A NOVEL FITNESS FOR DUTY APPROACH FOR ADVANCED REACTORS U.S.A

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Abstract

The NRC has initiated rulemaking to develop a comprehensive, transformative, and technology-inclusive regulatory framework for the licensing and regulating of advanced reactors. This new regulatory framework and implementing guidance would adopt technology-inclusive approaches and use risk-informed and performance-based techniques to ensure an equivalent level of safety to that of operating commercial nuclear power plants, while providing flexibility for licensing and regulating a variety of technologies and designs for new commercial nuclear reactors. A cornerstone of the rulemaking is the development of a risk-informed graded approach to the application of fitness-for-duty (FFD) program requirements to the workforces that will build and operate advanced reactors. An FFD program provides reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their assigned duties. An FFD program also provides reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse and includes measures for the early detection of individuals not fit for duty. The FFD program requirements for advanced reactors would be proportionate to the associated risks, which may be different than those posed by the current commercial nuclear power reactor fleet of large light water reactors in the U.S. Key aspects of FFD programs for advanced reactors include a risk-informed assessment that recognizes the diverse landscape of potential reactor designs and radiological consequences, the application of appropriate FFD program elements commensurate with the level of determined risk, and the use of innovative technologies to implement various programmatic elements (e.g., drug and alcohol testing, behavioral observation).

1. INTRODUCTION

In January 2019, President Trump signed the Nuclear Energy Innovation and Modernization Act (NEIMA) into law [1]. This law directed the 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 December 31, 2027. This paper explores the FFD program component of the NEIMA-directed "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," Title 10 of the *Code of Federal Regulations* (10 CFR) Part 53 (Part 53) rulemaking [2].

The NRC's requirements in 10 CFR Part 26 (Part 26), "Fitness for Duty Programs" [3], were established in 1989 [4] to regulate the workforces at commercial nuclear power reactors licensed under 10 CFR Part 50 (Part 50), "Domestic Licensing of Production and Utilization Facilities" [5]. In a 1993 final rule [6], the NRC applied Part 26 to Category I special nuclear material (SNM) facilities licensed under 10 CFR Part 70 (Part 70), "Domestic Licensing of Special Nuclear Material" [7]. In a 2008 final rule [8], the NRC amended Part 26, in part, to include a new optional and more flexible FFD program applicable to specific categories of personnel working at power reactor construction sites under "Subpart K, FFD Program for Construction." The 2008 final rule also expanded the applicability of Part 26 to commercial nuclear power reactors licensed under 10 CFR Part 52 (Part 52), "Licenses, Certifications, and Approvals for Nuclear Power Plants" [9].

The NRC has initiated rulemaking to develop a comprehensive, transformative, and technology-inclusive regulatory framework for the licensing and regulating of advanced reactors under a new Part 53. A cornerstone of the rulemaking is the development of a risk-informed graded approach to the application of FFD program requirements to the workforces at advanced reactor sites.

2. FFD PROGRAM REQUIREMENTS

2.1 History of Part 26 FFD programs

Since 1989, the workforces at commercial nuclear power reactors in the U.S. have been subject to the FFD program requirements under Part 26, with the application of Part 26 expanding to the workforces at Category I SNM facilities in 1993. An FFD program provides reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their assigned duties. An FFD program also provides reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse and includes measures for the early detection of individuals not fit for duty. An FFD program provides defense in depth through the implementation of a variety of programmatic elements, including: FFD policies and procedures; granting and maintaining FFD authorization; training (initial and refresher); drug and alcohol specimen collection and testing; review of test results and evaluation of fitness by trained professionals; behavioral observation of the workforce to identify possible impairment; management actions to address possible impairment; sanctions for FFD policy violations, including an appeals process; recordkeeping, reporting, and protection of information; and periodic program audits and actions to correct program deficiencies.

The NRC historically has relied on the U.S. Department of Health and Human Services (HHS) Guidelines to establish the technical requirements for urine specimen collection, drug and validity testing, and test result evaluation by appropriately trained professionals. In general, the NRC deviates from the HHS Guidelines for considerations specific to the nuclear industry. The HHS Guidelines govern the U.S. Federal employee workplace drug testing programs at more than 100 Federal agencies and Federal agency drug testing programs (e.g., U.S. Department of Transportation (DOT)) that test civilians in safety- and security-sensitive positions similar to personnel tested under Part 26.

