

Fitness for Duty Programs
10 CFR Part 26

“Status of Regulatory Issues”

Nuclear Energy Institute Annual Conference
July 25, 2016



Topics

1. Part 26 Rulemaking – 2008 HHS Guidelines*
2. Part 26 Rulemaking – Technical and Policy Issues
3. 3rd Party Arbitration Rulemaking – Potential Impact on Part 26
4. Decommissioning Rulemaking – Potential Impact on Part 26
5. Regulatory Guide 5.77 – Insider Mitigation Program
6. Marijuana
7. Questions and Feedback

* U.S. Department of Health and Human Services' Mandatory Guidelines for Federal Workplace Drug Testing

Part 26 Rulemaking – 2008 HHS Guidelines

- Better aligns Part 26 to the 2008 HHS Guidelines
- The proposed rule:
 - Lowers cutoffs for amphetamine, methamphetamine, and cocaine
 - Expands the test panel to include MDEA, MDMA, and MDA
 - Targets the 6-Acetylmorphine metabolite on initial testing
 - Special analysis testing of dilutes & specimens collected under direct observation
 - MRO review of time and temperature based on high pH
- Estimated 10 – 12 % increase in positives and identified subversion attempts
- Other changes for efficiency, clarity, and lessons learned
- The proposed rule package is in concurrence

Part 26 Rulemaking – Technical Issues

- Preliminary staff proposals were communicated to NEI and commercial nuclear industry on multiple occasions since 2010; most recent being a public meeting on April 19, 2016
- A rulemaking to address:
 - Policy Issues
 - Technical Issues (e.g., the proposed HHS guideline changes)
 - Recurrent Part 26 rulemaking
- A strategy could be to incorporate pro-active, performance-based, and risk-inform elements into the Part 26 framework to: (1) address changes in societal drug use; (2) policy and technical issues; and, (3) reduce the recurrent need for Part-26 rulemaking.

Part 26 Rulemaking – Technical Issues

- A Rule Plan being written to obtain Commission approval to continue Technical Issues rulemaking
 - The Rule Plan is planned to be provided to the Commission after the HHS Guidelines rulemaking package goes to the Commission
- Options for rulemaking to include:
 - No rulemaking
 - Limited-scope rulemaking
 - Staff-proposed changes accepted
- Recommending an Advanced Notice of Proposed Rulemaking (ANPR) be issued

Part 26 Rulemaking – Technical Issues

Proposed (new) HHS Guideline Changes

- Urine Guidelines
 - Adding 4 semi-synthetic opiates to the test panel
 - Expected publication in 2016
- Oral Fluid Guidelines
 - Same test panel as the urine guidelines
 - Expected publication in 2016
- Hair Guidelines
 - Same test panel as the urine and oral fluid guidelines
 - Different metabolites
 - Wash techniques and hair pigmentation issues are being resolved
 - Expect publication in 2017 or 2018

Part 26 Rulemaking – Technical Issues (staff considered)

- Policy Issues
 - 3 petitions for rulemaking
 - Interim and long-term storage of spent nuclear fuel (ISFSI, MRS, CISF, & GROA)
 - Moving Part 26 “authorization” requirements to § 73.56 – High Assurance
- Technical Issues
 - Proposed HHS Guidelines (semi-synthetic opiates, oral fluid, & hair)
 - Marijuana and other medically-disqualifying substances
 - Performance-based auditing and random and group testing
 - Risk-informed sanctions and behavioral observation
 - Enhanced security measures and specimen validity testing
 - Medical review officer access to state prescription databases
 - Oral fluid point-of-collection testing
 - Etc.

Part 26 Rulemaking – Technical Issues Rulemaking

Changes that may help reduce the need for future Part 26 rulemaking:

- i. Removing or revising select provisions from Part 26 that are equivalent to those in the HHS Guidelines to help prevent future rulemaking when the HHS Guidelines change;
- ii. Restructuring certain prescriptive Part 26 requirements to a performance-based framework and require licensee actions when performance dictates; and,
- iii. Use of the licensee's Security Plan and NRC regulatory guide (RG) to implement certain drug/alcohol testing provisions, if committed to by the affected industry.

