.613, Review process
        x. § 26.615, Audits
        xi. § 26.617, Recordkeeping and reporting
        xii. § 26.619, Suitability and fitness determinations

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.605, FFD program for facilities that do not meet the FFD criterion or is a holder of a Manufacturing License for assembling and/or fueling a reactor module under Part 53**
  a. For construction or construction activities, or is a holder of a Manufacturing License for assembling and/or fueling a reactor module under Part 53
     1. Applies to the individuals in § 26.602
     2. Implements the program elements in § 26.603
     3. Implements the following subparts and requirements:
        i. Subpart A—Administrative Provisions
        ii. Subpart I—Managing Fatigue (limited applicability)
        iii. Subpart O—Inspections, Violations, and Penalties
        iv. § 26.23, Performance objectives
        v. § 26.606, Written policies and procedures
        vi. § 26.607, D&A testing
        vii. § 26.608, FFD program training
        viii. § 26.609, Behavioral observation
        ix. § 26.610, Sanctions
        x. § 26.611, Protection of information
        xi. § 26.613, Review process
        xii. § 26.615, Audits
        xiii. § 26.617, Recordkeeping and reporting
        xiv. § 26.619, Suitability and fitness determination

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.605, FFD program for facilities that do not meet the FFD criterion**

  b. Before (1) the loading of fuel onsite into a reactor vessel, (2) integrating a fueled reactor module into the facility, or (3) operating, testing, performing maintenance of, or directing the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process has shown to be significant to public health and safety, the licensee shall establish, implement, and maintain an FFD program that:

  1. Applies to the individuals in § 26.602
  2. Implements the program elements in § 26.603(a) – (e)
  3. Implements the following subparts and requirements:
     - i. Subpart A—Administrative Provisions
     - ii. Subpart C—Granting and Maintaining Authorization
     - iii. Subpart D—Management Actions and Sanctions to be Imposed
     - iv. Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness
     - v. Subpart I—Fatigue Management
     - vi. Subpart N—Recordkeeping and Reporting Requirements
     - vii. Subpart O—Inspections, Violations, and Penalties
     - viii. § 26.23, Performance objectives
     - ix. § 26.606, Written policy and procedures
     - x. § 26.607, D&A testing
     - xi. § 26.608, FFD program training
     - xii. § 26.609, Behavioral observation
     - xiii. § 26.611, Protection of information
     - xiv. § 26.613, Review process
     - xv. § 26.615, Audits

