NRC Response to Public Comments

Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

NRC-2019-0062; RIN 3150-AK31

Volume #2 – Response to Comments on 10 CFR Part 26, 10 CFR Part 73, Guidance, and Other Topics

U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Office of Nuclear Security and Incident Response
Office of Nuclear Material Safety and Safeguards

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Acronyms and Abbreviations

ACI	American Concrete Institute
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
ADVANCE Act	Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024
AEA	Atomic Energy Act of 1954, as amended
AERI	alternative evaluation of risk insights
AI	Artificial Intelligence
AIPT	adversary interference precluded time
AISC	American Institute of Steel Construction
ALARA	as low as (is) reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
AOO	anticipated operational occurrence
APA	Administrative Procedure Act
ARAR	Applicable or Relevant and Appropriate Requirements
ARCAP	Advanced Reactor Content of Application Project
ARDC	advanced reactor design criteria
ASCE	American Society of Civil Engineers
ASME	American Society of Mechanical Engineers
BDBE	beyond-design-basis event
BOP	behavioral observation program
C/TPA	consortia/third-party administrators
CAA	Clean Air Act
CAB	community advisory board
CCTV	closed-circuit television
CDF	core damage frequency
CER	cumulative effects of regulation
CFR	*Code of Federal Regulations*
COL	combined license (combined construction and operating license)
CP	construction permit
CRCPD	Conference of Radiation Control Program Directors
DANU	Division of Advanced Reactors and Non-Power Production or Utilization Facilities
DBA	design-basis accident
DBE	design-basis event
DBEHL	design-basis external hazard level
DBHL	design-basis hazard level
DBT	design-basis threat
DC	design certification
DECON	a phase of reactor decommissioning
DG	draft regulatory guide
DID	defense in depth
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation

DRO	Division of Reactor Oversight
EO	Executive Order
EA	environmental assessment
EAP	Employee Assistance Program
EBT	evidential breath testing device
ECA	Energy Communities Alliance
EIS	environmental impact statement
EP	emergency preparedness
EPA	U.S. Environmental Protection Agency
EPZ	emergency planning zone
ERDS	Emergency Response Data System
ESP	early site permit
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
FFD	fitness-for-duty
FIOP	Federal Interagency Operational Plan
FOAK	first-of-a-kind
FR	*Federal Register*
FRN	*Federal Register* notice
FSAR	final safety analysis report
GAO	U.S. Government Accountability Office
GDC	general design criteria
GEIS	generic environmental impact statement
GLRO	generally licensed reactor operator
HALEU	high-assay low-enriched uranium
HFE	human factors engineering
HHS	U.S. Department of Health and Human Services
HSI	human system interface
IAEA	International Atomic Energy Agency
IEEE	Institute of Electrical and Electronics Engineers
IEFR	individual early fatality risk
ILCFR	individual latent cancer fatality risk
ISG	interim staff guidance
ISI	inservice inspection
ISO	International Organization for Standardization
IST	inservice testing
ITAAC	inspections, tests, analyses, and acceptance criteria
LBE	licensing-basis event
LER	licensee event report
LERF	large early release frequency
LMP	Licensing Modernization Project
LNT	linear no-threshold
LWA	limited work authorization
LWR	light-water reactor
MC&A	material control and accounting
MD	management directive
ML	manufacturing license

MHA	maximum hypothetical accident
MRO	medical review officer
mSv	millisievert
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act of 2019
NEPA	National Environmental Policy Act
NNAB	National Nuclear Accrediting Board
non-LWR	non-light-water reactor
NPS	National Preparedness System
NPUF	non-power production or utilization facility
NQA-1	Nuclear Quality Assurance-1 standard
NRC	U.S. Nuclear Regulatory Commission
NRF	National Response Framework
NRIA	Nuclear/Radiological Incident Annex
NSRSS	non-safety-related but safety-significant
NSS	Nuclear Security Series
NTIAP	Near-Term Implementation Action Plans
NTTAA	National Technology Transfer and Advancement Act of 1995
NUREG	NRC technical report designation
OAS	Organization of Agreement States
OCA	owner-controlled area
ODCM	offsite dose calculation manual
OL	operating license
OMB	Office of Management and Budget
PAG	protective action guide
PMRP	performance monitoring and review program
POCT	point of collection testing
POCTA	point of collection testing and assessment
PPS	performance-based physical security
PRA	probabilistic risk assessment
PSDAR	post-shutdown decommissioning activities report
QA	quality assurance
QHO	quantitative health objective
RA	regulatory analysis
rem	roentgen equivalent man
RE factor	relative effectiveness factor
RFC	request for comment
RG	regulatory guide
RHDRA	Rapid High-Volume Deployable Reactors in Remote Applications
RIDM	risk-informed decision-making
RIM	Reliability and Integrity Management
RO	reactor operator
ROWS	Remotely Operated Weapons System
SAE	substance abuse expert
SAFSTOR	nuclear decommissioning method
SAR	safety analysis report
SAT	systems approach to training

SBT	security bounding time
SDA	standard design approval
SDC	standard design certification
SECY	Commission
SGI	Safeguards Information
SMR	small modular reactor
SNM	special nuclear material
SR	safety related
SRE	systematic risk evaluation
SRM	staff requirements memorandum
SRMF	self-reliant mitigation facility
SRO	senior reactor operator
SRP	standard review plan
SSC	structure, system, and component
STA	shift technical advisor
TAG	EPA Technical Assistance Grant Program
TEDE	total effective dose equivalent
TI-RIPB	technology-inclusive, risk-informed, and performance-based
TNT	trinitrotoluene
U.S.C.	United States Code

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U.S. NUCLEAR REGULATORY COMMISSION
RESPONSE TO PUBLIC COMMENTS RECEIVED ON THE PROPOSED RULE RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR ADVANCED REACTORS

Introduction

This document presents the U.S. Nuclear Regulatory Commission's (NRC's) responses to written public comments received on the proposed rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors" (Part 53). The NRC's review and response to these comments can be found in two documents. Volume 1 addresses the comments received on the proposed Title 10 of the *Code of Federal Regulations* (10 CFR) Part 53 requirements, including specific questions on Part 53 that were asked in the *Federal Register* notice (FRN). Volume II, this document, addresses comments related to other sections of the 10 CFR (e.g., 10 CFR Part 26, 10 CFR Part 73), and supporting guidance (e.g., draft regulatory guides [DGs]), including specific questions on these topics that were asked in the FRN.

The following guidance documents are addressed in this document:

- Regulatory Guide (RG) 1.254 (formerly DG-1413), "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML25232A005)

- RG 5.81 (formerly DG-5071), "Target Set Identification and Development for Nuclear Power Reactors" (ML24229A186, nonpublic). DG-5071 was available for comment to those members of the public with a need to know as part of the "Alternative Physical Security Requirements for Advanced Reactors" (89 FR 65226; August 9, 2024) proposed rulemaking. RG 5.81 has now been incorporated into and finalized as part of the Part 53 rulemaking.

- RG 5.95 (formerly DG-5074), "Access Authorization Program for Commercial Nuclear Plants" (ML25232A007)

- RG 5.96 (formerly DG-5075), "Establishing Cybersecurity Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53" (ML25232A008)

- RG 5.97 (formerly DG-5076), "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants" (ML25232A009). DG-5072, "Guidance for Alternative Physical Security Requirements for Small Modular Reactors and Non-Light-Water Reactors" (ML23263A997) was issued for public comment as part of the "Alternative Physical Security Requirements for Advanced Reactors" (89 FR 65226) proposed rulemaking. Relevant sections of DG-5072 have also been included in RG 5.97.

- RG 5.99 (formerly DG-5078), "Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53" (ML25232A010)

- Division of Reactor Oversight (DRO) interim staff guidance (ISG) DRO-ISG-2023-01, "Operator Licensing Programs" (ML25232A011)

- DRO-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG–1791, ‘Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),’ for Licensing Commercial Nuclear Plants under 10 CFR Part 53” (ML25232A023)

- DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans” (ML25232A022)

The NRC published the proposed rule and notice of DG-1413, DG-5073, DG-5074, DG-5075, DG-5076, DG-5078, DRO-ISG-2023-01, DRO-ISG-2023-02, DRO-ISG-2023-03 in the *Federal Register* on October 30, 2024 (89 FR 86918). The guidance documents DG-5071 and DG-5072 were published in the *Federal Register* on August 9, 2024 (89 FR 65226) with the “Alternative Physical Security Requirements for Advanced Reactors” proposed rule. The 10 CFR Part 53 proposed rule (ML24096A161) and the above guidance documents are available from the Federal e-Rulemaking website at https://www.regulations.gov (Docket ID No. NRC-2019-0062 or Docket ID No. NRC-2017-0227) and through ADAMS.

4. Major Provisions of the Proposal – 10 CFR Part 26 (Fitness for Duty Programs)

4.1. Subpart M: Fitness-for-Duty Programs for Facilities Licensed Under Part 53 (§§ 26.601–26.619)

4.1.1. Request for Comment (RFC): Use of § 26.603(c) criterion and conforming changes to § 73.120

Comment Bin 4.1.1.A: A commenter stated that an intact behavioral observation program (BOP) is predicated on the observation, documentation, and reporting of anomalous behaviors and provides reasonable protections to mitigate the risk that potentially impaired individuals (e.g., mental health conditions, substance abuse disorders, comorbid conditions) could contribute directly or indirectly to a deleterious event.

The commenter stated that the proposed 10 CFR 26.604 should require a BOP for plants meeting the criteria in 10 CFR 53.860(a)(2) and suggested flexibility for plants meeting the criteria in 10 CFR 53.800(a)(1) or (2) to scale back fitness-for-duty (FFD) elements by removing random testing, and relying on BOP to respond and interdict impairment, maintaining for-cause and post-event testing, and subsequent referral for assessment and potential treatment. The commenter also asserted that even with the reduced risk to the public in the cases of self-reliant mitigation facilities, the insider threat risk remains, and BOP is the most effective in mitigating insider threats. Additionally, even when considering reduced risk to the public, the concern with onsite safety and reliability remains, as is protecting onsite staff and equipment (NEI2-0217).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that BOP is a critical element of any FFD program with respect to identifying contemporaneous observable impairment in individuals subject to an FFD program and that BOP also is a central element in the insider mitigation program. In fact, in the initially proposed rule language, BOP was the only method to identify contemporaneous impairment in the individuals subject to the proposed 10 CFR 26.604 FFD program, because drug and alcohol testing was not included as part of the proposed FFD program.

The NRC disagrees with the recommendation that a more limited FFD testing program apply to proposed 10 CFR 26.604, such that random testing would not apply, but for-cause and post-event testing would be retained. The NRC's response to Comment Bin 4.1.3.1.A describes the basis for the NRC decision to apply drug and alcohol testing to licensees that would have been subject to the 10 CFR 26.604 FFD program under the proposed rule. Public comments explained that without pre-access, random, and follow-up drug and alcohol testing, the 10 CFR 26.23(c) performance objective for the early detection of individuals who are not fit for duty could not be met. The comments also affirmed the limitations of BOP effectiveness in small workforces.

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.2. General Provisions

4.1.2.1. Fitness determination process (§ 26.603(a)(4))

Comment Bin 4.1.2.1.A: A commenter agreed with guidance included in DG-5073, "Fitness-for-Duty Programs for Commercial Nuclear Power Plants and Manufacturing Facilities

Licensed under 10 CFR Part 53," issued October 2024 on acceptable professionals who may perform determinations of fitness on individuals with substance abuse related issues under proposed 10 CFR 26.603(a)(4), which included "use of a medical or clinical professional…[who] should be educated, accredited, or trained in the specific area(s) of concern…." The commenter stated that the guidance appears to support using individuals with advanced education and knowledge in the substance abuse field, such as individuals with master's level university degrees in fields of study focused on the diagnosis and treatment of substance abuse (e.g., administrators of drug and alcohol programs or university professors with advanced training).

The commenter requested that the existing credential requirements in 10 CFR 26.187, "Substance abuse expert," also be amended to allow these types of substance abuse professionals to perform determinations of fitness because these professionals may have more experience and training than the currently permitted medical review officers (MROs) and psychologists (NEI2-0225, NEI2-0227).

NRC Response: The NRC agrees, in part, with the comments.

The proposed rule elements on the performance of determinations of fitness applicable to a subset of FFD programs under proposed Subpart M (i.e., 10 CFR 26.604 and 10 CFR 26.605(a)) did not provide specific details on the acceptable credentials that substance abuse professionals must have to conduct determinations of fitness. Therefore, the types of professionals described in the comment would be acceptable for use by the licensees and other entities of these FFD programs to assess individuals with substance abuse issues. Under 10 CFR 26.605(a), this applies to: licensees that satisfy the proposed 10 CFR 26.603(c) criterion (which appeared in 10 CFR 53.860(a)(2) in the proposed rule but was moved to 10 CFR 73.100(a)(1)(i) in the final rule); licensees of facilities under construction that do not satisfy the proposed 10 CFR 26.603(c) criterion; and holders of a manufacturing license (ML) under 10 CFR Part 53.

The NRC disagrees with the request to amend the acceptable credentials to serve as substance abuse expert (SAE), which appear under 10 CFR 26.187(b). Under 10 CFR 26.189(a)(1), an SAE is the only trained professional permitted to conduct a determination of fitness for substance abuse issues. Not only will 10 CFR 26.187(b) apply to reactors licensed under 10 CFR Part 53 that implement a 10 CFR 26.605(b) FFD program, but it already applies to the existing fleet of operating nuclear power reactors implementing programs under 10 CFR Part 26. Consequently, any change to 10 CFR 26.187(b) will impact existing licensees; it is the NRC's intent to avoid such impacts under the 10 CFR Part 53 rulemaking. In addition, a separate rulemaking is already underway to consider expanding the acceptable SAE credentials (SRM-SECY-24-0058, "Rulemaking Plan on Drug and Alcohol Testing: Technical Issues and Editorial Changes" [ML25136A330]).

Accordingly, the NRC did not change the rule language in response to these comments.

4.1.2.2. Performance monitoring and review program (§ 26.603(d))

Comment Bin 4.1.2.2.A: All comments received on the proposed 10 CFR 26.603(d) performance monitoring and review program (PMRP) opposed this program (NEI2-0221, AN6-0002, AN9-0001, AN7-0001).

- A commenter stated that relying on a PMRP for defense in depth instead of implementing a drug and alcohol testing program for 10 CFR 26.604 FFD programs is not feasible (AN6-0002).

- A commenter provided five reasons for opposing the PMRP. First, a reactor that is first of a kind will have no historical data on performance for comparison. Second, because the licensee sets the performance thresholds, the thresholds could be set so that no corrective actions were ever needed—an approach that would not maintain a safety equivalent to the existing power reactor fleet. Third, the PMRP metrics/thresholds in DG-5073 on positive rate and number of subversions are not indicative of poor program performance, because a high positive testing rate and a high number of subversion attempts can also demonstrate effective program performance (e.g., detection improvements, use of an expanded drug testing panel). Fourth, any suggested PMRP thresholds/metrics would be subjective, would not be good measures of performance, and would not correspond with the effectiveness-like performance indicators that correspond to a reactor's safety in the NRC's Reactor Oversight Process. Fifth, only the NRC FFD staff currently does anything like the PMRP that is being proposed. The commenter stated that drug and alcohol testing is more cost-effective and straightforward for greater safety benefits than the implementation of the PMRP and 10 CFR Part 26, Subpart M. The commenter also stated that 10 CFR Part 26, Subpart M and the PMRP have too many flaws to be implemented (AN6-0002).

- A commenter stated that the existing 10 CFR Part 26 program monitoring FFD program effectiveness has been in place for many years and works well (i.e., site-specific annual FFD data reporting to the NRC, site administration of a corrective action program, and implementing changes to address trends). The FFD data reported to the NRC annually inform operating sites of trends and the potential need for altering programs to meet societal changes. The corrective action program advises sites on trending issues and informs program personnel on the need to alter programs based on trends. There is no need to add additional burden and complexity of the PMRP to the administration of FFD programs of lesser risk (NEI2-0221).

- A commenter asserted that the proposed PMRP is reactive, costly, untimely, and unworkable because drug and alcohol use is fluid and not static; that accessing information from other sites will be impossibly difficult (no ability to compel other licensees to provide data); that the data if obtained would not be helpful because of the high degree of variability inherent in Part 53 FFD programs; and that the PMRP would require expertise to administer. The system, even if implemented, would be easily gamed by licensees who could set unreasonably low measures of performance and this rule provides that ability. The commenter also stated that the NRC must do its own oversight and is responsible for understanding program effectiveness and informing the public (AN7-0001).

- A commenter questioned whether the NRC estimated the substantial cost that a PMRP would impose on licensees and asserted that no technical basis had been offered to demonstrate the effectiveness of such a program or a need for one given that no program exists for the current "more risky" operating reactor fleet (AN9-0001).

NRC Response: The NRC agrees, in part, with these comments.

The NRC agrees that the PMRP would likely not be cost-effective or feasible for many licensees to implement. Accordingly, the NRC has removed all proposed PMRP requirements in 10 CFR 26.603(d) from the rule language in response to these comments. In response to

Comment Bin 4.1.3.1.A, the NRC also has revised the rule language to apply drug and alcohol testing to all 10 CFR Part 53 licensees.

Instead of the performance measures initially proposed as part of a PMRP, the NRC has revised 10 CFR 26.617 to include existing 10 CFR Part 26 FFD program performance measures on the reporting of drug and alcohol testing errors within 30 days of completing an investigation; the annual analysis of FFD program performance data and taking actions to address identified program weaknesses; and the documenting, trending, and correcting of nonreportable indicators of FFD programmatic weaknesses using the licensee's or other entity's corrective action program. These changes apply to Subpart M FFD programs under 10 CFR 26.605(a). (The FFD programs under proposed 10 CFR 26.605(b) already would implement the existing FFD performance and trending requirements under Subpart N, "Recordkeeping and Reporting Requirements," under existing 10 CFR Part 26.) The NRC also has revised 10 CFR 26.615(b) to require that the subject matter, scope, and frequency of audits reflect the updated FFD program performance measures in 10 CFR 26.617, instead of the measures proposed as part of the PMRP.

The NRC disagrees that 10 CFR Part 26, Subpart M, has too many flaws to be implemented, but the NRC has modified provisions within 10 CFR Part 26, Subpart M, in response to other comments received on the proposed rule, as discussed in other comment bins in this document. Accordingly, the NRC did not change the rule language in response to this comment.

4.1.3. Applicability of FFD program elements by facility type

4.1.3.1. § 26.604 facilities

Comment Bin 4.1.3.1.A: All comments received on the FFD programs for proposed 10 CFR 26.604 facilities expressed opposition to the lack of drug and alcohol testing requirements, with most commenters disagreeing with one or more of the NRC's five reasons in the proposed rule preamble (89 FR 86953 – 89 FR 86954) for excluding such testing (AN8-0001, UCS-0004, NYS2-0015, AN6-0002, AN7-0001).