In 1986, President Ronald Reagan signed Executive Order 12564—Drug-Free Federal Workplace [10], which designated HHS as the Federal agency responsible for establishing and maintaining the requirements and guidance for conducting Federal employee workplace drug testing in the U.S. HHS developed the “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (HHS Guidelines) that established a robust legal framework to protect individuals subject to testing by ensuring to the accuracy and precision of drug tests; specimen collection, custody, and control; and results review by an appropriately trained medical professional. The HHS Guidelines also established the laboratory certification and inspection requirements that must be met to conduct testing for the Federal employee workplace drug testing programs. Periodically, HHS updates the HHS Guidelines to enhance testing program effectiveness by incorporating scientific advancements in drug testing technologies, methodologies, and processes; updating the substances in the drug testing panel to address societal drug-use trends; and incorporating lessons learned from laboratory testing and inspections.

The NRC also relies on the Federal drug and alcohol testing program required by the DOT, which imposes similar requirements to those in Part 26. For example, because the HHS Guidelines do not cover the testing of alcohol (only drugs), the NRC relies on DOT’s regulations in 49 CFR Part 40 [11], in part, to ensure that alcohol testing devices and the testing process in Part 26 is scientifically sound and legally defensible. The DOT programs also test millions of individuals each year, which provides valuable lessons learned from implementing a testing program covering a much larger worker population than exists in the U.S. nuclear industry. The NRC and DOT [12] established drug and alcohol testing programs in 1989.

The first substantial revision to Part 26 was published in a March 2008 final rule [8]. The 2008 final rule updated the drug testing panel to align with the 2004 HHS Guidelines [13] and DOT testing requirements more closely. A number of important changes in the 2008 final rule included: (1) mandated validity testing of urine specimens to address the potential for subversion of the testing process; (2) incorporated advancements in drug and

alcohol testing technologies and testing cutoff levels; (3) established uniform minimum sanctions for FFD policy violations; (4) improved consistency between personnel access authorization requirements for nuclear power plants in 10 CFR 73.56, "Personnel access authorization requirements for nuclear power plants" [14], and security orders issued after the terrorist attacks in the U.S. on September 11, 2001; (5) created a fatigue management program (i.e., work hour controls applicable to individuals performing specific job functions at operating power reactors); and (6) created an optional and more flexible FFD program applicable to specific categories of workers at power reactor construction sites.

Recently, the NRC published a Part 26 final rule in November 2022 [15]. This narrowly scoped final rule primarily focused on enhancing urine drug testing capabilities (i.e., substances tested and testing cutoff levels used) by aligning with HHS Guidelines updates in 2008 [16] and 2017 [17]. The final rule also strengthened and expanded the use of testing methods to identify subversion attempts of the urine drug testing process.

2.2 FFD programs for advanced reactors licensed under 10 CFR Part 53

The proposed regulatory framework for FFD programs applicable to advanced reactors licensed under Part 53 offers a graded approach that is commensurate with the radiological risk posed by the reactor design and operations of the reactor. The proposed requirements aim to be flexible, risk informed, and performance based. These requirements are designed to maintain FFD program effectiveness and to align with the FFD programs for Part 50 and Part 52 licensed facilities. The NRC staff proposals are informed by operating experience gained in the U.S. from the FFD programs implemented at large light water commercial nuclear power reactor sites since 1989 and power reactors under construction since 2009. The NRC staff bounded the graded approach to FFD programs by evaluating licensed facilities that do not require FFD programs, but may have similar power levels and radiological consequences to some advanced reactor designs (i.e., non-power production or utilization facilities (NPUFs)).

As part of the Part 53 rulemaking, the NRC staff is proposing to create FFD program requirements for advanced reactors under a new Subpart M, "Fitness for Duty Programs for Facilities Licensed under Part 53," to Part 26. The Subpart M FFD program is largely consistent with the optional Subpart K FFD program for power reactor construction sites. However, the Subpart M FFD program is not entirely equivalent to a Subpart K FFD program because Subpart K only applies during reactor construction, whereas the Subpart M FFD program would apply during reactor construction and operation.