3rd Party Arbitration Rulemaking – Possible Impact on Part 26

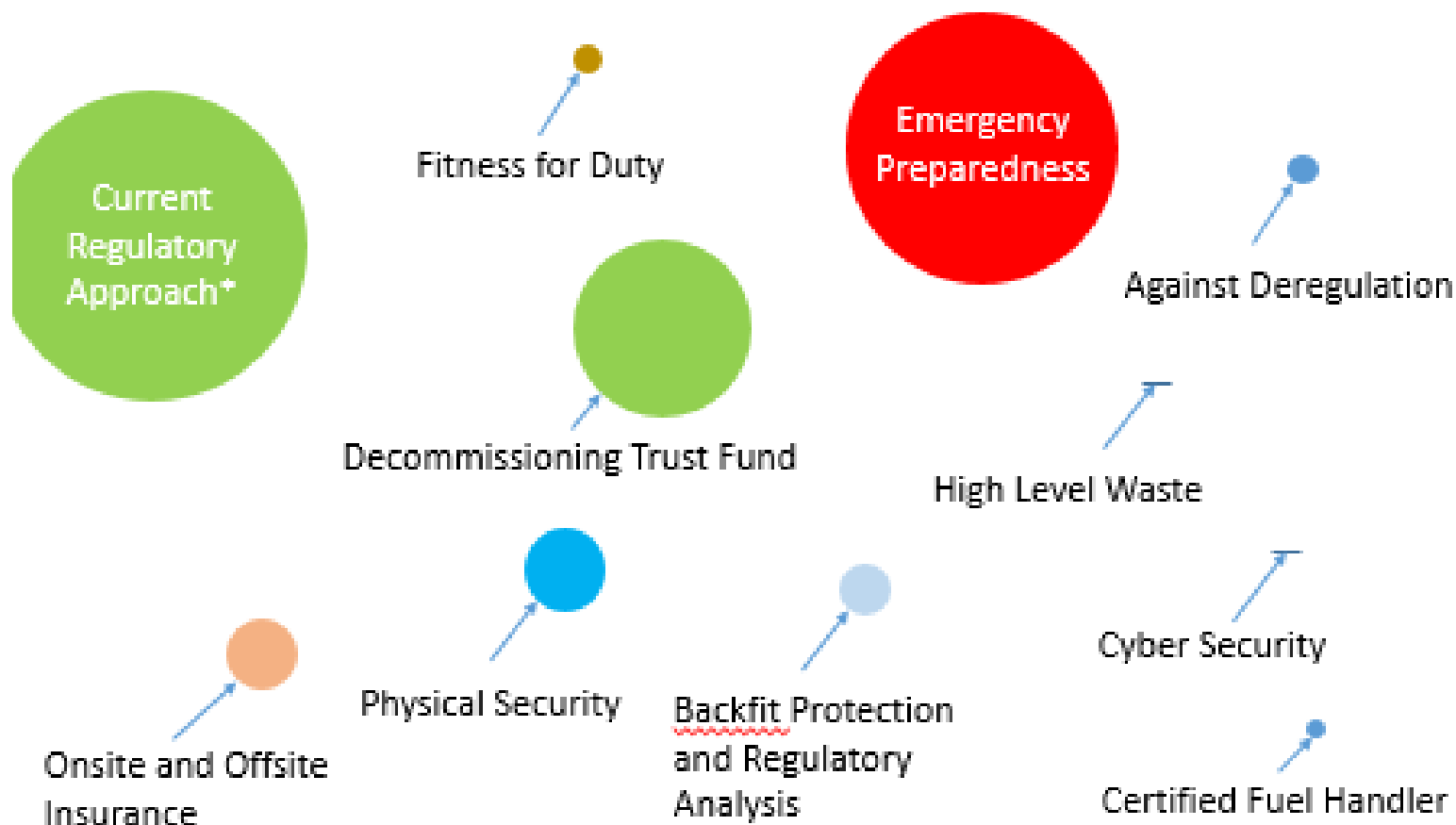
- Reviewing Official definition (exists in § 26.5, not in § 73.56)
- For turn-key FFD programs (INPO, Westinghouse) do we need to clarify the Part 26 use of Reviewing Official?
- MRO determinations, SAE-treatment plans, and administration of sanctions, and Reviewing Official review of potentially disqualifying FFD information – are these activities “employment decisions”?
 - Is the permanent denial of authorization a *defacto* employment decision?
- Who are “unauthorized personnel”?
- Consider enhancing the § 26.39 appeals process as directed by the Commission
 - The § 26.39 and § 73.56 appeals processes should at least be reasonably equivalent