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

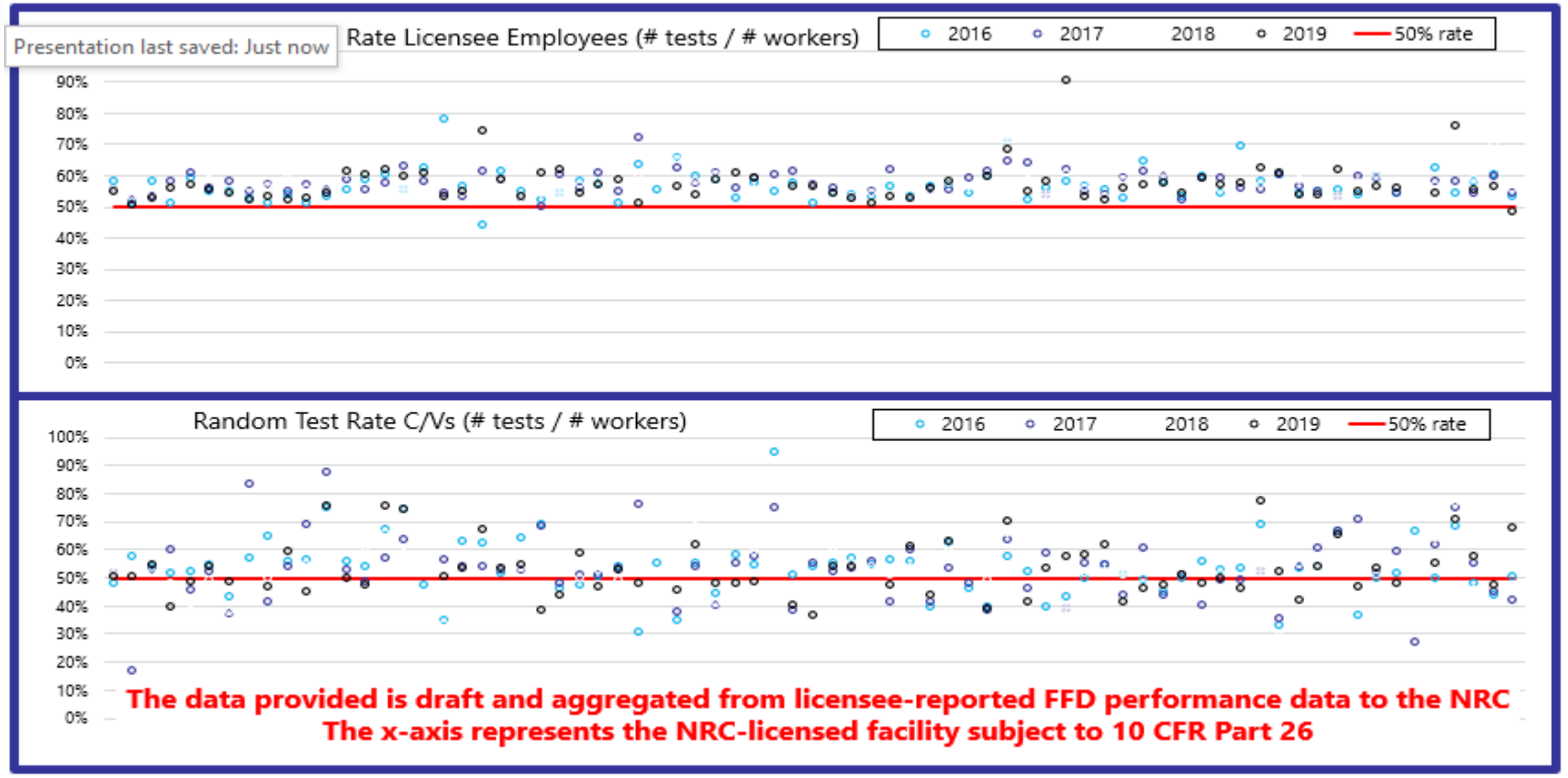
- **26.606, Written policy and procedures**
- **26.607, Drug and alcohol testing**
  1. Must deter and detect substance abuse
  2. Must use urine or oral fluid biological specimens and split specimen collections
  3. Must be conducted for the pre-access, random, for-cause, post-event, and follow-up test conditions
     i. Random testing must be ≥ 50 percent for both licensee employees and contractor/vendors (see next slide)
  4. Validity, initial, and confirmatory testing must be conducted at an HHS-certified laboratory (issuance of sanctions)
  5. Must used FDA-cleared devices
  6. May use a POCT device for screening – for random testing only
  7. Specimen collections may be conducted at a local hospital of collection facility – State certified or nationally accredited, and must be audited against Part 26, Subpart E, Collecting Specimens for Testing
  8. Must used approved Custody and Control Forms
  9. Must have MRO reviews
  10. Worker protections: limitations of testing, donor consent, testing of split specimens, MRO reviews, protection of information, and privacy

Random Testing Rate – a Discussion and Illustration

<u>Proposed</u>

Random testing at those facilities that must conduct D&A testing shall ensure that:

- Testing is conducted at an annual 50 % random rate
- The 50 % random rate must be applied to <u>both</u> the licensee employees & contractor/vendor populations



Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.608, FFD program training**
  - Training Periodicity – conducted prior to pre-access testing, with periodic refresher training
  - Training Review – periodically evaluated and revised as appropriate to reflect site and industry experience
- **26.609, Behavioral observation**
- **26.610, Sanctions**
- **26.611, Protection of information**
- **26.613, Review process**
- **26.615, Audits**
  - Program elements, which are not part of the FFD program performance and monitor review described in § 26.603(d), must be audited at a frequency that ensures their continuing effectiveness and that corrective actions are taken to resolve any problems identified

Section-by-Section – Amendments to Part 26 for Part 53 Licensees

- **26.617, Recordkeeping and reporting**
  - Records must be maintained
  - Reports to NRC – 24-hour reports and annual reports using the NRC-provided electronic reporting forms
  - Reports to other licensees regarding FFD-related information to support FFD and access authorization program implementation

- **26.619, Suitability and fitness determinations**
  - Procedures for evaluating whether to assign individuals to perform or direct those duties and responsibilities making them subject to this subpart.
  - Procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse.