- One commenter stated that the 10 CFR 26.23(c) performance objective to "[p]rovide reasonable measures for the early detection of individuals who are not fit to perform the duties" could not be met without drug and alcohol testing. The commenter referenced the NRC's 10 CFR Part 26 FFD data stating that every year pre-access testing is the best method of early detection of drug and alcohol use (60–70 percent of positive results), followed by random testing. The commenter stated that pre-access and random testing are proactive tests that identify use in individuals that do not appear impaired, which meets the 10 CFR 26.23(c) objective for early detection (AN7-0001).

- Several commenters disagreed that a BOP could effectively identify impairment in lieu of drug and alcohol testing. One commenter stated that BOP does not offer early detection of individuals not fit to perform duties (in reference to the 10 CFR 26.23(c) performance objective); rather, it is the last line of defense to stop an individual from continuing to work once impairment is identified in a controlled work environment. The NRC's 10 CFR Part 26 FFD data demonstrate relatively few for-cause testing positives each year as compared to pre-access and random tests. For-cause testing is performed when BOP identifies possible impairment in individuals (NYS2-0015). Other commenters stated that BOP is unreliable given that individuals with substance abuse problems can find ways to disguise impairment,

and that small group dynamics or “groupthink” can challenge BOP effectiveness because small crews are less likely to report on each other (i.e., as acknowledged in the proposed rule preamble [89 FR 86954]) (AN6-0002, AN7-0001). One commenter also noted that the BOP at a construction site is much different than one needed at an operating reactor site because a construction site contains no radioactive material and an impaired worker could not cause a radiological incident (NRC 2019-0062-0482-0001).

- One commenter disagreed with the NRC comparison that some commercial nuclear plants licensed under 10 CFR Part 53 could approach the radiological risk profile of a non-power production and utilization facility (NPUF), which does not implement an FFD program. The comment acknowledged the radiological risk comparison, but stated that NPUFs are not comparable in terms of location (not isolated, with access to security, emergency response capabilities, and medical facilities) and purpose (scientific research and not electricity generation) (AN8-0001).

- One commenter expressed that physical protection and cyber protection have nothing to do with FFD. FFD training is important to ensure that individuals understand the tenets of the FFD program, protects individuals from unjust action by a plant owner, and educates on the impacts of impairing substances and identifying impairment in others (AN7-0001).

- One commenter stated that the self-reporting of legal actions is reactive, but a background check prior to employment would be helpful if it identified an illegal activity such as driving under the influence or driving while intoxicated (AN7-0001).

- One commenter stated that the proposed PMRP and BOP cannot offer an equivalent level of safety to the existing nuclear fleet without conducting drug and alcohol testing (AN6-0002).

- Four commenters addressed personnel performing critical functions and the necessity of these individuals not to be impaired. FFD testing must apply if a human is required to keep the plant safe and secure. An improved design does not mean that impairment is acceptable or less impactful; to the contrary, it could be more impactful in smaller work forces that are relied on to perform critical functions (AN8-0001, AN7-0001, AN6-0002). One commenter noted that drug and alcohol use has been identified in personnel that perform critical plant functions in the existing fleet such as reactor operators and supervisors (NYS2-0015).

- Two commenters urged the NRC to consider the impact that a lack of a drug and alcohol testing program would have on public confidence (UCS-0004, NYS2-0015). One of these commenters noted that the inconsistencies in the NRC’s proposal as compared to the required drug and alcohol testing of truck drivers and personnel at operating nuclear power plants would undermine public confidence (UCS-0004).

- Two commenters focused on the necessity of drug and alcohol testing for the insider mitigation program (NEI2-0217, UCS-0004). One commenter stated that it is not apparent that the other proposed elements of the FFD program would compensate for the lack of drug and alcohol testing programs, and that without confidence that the “design-basis threat-initiated event” analyzed in 10 CFR 53.860(a)(2) includes the possibility of active insiders, assurance cannot be provided that the design is resistant to radiological sabotage even with active insider participation. The commenter added that the assumption of “credible acts of commission” for the determination of whether the 10 CFR 53.800 criteria are met may be violated if deliberate acts are considered. The commenter stated that the lack of a

drug and alcohol testing program could cause insider threat issues due to the potential for coercion of personnel with substance abuse problems (UCS-0004).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that drug and alcohol testing should be required for licensees that meet the proposed rule's 10 CFR 26.603(c) criterion because the 10 CFR 26.23(c) performance objective for early detection of individuals who are not fit for duty likely cannot be met without pre-access, random, and follow-up drug and alcohol testing. The NRC also agrees that BOP, while a critical component of FFD programs, has not identified the majority of drug and alcohol testing positives in the existing 10 CFR Part 26 FFD program and sites with small workforces may challenge BOP effectiveness. Thus, a reliance on BOP alone would be ineffective.

Accordingly, the NRC has revised the rule language to apply drug and alcohol testing to all 10 CFR Part 53 licensees. In addition, the NRC has revised the rule language to provide 10 CFR Part 53 licensees that implement a Subpart M FFD program with additional flexibilities to implement elements of drug and alcohol testing programs. These flexibilities include virtual collection of oral fluid specimens for drug and alcohol testing (see the NRC's response to Comment Bin 4.1.4.4.A) and use of consortium/third-party administrators (C/TPAs) to administer random testing programs (see the NRC's response to Comment Bin 4.1.4.6.A), which both address some of the implementation obstacles that could be encountered at licensed facilities with small workforces or that are remotely located.

The proposed elimination of drug and alcohol testing requirements for licensees that met the proposed 10 CFR 26.603(c) criterion was the only factor that distinguished the 10 CFR 26.604 FFD program from the 10 CFR 26.605(a) FFD program. Therefore, the NRC has eliminated 10 CFR 26.604 in the final rule and revised the rule language in 10 CFR 26.605(a) to include licensees that demonstrate compliance with 10 CFR 73.100(a)(1)(i) (which the NRC changed in the final rule from the proposed rule's 10 CFR 26.603(c) criterion).

The NRC also agrees that drug and alcohol testing provides reasonable assurance that individuals using impairing substances will be identified, which mitigates the potential risks of coercion by an adversary.

4.1.3.2. § 26.605(a) facilities

Comment Bin 4.1.3.2.A: A commenter stated that FFD requirements should apply to manufacturing facilities, as a reactor that is not built correctly is a major risk to the public, due to the danger of a nuclear accident; an occupational danger; a danger to the public; and, in cases where the reactor is the only source of power in an area, the danger of not having access to essential systems if power isn't being supplied (AN10-0001).

NRC Response: The NRC agrees with this comment, and the NRC determined that this comment was already addressed by the proposed rule language.

Under the proposed 10 CFR 26.3(f), FFD program requirements would apply to holders of licenses to manufacture reactors under 10 CFR Part 53. This remains the case for the final 10 CFR 26.3(f).

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.3.3. § 26.605(b) facilities

No comments are associated with this issue.

4.1.4. Drug and alcohol testing (§ 26.607)

4.1.4.1. Point of collection testing (POCT) - § 26.607(h)

Comment Bin 4.1.4.1.A: A commenter provided specific comments on several provisions related to point of collection testing (POCT) in 10 CFR 26.607(h). The commenter—

- requested clarification on whether a POCT test can be found forensically acceptable, as it is a screening test;
- suggested a urine or oral fluid specimen be collected prior to taking permanent action beyond removing the individual from duty;
- suggested that if an individual's actions indicate impairment but if the POCT result is negative, a U.S. Department of Health and Human Services' (HHS) specimen should still be collected; and
- stated that POCT is not sufficient for follow-up testing for drugs and suggested requiring an HHS test (LD-0002, LD-0005).

NRC Response: The NRC acknowledges these comments.

The NRC has revised the rule language to remove 10 CFR 26.607(h), "Point of collection testing and assessment," in response to Comment Bin 4.1.4.1.B. The response to Comment Bin 4.1.4.1.B, in part, addressed the comment pertaining to whether the testing method was forensically acceptable. The remaining elements of the comment no longer apply because the NRC has removed 10 CFR 26.607(h) from the rule language.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 4.1.4.1.B: A commenter expressed opposition to the proposed use of POCT in 10 CFR 26.607 for three reasons. First, POCT is prohibited from use in federally regulated testing programs. Second, POCT is an invasion of a donor's medical privacy because a test result could identify use of legitimately prescribed non-impairing medications (e.g., amphetamine for Attention-Deficit/Hyperactivity Disorder) and would result in an immediate impact to work (removal pending additional testing). Third, POCT is not as accurate as the existing testing methods, and false positives would burden a worker. The commenter stated that the current testing process under 10 CFR Part 26 protects all individuals by requiring laboratory testing of specimens using two testing methods to ensure accuracy and the review of positive test results by a medical doctor for legitimate medical use before any action, if needed, is taken against a donor (AN12-0002).

NRC Response: The NRC agrees with this comment.

POCT is not currently permitted for use in federally regulated testing in the U.S.; is not as accurate as instrument-based testing performed by HHS-certified laboratories; and would negatively impact individuals using prescription medications that are included in the drug testing panel, such as amphetamine. Given these concerns, the NRC has determined that POCT is not an acceptable testing method.

Accordingly, the NRC revised the rule language to remove 10 CFR 26.607(h) in response to this comment.

Comment Bin 4.1.4.1.C: A commenter stated that the explicit mention of point of collection testing and assessment (POCTA) technologies permitted in 10 CFR Part 26, Subpart M, gives the impression that these technologies are used by the existing fleet and adds confusion to Subpart M. The commenter suggested the NRC include a higher level flexibility section for the inclusion of future technologies instead (AN6-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC acknowledges that POCTA technologies are not in use by any of the licensees or other entities currently subject to 10 CFR Part 26.

In response to Comment Bin 4.1.4.1.B, the NRC has determined that POCT is not an acceptable testing method and has revised the rule language to remove proposed 10 CFR 26.607(h). Moreover, the NRC did not revise the rule language to include a section regarding future testing and assessment technologies.

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.4.2. Portal area screening - § 26.607(j)

Comment Bin 4.1.4.2.A: A commenter stated that the explicit mention of portal area screening technologies in the rule text gives the impression that these technologies are used by the existing fleet and adds confusion to Subpart M. The commenter suggested that the NRC include a higher-level section for the inclusion of future technologies instead (AN6-0001).

NRC Response: The NRC agrees, in part, with this comment.

The NRC acknowledges that portal area screening technologies are not in use by any licensees and other entities currently subject to 10 CFR Part 26.

The NRC disagrees that a higher-level section be created in the final rule for future technology use. The comment did not contain any other emerging technologies beyond portal area screening. Further, the portal area screening approach is technology-neutral (in that it does not prescribe a specific type of screening), performance-based (as revised in response to Comment Bin 4.1.4.2.B), and balances worker protections (as discussed in response to Comment Bin 4.1.4.2.B).

Accordingly, the NRC did not revise the rule language in response to this comment.

Comment Bin 4.1.4.2.B: A commenter asserted that the proposed rule did not provide a basis for the use of advanced technologies and that forensic toxicologists are not trained to assess the efficacy and accuracy of advanced technologies (AN12-0004).

NRC Response: The NRC agrees, in part, with these comments.

The NRC interprets the comment's reference to "advanced technologies" as those that are not currently used by existing 10 CFR Part 26 regulated entities or by any other federally regulated entities that require workforce testing in the U.S. (e.g., Federal employee workplace drug testing programs administered under the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs"; U.S. Department of Transportation (DOT) drug and alcohol testing programs administered under 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs"). Under this interpretation, the proposed rule included two testing methods that would be considered advanced technologies: POCT under 10 CFR 26.607(h) and portal area screening under 10 CFR 26.607(j).

In response to Comment Bin 4.1.4.1.B, the NRC has revised the rule language to remove POCT as a testing option due to testing accuracy concerns (i.e., false positives and false negatives) and the unresolvable impacts to individuals using legally prescribed medications that are included in the minimum drug testing panel (e.g., medical privacy concerns, impacts on employment from denial of access pending additional specimen testing).

In response to Comment Bin 4.1.5.2.B, the NRC has clarified that portal area screening technologies are to be used only to bolster BOP by providing an additional means to identify credible information about possible alcohol use or illegal drug use that would initiate required for-cause testing.

The NRC agrees that forensic toxicologists likely do not have the training or education to assess the efficacy and accuracy of portal area screening tests. Accordingly, the NRC revised the rule language in 10 CFR 26.607(j) to instead use a performance-based approach to verify the accuracy of portal area screening tests. A portal area screening test can be used so long as the accuracy of the test result for a specific substance is confirmed by the resultant for-cause testing performed on an oral fluid or urine specimen for drugs, oral fluid or breath specimen for alcohol, or both. If a portal area screening result for a specific drug or drug metabolite is confirmed by drug testing performed at an HHS-certified laboratory, or oral fluid or breath alcohol testing for at least 85 percent of the specimens testing positive on portal area screening in the past 12-month data reporting period for a specific substance, the portal area screening test for that substance can continue to be used. This performance-based approach is analogous to the policy in existing 10 CFR 26.75(i) that enables licensees and other entities that performed initial drug testing at licensee testing facilities to administratively withdraw access for an individual with an initial marijuana or cocaine positive test result, as long as the HHS-certified laboratory testing confirmed at least 85 percent of the specimens determined to be positive by licensee testing facility testing during the past 12-month data reporting period. This performance-based measure would balance the use of the technology and protect individuals from unnecessary testing.

The NRC disagrees that a technical basis was not provided for the use of advanced technologies. The use of advanced technologies enabled by Subpart M of Part 26 provides licensees and other entities with additional flexibilities to address the unique challenges that may be incurred in implementing drug and alcohol testing programs for 10 CFR Part 53 licensed facilities (e.g., remote locations, small workforces). Based on the final rule changes in response to Comment Bin 4.1.5.2.B, the advanced technologies, if used, will improve licensee BOPs. Accordingly, the NRC did not change the rule language in response to this comment.

4.1.4.3. FDA validation of immunoassays - § 26.607(f), (g), and (i)

Comment Bin 4.1.4.3.A: One commenter recommended removing the U.S. Food and Drug Administration (FDA) clearance requirement contained in proposed 10 CFR 26.607(f), (g), and (i), because the requirement was removed from the HHS “Mandatory Guidelines for Federal Workplace Drug Testing Programs” (LD-0001, LD-0004).

NRC Response: The NRC agrees with these comments.

The NRC already required that urine and oral fluid specimens be tested at HHS-certified laboratories under the proposed and final rule requirements in 10 CFR 26.607(c)(4) and under 10 CFR 26.607(i) for hair specimens. As a result, it is unnecessary to specify the FDA clearance requirements in 10 CFR 26.607(f), (g), or (i) because these requirements, if applicable, already would be included in the HHS “Mandatory Guidelines for Federal Workplace Drug Testing Programs” that govern the certification and testing of each specimen type at these laboratories. No unique circumstance specific to the FFD programs implemented by NRC licensees and other entities necessitate the inclusion of the FDA clearance requirements, if applicable, under Subpart M.

The NRC agrees that the FDA clearance requirement for oral fluid collection devices was removed in the 2023 revisions to the HHS Guidelines for oral fluid testing (88 FR 70814; October 12, 2023). Accordingly, the NRC has revised 10 CFR 26.607(g) to remove the requirement for premarket approval of oral fluid collection devices by FDA.

The NRC also agrees that the FDA clearance for initial drug test kits for immunoassays was removed in the 2017 HHS Guidelines for urine testing (82 FR 7920; January 23, 2017). Accordingly, the NRC has revised 10 CFR 26.607(f) to remove the FDA commercial distribution clearance requirement for immunoassays.

Although HHS has published proposed HHS Guidelines to establish the testing of hair specimens (85 FR 56108; September 10, 2020), HHS has yet to finalize these guidelines. Because proposed and final 10 CFR 26.607(i) requires the use of an HHS-certified laboratory to conduct hair testing, the NRC has determined that it is unnecessary also to include the specific requirement regarding the use of immunoassay test kits cleared by the FDA. Accordingly, the NRC has revised 10 CFR 26.607(i) to remove the requirement that test kits must be FDA cleared.

4.1.4.4. Specimens for drug testing - oral fluid - § 26.607(g)

Comment Bin 4.1.4.4.A: A commenter recommended that the NRC consider enabling the virtual collection of oral fluid specimens for drug and alcohol testing by videoconference, where a trained collector from a C/TPA could conduct the specimen collection, and a monitor could be present in the collection room to observe elements of the collection process that could not be seen or completed by the virtual collector. The commenter also suggested that the monitor could video record the collection to ensure a robust representation of the collection was available in case the videoconference feed was interrupted or if the donor tried to cheat the testing process (AN13-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that enabling the virtual collection of oral fluid specimens for drug and alcohol testing may be appropriate for sites with small workforces in remote locations where accessing an in-person specimen collector might be difficult, untimely, and/or costly. Because all aspects of an oral fluid collection are directly observed by the specimen collector, a video teleconference could accomplish many key elements of the collection process.

The use of video teleconference technology also is not new to the NRC, as some clinicians complete other required evaluations using video teleconference technology, such as performing a psychological assessment under the personnel access authorization requirements in 10 CFR 73.56(e)(4) or a determination of fitness performed under 10 CFR 26.189(b) by an SAE when potentially disqualifying FFD information is discovered about an individual that is subject to 10 CFR Part 26. In addition, existing 10 CFR 26.31(b)(1)(iii) enables the use of a monitor to assist a specimen collector in completing aspects of a urine collection when a trained collector is not able to complete the activity, and existing 10 CFR 26.109(b)(1) permits a hydration monitor to observe a donor during the shy-bladder process, in lieu of the collector conducting the activity. In both cases, the monitor must receive information from the collector on his or her responsibilities.

For a licensee or other entity to utilize a virtual oral fluid collection process, the following must apply or should be considered:

- The specimen collector completing the virtual collection must meet the requirements in 10 CFR 26.85, “Collector qualifications and responsibilities.”
- The collection of oral fluid specimens for drug and alcohol testing must be completed as described under:
    - 10 CFR 26.97, “Collecting oral fluid specimens for alcohol and drug testing,” and
    - 10 CFR 26.99, “Determining the need for a confirmatory test for alcohol.”
- An individual other than the donor (i.e., a virtual collection monitor) may be needed in the location where the specimen collection is to be performed to assist the virtual collector in completing activities, performing observations, or both (e.g., completing required Federal Custody and Control Form paperwork; ensuring that the donor does not attempt to subvert the testing process by observing activities outside the viewable area of the video teleconference equipment; providing information to the virtual collector if/when requested;

ensuring that the oral fluid specimen(s) once packaged for shipping are secured until picked up for transportation to the HHS-certified laboratory).