The Subpart M FFD program requirements are performance based and informed by the potential risks inherent in an advanced reactor's design and operations, which includes human actions necessary to: (1) effectively operate, maintain, surveil, decommission, and protect the facility, materials, and sensitive information (e.g., classified, safeguards, medical, private); (2) prevent or mitigate the radiological consequences of a structure, system, or component (SSC) failure, a reactor transient or accident, or other abnormal occurrence; and (3) detect, assess, and respond to an internal or external security incident or an adverse environmental condition (e.g., hazardous chemicals, earthquake, flood). Subpart M would enable the collection and drug testing of a variety of biological specimens (e.g., oral fluid, hair), as well the use of drug and alcohol testing technologies not generally permitted under the existing Part 26 FFD program requirements (e.g., point of collection testing that provides immediate results, passive monitoring equipment to screen individuals for alcohol and drugs before they enter the facility). FFD program flexibility is intended to accommodate for radiological risk, innovations in technology, and variations in workforce size and the geographic siting of advanced reactors.

The Subpart M consists of three tiers of FFD program requirements. A first-tier FFD program would apply during advanced reactor construction, including the manufacturing and assembly of a reactor. A second tier FFD program would apply during the operating phase of an advanced reactor and would include additional FFD program elements that must be implemented prior to initiating reactor operation. An optional third-tier FFD program would

apply if an evaluation determined that the advanced reactor is a low consequence facility. A low consequence facility under proposed 10 CFR 26.604(a) is one for which the radiological consequences of a design-basis threat initiated 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 proposed 10 CFR 53.210, "Safety criteria for design-basis accidents." The offsite dose criterion is "An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem."

2.2.1 First-tier FFD program requirements – 10 CFR 26.605(a)

First tier FFD program requirements would apply to advanced reactors under construction that do not meet the low consequence facility criterion or elect not to implement the low consequence facility FFD program. The first tier FFD program requirements would also apply to the holders of manufacturing licenses who assemble or test manufactured reactors. The first-tier FFD program would apply before the loading of fuel onsite into a reactor vessel; before receiving a manufactured reactor; or before operating, testing, performing or directing maintenance or surveillance on security-related equipment or equipment that has shown to be significant to public health and safety.

The first-tier FFD program requirements in 10 CFR 26.605(a) are essentially equivalent to the current optional Part 26, Subpart K program for reactor construction sites, but also includes select requirements in current Subparts E, "Collecting Specimens for Testing," and I, "Managing Fatigue," and all requirements in current Part 26 Subparts A, "Administrative Provisions," and O, "Inspection, Violations, and Penalties." The first-tier FFD program elements consist of FFD policies and procedures, training, behavioral observation, fatigue management, drug and alcohol testing, determinations of fitness, an appeals process for FFD policy violation determinations, sanctions, auditing, change control, performance monitoring, and recordkeeping and reporting.

2.2.2 Second-tier FFD program requirements – 10 CFR 26.605(b)

The second-tier FFD program requirements in 10 CFR 26.605(b) consist of all first-tier FFD program requirements and the following existing Part 26 requirements in Subparts C, "Granting and Maintaining Authorization;" D, "Management Actions and Sanctions to be Imposed;" H, "Determining Fitness-for-Duty Policy Violations and Determining Fitness;" and N, "Recordkeeping and Reporting Requirements." The NRC proposes to apply the additional FFD program requirements in Subparts C, D, H and N of Part 26 because of the risks presented from the assembly, testing, fueling, and operation of an advanced reactor and the necessity for human action in certain event sequences. The inclusion of these current Part 26 FFD program requirements would align with those that already apply to the workforces at Part 50 and 52 licensed commercial nuclear power reactors and Category I SNM facilities.

2.2.3 Third-tier FFD program (low consequence facilities) – 10 CFR 26.604

The third-tier FFD program requirements would apply if an advanced reactor were determined to be a low consequence facility. A 10 CFR 26.604 FFD program for low-consequence facilities would rely on behavioral observation to provide reasonable assurance that individuals are fit for duty, trustworthy, and reliable. No drug and alcohol testing would be required unless FFD program performance declines. The third-tier FFD program requirements are equivalent to first-tier FFD program requirements except no drug and alcohol testing is required. The third-tier FFD program focuses on human performance (i.e., workers performing assigned duties and responsibilities). The human performance would be verified through behavioral observation, the evaluation of FFD concerns, performance monitoring, fatigue management, and determinations of fitness.