Discussion

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10 CFR Part 26, Subpart I, "Managing Fatigue" Considerations for Part 53 Licensees

- For Part 26, Subpart I, “Managing Fatigue,” not much will be changing in the rule text.
  - Changes under consideration are primarily administrative in nature, serving to apply Subpart I requirements to Part 53 licensees.
- **Key consideration:** For work hour controls, the NRC is considering enabling *flexibility* under the existing rule text.
  - Degree of flexibility permissible will depend on the results of the applicant’s risk-informed safety evaluation
  - Applicants may be able to demonstrate that work hour controls are not needed for the same individuals or in the same circumstances as they would traditionally be needed for a large light water reactor site.

An example of how work hour controls could be considered with flexibility – ***designs with less reliance on operator actions for safe operation***

- The work hour controls listed in 10 CFR 26.205 are applicable to the individuals listed in § 26.4(a).
  - § 26.4(a)(1) ties in individuals whose duties include "operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety."
- If an applicant determined, through their risk-informed evaluation, that operators at a facility will not be operating risk-significant systems or components, those operators may not need to be subject to work hour controls.
  - Such facilities would likely be those that incorporate designs relying on a greater degree of automation, passive safety features, and/or inherent safety characteristics for safe operation.
  - The associated risk evaluation would need to demonstrate that the systems relied upon for safety are adequately robust and incorporate sufficient defense-in-depth into their design.

Another example – ***designs for which operator actions are relied upon for safety only during limited periods of operation***

- A licensee's risk-informed evaluation could determine that operator action is only relied upon for safety during certain plant evolutions.
  - For example, the applicant's evaluation could conclude that plant safety during the startup of a facility relies on operator action, while plant safety does not rely on operator action during periods of normal/steady-state operation.
- In such instances, operators may only need to be subject to work hour controls during certain periods.
  - In the example above, operators would need to be subject to work hour controls during startup, but they might not need to be subject to work hour controls during periods of normal/steady-state operation.

Key consideration for applicants that intend to utilize flexibility in applying work hour controls:

Applicants that intend to *not* apply work hour controls to operators during any period while the plant is operating will need to provide sufficient justification in their risk-informed evaluations.

Another consideration: **work hour control applicability to remote workers**

- In various instances throughout the § 26.4(a) text, the requirements refer to the "onsite directing" of activities associated with risk-significant structures, systems, and components.

- Some facilities licensed under Part 53 may, as part of their design basis, perform applicable operations or maintenance activities from a remote facility (for example, a remote control room or a remote control station/console).
  - In such instances, the NRC would consider such a remote facility to be an extension of the "site" for the purposes of considering "onsite directing."

Discussion

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Discussion of Other Part 53 Sections and Subparts

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Other Part 53 Sections and Subparts

- Subpart B – Technology-Inclusive Safety Requirements (3rd iteration) (ML21202A162)
- Subpart C – Requirements for Design and Analysis (3rd iteration) (ML21202A162)
- Subpart F – Requirements for Operation (Staffing) (ML21267A006)
- Subpart H – Licenses, Certifications, and Approvals (ML21267A004)
- Subpart I – Maintaining and Revising Licensing Basis Information (ML21202A175)
- Subpart J – Reporting and Other Administrative Requirements (ML21225A224)

Other Part 53 Sections and Subparts

Discussion

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Final Discussion and Questions