- If a monitor is used to assist the virtual specimen collector in completing an oral fluid specimen collection, the virtual specimen collector must explain the collection process to the monitor and provide instruction to the monitor on required activities to be performed. The monitor's name must be recorded on the Federal CCF.

- Video teleconference communication method(s) must provide sufficient visual and aural clarity to complete the process and ensure that a donor is not able to subvert the testing process.

- Collection kit materials must be maintained in a secure fashion until the virtual collector initiates the virtual collection process with the donor.

- The virtual collection procedure must address problem collections, such as the video teleconference becomes inoperable during the collection process or the donor is unable to provide an oral fluid specimen of sufficient quantity to complete the specimen collection process for drug or alcohol testing.

- The virtual collection procedure must include steps to collect a breath specimen using an evidential breath testing device (EBT) if the oral fluid specimen tests positive for alcohol. The screening alcohol testing devices provide a test result during the collection process, but the result is not evidential. At a minimum, a donor with an oral fluid alcohol positive test result must be removed from duty pending additional testing.

The NRC agrees that a virtual collector could be provided by a C/TPA, but the NRC notes that personnel from another contractor/vendor or an employee of the licensee at another location could also serve as a virtual collector.

Accordingly, the NRC has revised the rule language in response to this comment by adding a virtual oral fluid specimen collection process in 10 CFR 26.607(g)(2).

Comment Bin 4.1.4.4.B: A commenter stated that the testing technologies described in Subpart M of Part 26 are speculative, not deployable, and offer no assurance. The commenter also stated that all specimens tested under 10 CFR Part 26 must be equivalent for all worker populations and suggested that the NRC stay with the current approved tests in 10 CFR Part 26, expand the use of oral fluid testing to all circumstances, and set a minimum testing panel for all worker populations (AN12-0001).

NRC Response: The NRC agrees, in part, with the comment.

In response to Comment Bin 4.1.4.1.B, the NRC has revised the rule language to remove POCT as a testing option. This change ensures that all specimens collected for drug testing will be tested at an HHS-certified laboratory, ensuring that all worker populations will be subject to standardized testing methods.

As addressed in the discussion of Comment Bin 4.1.4.2.B, the final rule provides the flexibility to use portal area screening technologies to bolster the identification of possible drug and/or alcohol use in individuals entering a protected or vital area of a licensed facility as part of a

licensee's BOP, as long as the screening technologies are limited to providing credible use information that would then initiate for-cause testing under 10 CFR 26.607(b)(3) (i.e., drug testing of an oral fluid or urine specimen at an HHS-certified laboratory; alcohol testing using an oral fluid specimen for initial testing or an EBT for initial and confirmatory testing, if necessary).

The NRC disagrees that the currently approved tests in 10 CFR Part 26 be the only testing methods available to 10 CFR Part 53 applicants, licensees, and other entities. A principal benefit of a 10 CFR Part 26, Subpart M, FFD program is that it provides a regulatory framework that affords flexibilities in the conduct of drug and alcohol testing. The final rule enables the testing of hair specimens at an HHS-certified laboratory for pre-access tests, and also permits 10 CFR Part 53 applicants, licensees, and other entities to collect and drug test oral fluid specimens for all reasons for testing.

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.4.5. Specimens for drug testing - hair - § 26.607(i)

Comment Bin 4.1.4.5.A: A commenter expressed confusion on the language in proposed 10 CFR 26.607(i)(3), which prohibits a licensee from issuing a sanction for an FFD policy violation because of a positive drug test from the testing of a hair specimen at an HHS-certified laboratory, noting the language seemed contradictory (LD-0003).

NRC Response: The NRC agrees, in part, with this comment.

The language of proposed 10 CFR 26.607(i)(3) may seem contradictory, but the basis for its prohibition is unambiguous. The proposed rule provides the option under a 10 CFR Part 26, Subpart M, FFD program to perform pre-access hair testing on job applicants to evaluate for illicit drug use for an extended period of time, as hair testing can identify use for up to 90 days. Under proposed 10 CFR 26.607(i)(3), a licensee or other entity is prohibited from sanctioning an individual based only on a positive drug test result from the testing of a hair specimen. Positive drug test results from hair specimens would be considered as potentially disqualifying FFD information, but not an FFD policy violation unless the individual subverts the screening process.

If a hair specimen produced a positive drug test result, and the licensee or other entity determined that it still wanted to consider the individual for employment, drug testing of an oral fluid or urine specimen under 10 CFR 26.607(i)(1) would need to be performed. Oral fluid and urine drug test results provide evidence of recent use (i.e., at the time the individual was applying for employment). If an applicant, licensee, or other entity performs drug testing of only a job applicant's hair specimen, a sanction could not be assessed to the individual, because contemporaneous use could not be determined; only an oral fluid or urine drug test could provide that information.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 4.1.4.5.B: A commenter expressed opposition to using hair testing or other testing technologies or approaches that are not already being used in a federally regulated program, urging the NRC to stick with the current approved specimens for testing in the HHS

Guidelines. The commenter stated that the current Federal testing programs have been tested in the courts, have been standardized for effectiveness, and do not impose a legal liability on the stakeholders implementing the programs. Conversely, the commenter suggested that it might be difficult for entities using Subpart M to find medical doctors to do the work, given the professional liability that might be incurred by reviewing test results from unproven technologies and the potential harm and consequences to tested workers (AN12-0003).

NRC Response: The NRC agrees, in part, with this comment.

The principal benefit of the 10 CFR Part 26, Subpart M, FFD program is the flexible regulatory framework consistent with potential types of facilities licensed under 10 CFR Part 53, including how these FFD programs conduct drug and alcohol testing. All specimens collected for drug testing must be tested by an HHS-certified laboratory, which ensures that all specimens are tested consistently.

The NRC disagrees that the drug testing of hair specimens should not be an option under Subpart M of 10 CFR Part 26. Under 10 CFR 26.607(i), hair specimen drug testing is permitted only for pre-access tests and must be conducted at an HHS-certified laboratory approved to conduct such testing. In addition, if a hair specimen tests positive for a drug, then that result would be considered potentially disqualifying FFD information, but not an FFD policy violation unless the individual is determined to have subverted the testing process. While hair testing must be conducted in accordance with the HHS Guidelines, at this time, HHS has not issued final “Mandatory Guidelines for Federal Workplace Drug Testing Programs” for the testing of hair specimens. Because the testing would be performed by an HHS-certified laboratory under the HHS Guidelines, there should be no legal or professional liability risks.

In response to Comment Bin 4.1.4.1.B, the NRC has revised the rule language to remove POCT as a testing option, and in response to Comment Bin 4.1.4.2.B, the NRC has clarified that portal area screening tests under 10 CFR 26.607(j) can be used only to bolster BOP by providing credible information to initiate for-cause testing of an oral fluid or urine specimen for drugs, oral fluid or breath specimens for alcohol, or both.

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.4.6. Random testing - § 26.607(b)(2)

Comment Bin 4.1.4.6.A: A commenter discussed random drug and alcohol testing under proposed 10 CFR 26.607, stating that it may be difficult to implement and manage for 50 percent of the worker population subject to testing at sites with substantially smaller worker populations than current sites subject to 10 CFR Part 26. The commenter offered three suggestions for applying random testing to smaller workforces (NEI2-0228):

(1) adjust the testing percentage (e.g., 10–20 percent on a quarterly basis);

(2) utilize a consortium where workers from multiple licensee sites could be included in a combined random testing pool; or

(3) consider annually adjusting the random testing rate similar to the DOT program.

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that using a C/TPA to include the small site populations in a single random testing pool would significantly improve the effectiveness of the random testing program for sites with small worker populations and would ensure that individuals would not be able to predict whether random testing would be conducted in a given period of time. Accordingly, the NRC has revised the rule language in response to this comment to require NRC-licensed sites with small workforces that cannot implement a random testing program without predictability to use a C/TPA to manage the random testing pool and make test selections under a new 10 CFR 26.607(b)(2)(vi).

The NRC disagrees with the recommendation to consider conducting testing on a quarterly basis because testing conducted in this manner would be predictable. The NRC also disagrees with the recommendation to consider adjusting the random testing on an annual basis, similar to the approach used by the DOT. The NRC does not have data or any operating experience on reactors that will use a 10 CFR Part 26, Subpart M, FFD program to consider this proposal at this time.

4.1.4.7. For-cause testing - § 26.607(b)(3)

Comment Bin 4.1.4.7.A: A commenter discussed the guidance in DG-5073 specific to performing for-cause testing under 10 CFR 26.607. The commenter asserted that substance use can lead to subtle alterations in behavior that are not overtly present on behavioral observation and that testing for both drugs and alcohol is necessary for all for-cause testing events to eliminate all potential contributors to anomalous behavior when determining fitness. (NEI2-0230).

NRC Response: The NRC agrees with this comment.

For-cause testing events are rare occurrences in the current fleet of facilities implementing 10 CFR Part 26 (e.g., in 2024, 0.17 percent of total tests performed were for-cause tests) and the NRC does not have data on how often individuals subject to for-cause testing are tested just for alcohol, just drugs, or both. However, FFD program performance data for existing licensees and other entities implementing 10 CFR Part 26 FFD programs demonstrates that detection of the most identified for-cause testing substance, alcohol, is more likely to be identified by non-impairment-based tests (i.e., random and follow-up), than by for-cause testing. This data suggests that identifying impairment for specific substances is difficult and that testing for drugs and alcohol in these limited for-cause testing circumstances is justified, given the contemporaneous behavior(s)/physical condition(s) present. (FFD program performance trends for 2024 can be reviewed in the NRC's presentation to the Nuclear Energy Institute's (NEI's) Access Authorization and Fitness For Duty Workshop held in June 2025; ML25148A130).

Accordingly, the NRC has revised 10 CFR 26.607(b)(3) to require drug and alcohol tests to be performed when the basis for performing for-cause testing is an individual's observed behavior or physical condition indicating possible impairment.

4.1.4.8. Medical review officer - § 26.607(m)

Comment Bin 4.1.4.8.A: A commenter stated that ensuring that MRO reviews conducted under 10 CFR Part 26, Subpart M, FFD programs are consistent with the MRO reviews conducted at

other facilities subject to 10 CFR Part 26 is the responsibility of the regulator, and that this part of 10 CFR 26.607(m)(2) should be removed from the rule (TG2-0002).

NRC Response: The NRC agrees, in part, with this comment.

The proposed rule FRN discussion on the MRO training requirements in 10 CFR 26.607(m)(2) stated that it "would help ensure that MRO reviews are consistent with those MRO reviews conducted at other NRC-licensed facilities subject to part 26…." The NRC agrees that it is the responsibility of the regulator to ensure that MRO reviews are consistently implemented for 10 CFR Part 26 FFD programs. To that end, under 10 CFR 26.607(m)(2), the NRC requires that all MROs satisfy the requirements in 10 CFR 26.183, "Medical review officer," and receive training prior to conducting any activities under 10 CFR Part 26. The 10 CFR 26.183 requirements specify the qualification, conflict of interest provisions, and responsibilities of MROs, as well as the functions that can be performed by MRO staff under the MRO's supervision. The 10 CFR 26.183 requirements apply to the current fleet of licensed facilities subject to 10 CFR Part 26, as well as to those who may be licensed under 10 CFR Part 53 and implement a Subpart M FFD program under 10 CFR Part 26.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 4.1.4.8.B: A commenter recommended that requalification training for an MRO occur every 5 years with an exam, instead of every 3 years with no exam, as proposed in 10 CFR 26.607(m) (TG2-0003).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the timeframe for an MRO to receive retraining should be 5 years, which is consistent with the standards of peer Federal agency testing partners. Section 13.1(a)(5) of the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (October 12, 2023, 88 FR 70768), and section 40.121(d) of the DOT's requirements in 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs," require MRO requalification training every 5 years.

The NRC disagrees that an examination is needed as part of requalification training, because it may unnecessarily limit the types of trainings MROs could attend to meet the training requirement.

Accordingly, the NRC has revised the rule language in response to this comment to change the requalification training requirement in 10 CFR 26.607(m)(3) from every 3 years to every 5 years.

Comment Bin 4.1.4.8.C: In reference to the preamble discussion on proposed 10 CFR 26.607(m)(4), in which the NRC stated that diabetes is a physiological condition that may cause an abnormally high blood alcohol concentration, a commenter stated that diabetes does not cause a high blood alcohol level, only a high urine alcohol level, and only in specific circumstances, and suggested the NRC verify the accuracy of language in the proposed rule preamble related to physiological conditions that can cause an abnormally high blood alcohol level (LD-0006).

NRC Response: The NRC agrees with the comment.

Under 10 CFR 26.607(c)(3)(i), the EBTs that licensees and other entities must use to conduct confirmatory breath alcohol testing must meet the requirements in 10 CFR 26.91. An EBT must distinguish between alcohol (i.e., ethanol) and acetone (the molecule that may be present in the breath of a diabetic or an individual in ketosis from diet). Therefore, the test results of EBTs would not be impacted by the presence of acetone in a donor's breath and would not report an alcohol positive test result.

Accordingly, the NRC has removed the referenced language from the final rule FRN in response to this comment.

Comment Bin 4.1.4.8.D: A commenter asked if an MRO is expected to be available 24 hours a day, 7 days a week, to determine whether individuals are fit for duty and trustworthy and reliable (TG2-0005).

NRC Response: The NRC acknowledges this comment.

An MRO is not expected to be available 24 hours a day, 7 days a week. However, under 10 CFR Part 26, certain applicants, licensees, and other entities are required to create and maintain procedures to take immediate action if an individual is demonstrating signs of impairment or appears unfit for duty (e.g., remove the individual from performing covered responsibilities; perform a determination of fitness, fatigue assessment, for-cause testing determination). In the proposed and final rules under 10 CFR 26.606(b)(2), a licensee or other entity must establish, implement, and maintain procedures to immediately address situations such as an individual being impaired; being involved in the sale, use, or possession of illegal drugs; and demonstrating that they cannot be trusted or relied upon to perform required duties. This comment did not recommend any changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.5. Other comments on Subpart M (e.g., program applicability for individuals, program training, behavioral observation, fitness determinations)

Comment Bin 4.1.5.A: A commenter expressed support for the proposed consolidation of all proposed 10 CFR Part 26 requirements into one subpart for easy reference, and suggested the NRC consider similar consolidation in other subparts (NYS2-0014).

NRC Response: The NRC acknowledges this comment.

This comment supports the organization of the FFD program elements applicable to 10 CFR Part 53 licensees under Subpart M of 10 CFR Part 26. The comment suggested no specific changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

4.1.5.1. Contents of written policy - § 26.606

Comment Bin 4.1.5.1.A: A commenter stated that the 5-hour abstinence rule for alcohol consumption prior to initiating work activities is well established for current operating sites but recommended that the contents of the written policy in 10 CFR 26.606(a) also cover abstaining from other impairing substances (NEI2-0223).

NRC Response: The NRC agrees, in part, with this comment.

The NRC notes that the FFD policy statement requirements in proposed 10 CFR 26.606 did not contain the 5-hour abstinence requirements that are specified in 10 CFR 26.27(b)(4) and (5) of the existing 10 CFR Part 26. However, proposed 10 CFR 26.606(a)(5) does require that the "FFD policy statement describes the individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished." In response to this comment, the NRC has chosen to include the 5-hour abstinence period information in the written policy to provide clarity and specificity regarding an individual's responsibility "to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities." Accordingly, the NRC has revised the rule language in response to this comment.

The NRC disagrees that including an abstinence period for other impairing substances should be included in the FFD policy statement. Unlike with alcohol, the potentially impairing effects of using a specific prescription medication or over the counter product are highly variable, thereby making the effectiveness of a specific abstinence period for other substances just as uncertain. The FFD program training in 10 CFR 26.608(a)(2)(iii) requires training on impairment from any cause that, if left unattended, could result in in attentiveness or human errors. Accordingly, the NRC did not change the rule language in response to this comment.

4.1.5.2. Behavioral observation program - § 26.609

Comment Bin 4.1.5.2.A: A commenter highlighted that no FFD refresher training interval was included in 10 CFR 26.608, "FFD program training." The commenter noted that the current operating sites subject to Part 26 must complete FFD refresher training on an annual basis and recommended that a biannual retraining frequency be adopted for the 10 CFR Part 53 framework. The commenter stated that FFD training is essential for awareness of societal changes that impact trustworthiness and reliability and that it must be reinforced for safe competent operation (NEI2-0224).

NRC Response: The NRC agrees with this comment.

The NRC agrees that the proposed training and assessment requirements in 10 CFR 26.608(b) require that FFD program refresher training and trainee assessments be completed periodically, but they do not specify a frequency. The NRC also agrees that establishing a minimum refresher training frequency is appropriate given the concerns raised by the comment.

Accordingly, the NRC has revised the rule language to include a minimum 24-month FFD program refresher training interval, or more frequently where the need is indicated. The

language detailing when training might need to be conducted more frequently was obtained from an existing requirement in 10 CFR 26.29(c)(2).

Comment Bin 4.1.5.2.B: A commenter expressed concerns with the use of advanced technologies for drug testing under 10 CFR Part 26, Subpart M, but noted support for these technologies to provide credible use information to bolster the effectiveness of BOPs, and trigger specimen collection and testing using traditional methods (AN12-0004).

NRC Response: The NRC agrees with this comment.

The NRC interprets the comment's reference to "advanced technologies" as those that are not currently used by existing 10 CFR Part 26 regulated entities or by any other federally regulated entities that require workforce testing in the U.S. (e.g., Federal employee workplace drug testing programs administered under the HHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs"; DOT drug and alcohol testing programs administered under 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs"). Under this interpretation, the proposed rule included two testing methods that would be considered advanced technologies: POCT under 10 CFR 26.607(h) and portal area screening under 10 CFR 26.607(i).

In response to Comment Bin 4.1.4.1.B, the NRC has eliminated POCT from the final rule as an acceptable testing option given concerns regarding testing accuracy (i.e., false positives and false negatives) and impacts on individuals taking valid prescription medications (e.g., medical privacy concerns, impacts on employment from denial of access pending additional specimen testing).

The NRC agrees that portal area screening tests, if they become available for use in the future, should be used to strengthen BOP by providing credible use information that is then further assessed by performing for-cause testing. This was the intent of the proposed 10 CFR 26.607(j)(2), which required additional testing be performed in response to a positive portal area screening test for alcohol, a drug, or a drug metabolite. The NRC revised the rule language in 10 CFR 26.607(j)(2) to clarify that for-cause testing for alcohol, drugs, or both, is to be performed in response to portal area screening result(s) received for an individual. Unless observable behavior(s) or physical condition(s) also indicate contemporaneous impairment when a portal area screening result is received, the for-cause testing to be performed on the individual is to be limited to the specific results from portal area screening that warranted the testing (i.e., alcohol only, drug only, or both).