The NRC is not proposing to require drug and alcohol testing for the low consequence third-tier FFD program for five reasons. First, the Part 26 FFD program performance objectives can be met through effective implementation of a defense-in-depth regulatory framework consisting of behavioral observation, self-reporting of legal actions, a performance monitoring and review program (PMRP), and training; along with the other regulatory programs applicable to advanced reactors (i.e., physical protection, access authorization (AA), cyber protection, and licensing of operators). Second, the proposed new PMRP would require FFD program performance monitoring against historical site performance, fleet-level performance (if applicable), and industry performance. Corrective actions would be required if FFD performance meets a licensee- or other entity-established threshold or to resolve an internal audit finding to restore FFD performance and correct root causes, contributing causes, or both. Third, the behavioral observation program requirements in proposed 10 CFR 26.609 are more robust than those applicable to power reactor construction sites under Subpart K (10 CFR 26.407) and are proposed to synchronize with and reinforce the behavioral observation program requirements under the AA program in 10 CFR 73.56 or the proposed requirements under 10 CFR 73.120, "Access authorization program for commercial nuclear plants" [2]. Fourth, a low consequence advanced reactor facility will have a low radiological risk profile and could approach that of an NPUF (which does not implement an FFD program). Finally, an advanced reactor could be designed and constructed in such a manner to reduce reliance on an onsite security force to protect SSCs, NRC-licensed materials, and sensitive information, with enhanced capabilities for the detection, assessment, and delay of a design-basis threat adversary.

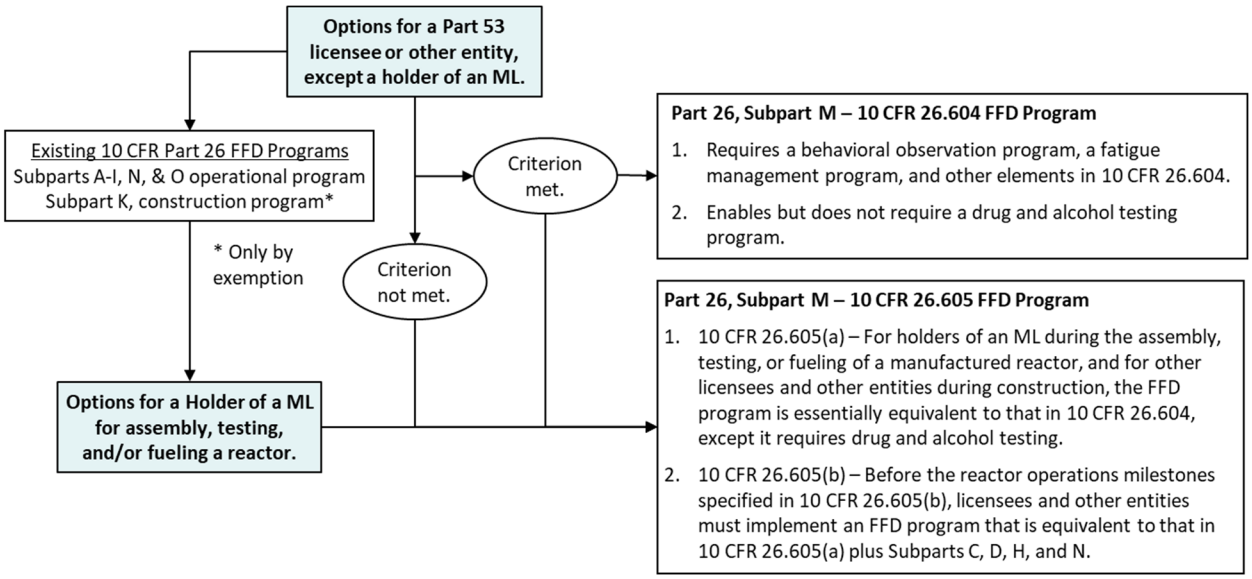

Figure 1. FFD Program Options for Part 53 Applicants and Licensees

2.3 Non-power production or utilization facility comparison

Advanced reactors licensed under Part 53 could be designed with similar power levels and radiological consequences as currently licensed NPUFs. The NRC's FFD program requirements do not apply to NPUFs. As part of developing the third-tier FFD program requirements for low consequence facilities, the NRC reviewed current advanced reactor designs against those of licensed NPUFs. From this review, three principal considerations supported the FFD program requirements for low consequence facilities.