Decommissioning Rulemaking – Possible Impact on Part 26

- Decommissioning Rulemaking
 - ANPR issued: November 19, 2015
 - Public Meeting: December 9, 2015
 - Draft Regulatory Basis: November 2016
 - Proposed Rule: April 2018
 - Final Rule: 2019
- Part 26
 - Broaden the 26.3, “Scope”
 - Apply a measured and risk-informed approach
 - Use guidance in RG 5.77, rev. 1 (not approved) as an initial approach

Decommissioning Rulemaking

Diameter of circle shows relative length of comments submitted by topic



* - includes 60 year limit on decommissioning, options for decommissioning, and the appropriate roles of state and local governments in the decommissioning process

Decommissioning Rulemaking – A Possible Bifurcated Rule

- Nuclear Energy Institute has requested the staff to pursue a bifurcated (two part) rule

Part 1

- Would focus on gained efficiencies by addressing decommissioning-related exemptions and amendments
- NEI requested NRC to publish first part of proposed rule for public comment in November 2016

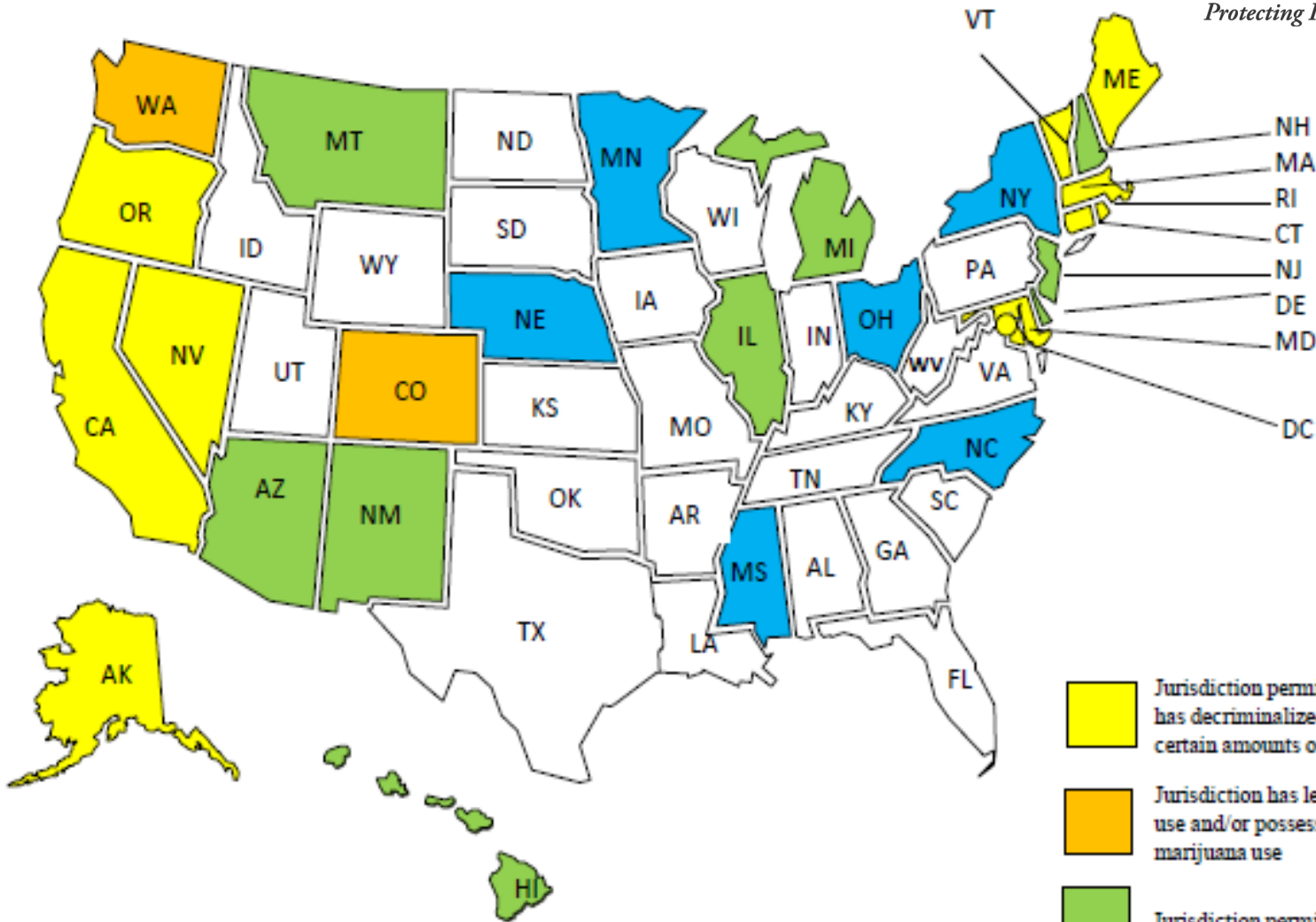
Part 2

- Would focus on other rule changes
- Commission directed the staff to complete the rule in 2019
- Staff intends to include options for a bifurcated rule as an option in the draft Regulatory Basis





Regulatory Guide 5.77 – Insider Mitigation Program

- § 73.55(b)(9) requires licensees to implement “elements from” fitness for duty, access authorization, cyber, and physical protection programs
- § 73.55 is focused on protecting against the Design Basis Threat
- RG 5.77 issued to provide guidance on what program elements are necessary for an IMP – first issued in March 2009 – focused on drugs and alcohol
- Staff-proposed RG 5.77, rev. 1, presented at public meeting on May 17, 2016