If entities licensed under 10 CFR Part 53 use portal area screening, the entities must mitigate the potential impacts on individuals using valid prescription medications (e.g., daily use of a prescription medication would result in an individual continually testing positive each time they entered the facility portal where the screening test was being used, which would render such equipment unusable because of medical privacy concerns and continual positive tests). The NRC notes that most substances included in the minimum drug testing panel in 10 CFR 26.31(d)(1), as referenced in 10 CFR 26.607(c)(1), are Schedule II Controlled Substances under 21 U.S.C. 812 (i.e., have a legitimate medical use and can be legally prescribed in the U.S.). One method to address these concerns would be for a licensee to limit the substances tested by the portal area screening instrument to alcohol and Schedule I substances (i.e., illegal drugs with no currently accepted medical use in the U.S.).

Accordingly, the NRC has revised the rule language in response to this comment.

4.1.5.3. Sanctions - § 26.610

Comment Bin 4.1.5.3.A: A commenter addressed proposed 10 CFR 26.610, “Sanctions,” in Subpart M and recommended that a minimum sanction remain at 14 days, a repeat violation be assigned a sanction of 3 to 5 years, and third violation result in a permanent sanction because a user was unsuccessful to rehabilitate on two separate occasions. The commenter offered that many program offenders respond well to education and counseling and can return to the workplace within the minimum sanction period. Personnel with chronic addictive and comorbid diagnosis could be out of work for months with some requiring inpatient treatment requiring extended leave. Increasing the sanction for those who make a first-time wrong decision involving experimental drug use should not be subjected to more than the minimum sanction of 14 days.

The commenter also disagreed with the guidance on sanctions in DG-5073 that stated that licensees and other entities should consider developing different sanctions based on the risk significant level of assigned duties and responsibilities of individuals. The commenter stated that increasing the sanction based on factors other than the individual's failure to meet FFD mandates and expectations seems out of place. The commenter noted the disconnect of applying more stringent sanctions for FFD policy violations committed by individuals working at 10 CFR Part 53 licensed facilities than those working at the current fleet of operating reactors. (NEI2-0231).

NRC Response: The NRC agrees with this comment.

The NRC has revised the rule language to establish minimum denial periods for FFD policy violations for a first and a second confirmed positive drug or alcohol test result under Subpart M, an approach that is consistent with 10 CFR 26.75, “Sanctions.” As with the current FFD programs implemented under 10 CFR Part 26, licensees and other entities can continue to implement more stringent sanctions than those specified by rule. Proposed 10 CFR 26.610 required licensees to establish sanctions for FFD policy violations that escalated with the number of occurrences and severity of the violation, but did include minimum sanctions for a first or second positive drug or alcohol test result. Proposed 10 CFR 26.610 did include a minimum sanction for the sale, use, or possession of illegal drugs or consumption of alcohol within the protected area (5 years), and a permanent denial of authorization for three FFD policy violations or a subversion attempt. These proposed sanctions have been retained.

The proposed guidance in DG-5073 offered recommendations on how a licensee was to consider implementing sanctions for violations of the FFD policy under Subpart M based on the roles and responsibilities of individuals. This guidance is no longer relevant based on the revisions to the final rule language in 10 CFR 26.610. The NRC will address this in RG 5.94 (formerly DG-5073), which the NRC plans to issue after the publication of the final Part 53 rulemaking.

Accordingly, the NRC revised the rule language in response to this comment.

4.1.5.4. Suitability and fitness determinations - § 26.619

Comment Bin 4.1.5.4.A: For the fitness determination proposed in 10 CFR 26.619, a commenter said that the flexibility to perform fitness determinations via electronic means would be an enhancement to existing 10 CFR Part 26 requirements, but requested that the phrase "appropriately trained individuals" be defined. The commenter additionally suggested that determinations be allowed to be without a third party, if a secure interview could be assured, to protect program integrity. The commenter discussed that the current BOP and clinical interviews performed by psychologists can be or are routinely conducted electronically, and that current American Psychological Association guidelines for psychologists may prohibit the introduction of a third party in the room (NEI2-0226).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees that for most determinations of fitness performed by video teleconference, a third-party should not be present with the individual during the evaluation, given that applicable medical and treatment standards prohibit such attendance (e.g., American Psychological Association guidelines).

The one exception is when an individual is demonstrating signs of contemporaneous impairment, and a timely assessment of the individual is required to determine if for-cause drug and alcohol testing needs to be performed. In the instance of for-cause drug and alcohol testing and fatigue assessment determinations, a trained third party (i.e., an individual that has received training under the FFD program on behavioral observation) likely would be needed to answer questions from the remotely located/virtual decisionmaker (e.g., describing odors, describing the physical condition of the individual that is outside the viewable area of the video teleconference).

Accordingly, the NRC has revised the rule language in 10 CFR 26.619 in response to this comment.

4.1.5.5. Employee assistance programs

Comment Bin 4.1.5.5.A: Two commenters observed that the employee assistance program (EAP) appears to be absent from the proposed rule (NEI2-0222, AN6-0003). One of the commenters stated that licensee employees should be encouraged to self-report and seek help to promote a safety conscious work culture (AN6-0003).

A commenter emphasized that the EAP is well-established and enhances the FFD program because employees can confidentially self-refer to EAP for the brokering of services to address issues related to mental health, substance abuse, and stress and anxiety. The commenter supported guidance included in DG-5073 on the use of an EAP consortium where sites could collectively join, which would be an effective method for helping employees. The commenter also stated that not providing access to EAP for contractor vendors has been an ongoing issue with the current operating fleet and recommended the option for EAP access be provided to contractors and vendors (NEI2-0222).

NRC Response: NRC agrees, in part, with these comments.

Requiring licensee employee access to EAP has been a fundamental element of the FFD program regulatory framework since the issuance of the final rule (54 FR 24468) that established 10 CFR Part 26 on June 7, 1989. The 1989 final rule required “licensee workers have access to an employee assistance program designed to provide assessment, short-term counseling, referral services, and treatment and follow-up monitoring (54 FR 24473).” The 1989 final rule also required EAP staff to “provide confidential assistance except where safety considerations must prevail and when the employee assistance program counselor believes that a worker's condition poses a hazard to himself or herself or others. Otherwise, voluntary self-referrals to the employee assistance program are treated confidentially and are not reported to management (54 FR 24486).” The March 31, 2008, Part 26 final rule (62 FR 16966), which created the optional Subpart K, “FFD Programs for Construction,” that the NRC has relied on, in part, in the development of the Subpart M FFD program, did not include an EAP requirement for individuals subject to Subpart K (i.e., 10 CFR 26.4(f)). However, licensee employees performing functions under 10 CFR 26.4(e) and (g) during construction are required to have access to EAP because these individuals must be subject to an FFD program meeting all the requirements of 10 CFR Part 26, except for Subparts I and K.

The NRC agrees that the current 10 CFR 26.35, “Employee assistance program,” requirements should apply to licensee employees subject to an FFD program under Subpart M of 10 CFR Part 26. Accordingly, the NRC has revised 10 CFR 26.605(a) and (b) to include EAP among the required elements of FFD programs implemented under these paragraphs.

The NRC also revised the final rule to include a new 10 CFR 26.606(b)(2)(vii) to require licensees and other entities to establish, implement, and maintain written procedures to take immediate and follow-up actions to address reports received from EAP personnel that an individual’s condition or actions pose or have posed an immediate hazard to himself, herself, or others. In addition, the NRC revised 10 CFR 26.35(c)(3) to include a reference to the new 10 CFR 26.606(b)(2)(vii). Section 10 CFR 26.35(c)(3) requires a licensee or other entity to take action when it receives a report from the EAP under 10 CFR 26.35(c)(2)

The NRC disagrees that EAP access to contractors and vendors should be required for FFD programs under Subpart M, although a licensee or other entity may choose to offer EAP access to its contractors and vendors. The 10 CFR Part 26 FFD program has never required licensees or other entities to provide EAP access to contractors or vendors, and this decision was based on multiple public comments received on the original and 2005 10 CFR Part 26 proposed rules. In contrast, the NRC received only one comment on the proposed rule regarding this topic. Furthermore, the NRC does not have sufficient information about the types of contractors and duration of support currently provided to licensees and other entities to assess the possible impacts of a change in this area. Accordingly, the NRC did not change the rule language in response to this comment.

The NRC also acknowledges the support for guidance included in DG-5073 with respect to providing access to EAP by discussing the provision of these services through a C/TPA. Nevertheless, the NRC has not issued RG 5.94 (formerly DG-5073) as part of this final rule but plans to issue RG 5.94 after the publication of the final Part 53 rulemaking. However, in response to Comment Bin 4.1.5.6.A., the NRC has revised the rule language in 10 CFR 26.5 to include a definition for C/TPA. The definition for C/TPA includes a reference to EAPs.

4.1.5.6. Consortium/Third party administrators

Comment Bin 4.1.5.6.A: A commenter suggested the NRC consider using the 49 CFR Part 40 regulations on C/TPAs, which would allow for the centralization of key testing program functions, which is especially important for small workforce sized regulated entities. The commenter added that a C/TPA could provide SAE and MRO services, contract with an HHS-certified laboratory for specimen testing, and could develop a standard FFD policy for use by the 10 CFR Part 53 FFD program members (AN13-0001).

NRC Response: The NRC agrees with this comment.

Under current 10 CFR Part 26, a licensee or other entity may use a contractor/vendor to provide FFD program services. While not specifically described in current 10 CFR Part 26, use of a C/TPA would fall within the scope of 10 CFR 26.3(d) of the current rule and would be an acceptable method for licensees to implement their FFD programs.

Under 10 CFR Part 53, the unique potential challenges presented by some FFD programs may necessitate the use of an entity like a C/TPA to implement required program elements effectively (e.g., random testing of small worker populations) as well as to reduce the burden of compliance (e.g., facilities with small staff sizes may not have the capacity to perform specific FFD program functions, which could be provided by a C/TPA).

Accordingly, the NRC has revised the rule language in response to this comment to include a definition in 10 CFR 26.5 for the term “Consortium/Third party administrator (C/TPA).” In addition, in response to Comment Bin 4.1.4.6.A, the NRC has added 10 CFR 26.607(b)(2)(vi) in the rule language to require NRC-licensed sites with small workforces that cannot implement a random testing program without predictability to use a C/TPA to manage the random testing pool and make testing selections.

4.1.5.7. Complexity of Subpart M

Comment Bin 4.1.5.7.A: Several commenters discussed the complexity of Subpart M (AN13-0001, TG2-0001, NEI2-0220, RD-0002, RD-0008). One commenter recommended reducing the FFD requirements to be simpler and more transparent (RD-0002, RD-0008), while another recommended providing fewer pathways for licensees to choose from in order to reduce costs (TG2-0001). Additionally, one commenter recommended the NRC use the existing 10 CFR Part 26 FFD program instead (AN13-0001).

Another commenter discussed that the FFD program currently in operation offers a detailed but easy-to-follow approach and expressed concern that the proposed FFD requirements under 10 CFR Part 53 are difficult to navigate, particularly for inexperienced program personnel. The commenter stated that discussion of FFD in the proposed rule references other sections that may or may not apply to a program and that the proposed FFD requirements should have been easier to read given the reduced risk associated with advanced technology (NEI2-0220).

NRC Response: The NRC agrees, in part, with these comments.

While the NRC did not change the rule language in response to these comments, the NRC has made other revisions to address specific commenter concerns and to simplify certain elements of the rule in a number of ways, such as removing POCT as an acceptable means of specimen

testing (Comment Bin 4.1.4.1.B), removing PMRP (Comment Bin 4.1.2.2.A), and applying drug and alcohol testing to facilities that demonstrate compliance with 10 CFR 73.100(a)(1)(i) (which the NRC changed in the final rule from the proposed rule's 10 CFR 26.603(c) criterion, Comment Bin 4.1.3.1.A), which led to the elimination of the 10 CFR 26.604 FFD program.

Additionally, under 10 CFR Part 53, applicants, licensees, and other entities have the option to implement the existing 10 CFR Part 26 FFD program requirements. Subpart M of 10 CFR Part 26 provides additional flexibilities to accommodate for the potential broad spectrum of facilities licensed under 10 CFR Part 53, but use of the requirements in Subpart M in lieu of the existing requirements is optional.

Accordingly, the NRC did not change the rule language in response to these comments.

4.1.5.8. Donor protections

Comment Bin 4.1.5.8.A: A commenter stated there are a few places where the proposed rule states that protection is being provided to the individual, but urged the NRC to further consider donor protections. The commenter also stated a neutral person should be asked to evaluate whether too many regulatory responsibilities have been transferred to the plant operator under the proposed 10 CFR Part 26, Subpart M (TG2-0004).

NRC Response: The NRC disagrees with this comment.

The comment did not provide specific details on the proposed rule requirements for consideration.

However, while an additional review by a neutral entity is not part of the NRC's rulemaking process, the notice and comment portions of this process provide opportunities for stakeholders to assess whether the rule appropriately balances donor protection with flexibility for the plant operator.

Additionally, in response to other comments, the NRC has revised the final rule FRN in ways that further improve or clarify donor protections. These include clarifying that the use of portal area screening in 10 CFR 26.607(j) is only to inform the BOP (see the NRC's response to Comment Bin 4.1.5.2.B); establishing a minimum FFD program refresher training frequency in 10 CFR 26.608(b) (see the NRC's response to Comment Bin 4.1.5.2.A); and applying consistent sanctions for FFD program violations, where the proposed rule enabled the licensee or other entity to establish its own sanctions for various FFD policy violations, in 10 CFR 26.610 (see the NRC's response to Comment Bin 4.1.5.3.A). The proposed and final rules also include 10 CFR 26.613, "Appeals process," which affords an individual that is subject to an FFD program under Subpart M of 10 CFR Part 26 the opportunity to request that an objective and impartial review be conducted for any FFD policy violation. These elements of the final rule, along with other program elements, support donor protections.

Accordingly, the NRC did not change the rule language in response to this comment.

4.2. Fatigue management

4.2.1. Changes to Subpart I (§§ 26.201-26.211)

No comments are associated with this issue.

4.2.2. RFC: Technology-inclusive approaches to fatigue management during unit outages (§ 26.205(d)(4))

Comment Bin 4.2.2.A: A commenter described the proposed fatigue management approach as "appropriate" but suggested the generic approval of waiver requirements for natural phenomena for plants in hurricane-prone areas (NEI2-0218).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that some efficiency could be achieved through the generic approval of waivers of work hour control requirements for natural phenomena. However, the efficacy of this approach would require a more detailed analysis. The NRC acknowledges this as an area for future consideration. Applicants can still submit an exemption request to receive relief from 10 CFR 26.205(c) and (d) as provided in 10 CFR 26.207(d) before the onset of hurricane force winds, or before entry into the site's emergency plan because of high wind conditions.

Accordingly, the NRC did not change the rule language in response to this comment.

4.2.3. RFC: Draft regulatory guidance approach for fatigue management

Comment Bin 4.2.3.A: A commenter expressed support for option 3, to revise current industry guidance and incorporate DG-5078, in order to better align with the initiative underway to revise NEI 06-11 to better align with the NRC endorsement in RG 5.73 and to correct formatting and grammatical issues in the document (NEI2-0219).

NRC Response: The NRC agrees with the comment.

The comment suggested no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to the comment.

4.3. Changes to other parts of 10 CFR Part 26 (§§ 26.3–26.8, 26.51–26.63, 26.73, 26.81, 26.825)

No comments are associated with this issue.

4.4. Other fitness-for-duty comments

Comment Bin 4.4.A: A few commenters said that the proposed 10 CFR Part 26 requirements are too prescriptive (HPT14-0001, RD-0002, RD-0008, HPT23-0001, HPT35-0001). One commenter said one example of this is the proposed 10 CFR 53.610(a)(5) requiring an FFD program for construction (HPT23-0001). Another commenter added that the requirements are also not risk-informed, do not provide enhanced efficiency, and should include uncertainty due to human error (RD-0002, RD-0008). A commenter stated that modification of 10 CFR Part 26 is not needed to assure safe construction and operation of advanced nuclear plants, and added that the proposed modifications, particularly 10 CFR Part 26, Subpart M, will be onerous and expensive with no improved safety (SG3-0001).

One commenter stated that the risk to the public is insignificant when considering the various other defense in depth elements of 10 CFR Part 53, which ensure that no individual can materially impact the public relative to the risk associated with hazardous radiation (HPT23-0001). A couple of commenters added that instead, the NRC should simplify requirements, state in the rule that licensee programs are required for FFD, and require the use of industry codes and standards and commercial practices commonly used to ensure that the workforce is fit for duty (HPT23-0001, HPT35-0001). Additionally, a commenter stated that the proposed requirements are overly fixated on reactor operators while not considering the highly automated nature of advanced reactors (HPT35-0001).

A few commenters questioned whether the prescriptive nature of the requirements complies with the Nuclear Energy Innovation and Modernization Act of 2019 (NEIMA) and congressional directives concerning the efficiency of the licensing process (HPT14-0001, HPT23-0001, HPT35-0001). A commenter stated that the proposed 10 CFR Part 26 is complicated and out of proportion relative to the risk-informed requirements in NEIMA, and recommended an appendix to 10 CFR Part 53 be employed instead of the proposed 10 CFR Part 26 (HPT19-0001). A couple of commenters also discussed that the proposed rule included extensive NRC justifications (HPT14-0001, HPT35-0001).

NRC Response: The NRC disagrees with these comments.

Applicants, licensees, and other entities have the option to implement the existing 10 CFR Part 26 FFD program requirements, or the Subpart M FFD program requirements. Subpart M provides additional flexibilities to accommodate for the potential broad spectrum of facilities licensed under Part 53 and is based on a technology-inclusive, risk-informed, and performance-based (TI-RIPB) approach to FFD. The NRC is using operating experience to provide regulatory flexibility in the Subpart M framework, which is intended to help in FFD program implementation because of the wide variety of staff sizes at Part 53 facilities and the geographically remote locations in which they may be cited. The NRC disagrees with the suggestion to provide an appendix to Part 53 instead of including provisions from 10 CFR Part 26, as certain provisions from existing 10 CFR Part 26 remain applicable to 10 CFR Part 53 licensees to ensure effective and consistent implementation of the FFD program.