First, an advanced reactor that satisfies the lower consequence facility criterion in 10 CFR 26.604 may still present a greater potential radiological consequence to workers and the public in the vicinity of the facility than does

an NPUF. Second, the operating characteristics of an advanced reactor are unlike those of an NPUF because of the potential for a higher reliance on human action to safely and competently operate, maintain, surveil, and secure SSCs (e.g., systems that provide secondary heat transfer, reactor coolant flow, pressure control, and at-power core refueling). Differences in operating characteristics could include, for example: long-term, full power operation with automated reactivity control systems for load-following; active and passive safety and security systems; innovative non-light water heat transfer systems; and energy storage and hazardous chemical systems. Workers at advanced reactors also may be required to communicate with individuals onsite and offsite about any conditions adverse to safety, security, or quality, such as electrical load dispatchers. Third, advanced reactors may be sited in geographically remote locations that may not have a physically available administrative or corporate support team to provide face-to-face oversight, engineering expertise, and maintenance support like that at NPUFs. This places a higher reliance on the workers at an advanced reactor facility being fit for duty and trustworthy and reliable because replacement personnel may not be readily available.

3. DRAFT REGULATORY GUIDANCE

Draft Regulatory Guide (DG)-5073, “Fitness-of-Duty Programs for Commercial Nuclear Plants and Manufacturing Facilities Licensed under 10 CFR Part 53” [18], is a companion guidance document developed by the NRC staff to provide one acceptable approach to implement the FFD program requirements under Subpart M of Part 26. The draft guidance would apply to applicants and holders of a Part 53 license that implement an FFD program under Subpart M of Part 26. DG-5073 could be used when preparing an application for a Part 53 operating license, manufacturing license, combined license, limited work authorization, construction permit, or early site permit and when implementing the FFD program during construction, operation, and decommissioning.

4. KEY TAKEAWAYS AND CONCLUSIONS

- The existing FFD program requirements in Part 26 apply to Part 50 and Part 52 licensed commercial nuclear power reactors, and Category I SNM facilities licensed under Part 70.

- An optional Subpart K, “FFD Program for Construction,” applicable to commercial nuclear power reactors under construction was created in a 2008 Part 26 final rule and has been implemented at two power reactor sites over a time period of 2009 through 2023 (Vogtle 3 and 4 from 2009-2023 and V.C. Summer 2 and 3 from 2011-2017). Operating experience and NRC inspection have demonstrated that Subpart K FFD programs have provided reasonable assurance that individuals can safely and competently perform assigned duties at power reactor construction sites.

- An FFD framework for advanced reactors licensed under Part 53 is being proposed under a new Subpart M to Part 26. The Subpart M requirements leverage the Part 26 requirements in Subpart K.

- The FFD framework for advanced reactors includes three FFD program tiers. The first-tier FFD program would apply to advanced reactors under construction that do not meet the low consequence facility criterion and also to manufacturing licenses who assemble or test manufactured reactors. The second-tier FFD program would apply additional FFD program requirements because of the risks presented from the assembly, testing, fueling, and operation of an advanced reactor and the necessity for human action in certain event sequences. An optional third-tier FFD program would apply to advanced reactors determined to be low consequence facilities. For low consequence facilities, drug and alcohol testing is not required.

- The proposed FFD framework includes flexibilities in areas such as the biological specimens permissible for drug and alcohol testing (e.g., oral fluid, hair); technologies to test for alcohol and drugs (e.g., point of collection testing that provides immediate results; passive monitoring equipment to screen individuals for

alcohol and drugs before facility entry); and performance of behavioral observation (e.g., camera systems to verify identity and assess possible impairment).

– The FFD framework requires licensee's to develop and implement a PMRP to evaluate FFD program effectiveness. Licensees must establish performance measures and thresholds and monitor performance against the measures and thresholds on an annual basis and implement timely corrective actions if an adverse trend is identified.

ACKNOWLEDGEMENTS

Paul Harris developed the proposed Part 53 FFD program requirements and regulatory guidance in DG-5073. This paper summarizes his work. Paul retired from the NRC in January 2024.

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