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Future Public Meetings

- The NRC staff will continue to announce public meetings to discuss and receive feedback on various regulatory topics and preliminary proposed rule text.
  - Preliminary proposed rule language will be posted on regulations.gov under docket ID NRC-2019-0062 before the public meetings.
- The NRC staff is scheduled to meet with the ACRS on February 2, 2022.
  - Subpart F – "Requirements for Operations." Discussions on staffing, personnel qualifications, training, and human factors requirements

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Closing Remarks

Rulemaking Contacts

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Regulations.gov docket ID: **NRC-2019-0062**

Please provide feedback on this public meeting using this link:
https://www.nrc.gov/public-involve/public-meetings/contactus.html

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Acronyms and Abbreviations

ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Document Access Management System
BOP	Behavioral observation program
C/V	Contract Vendors
D&A	Drug and Alcohol
CFR	Code of Federal Regulations
FDA	U.S. Food and Drug Administration
FFD	Fitness for Duty
HHS	U.S. Department of Health and Human Services
MRO	Medical review officer
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
PA	Protected area
POCT	Point of collection testing

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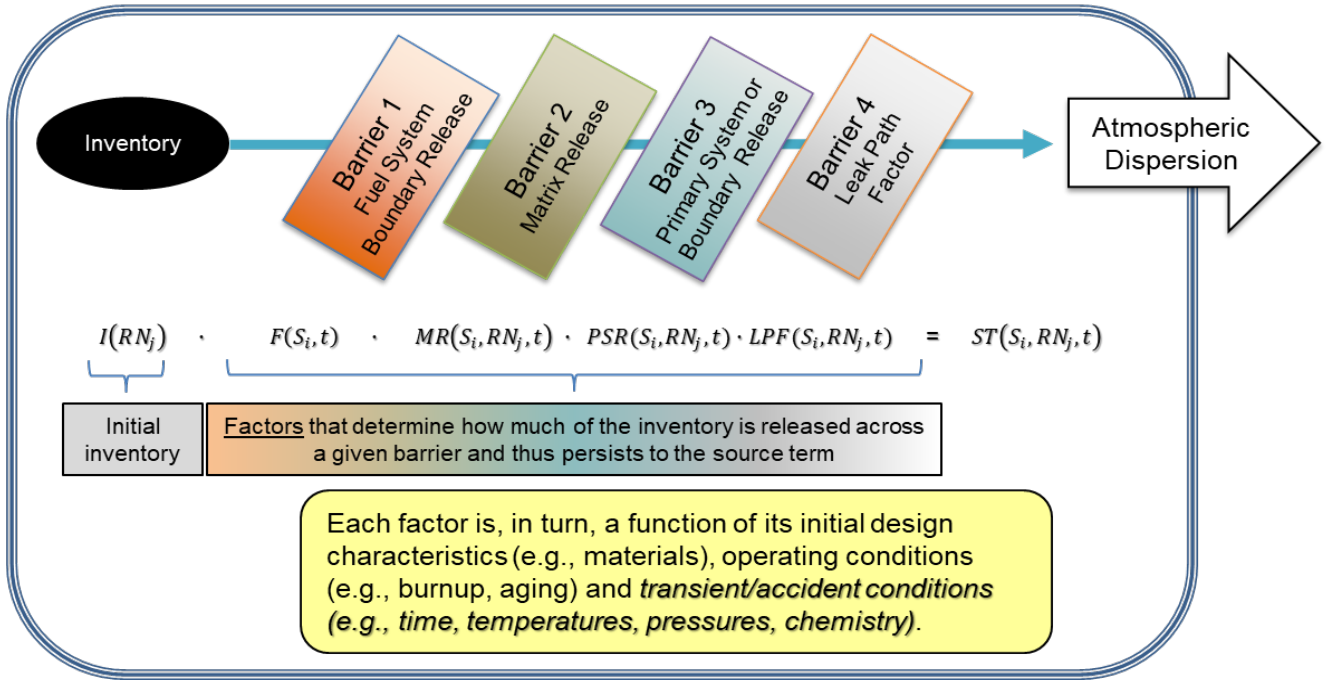
Background Slides

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"