The NRC also disagrees that the proposed requirements are overly focused on reactor operators. The applicability of FFD program requirements to individuals is not specific to reactor operators; rather, it is more broadly applied based on facility access (e.g., unescorted access to the protected area of a power reactor), access to information (e.g., procedures or records for safeguarding strategic special nuclear material) or specific functions (e.g., security duties, personnel managing the FFD program). These categories of individuals are described in 10 CFR 26.4. If, for example, a facility was automated and did not have functions performed by

a licensed operator, then the licensee's FFD program would not include provisions for licensed operators.

Accordingly, the NRC did not change the rule language in response to these comments.

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5. Major Provisions of the Proposal - 10 CFR Part 73 (Physical Protection of Plants and Materials)

5.1. Physical security requirements (§ 73.100), including RFC on content of regulations versus guidance in DG-5076

Comment Bin 5.1.A: Several commenters expressed support for 10 CFR 73.100. A commenter said that the physical protection program is relatively sound (NP-0004). A few commenters said that proposed 10 CFR 73.100 provides a sufficient level of detail to be readily understood and easily applied to the licensing and oversight of new and advanced power reactors (BI1-0010; NEI2-0235; ROSE-0009; SCWG-0008).

The commenters also discussed that proposed 10 CFR 73.100 provides a sufficient level of detail and that no objective and measurable security performance standards recommendations need to be moved from DG-5076 into 10 CFR 73.100 (BI1-0010; NEI2-0235; ROSE-0009; SCWG-0008). Another commenter expressed support for NEI's response to the request for comment on 10 CFR Part 73.100 (NEX-0013).

NRC Response: The NRC agrees with these comments. The comments support the proposed 10 CFR 73.100 and suggest no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 5.1.B: A commenter stated that the general performance objective presented in 10 CFR 73.100(b)(1) lacks specificity as to the actual performance-based requirement and proposed two alternate performance-based requirements for consideration. The commenter suggested the following language as the preferred proposed approach:

> The licensee must establish, implement, and maintain a physical protection program and a security organization providing reasonable assurance that (1) no target set objective can be achieved by the design basis threat of radiological sabotage; or (2) measures can be taken to prevent a release of radionuclides resulting in consequences exceeding the offsite dose reference values defined in 53.210 of this chapter in the event a target set objective is achieved.

Alternatively, the commenter suggested a general performance objective based on text found in 89 FR 86976:

> The licensee must establish, implement, and maintain a physical protection program and a security organization that provides reasonable assurance of adequate protection against any deliberate act by the design basis threat of radiological sabotage which could directly or indirectly endanger the public health and safety by exposure to radiation.

For either approach, the commenter suggested that the necessary consequence limits be included in the Statements of Consideration and guidance (NEI2-0237). Another commenter expressed support for this approach (NEX-0014).

NRC Response: The NRC agrees with these comments.

Accordingly, the NRC revised the rule language in response to this comment. The NRC updated the introduction to 10 CFR 73.100 to provide licensees with implementation options based on achievability of target sets and added a performance objective to 10 CFR 73.100 that requires the physical protection program to be designed to prevent the release of radionuclides from any source from exceeding the dose reference values defined in 10 CFR 53.210. In addition, target set requirements were changed to include identification of achievable target sets. The NRC also revised RG 5.81 (formerly DG-5071) and RG 5.97 (formerly DG-5076) to support the rule language change.

Comment Bin 5.1.C: A commenter said it is unclear how the State will be afforded meaningful, site-specific engagement on an applicant's proposed alternative approaches. The commenter said that the Commission should require applicants to provide host states with access to all Safeguards Information (SGI), subject to lawful nondisclosure agreements by the states, pertinent to development and implementation of site security plans (NYS2-0020).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees that the Commission should require applicants to provide host states with access to all SGI. The sensitive nature of security plans, which include specific criteria used by a licensee to implement its physical protection program, dictates that they not be made available to the general public. Security plans are designated as SGI and subject to the protection requirements in 10 CFR 73.21 and 73.22. Although State officials who may want to view a licensee's security plans may meet the trustworthiness and reliability-related requirements in 10 CFR 73.22(b), they would still be responsible for establishing an official need to know the security plan information before a licensee would be able to share it.

An applicant's physical security plan must be submitted and reviewed by the NRC before a license will be granted. A determination on the suitability of the applicant's security measures will be made by the NRC based on the ability of the physical protection program to meet the requirements of 10 CFR 73.55 or 10 CFR 73.100.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 5.1.D: Two commenters discussed requirements for an armed response force (NEI2-0238, ROSE-0017, ROSE-0019).

A commenter discussed the proposed requirements for the physical protection program in 10 CFR 73.100(b)(3)(iv) and recommended that the NRC reconsider the interdiction and neutralization requirement. The commenter expressed that there is a category of advanced reactor facilities not adequately considered that possesses the safety and security design features to maintain adequate protection of public health and safety without action by an armed response force. The commenter stated that the requirement for armed response is a

disincentive for designers to maximize security-by-design features and recommended that proposed 10 CFR 73.100 be amended to accommodate facilities that will not require an armed response to maintain releases below the offsite consequence limits. The commenter stated these facilities would still be required to notify a supporting offsite organization capable of providing an armed response, with the response timeline determined by the incident commander. Alternatively, the commenter suggested that the NRC could retain the interdiction and neutralization capability but remove the proposed requirements in 10 CFR 73.100(b)(3)(iv)(A)(2) through (5) for facilities satisfying the offsite consequence limit and response criteria (NEI2-0238). Another commenter said that the NRC should remove prescriptive requirements for armed responders from 10 CFR 73.100 to acknowledge that some facilities will not need an armed response capability to comply with offsite dose reference values defined in 10 CFR 53.210(b) (ROSE-0017, ROSE-0019).

Another commenter said that that the legal basis for requiring civilian reactors to cope with warfare is unclear. The commenter said that the Federal Government is responsible for the common defense under the U.S. Constitution, not private industry (HPT40-0002).

NRC Response: The NRC agrees, in part, with these comments.

The NRC agrees that an onsite armed response may not be necessary for some power reactor designs. The NRC added rule text at 10 CFR 73.100(a)(1) to provide applicants and licensees with a flexible framework for implementing adequate physical protection requirements. The degree to which, if any, an applicant or licensee needs to implement the physical protection requirements in 10 CFR 73.100 is determined by the extent to which an applicant or licensee relies on active physical protection measures to protect its reactor facility against threats up to and including the design-basis threat (DBT) of radiological sabotage. The NRC disagrees that the legal basis for protecting nuclear power plants against threats is unclear as the Commission has determined that the DBTs, as articulated in 10 CFR 73.1, are based on adversary characteristics against which a private security force can reasonably be expected to defend.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 5.1.E: A commenter said that the security related requirements in the existing 10 CFR Part 73 are astoundingly prescriptive, with no consideration of the risk-informed direction of the NEIMA (HPT40-0001). The commenter also said that 10 CFR Part 73 puts a severe burden on applicants at the expense of safety (HPT40-0005).

The commenter said that many of the emerging generation of reactors are passively fail-safe, and it would take a major full-scale assault to breach containment and the reactor to significantly compromise the reactor. The commenter said that alternative security rules were proposed in docket NRC-2017-0227 and a number of major issues were raised by commenters. The commenter said that given the closing date of NRC-2017-0227, the comments and concerns have not been taken into consideration for proposed 10 CFR Part 73 (HPT40-0003).

The commenter also said that emerging advanced reactors do not share the offsite radiation release issues that prompted the highly prescriptive security requirements in 10 CFR 73 (HPT40-0007).

The commenter further said that the proposed security requirements should conform to the NEIMA (HPT40-0003; HPT40-0007).

NRC Response: The NRC disagrees with these comments.

The current 10 CFR 73.55 physical security requirements for nuclear power reactors licensed under 10 CFR Part 50 and 10 CFR Part 52 use a combination of performance criteria (e.g., 10 CFR 73.55(b)(1) through (3)) and numerous prescriptive requirements developed to achieve performance objectives (e.g., 10 CFR 73.55(k)(5)(ii)). By contrast, in the proposed performance-based approach to physical security for 10 CFR Part 53, performance objectives and requirements would be the primary bases for regulatory decision-making, giving the licensee the flexibility to determine how to demonstrate compliance with the established performance criteria for an effective physical protection program.

In addition, in response to Comment Bin 5.1.B the NRC has added a performance objective to 10 CFR 73.100 noting that the physical protection program is designed to prevent a release of radionuclides from any source from exceeding the dose reference values defined in 10 CFR 53.210. This change allows advanced reactors to design their physical protection program, in part, on site-specific radiological releases.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 5.1.F: A commenter said that the current 10 CFR 73.55 sufficiently covers the requirements in 10 CFR 73.100 through the use of 10 CFR 73.55(r) (AN5-0006). Another commenter said that 10 CFR 73.100 should be removed entirely and the full suite of requirements in 10 CFR 73.55 should be the only option for 10 CFR Part 53 applicants (UCS-0014).

NRC Response: The NRC agrees, in part, with these comments.

While the principles defined in NEIMA have been applied to ensure that 10 CFR 73.100 is a risk-informed, technology-inclusive, performance-based evaluation, an applicant must still demonstrate compliance with the established performance criteria for an effective physical protection program. The NRC agrees that using the alternative measures process in 10 CFR 73.55(r), “Alternative measures,” can be used to provide a measure for protection against radiological sabotage other than those required in 10 CFR 73.55, if the measures meet the same performance objectives and requirements; however, regulating through individual, site-specific license amendments generally provides less opportunity for public engagement and can lead to less regulatory certainty and increased costs for the NRC and the applicant or licensee. Proceeding by rulemaking therefore supports the NRC's principles of good regulation, including openness, clarity, and reliability.

The NRC has provided sufficient detail in RG 5.97 (formerly DG-5076) to effectively implement the general performance objectives to provide protection against any deliberate act within the DBT of radiological sabotage, including spent fuel sabotage, which could directly or indirectly endanger public health and safety by exposure to radiation.

Accordingly, the NRC did not change the rule language or the guidance in response to these comments.

Comment Bin 5.1.G: A commenter said that probabilistic risk assessment (PRA) and risk-informed decision-making (RIDM) are not mentioned in 10 CFR Part 73 governing “physical security, cybersecurity, and access authorization ... for commercial nuclear reactors.” The commenter wrote that instead the emphasis is on deterministic DBTs and noted that the security requirements would be a significant burden especially for small sites. The commenter wrote that this resulted in separate application of defense in depth across FFD and radiological DBTs. The commenter recommended harmonizing 10 CFR 73.100 with 10 CFR 53.415 (RD-0008, RD-0022).

NRC Response: The NRC agrees with these comments.

In response to Comment Bin 5.1.B, the NRC has added a performance objective to 10 CFR 73.100 noting that the physical protection program is designed to prevent a release of radionuclides from any source from exceeding the dose reference values defined in 10 CFR 53.210. As described in 10 CFR 73.100(b)(5), the licensee must identify and analyze site-specific conditions, including target sets, that may affect the physical protection program needed to implement the requirements of this section. The target set process relies on PRA to identify what a physical protection program should consider in its design. Additionally, FFD regulations refer to target set requirements to ensure a defense-in-depth approach to prevent radiological sabotage.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 5.1.H: A commenter presented concerns that small modular reactors (SMRs) or transportable reactors could be stolen in transport (TG17-0001).

NRC Response: The NRC agrees with the comment.

The NRC agrees that the comment raises a valid concern of potential loss or theft of SMRs or transportable reactors during transport. However, the NRC also finds that the graded transportation security requirements in 10 CFR 73.67 are applicable to the shipment of fueled reactors containing special nuclear material (SNM) and are sufficient to address this concern.

Accordingly, the NRC did not change the rule language in response to this comment.

5.2 Cybersecurity requirements (§ 73.110), including RFC on cybersecurity for SNM

Comment Bin 5.2.A: Two commenters expressed support for the graded approach to cybersecurity with focus on radiological consequences proposed in 10 CFR 73.110. The commenters discussed licensees’ actions to prevent radiological sabotage, adding that the outcome of risk-informed, consequence-based cybersecurity analyses would help inform control measures necessary to protect reactor functions from adverse impacts (NEI2-0236; ROSE-0010; ROSE-0017).

NRC Response: The NRC agrees with these comments.

The comments support the proposed 10 CFR 73.110 and suggest no changes to the proposed rule.

Accordingly, the NRC did not revise the rule language in response to these comments.

Comment Bin 5.2.B: A commenter asked the NRC to clarify the scope of 10 CFR 73.110, including the following:

- whether non-safety-related but safety-significant (NSRSS) systems, structures, and components are within the scope of 10 CFR 73.110 (IG-0001);
- whether emergency preparedness (EP) digital assets are within scope of 10 CFR 73.110 (IG-0002);
- to clarify the term “scenario” in the preamble discussion to avoid the potential for misconception that there is no bound on the scope of the cyber risk assessment in support of 10 CFR 73.110 (IG-0003); and
- to consider revising the word “used” in 10 CFR 73.110(a)(2) to ensure only those digital assets that are necessary for safety, security, and EP functions are in scope (IG-0005).

The commenter also asked how “adversely impacting the functions” is defined or determined (IG-0006).

A commenter said that the phrase “systems are adequately protected” in the proposed rule related to 10 CFR 73.110 reads as though licensees are required to protect the systems that perform functions (IG-0007). The commenter also suggested that the word “would” should be removed from 10 CFR 73.110(a)(1) as it is not allowed in rule text (IG-0008).

NRC Response: The NRC agrees with these comments.

Accordingly, the NRC has revised the following in response to these comments:

- Section V.B. of the final rule FRN related to 10 CFR 73.110 and RG 5.96 (formerly DG-5075) to clarify that NSRSS structures, systems, and components (SSCs) are within the scope of the rule because they warrant special treatment and are relied upon to achieve adequate defense in depth or perform risk-significant functions.
- Section V.B. of the final rule FRN related to 10 CFR 73.110 and 10 CFR 73.110(a)(1) of rule text to clarify that EP digital assets are within the scope of 10 CFR 73.110, and thus would require the protection of digital assets associated with critical functions such as safety, security, and EP functions which provides consistency with the guidance, RG 5.96.
- Section V.B. of the final rule FRN related to 10 CFR 73.110 to clarify that the scope of the scenarios covered by the cyber risk assessments are bounded by the consequences of 10 CFR 73.110(a)(1) and (2).
- Section V.B. of the final rule FRN related to 10 CFR 73.110 to clarify the digital computer and communications systems and networks associated with safety, security, and EP functions are adequately protected.

- the rule text for 10 CFR 73.110(a)(2) to clarify that only those digital assets that are necessary for security functions are within scope. The NRC has also revised Section V.B. of the final rule FRN and revised RG 5.96 to provide clarification for consistency.
- 10 CFR 73.110(a)(1) of the rule text to remove the word “would.”
- Section V.B. of the final rule FRN related to 10 CFR 73.110 and the guidance, RG 5.96 to clarify the meaning of "adverse impact" as currently defined and used in RG 5.71, Revision 1.

Comment Bin 5.2.C: A commenter said given the importance of safeguarding SNM and the potential consequences of a cyberattack on security systems, it is imperative to require robust cybersecurity measures to protect these systems. The commenter said the NRC should require a cybersecurity framework for systems and digital assets responsible for the physical protection of SN1M. The commenter said that this language would outline the general requirement for cybersecurity protections without specifying how to achieve them, ensuring it remains applicable to all future reactor types (SCWG-0009).

Another commenter said that any critical digital assets that are relied on for the protection, control, and accounting of SNM must be protected against cyberattacks that could compromise their functions and facilitate theft or diversion (UCS-0015).

Another commenter said that updates to SNM system software, like their control systems counterparts, should be provided solely by qualified, onsite personnel using erasable programmable read-only memory and encrypted signatures (FTI-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees with the first two comments. The comments support the proposed rule and suggest no changes to the proposed rule and guidance.

The NRC agrees, in part, with the third comment. The rule language within 10 CFR 73.110 requires applicants and licensees to implement defense-in-depth protective strategies to ensure reasonable assurance that digital computer and communication systems are adequately protected against cyberattacks. While not as prescriptive as mentioned in the comment, the associated guidance (RG 5.96) provides a method that the NRC deems acceptable for implementing the requirements of 10 CFR 73.110 for establishing, implementing, and maintaining a cybersecurity program at commercial nuclear plants that would be licensed under 10 CFR Part 53.

Accordingly, the NRC did not change the rule language or guidance in response to these comments.

5.3. Access authorization requirements (§ 73.120)

Comment Bin 5.3.A: A commenter discussed the proposed behavioral observation requirements in 10 CFR 73.120(c)(2) and stated that it would be “unreasonable and

unnecessarily risky" for personnel to conduct observation without training. The commenter discussed that it is essential to understand the impact of mental health and substance abuse on human behavior and that the risk of an insider threat also supports a need for training. The commenter recommended a bi-annual awareness training without an exam requirement to support the proposed observation requirements (NEI2-0232).

NRC Response: The NRC agrees, in part, with the comment.

The requirement in 10 CFR 73.120(c)(2) is a scaled version of the BOP as required under 10 CFR 73.56(f). Commensurate with the lower risk and consequence of a commercial nuclear reactor meeting the eligibility requirements, this provision does not require the establishment of as full a training program for behavioral observation (i.e., initial and refresher training including knowledge checks) as required for power reactors administering a program under 10 CFR 73.56. The alternative requirement of 10 CFR 73.120(c)(2) instead only sets the requirement that personnel subject to access authorization program requirements report questionable behavior that may be adverse to the safety and security of the site or to the workforce to the appropriate levels of management. This requirement provides licensees with greater flexibility to consider BOP options for individuals granted unescorted access to the commercial nuclear reactor's protected area.

Licensees subject to the applicable requirements of 10 CFR Part 26 will still be required to implement behavioral observation training as part of their FFD program. Licensees also have the option to go above the established requirements, at their discretion. A licensee may, for example, elect to bolster its BOP through the implementation of training beyond that required under NRC regulations.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 5.3.B: A commenter said that factory-built nuclear reactors need to be built by workers who will not purposely introduce flaws into the reactor that will result in malfunctions. The commenter said that access authorization requirements must apply to these workers (AN10-0002).

NRC Response: The NRC agrees, in part, with this comment.

The final rule requires, in 10 CFR 53.620(b)(1), that ML holders establish access controls to the portions of each facility involved in the manufacturing processes governed by the ML. Further, a manufacturing licensee authorized to load fuel in a manufactured reactor, but not authorized to operate the reactor, would be subject to the requirement in 10 CFR 53.620(d)(2)(i)(D) to screen individuals to confirm their identity, trustworthiness, and reliability prior to granting unescorted access to SNM.

As discussed in the proposed and final rules, an eligible licensee under Part 53 implementing an access authorization program administered under the requirements 10 CFR 73.120 must establish, maintain, and implement their program before initial fuel load into the reactor (or, for a fueled manufactured reactor, before removal of the features to prevent criticality required under 10 CFR 53.620(d)(1)). The NRC has determined the removal of mechanisms to prevent criticality to be an appropriate milestone for requiring the implementation of an access authorization program applicable to operating reactors.