 - Comments received primarily on cyber and removing “decommissioning”
- Commission public meeting on June 23, 2016
 - SRM-M160623B
- A revised RG 5.77, rev. 1, presented to stakeholders on July 18, 2016
 - 2nd public meeting on July 19, 2016
- Staff expects rev. 1 publication in January 2017

Marijuana in the United States*



* As of August 2014

-  Jurisdiction permits medical marijuana use and has decriminalized use and/or possession of certain amounts of marijuana
-  Jurisdiction has legalized recreational marijuana use and/or possession and permits medical marijuana use
-  Jurisdiction permits medical marijuana use
-  Jurisdiction has decriminalized use and/or possession of certain amounts of marijuana

Marijuana

- If marijuana is reschedule, the staff plans to propose that marijuana use be considered medically disqualifying
 - There is no linear threshold of impairment
 - Smoked or consumed Marijuana cannot be titrated
- Staff may consider:
 - Effect on ANS/ANSI3.4-2013, licensed operator medical qualifications
 - Effect on NRC-licensed operators at non-power reactors
- If not medically-disqualifying by rule or order, then the industry would need to treat marijuana prescriptions like other prescriptions
 - Yet, this does not address non-prescription marijuana use



Cesamet®
(nabilone)



Marinol®
(dronabinol)

Sativex®
(dronabinol)



Questions and Feedback

Questions?

Feedback?

Fitness for Duty Program Staff



U.S. Nuclear Regulatory Commission

Office of Nuclear Security and Incident Response
Division of Security Policy
Fuel Cycles and Transportation Security Branch

Paul Harris, Senior Program Manager
Paul.Harris@nrc.gov (301-287-9294)

Will Smith, Security Specialist
Will.Smith@nrc.gov (301-287-3541)

Brian Zaleski, FFD Program Specialist
Brian.Zaleski@nrc.gov (301-287-0638)