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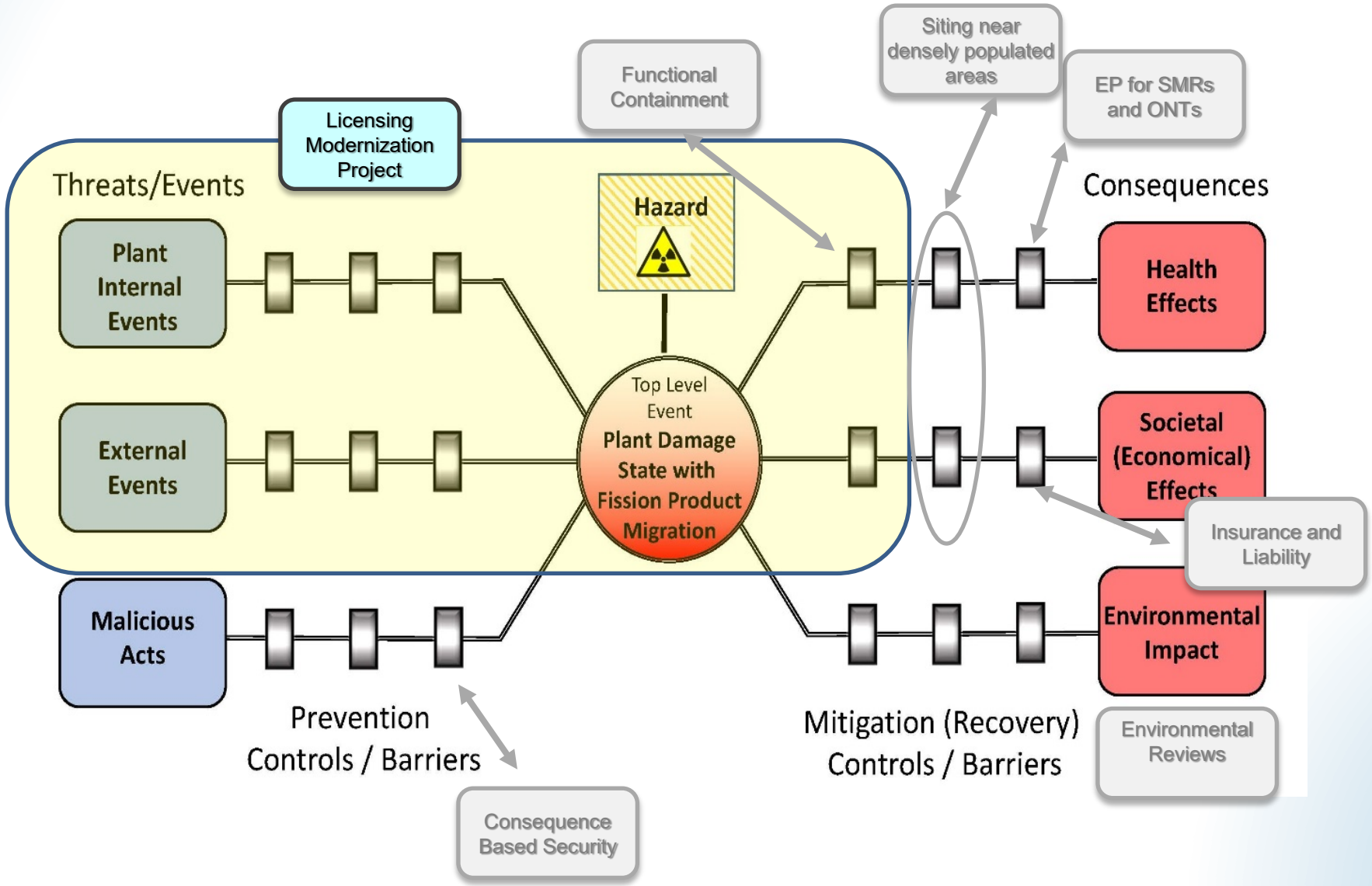
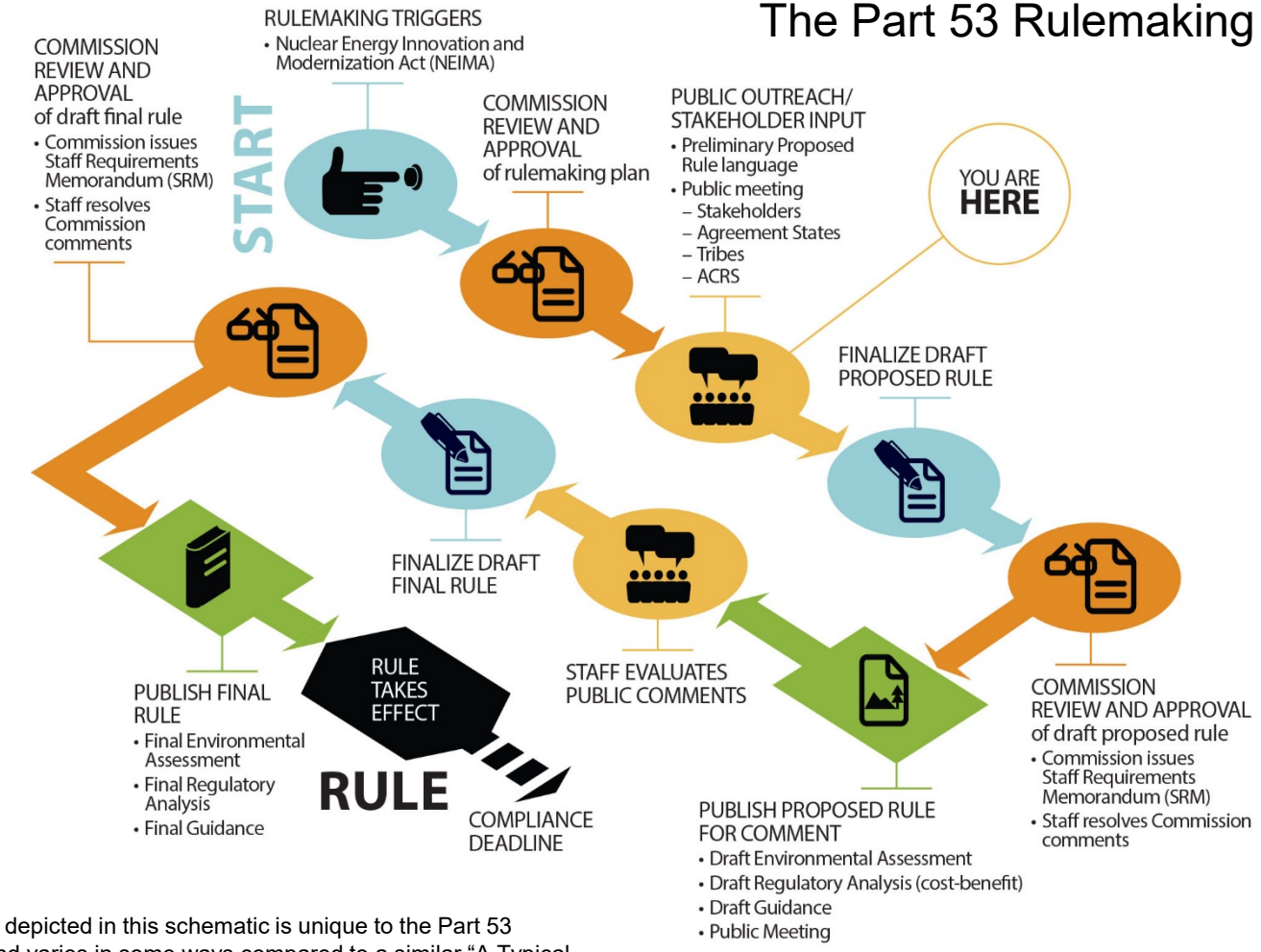
Integrated Approach



Part 53 Rulemaking

The 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.

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Background

- Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439) signed into law in January 2019 requires the NRC to complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use for commercial advanced nuclear reactors no later than December 2027
  - (1) ADVANCED NUCLEAR REACTOR—The term “advanced nuclear reactor” means a nuclear fission or fusion reactor, including a prototype plant… with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, …

NRC Staff Plan to Develop Part 53