Accordingly, the NRC did not change the rule language in response to this comment.

5.4. Changes to other parts of 10 CFR Part 73 (§§ 73.1-73.77, 73.1200-73.1215)

Comment Bin 5.4.A: A commenter expressed concern with 10 CFR Part 73 and whether the proposed changes comply with the NEIMA and congressional directives (HPT14-0001).

NRC Response: The NRC agrees, in part, with the comment.

Consistent with NRC strategies to address NEIMA, including NRC readiness to efficiently and effectively conduct its mission for advanced reactors, 10 CFR 73.100 provides a flexible and technology-inclusive regulatory framework for the design, implementation, and maintenance of a physical protection program and security organization for certain commercial nuclear plants licensed under 10 CFR Part 53. The NRC made changes to 10 CFR 73.100, based on other public comments (refer to the NRC's response to Comment Bin 5.1.B), to ensure compliance with NEIMA and congressional directives.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 5.4.B: A commenter asked if in 10 CFR 73.55(a)(6), it should be "issued after May 26, 2009" or "issued before May 26, 2009."

For 10 CFR 73.55[(p)(1)](i), the commenter said they do not believe all advanced plants will have licensed senior operators, only generally licensed operators.

The commenter also discussed 10 CFR 73.55[(r)](4)(iii) and said that the cost justification logic appears to be backwards, as the cost for compliance is higher than the cost for partial compliance.

The commenter asked if in 10 CFR 73.57(a)(3), it is "may submit fingerprints or "shall submit fingerprints".

Lastly, the commenter asked the NRC to clarify if, in 10 CFR 73.77[(a)](2)[(iii)], it is "After notification *of* a local, State, or other..." or "After notification *by* a local, State, or other..." (TG16-0003).

Another commenter said that the NRC should add conforming changes in 10 CFR 73.55 to include the following language from 10 CFR 73.100: "The licensee must establish, implement, and maintain a cybersecurity program under [multiple sections] 73.54 or 73.110 and must describe the program in the cybersecurity plan" to allow the applicant the flexibility to implement cyber requirements under 10 CFR 73.54 or 73.110 using 73.55 (IG-0004).

NRC Response: The NRC agrees, in part, with these comments.

To clarify, the 10 CFR 73.55(a)(6) citation is correct. Applicants that reference a standard design certification issued after May 26, 2009, must meet the requirement of 10 CFR 73.55(i)(4)(iii). Applicants referencing a standard design certification issued before May 26, 2009, are not subject to the requirement of 10 CFR 73.55(i)(4)(iii).

Regarding 10 CFR 73.55(p)(1)(i), the NRC agrees that a 10 CFR Part 53 licensee may not have licensed senior operators. Accordingly, the NRC has revised 10 CFR 73.55(p)(1)(i) and (ii) to refer to “a licensed senior operator or a generally licensed reactor operator, as applicable.”

Regarding 10 CFR 73.55(r)(4)(iii), this is a conforming change that is further explained in the 2006 proposed rule at 71 FR 62732. Specifically, the rule language stipulates that alternative measures for vehicle barrier systems will be reviewed by the NRC and approval would be contingent upon a demonstration by the licensee that the proposed alternative measure is cost-justified.

To clarify, the rule language in 10 CFR 73.57(a)(3) is correct. Each applicant for a license to operate a nuclear power reactor or a nonpower reactor may submit fingerprints before the Commission issues the operating license or makes its finding under 10 CFR 52.103(g). After the operating license is issued or the 10 CFR 52.103(g) finding is made, licensees shall fingerprint all individuals who will be granted unescorted access to the nuclear power facility or nonpower reactor facility.

The NRC agrees, in part, with the part of the comment that references “10 CFR 73.77(2).” For clarification, the NRC understands the comment to reference 10 CFR 73.77(a)(2)(iii), which stated in the proposed rule, “After notification of a local, State, or other....” Accordingly, the NRC revised the rule language in response to this comment. The NRC revised the word “of” to “to” in 10 CFR 73.77(a)(2)(iii) to make clear that the notification to the NRC follows a notification made by the licensee to another government agency.

The NRC agrees with adding conforming changes to 10 CFR 73.55. Accordingly, the NRC revised the rule language in response to this comment. The NRC revised Section V.B. of the final rule FRN related to 10 CFR 73.110 and the 10 CFR 73.55 rule text to clarify that 10 CFR Part 53 applicants have the option to implement either 10 CFR 73.54 or 10 CFR 73.110 cybersecurity requirements in combination with 10 CFR 73.55 physical security requirements.

5.5. Other security comments

No comments are associated with this issue.

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6. Changes to Other Parts of 10 CFR Chapter I

6.1. Changes to 10 CFR Part 50

6.1.1. Emergency preparedness (including applicability of § 50.160 and other general comments about emergency preparedness for advanced reactors)

Comment Bin 6.1.1.A: A commenter asked if an emergency response organization will be established, trained, and financially supported at smaller advanced reactors (TG20-0001).

NRC Response: The NRC acknowledges this comment.

The answer to the commenter’s question is yes. The proposed and final rules both contain requirements for applicants and licensees to develop, support, and maintain an emergency

response organization as part of their NRC-approved emergency plan. A licensee is responsible for financial support of its onsite plan. However, NRC regulations do not mandate funding support for offsite planning activities (see the NRC's response to Comment Bin 3.6.3.1.A). This comment did not suggest changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

6.2. Changes to 10 CFR Parts 1, 2, 10, 11, 19, 20, 21, 25, 30, 40, 51, 70, 72, 74, 75, 95, 140, 150, 170, and 171

Comment Bin 6.2.A: Two commenters noted that "parts" was misspelled as "parst" in 10 CFR 70.22 (MR-0010, TG16-0002).

NRC Response: The NRC agrees with these comments.

Accordingly, the NRC revised the amendatory instructions in response to these comments. Specifically, the NRC has ensured that the amendatory language for 10 CFR 70.22 eliminates the typographical error identified by these comments.

Comment Bin 6.2.B: Referring to "FY 2022 annual fee" in 10 CFR 171.15(c)(1), a commenter asked if this should be updated (TG17-0004).

NRC Response: The NRC agrees with this comment.

The rule language in the proposed rule 10 CFR 171.15(c)(1) was based on the language in "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2022" (87 FR 37197), but with the addition of 10 CFR Part 53, as applicable. Since the NRC issues the Fee Rule (10 CFR Part 171) annually, prior to the publication of the final 10 CFR Part 53 rule, the NRC will update the language in 10 CFR 171.15(c)(1) to reflect the most recently published Fee Rule.

Accordingly, the NRC has revised the rule language in response to this comment.

Comment Bin 6.2.C: A commenter asked if 10 CFR 72.32(c)(2)(i) and (2)(ii) is saying that the full extent of the emergency plan does not extend out beyond the exclusion area and asked if that is adequate (TG16-0004).

NRC Response: The NRC disagrees with the comment.

10 CFR Part 72 contains the licensing requirements for independent storage of spent nuclear fuel, high-level radioactive waste, and reactor-related greater than Class C waste. The changes that were proposed to 10 CFR 72.32 (c)(2)(i) and (2)(ii) are in reference to an emergency plan for an independent spent fuel storage installation that is located within the exclusion area boundary for an existing licensed facility. The distance out to which the emergency plan would extend would be determined by the regulatory framework chosen by the applicant in either 10 CFR 50.47 and 10 CFR Part 50, Appendix E, or 10 CFR 50.160.

Accordingly, the NRC did not change the rule language in response to this comment.

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7. Other Comments on the Proposed Rule

Comment Bin 7.A: Two commenters suggested that the NRC include black-start capability within the regulatory framework for advanced reactors. The commenters said that black-start capability allows a power plant to restart independently without relying on the external electric power grid, which is highly relevant to the proposed regulation as it directly contributes to resilience and reliability and achieving the goals of safety and sustainability (MR-0002, NA-0001).

NRC Response: The NRC disagrees with these comments.

While having black-start capability may be advantageous for certain reactor designs and associated applications, it is not an essential attribute for all situations and the plants currently operating do not have such a capability.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 7.B: A commenter suggested that 10 CFR Parts 51 and 53 should be better integrated and environmental monitoring planning processes should be improved. The commenter said that the proposed modifications to 10 CFR Part 51, under the Generic Environmental Impact Statement (GEIS) for Licensing of New Nuclear Reactors rule, includes requirements for the identification and assessment of potential environmental impacts during the construction, operation, and decommissioning of new nuclear reactors as required by the National Environmental Policy Act (NEPA). However, the commenter expressed that while proposed 10 CFR Part 53 relates to these modifications, there are no explicit cross references specifically related to the siting provisions of 10 CFR Part 53.

Additionally, the commenter said that the 10 CFR Part 53 rule appears to assume that the proposed 10 CFR Part 51 rule will be adopted, but if it is not, then portions of 10 CFR Part 51 that relate to 10 CFR Part 53 must be addressed elsewhere. The commenter recommended that the NRC consider focusing more attention on the process through which environmental monitoring plans (EMPs) should be developed and implemented. The commenter suggested that the NRC should consider adopting a process similar to the U.S. Environmental Protection Agency's (EPA's) Applicable or Relevant and Appropriate Requirements (ARAR) process when creating and implementing EMPs. Lastly, the commenter said that an ARAR-type process for NRC-licensed facilities should also facilitate applicable NEPA processes and reviews (UT1-0008).

NRC Response: The NRC disagrees with the comment.

The Part 53 and the new reactor GEIS rulemakings address different aspects for the licensing of new reactors. The Part 53 rulemaking establishes a new licensing process for commercial nuclear plants. References to the 10 CFR Part 51 regulations in the Part 53 final rule are to ensure that an application under 10 CFR Part 53 provides the proper environmental report for the type of application being sought or points to a specific process under 10 CFR Part 51 (e.g., in 10 CFR 53.1470(f) on scoping for an environmental impact statement in accordance

with 10 CFR 51.28 or 51.29). For the new reactor GEIS rulemaking, the NRC is pursuing a rulemaking to meet the agency's obligations under NEPA in a more streamlined and efficient environmental review process for any new reactor application, whether under 10 CFR Part 50, Part 52, or Part 53. Therefore, any citation to 10 CFR Part 51 in this 10 CFR Part 53 rulemaking is not dependent on any 10 CFR Part 51 changes under the new reactor GEIS rulemaking.

With respect to the commenter's statement that "there is currently no discussion in Part 51 or Part 53 regarding environmental monitoring and the evaluation of impacts to the environment through the life cycle of the licensed facility," the 10 CFR Part 51 regulations are related to the NRC's NEPA obligations, and establishment of a radiological environmental monitoring program at a nuclear reactor is outside of those regulations. Rather, nuclear power plants must comply with specific public dose limits set by the NRC and the EPA and performance objectives established by the NRC, such as those in 10 CFR 53.425. The EPA's rules related to environmental radiation protection standards for nuclear power operations can be found in 40 CFR Part 190. The NRC rules related to standards for protection against radiation are in 10 CFR Part 20 and are supplemented in 10 CFR Part 53 through sections such as 10 CFR 53.850, which requires an offsite dose calculation manual (ODCM), and 10 CFR 53.1645, which requires routine reports on radiation exposure to members of the public. The radiological environmental monitoring program can be constructed using NEI 07-09A, "Generic FSAR Template Guidance for Offsite Dose Calculation Manual Program Description," issued March 2009, and RG 4.1, Revision 2, "Radiological Environmental Monitoring for Nuclear Power Plants," to comply with the requirements of 10 CFR 20.1302. Plant operators must report to the NRC any time radiological dose and effluent levels in 10 CFR Part 20 are exceeded and, for licenses under 10 CFR Part 53, must make periodic reports on effluent releases and public doses under 10 CFR 53.1645.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.C: A commenter stated that nuclear safety and risk is a complex topic that is not made easier by the proposed rule. The commenter discussed the difficulty of enabling direct RIDM given mathematical, decisional, and mechanistic complexities, and said that multiple units at multiple sites are part of a distribution system or power grid with shared external and internal connections in addition to potential shared facilities or infrastructure, a complexity not addressed in the proposed rule. Additionally, the commenter expressed that terms like "SSCs" or "LBE" (licensing-basis event) or "DBA" (design-basis accident) events are not applicable or extendable for risk analysis purposes since the full spectrum of potential or actual sites, hazards, and configurations must be considered. The commenter also said that the well-established "best estimate and uncertainty" methodology is not mentioned and constitutes a serious omission. The commenter recommended that the NRC revisit and revise the entire claimed RIDM basis (RD-0001). The commenter added that the NRC should explicitly acknowledge that the use of RIDM is only to support decision-making and is an imperfect process (RD-0004).

NRC Response: The NRC disagrees with these comments.

A commercial nuclear plant licensed under 10 CFR Part 53 must address grid-related issues that can potentially impact nuclear safety on a site-wide basis. Terms like SSCs, LBE, and DBA have a long history of use and are used in 10 CFR Part 53 consistent with their use in NEI 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," issued August 2019, as endorsed by

RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Bais and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” issued June 2020, and other documents related to the Licensing Modernization Project (LMP) methodology. 10 CFR Part 53 accommodates different types of risk-informed approaches and includes various requirements that explicitly address uncertainties in analyses.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 7.D: A commenter discussed independent reviews, which represent a major requirement for any technical matter, scientific topic, or safety issue, but are not mentioned or required in the proposed rule. Given the inevitable limited expertise for any one concept or design, the commenter suggested that the NRC utilize external consultants, contractors, independent bodies, and outside reviewers to assist in forming internal RIDM judgements. The commenter specified that while the proposed rule mentions the Advisory Committee on Reactor Safeguards (ACRS), there are no explicit requirements for ACRS to—

- specifically review risk metrics, PRA, LBEs, etc.;
- provide recommendations and revisions to the rules and processes;
- possess any explicitly designated remit, delegated power, or authority to reject or challenge NRC or Commission decisions or positions; or
- ensure that their review findings and recommendations are utilized and accepted and if not, determine why not.

The commenter recommended that the NRC update the ACRS role, funding, and mandate, thus modifying the proposed and current ACRS Charter (RD-0019).

NRC Response: The NRC agrees, in part, with the comment.

The NRC retains the necessary technical expertise, including the use of contractors when appropriate, to perform its regulatory functions based on the needs of its regulated community. The various requirements in Subpart H of 10 CFR Part 53 related to items referred to the ACRS are sufficiently broad to accommodate ACRS review of any safety-related (SR) items associated with an application under 10 CFR Part 53. Additionally, those requirements are generally consistent with the related requirements under 10 CFR Part 50 and 10 CFR Part 52. Changes to functions of the ACRS are outside the scope of this rulemaking activity.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.E: A commenter recommended that the NRC define a clear path or process for licensing and operating a first-of-a-kind (FOAK), prototype, factory module, or pilot plant, including the gathering of data and experience for qualification, verification, and validation of PRA and mechanistic codes and methods. The commenter stated that the NRC can then apply this logic to standard design certification to ensure this process melds seamlessly with the “standard plant” licensing processes while allowing design and scale changes (RD-0020,

RD-0032). The commenter also said that qualification of analytical codes in 10 CFR 53.450 is difficult given the lack of full-scale data and prototypes, and recommended that the NRC revise this requirement and consider the use and issuance of provisional licenses to operate to allow for testing and data gathering (RD-0023).

Another commenter said that the NRC should not drastically scale back its safety and security standards across the board based on wholly unrealistic expectations about speculative future reactor designs with little or no experimental validation. The commenter stated that designs should undergo rigorous operational full-scale prototype testing that demonstrates that they are highly likely to perform as designed (UCS-0001). The commenter said that the proposed rule needs comprehensive stress tests which would search for hidden vulnerabilities. The commenter discussed that, though daunting, these tests are not unlike the post-Fukushima stress tests conducted in other countries or the Integrated Response Program tabletops conducted with Federal partners (UCS-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees that 10 CFR Part 53 needs to be revised to define a clear path for licensing and operating a FOAK, prototype, factory module, or pilot plant; that all designs should undergo rigorous operational full-scale prototype testing; and that the rule should require comprehensive stress tests to search for hidden vulnerabilities. The provisions in 10 CFR 53.440(a) already require that applicants demonstrate that each required design feature meets the defined functional design criteria through analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof. This requirement offers applicants flexibility in demonstrating the safety of their design, closely aligns with the existing requirement in 10 CFR 50.43(e), and is proposed in 10 CFR Part 53 as a similar foundational requirement. In addition, the requirements of 10 CFR 53.450(a) require a PRA or other systematic risk evaluation to identify potential failures, susceptibility to internal and external hazards, and other contributing factors to event sequences that might challenge the identified safety functions to support demonstrating that each commercial nuclear plant meets the safety criteria.

While the NRC agrees that qualification of analytical codes may prove challenging given the lack of full-scale data and prototypes, issues related to a lack of operating experience can be addressed as part of preapplication interactions and reviews. It can also be addressed through the establishment of operational monitoring and assessment programs for such FOAK applications, with regulatory oversight provided through the NRC's inspection and oversight programs. The NRC disagrees with one commenter's characterization of 10 CFR Part 53 as an effort to drastically scale back its safety and security standards across the board. The framework provided by 10 CFR Part 53 and 10 CFR Part 73 is sufficiently robust but appropriately flexible to address the licensing of FOAK reactor designs and, if pursued, to provide the benefits of licensing and deploying next-of-a-kind reactors incorporating lessons learned from the initial operations of the FOAK reactor.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 7.F: A commenter said that there is no road map of how to proceed through the proposed regulatory 10 CFR Part 26, 10 CFR Part 53, and 10 CFR Part 73 framework. The commenter recommended that the NRC undertake a full test and demonstration for a hypothetical system to establish feasibility; refine risk measures; ensure applicability and avoid

unnecessary duplication or efforts; reduce complexity; and provide a demonstrated, workable road map (RD-0009).

NRC Response: The NRC agrees, in part, with the comment.

Guidance on the content of applications is under development and, as discussed in the proposed and final rule FRNs, the NRC will issue revisions to existing advanced reactor application-related guidance documents or 10 CFR Part 53–related companions, which will be finalized and issued with or after the 10 CFR Part 53 final rule.

The NRC disagrees with testing the 10 CFR Part 53 regulatory framework before finalizing it as the development of the framework has benefited from a substantial number of interactions and opportunities for stakeholders to provide feedback on 10 CFR Part 53 during its development.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.G: A commenter discussed that 10 CFR Part 53 is designed to be more adaptable to new technologies and reactor designs, which may include advanced waste management techniques and that Part 53 does provide more specific requirements for waste management programs and documentation such as an ODCM and a Process Control Program for solid waste.

The commenter said that a study published in the *Proceedings of the National Academy of Sciences* and co-authored by former NRC Commissioner MacFarlane found that the spent nuclear fuel from SMRs will be generated in greater volumes per unit of energy extracted, and that its composition can be far more complex than the spent fuel resulting from existing power plants. The commenter stated that since the full universe of all technologies and potential waste streams is unknown, there could be concerns in the future (NYS2-0024).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees that 10 CFR Part 53 is designed to be more adaptable to new technologies, and these technologies may raise new issues for waste management. The NRC acknowledges the concerns about the volume and composition of waste for potential future commercial nuclear power plants. These concerns are outside the scope of this rulemaking and will be resolved during plant-specific licensing proceedings; the comment suggests no changes to the proposed rule or guidance.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.H: A commenter said that the NRC should prioritize affordability, sustainability, and rapid development with a clear and predictable pathway supporting reactors that use fuel more efficiently, minimize environmental impacts, and provide grid stability. The commenter also stated that advanced reactors should be deployable at scale within the next decade to meet pressing climate and energy security needs (NNY-0002).

NRC Response: The NRC agrees, in part, with the comment.

As described in the final rule, 10 CFR Part 53 is developed to meet the requirements of NEIMA, which includes provisions that would account for improvements to nuclear reactors such as (1) additional inherent safety features, (2) significantly lower levelized cost of electricity, (3) lower waste yields, (4) greater fuel utilization, (5) enhanced reliability, (6) increased proliferation resistance, (7) increased thermal efficiency, and (8) ability to integrate into electric and nonelectric applications. The comment suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.I: A commenter said that 10 CFR Part 53 should be flexible enough to accommodate the types of licensing pathways originally envisioned under Framework B (USNIC2-0011).

NRC Response: The NRC disagrees with this comment.

The 10 CFR Part 53 regulatory framework would not accommodate approaches contemplated under what is referred to as Framework B in SECY-23-0021, “Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31),” issued March 2023, because the regulatory constructs in 10 CFR Part 53 are fundamentally different. In that regard, the exclusive use of bounding assessments or a development of a safety case that relies on requirements similar to those found in 10 CFR Part 50 would not be sufficient to meet certain requirements under 10 CFR Part 53 such as 10 CFR 53.450(b) and 10 CFR 53.450(e) related to the classifying SSCs based on safety significance and identifying significant event sequences.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.J: A commenter said that it is important that licensed reactors can be licensed and operated in Canada, Europe, and other parts of the world with minimal country-specific additional regulations. The commenter also stated that 10 CFR Part 53 should allow for approaches consistent with high-level standards adopted by the International Atomic Energy Agency (IAEA) (USNIC2-0006).

Another commenter said that due to the global demand for new nuclear power, 10 CFR Part 53 needs to be able to leverage international approaches, such as IAEA milestones, when licensing a facility through 10 CFR Part 53 (CP-0007).

NRC Response: The NRC agrees, in part, with the comment.

The regulation in 10 CFR Part 53 accommodates the use of international standards that may be used to license commercial nuclear plant designs in other countries as well as the U.S. However, NRC reviews of the use of international standards will be assessed in the context and based on the needs of a given application.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 7.K: A commenter wrote that there is the potential under 10 CFR Part 53 to create a general license process for certain reactors, including microreactors. The commenter wrote that, as discussed in the NEI report on rapid high-volume deployment of microreactors, the Atomic Energy Act of 1954, as amended (AEA) may need to be amended to authorize a general license approach for reactors, and this would also require the development of appropriate NRC policy, regulations, and guidance. The commenter wrote that appendix 5 to that report proposes a pathway for minimizing the scope and level of information required in a site-specific license application. The commenter suggested adding into Subpart D a pathway to a general license for microreactors, and simplified siting requirements to the extent allowable by statute if bounding consequence requirements or defined site parameters are met. The commenter noted that a pathway to a general license for microreactors would require significant engagement between the NRC and industry (NEI2-0062, NEI2-0256).

A commenter submitted a paper entitled “Service Provider Licensing and Oversight: An Alternative Conceptual Strategy for Regulating Fleet-wide Small and Mobile Reactors” as a conceptual alternative to the proposed rule. In the paper, the commenter wrote, they explain that the NRC’s efforts to establish a modern regulatory framework do not fully reflect risk-informed and performance-based concepts due to, for example, the rule’s overreliance on PRA and other prescriptive requirements. The commenter encouraged the NRC to break from conventional thinking and practices and deliver an efficient, effective regulatory framework that accommodates various deployment models. While the paper refers to SMRs, the commenter said, many of the concepts can apply to any advanced reactor. Lastly, the commenter urged the NRC to consider concepts in the paper broadly as it modernizes its regulations, policies, programs, and practices across reactor and materials business lines (RF-0001). Another commenter urged the NRC to achieve the goal of enabling high-volume licensing with 10 CFR Part 53, stating that 10 CFR Part 53 could be transformational for new business models. The commenter further asserted that 10 CFR Part 53 could be a way to implement broader improvements to licensing of new reactors (e.g., general permits) and future direction to develop a permit-by-rule for licensing reactors (CP-0009).

A commenter suggested that the NRC should explicitly address how 10 CFR Part 53 will be efficient and reliable for Nth-of-a-kind reactor license applications (USNIC2-0007). The commenter also said that the NRC’s regulatory approach should maintain flexibility, including the potential for batch licensing, to avoid the regulatory burden of excessive reliance on repeated licensing of each individual unit (USNIC2-0008). Another commenter expressed concern that the rule does not accommodate a rapid high-volume reactor deployment model (RAD-0001).

Relatedly, a commenter stated that a fleet-scale approach to licensing and oversight of small and mobile reactors under a service provider license would efficiently integrate the NRC's regulatory functions over the life cycle of manufactured reactors. The commenter also discussed that maximum use of performance monitoring would minimize the need for costly, inefficient inspection and reduce costs associated with Nth-of-a-kind deployment and decommissioning (ROSE-0004). Another commenter similarly expressed support for the exploration of a service provider licensing and oversight approach for manufactured reactors (RAD-0001).

NRC Response: The NRC disagrees with these comments.

The NRC disagrees with the proposal of adding a pathway for a general license for microreactors in Subpart D of 10 CFR Part 53. Whereas Chapter 7 of the AEA, which deals with source material, includes provisions for the issuance of a general license, the sections of the

AEA that govern the licensing of utilization facilities require specific licenses for the construction and operation of nuclear reactors, and those licenses have traditionally specified a place of use. However, the NRC notes that design standardization is already supported by design certifications and approvals, MLs, the GEIS, and other guidance, but it does not support a general license. Therefore, while the NRC concludes that the flexible approach to licensing in 10 CFR Part 53, supported by these design standardization procedures, could facilitate a high volume of reactor licensing, particularly for Nth-of-a-kind reactors, through technology-inclusive provisions, providing for a general license to operate reactors may, as mentioned in the comment, require amendments to the AEA, which is beyond the scope of the rulemaking.

Accordingly, the NRC did not change the rule language in response to these comments.

However, the NRC is assessing possible alternative approaches specifically for microreactors in response to the Executive Order (EO) 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” dated May 23, 2025. The NRC has initiated development of an additional rulemaking to expedite licensing of qualifying microreactors and other potentially low-risk, low-consequence reactors, consistent with the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act (ADVANCE Act) and EOs issued in 2025. This activity, along with other NRC guidance development activities, is intended to address questions such as those raised by the comments. Microreactors are seen as the most likely technology to benefit from alternatives to the traditional approach of issuing site-specific licenses to satisfy the requirements of the AEA.

Comment Bin 7.L: A commenter asked the NRC to clarify whether the proposed rule or another rulemaking would address the security and material accounting measures for high-assay low-enriched uranium (HALEU) and other attractive nuclear materials that may be present in advanced reactor fuel cycles and recommends that the NRC should initiate a rulemaking on this topic (TG24-0001).

NRC Response: The NRC disagrees with this comment.

In 10 CFR 73.67, “Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance,” the NRC addresses protection for enrichments below 20.0 weight percent U-235. Because existing requirements in 10 CFR 73.67 address HALEU enrichments, the NRC has determined that changes to physical security requirements are not required.

Accordingly, the NRC did not change the rule language in response to this comment.

<u>Commenters supporting other comments or general stakeholder engagement comments</u>

Comment Bin 7.M: Many commenters expressed the need for the NRC to streamline the proposed rule. A commenter discussed that the phrase “A new alternative technology-inclusive, risk-informed, performance-based framework” appears in the proposed rule 89 times, and “review” appears 235 times, but that “simplification” appears zero times. The commenter said that any improvements to the NRC review process, time, or effort by both staff and licensees are not addressed, discussed, or proposed (RD-0003). The commenter also said that the proposed

rule adds over 100 additional “guidance” documents and extensive sub-references (RD-0031). The commenter also said that the complex rationale and overlaid structure is very traditional and outdated for new and advanced concepts (RD-0005). The commenter recommended that the NRC identify areas to reduce unnecessary repetition, simplify processes, and avoid repetitive reviews (RD-0003, RD-0031, RD-0005). Another commenter said that the NRC must streamline its licensing process to ensure that the public can benefit from advanced nuclear energy without unnecessary regulatory delays or costs (NNY-0007).

Similarly, several commenters expressed support for the NEI recommendation that the NRC pursue more aggressive changes throughout 10 CFR Part 53 to fully address the ADVANCE Act and other EOs (APS-0002, IDNL-0002, NEX-0003, USNIC2-0001, DOM-0001, SOU-0002, BWXT-0001, ENT-0001, ROSE-0001, NUS2-0001, DOM-0003, APS-0004, KAP-0001, CP-0004, SHP-0001, RAD-0001, WEST1-0004, WEST1-0005, ENW-0001). One of the commenters said that the NRC should be bold with 10 CFR Part 53 and look at duplicative regulatory requirements, efficient frameworks for advanced reactor technologies, and enhancements to current siting rules (APS-0002). Other commenters said that the industry stands ready to provide input in the rulemaking process, including development of necessary guidance (ENT-0002, APS-0004). One commenter said that the proposed rule is generally usable, but falls short of its potential and is unlikely to be utilized by all but a few industry participants (CP-0005).

Many commenters also stated that they participated in the NEI’s 10 CFR Part 53 Task Force in development of the comprehensive comment package (APS-0002, IDNL-0002, NEX-0003, BWXT-0001, SHP-0001, RAD-0001). Other commenters expressed support for the “Stakeholder Consensus on Proposed Part 53 Major Topics” submitted by the Breakthrough Institute and the Nuclear Innovation Alliance (USNIC2-0001, NNY-0008, FK-0001, KAP-0001, CP-0004, GA-0001, BI1-0001, NUC-0001, VD-0001, NIA2-0008, TP-0001, FTI-0001, ANI-0001, MM-0001). Relatedly, other commenters expressed support for the comments provided by the United States Industry Council and ClearPath (KAP-0001, BI1-0001).

One commenter requested that the NRC consider their previous comment, Commission Hearing Testimony, and other publications that are relevant to the overall structure and implementation of the rule (CP-0004). A commenter said that they also endorse a comment titled “Joint Non-Governmental Organization Comments on NRC's Rulemaking on the Part 53, Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors” (NIA2-0008).

NRC Response: The NRC agrees, in part, with the comments.

Regarding repetition of and streamlining of requirements, the NRC has revised rule language in several portions of 10 CFR Part 53 in response to comments, which includes but is not limited to changes to various licensing requirements in Subpart H, definitions in 10 CFR 53.020, and design requirements in 10 CFR 53.440. The NRC also notes that the review process, time, or the level of effort by both staff and licensees are largely determined by factors other than the regulations themselves. Major contributors to determining the schedule and resources needed for each review include the complexity of the reactor design; the availability and applicability of analyses, appropriate test programs, prototype testing, and operating experience; and the quality of the application.

In terms of comments that specifically supported other comment submissions, the specific comments in question have been addressed throughout this comment response document, and the NRC acknowledges the comments supporting those comment submissions.

Accordingly, the NRC did not change the rule language in response to these comments.

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8. Accompanying Guidance

8.1. DG-1413, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants"

Comment Bin 8.1.A: A commenter discussed that the reason for issuance in DG-1413 is inconsistent with guidance provided later in the document. The commenter stated that box 8 identifies acceptable methods as use of inductive or deductive designs, but that box 13 includes the review of initiating event analysis performed for other designs. The commenter also said that appendix A describes comparing initiating events to the generic list of initiating events. The commenter recommended that the description in the reason for issuance to "[start] with a blank sheet of paper" be revised to capture the blended approach in appendix A and the approach from box 13 (NUS1-0001).

NRC Response: The NRC disagrees with the comment.

The objective of RG 1.254 (formerly DG-1413) is to provide technology-inclusive guidance for identifying a comprehensive set of licensing events. To help ensure that unique aspects of novel designs are not overlooked, initiating event identification should begin without preconceptions or using existing lists. Once a preliminary list of initiating events has been developed, it should be compared to analyses of previous designs to help ensure completeness. This two-phased approach implements recommendations by the ACRS and is consistent with national consensus standards for developing PRAs that have been endorsed by the NRC.

Accordingly, the NRC did not revise RG 1.254 (formerly DG-1413) in response to this comment.

Comment Bin 8.1.B: A commenter recommended adding guidance to DG-1413 to describe an approach to identify combinations of events, including events used to inform design (NUS1-0002).

The commenter also stated that appendix A, sections A.1 and A.2, to DG-1413 list but do not provide a complete set of descriptions for several inductive methods and deductive techniques. The commenter suggested that references be added for methods and techniques not described in more detail, such as the double failure matrix and cause consequence analysis (NUS1-0003).

NRC Response: The NRC agrees with the comments.

Accordingly, the NRC revised RG 1.254 (formerly DG-1413) in response to these comments.

8.2. DG-5073, "Fitness-For-Duty Programs for Commercial Nuclear Plants and Manufacturing Facilities Licensed Under 10 CFR Part 53"

DG-5073, "Fitness-For-Duty Programs for Commercial Nuclear Plants and Manufacturing Facilities Licensed Under 10 CFR Part 53," has not been issued as part of the 10 CFR Part 53 final rule package. As appropriate, comments received on this DG will be incorporated into a

future issuance of this DG/RG and are not included in this comment response document. The NRC plans to issue RG 5.94 (formerly DG-5073) after the publication of the final Part 53 rulemaking.

8.3. DG-5074, “Access Authorization Program for Commercial Nuclear Plants”

Comment Bin 8.3.A: A commenter recommended that DG-5074 consider linking suspension of access authorization to incidences where the individual is unobserved, similar to the current program in 10 CFR 73.56. The commenter added that the reviewing official should evaluate whether an individual is no longer compliant following a 30-day period of not entering the protected area (NEI2-0233).

NRC Response: The NRC agrees with this comment.

The NRC already draws the correlation in RG 5.95 (formerly DG-5074), “Access Authorization Program for Commercial Nuclear Plants,” between a 30-day lapse in behavioral observation and the nexus to suspend unescorted access. In its discussion of responsibilities for a reviewing official, the guidance states that the reviewing official should suspend any individual’s unescorted access who has not entered the protected area or controlled area for more than 30 days until the reviewing official has fully evaluated an access determination for that individual.

Accordingly, the NRC did not change the rule language or guidance in response to this comment.

Comment Bin 8.3.B: A commenter discussed that behavior observation, described in paragraph 112 of DG-5074 as part of an annual management review, is a continual requirement needed to detect and report concerning and aberrant adverse behaviors. The commenter stated that an annual review requirement places additional burden of little value on program personnel to complete a form. The commenter recommended that supervisors and all personnel immediately report and appropriately document behaviors to access authorization personnel, but that no annual reporting form be required (NEI2-0234).

NRC Response: The NRC agrees, in part, with this comment.

Behavior observation is a continual requirement to observe adverse behaviors determined to be aberrant and concerning that are required to be reported when detected. However, 10 CFR 73.120(c)(4) clarifies the responsibility of the reviewing official to verify the trustworthiness and reliability and continued need of personnel who maintain unescorted access, and to review determinations annually. Completing an annual review ensures that the reviewing official can make this determination for those employees with whom the reviewing official does not maintain frequent interaction, or those employees who may transfer from site to site during refueling outages and are not with the same supervisor when access is reinstated at the current licensee or at a downstream facility. The NRC has revised paragraph C.112 of the guidance in RG 5.95 to clarify that an annual review of employee behavior should be included as part of the required annual review of unescorted access.

Accordingly, the NRC did not change the rule language, but did revise RG 5.95 (formerly DG-5074) in response to this comment.

8.4. DG-5075, “Establishing Cybersecurity Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53”

Comment Bin 8.4.A: With respect to section/paragraph A3.2 of DG-5075, a commenter stated that Critical Digital Assets classified as “most critical” should only need to implement security controls necessary to protect from cyberattacks, as this provides the requisite defense in depth in a performance-driven approach to cybersecurity, or be able to define certain controls as additional margin becomes available (NEI2-0239).

NRC Response: The NRC agrees with the comment.

Accordingly, the NRC revised RG 5.96 (formerly DG-5075) to clarify what security controls are needed to protect "Most Critical" systems in response to this comment.

Comment Bin 8.4.B: A commenter recommended that DG-5075 be revised to explain why a blended-attack involving both cyber and physical events is not part of the analysis discussed in the guidance document (IG-0010).

NRC Response: The NRC agrees with this comment.

Accordingly, the NRC revised RG 5.96 (formerly DG-5075) to discuss why a blended attack is not part of the analysis in response to this comment.

Comment Bin 8.4.C: A commenter suggested that the three-tiered review approach included in DG-5075 excludes a digital asset if an alternate method credited for performing the EP function is available and trained upon, consistent with the approach to EP in NEI 10-04, Revision 3 (NEI2-0241).

NRC Response: The NRC agrees, in part, with the comment.

RG 5.96 (formerly DG-5075) already includes guidance for analyzing a critical function that is performed by alternative means; however, the NRC revised RG 5.96 (formerly DG-5075) to provide additional guidance specifically for EP functions that is consistent with NEI 10-04 in response to this comment.

Accordingly, the NRC revised the guidance in response to this comment.

Comment Bin 8.4.D: A commenter stated that the phrase “near real-time assurance” in section/paragraph A3.2 of DG-5075 could lead to a variety of interpretations, adding that the definition of security information and event management similarly uses the phrase “near real-time” (NEI2-0240).

NRC Response: The NRC agrees, in part, with the comment.

The NRC disagrees that the use of the term “near real-time” in the security information and event management definition is vague and will lead to a variety of interpretations, as this term is already used in existing NRC cybersecurity guidance, RG 5.71, Revision 1, as well as NEI 08-09, Revision 6, “Cyber Security Plan for Nuclear Power Reactors,” issued April 2010.

The NRC agrees that the phrase “near real-time assurance” is unnecessary to discuss the security controls that should be applied to “Most-Critical” systems.

Accordingly, the NRC revised RG 5.96 (formerly DG-5075) to delete the phrase “near real-time assurance.”

Comment Bin 8.4.E: A commenter requested that the NRC provide guidance on the definition of “periodically” as it appears throughout DG-5075 in context of analyses (NEI2-0242).

NRC Response: The NRC agrees, in part, with the comment.

The NRC disagrees with providing general guidance on what is meant by "periodically" in RG 5.96 (formerly DG-5075). The NRC does agree that RG 5.96 should be revised to generally avoid the use of the term and to provide language that clearly states the intent where the term is used.

Accordingly, the NRC revised RG 5.96 (formerly DG-5075) in response to this comment.

Comment Bin 8.4.F: A commenter requested that the NRC ensure that cited references in DG-5075 are correct and that terms defined in the guidance are consistent with definitions established in other agency documents (IG-0011).

NRC Response: The NRC agrees with this comment.

Accordingly, the NRC revised the cited references in RG 5.96 (formerly DG-5075) to correct typographical errors and revised the terms defined to ensure consistency with definitions established in other agency documents in response to this comment.

Comment Bin 8.4.G: A commenter requested that the statement “meet the intent” of IAEA Nuclear Security Series (NSS) 17-T found in DG-5075 be revised but did not specify an alternative statement (IG-0012).

NRC Response: The NRC agrees with this comment.

Accordingly, the NRC revised RG 5.96 (formerly DG-5075), sections C.58 and C.63, in response to this comment to remove the statements related to meeting the intent of IAEA NSS 17-T.

Comment Bin 8.4.H: A commenter discussed that criterion 140 in DG-5075 references EP but that clarification of EP functions is needed (IG-0002).

NRC Response: The NRC agrees with this comment.

See the NRC's response to Comment Bin 5.2.B, where the NRC revised 10 CFR 73.110, Section V.B of the final rule FRN, and the rule language to clarify that EP digital assets are within scope of 10 CFR 73.110, thus requiring the protection of digital assets associated with critical functions such as safety, security, and EP functions. The NRC also revised the guidance, RG 5.96 (formerly DG-5075), for consistency with the rule language changes in 10 CFR 73.110.

Accordingly, the NRC revised the guidance in RG 5.96 in response to this comment.

Comment Bin 8.4.I: A commenter requested that figures 3 through 9 and associated text in DG-5075 be revised to accurately reflect the written guidance (IG-0009).

NRC Response: The NRC agrees with this comment.

Accordingly, the NRC revised figures 3 through 9 in RG 5.96 (formerly DG-5075) to correct editorial and typographical errors in response to this comment.

Comment Bin 8.4.J: A commenter stated that detailed implementing guidance such as DG-5075 would provide the technical details and measurable performance standards to support high-level cybersecurity requirements in 10 CFR 73.110. The commenter added that the implementing guidance would outline specific actions and strategies that licensees could implement to meet the cybersecurity objectives of proposed 10 CFR 73.110 (SCWG-0009).

NRC Response: The NRC agrees with the comment.

The comment supports the proposed guidance and suggests no changes to the proposed guidance.

Accordingly, the NRC did not revise the rule language or RG 5.96 (formerly DG-5075), as both adequately address the commenter's concern, in response to this comment.

8.5. DG-5076, "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants"

Comment Bin 8.5.A: A commenter discussed detection probability as described in section C 4.1.1.1.A in DG-5076, "Guidance for Technology Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants." The commenter stated that the criteria for a 90 percent detection probability with 95 percent confidence was adopted from RG 5.44, Revision 2, "Perimeter Intrusion Alarm Systems," issued May 1979 which includes additional details not available in DG-5076 such as—

- dividing the perimeter alarm system into independently alarmed segments;

- the detection probability prescribed at the segment-unit level;
- methods and the number of tests required to achieve the 90 percent probability with 95 percent confidence; and
- a relaxed detection probability down to 88 percent (rounded number), potentially based on the Clopper Pearson interval as opposed to the normal distribution approximation, for tests fewer than 100, as listed in table 6 and detailed in appendix B.

The commenter also discussed details from RG 5.44 regarding the definition of "segment" and the phased approach to testing requirements. However, the commenter expressed that RG 5.44 does not clarify the methodology behind the relaxed detection probability, but that the RG has been the standard used for light-water reactors (LWRs) and the relaxation should also apply to advanced reactors under 10 CFR Part 53. The commenter stated that a reduction of 2 percent detection probability would not significantly compromise protection measures while allowing for a practical number of tests performed to be practical that still satisfy statistical theories for distributions.

The commenter proposed updating the phrase "to provide a detection probability of 90 percent with 95 percent confidence" in DG-5076 to the following language:

> to provide a segment detection probability of at least 90% with 95% confidence when the number of tests is 100 or more. For the total number of tests less than 100 on each segment, the performance criteria are relaxed to be at least 88% probability of detection in a segment with 95% confidence. ... Methods in RG 5.44 Appendix A & B may be used to meet requirements for confidence in minimum detection probabilities.
>
> A segment may be defined as the detection technologies found on an adversary pathway before a critical detection point.

Further, the commenter recommended that if DG-5076 does not replace or invalidate RG 5.44, that language be added to refer applicants to RG 5.44 for testing details. The commenter also suggested that DG-5076 provide clarification that the 95 percent confidence in detection probability entails that the lower limit is 90 percent and that a detection probability higher than 90 percent should be acceptable (IDNL-0015).

The commenter also discussed the "90/95 rule" for detection probability in context of access control devices, as described in sections C 4.1.1.6.A and 4.1.1.6.B in the draft guidance. The commenter expressed that there is no corresponding requirement in U.S. Department of Energy (DOE) Order 473.1A, and that applying the 90/95 rule to access control devices would require 30-for-30 test on every device at a facility, which may be time consuming, increase costs for the security system, and decrease operational efficiency. The commenter suggested that it may be more beneficial for the guidance section to discuss requirements for acceptance testing access control devices rather than long-term application of 90/95 probabilities of detection. The commenter further recommended that performance requirements be applied at the system level, and defense-in-depth expectations applied (IDNL-0023).

For the interior intrusion guidance described in section C 4.1.1.1.B in DG-5076, the commenter relatedly stated that detection sensors have not previously been required to have a 90/95 application for probability of detection and that no current NRC documents were found that require or suggest a 90/95 probability of detection for interior intrusion sensors. The

commenter discussed that interior sensors could include passive infrared sensors, balanced magnetic switches, and dual-technology sensors and be found in many locations throughout a nuclear facility, which would greatly increase the overall maintenance and performance testing program for a physical protection system. The commenter suggested that the guidance language be revised for detection probabilities to reflect protective strategy needs, and that the phrase “The design should meet the criteria set forth for exterior intrusion detection systems above” be modified to reflect that interior intrusion detection systems are not vulnerable to and should not require protection from weather events (IDNL-0017).

The commenter addressed the 90/95 rule in context of section C 4.1.1.6.B, stating that DG-5076 provides an expectation on searches and SNM detection redundancy and 90/95 detection but lacks clarity whether this guidance pertains to fuel vault sensors or if the expectation is SNM doorway monitors are implemented for staff leaving an area or site. The commenter requested additional information regarding the regulatory basis for this expectation. The commenter also suggested that, if directed at Category II nuclear power plant sites, the guidance include specific language on applicability to materials present on site, and the inclusion of a performance-based approach that credits the whole performance of a nuclear material accounting and control program and SNM detection SSCs and procedures (IDNL-0024).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that detailed guidance regarding intrusion detection and assessment systems is important. To avoid creating duplicative guidance, the NRC included RG 5.44, RG 5.12, and NUREG-1964, “Access Control Systems,” issued April 2011 in the list of related guidance for RG 5.97 (formerly DG-5076). Specifically, the NRC revised RG 5.97 to ensure that those guidance documents are adequately referenced to ensure that applicants and licensees know to refer to those documents for specific guidance regarding acceptable installation, testing, and maintenance standards for interior access control devices and intrusion detection and assessment systems.

The NRC disagrees that it needs to relax the design goal for intrusion detection and assessment devices or systems. The NRC considers intrusion detection and assessment to be adequate when a device or system has a design goal of 90 percent probability of detection with 95 percent confidence. This goal accounts for the uncertainties created by factors that occur during testing but not during an actual intrusion attempt. An example is the uncertainty created due to licensee testing personnel having to adhere to personnel safety considerations or standards; a DBT adversary is willing to kill or be killed and therefore could attempt to penetrate an alarm zone in an unsafe, but potentially effective, manner. It is important to note that Revisions 2 and 3 to RG 5.44 clearly indicate that the NRC sometimes considers a slightly lesser detection probability to be acceptable (e.g., 39 successful detections out of 40 performance tests, which results in a detection probability of 88.7 percent with 95 percent confidence; 48 successful detections out of 50 performance tests, which results in a detection probability of 87.9 percent with 95 percent confidence). If an applicant or licensee prefers to use a different design goal for its detection and assessment devices or systems, it is free to demonstrate that a different standard is adequate to defend against threats up to and including the applicable DBT.

There is the potential for some reactor licensees to have SNM in a form that is susceptible to theft and diversion. The NRC does not expect this to be a common situation. However, if applicable, it is important to consider this in designing an effective physical protection program. For those licensees that do have material that can be easily transported or concealed, SNM

detection is needed to mitigate this scenario. The intent is not to require a permanently installed SNM detector at the access point for the material storage area. This threat can be effectively mitigated with a hand-held detector.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.97 (formerly DG-5076) as described above.

Comment Bin 8.5.B: A commenter discussed section C 4.1.1.4 A in DG-5076, stating that other guidance sections in C.4.1.1.5.A and C.4.1.1.5.B, but not the blast protection guidance in C.4.1.1.4.A, discuss standoff distances based on 1.5 times the DBT vehicle-borne explosive device. The commenter recommended consistency throughout the document.

The commenter also expressed that the phrase “defense in depth” is inappropriately applied in the discussion of blast protection and that a more appropriate description would be a safety factor or conservatism. The commenter stated that defense in depth is captured for safety equipment in the safety analysis, but for the purposes of a performance-based physical security (PPS) program applicants should detail the successive layers of detection, delay, and response of the physical security program that would serve the functionality of the lost PPS item. The commenter recommended that the NRC revise the guidance section to request that defense-in-depth analysis be completed for the effects of vehicle-borne explosive devices on the response component of the PPS, which could credit vehicle control measures, fighting position design, personal protective equipment, or programmatic aspects (IDNL-0020).

The commenter also discussed the reference to 10 CFR Part 73 in section C 4.1.1.5.A in the guidance document, stating that physical SSCs must be designed to defend against DBT, but not beyond DBT. The commenter recommended that the language “1.5 times” be removed from guidance sections C 4.1.1.5.A and C 4.1.1.5.B to align with section C 4.1.1.8 and to be consistent with 10 CFR Part 73 (IDNL-0022, IDNL-0025).

The commenter also suggested that RG 1.91, Revision 3, be included in the reference list in section C 4.1.1.5, as it informs the method, parameters, and acceptance criteria of a blast analysis (IDNL-0022).

NRC Response: The NRC agrees, in part, with these comments.

The 1.5 multiplier recommended in RG 5.97 (formerly DG-5076) is intended to ensure that applicants and licensees adequately account for the range of explosive types that are available to threats up to and including the DBT. Some explosives have relative effectiveness factors (RE factors) that reflect those explosives’ potential to create more severe damage than trinitrotoluene (TNT) or dynamite, given the same weight of each explosive. When estimating the physiological response to blasts or the blast, cratering, or blast effects on structures, it is important for applicants and licensees to consider the RE factor of the explosive(s) they are evaluating. Therefore, for consistency, the NRC revised the Blast Protection paragraph of RG 5.97 (formerly DG-5076) to recommend that applicants and licensees refer to Revision 1 to RG 5.69 for guidance regarding the range of the potential hand-carried and vehicle-borne explosives, charge weights, and RE factors against which their physical protection programs and protective strategies need to be designed to defend.

The NRC also agrees that RG 5.97 should cite an acceptable methodology for performing an acceptable blast analysis. Rather than refer to Revision 3 to RG 1.91, the NRC added a

reference for NUREG/CR-7201, “Characterizing Explosive Effects on Underground Structures,” issued September 2015. It would be more prudent to cite NUREG/CR-7201 because table 2-1 has RE factors for explosives that are relevant to security applications, many of which exceed the TNT equivalent. The TNT equivalencies identified in section C.1 of RG 1.91 relate to hazardous substances, not high explosives, and all but one of them are significantly below the TNT equivalent. Applicants or licensees that perform blast analyses based on the TNT equivalencies in RG 1.91 could significantly underestimate the blast effects of a DBT adversary’s explosives capabilities.

The NRC disagrees that recommending that applicants and licensees multiply evaluated hand-carried charge weights by 1.5 is beyond the NRC’s DBT. The NRC considers the multiplication factor of 1.5 to be a reasonable estimate for the range of RE factors associated with the explosives types that a DBT adversary could use against a power reactor facility. For that reason and the factors discussed in the preceding paragraph, the NRC did not remove the 1.5 multiplication factor for hand-carried explosives from RG 5.97 (formerly DG-5076).

The NRC disagrees that defense in depth is inappropriately applied in the blast protection guidance for the response element of an applicant’s or licensee’s physical protection program. The guidance refers to redundancy, independence, separation, and diversity as critical for ensuring that a failure at one response layer does not result in the loss of a licensee’s capability to neutralize threats up to and including the DBT. However, the NRC agrees that applicants and licensees should perform a defense-in-depth analysis to identify the effects of vehicle-borne explosives on the response element of the physical protection program, and the NRC revised the guidance in RG 5.97 to reflect that recommendation.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.97 (formerly DG-5076) as described above.

Comment Bin 8.5.C: A commenter discussed section C 4.1.1.4 A in DG-5076, stating that a maximum engagement range of 200 yards per sector covered is a prescriptive rather than performance-based expectation for exterior defense. The commenter expressed that maximum engagement range proficiency should be identified in the security plan, contingency plans, and training and qualification programs for each armed member of the security force, and that responders should qualify for the maximum engagement range on the listed weapon platform according to the training and qualification program. The commenter said that this approach would ensure that operators are qualified and tested to respond to threats according to the developed security and contingency plans while allowing for flexibility in design strategies to identify the security plan and maximum engagements that best fit an operator’s deployment location and training programs. The commenter requested that the NRC remove the guidance section and retain the current methodologies (IDNL-0019).

Additionally, the commenter requested that the guidance section be clarified to describe what portions of the Remotely Operated Weapons System (ROWS) platform would require at least two lines of power and communication to the weapon platform and imager and to characterize any redundancy expectations for the platform within a functionality defense-in-depth framework and not as a single component or system (IDNL-0021).

NRC Response: The NRC agrees, in part, with these comments.

The NRC agrees that a security responder's engagement range will be determined by numerous factors, including a licensee's designs for its facility's physical protection program and protective strategy; the weapons, equipment, and training it provides to facility security personnel; and the terrain at and immediately surrounding the facility. The NRC recommends a 200-yard maximum engagement range in RG 5.97 (formerly DG-5076) based on decades of operating experience with security drills and exercises at large LWR facilities and the practical challenges they sometimes encountered with greater engagement distances. For example, it can be difficult for facility security personnel to discriminate between an actual threat and other authorized or unauthorized activities when those activities are occurring several hundred yards away, particularly if the activities are also outside the outermost security perimeter. Also, because engagement in the context of threat neutralization typically involves the application of deadly force, it may be problematic under some States' use-of-force laws for security personnel to justify using deadly force, in lieu of other less-lethal use-of-force options that may be available, against a potential threat that is a significant distance from a sabotage location.

Regarding ROWS power and communications redundancies, the NRC revised the guidance in RG 5.97 (formerly DG-5076) to indicate that an uninterrupted power supply is one type of backup power, and having primary and backup power for ROWS is sufficient; the proposed guidance originally indicated that applicants and licensees should design their ROWS to have primary, secondary, and uninterrupted power supply power. The NRC provides high-level guidance in RG 5.97 to help ensure effective functioning of an entire remotely operated weapons system, not any single weapon within that system. Designed redundancies are important measures for overcoming component failures and defending against DBT active insider threats, the latter of which have the capability to exploit design flaws to potentially render the entire ROWS inoperable (i.e., reducing or eliminating the capability to perform interdiction or neutralization). The level of redundancy must be sufficient for the system to effectively perform the function(s) described in an applicant or licensee's physical protection program (e.g., delay, interdiction, neutralization) and required by the facility's protective strategy for effective defense against threats up to and including the DBT. Applicants and licensees may use a ROWS that does not have, for example, more than one image capturing device on any weapon even though the design may include separate and redundant communications methods for image signals. In such cases, the applicant or licensee should ensure that its ROWS design has sufficient weapons platforms to provide effective interdiction and neutralization if any single weapons platform becomes inoperable on any defensive (i.e., interdiction and neutralization) layer. Applicants and licensees should ensure their ROWS redundancies are effective for at least a facility's site-specific adversary interference precluded time (AIPT) or the reasonable assurance of protection time of 8 hours, whichever is longer.

The NRC disagrees that the guidance in section C.4.1.1.4.A. should be removed. The guidance in RG 5.97 (formerly DG-5076) represents one method the NRC would find acceptable for meeting the physical protection-related requirements in 10 CFR 73.100. The guidance clearly states that the information is NRC's recommendations for consideration, and applicants and licensees are free to establish any engagement range for which they can provide a technical basis.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.97 (formerly DG-5076) as described above.

Comment Bin 8.5.D: A commenter stated that the guidance included in section 4 of DG-5076 does not provide performance-based guidance in line with the NRC definition of "performance-based regulation" and with content in NUREG/BR-0303 appendix B and figure B-1. The commenter discussed the NRC's approach to enforcement of RGs, including enforcement expectations based on the use of standard terms such as "shall" for regulatory requirements and "should" for recommendations. The commenter expressed that while "should" is used throughout DG-5076, the use of the term "minimums" and limited examples establish prescriptive expectations.

The commenter suggested that the definition of a performance-based objective's hierarchy would support the implementation of several performance targets and the overall performance objective. The commenter stated that proposed 10 CFR 73.100(b)(1) would provide the fundamental objective in a performance-based hierarchy for a physical protection program, with the functional requirements of detection, delay, and response as cornerstones and with key attributes based on proposed 10 CFR 73.100(b)(3).

The commenter further recommended that the NRC provide key attribute level expectations that center on attributes of the plant physical security rather than specific components or locations, that guidance clearly define acceptable performance-based defense in depth at the cornerstone or key attribute level, and that prescriptive testing expectations be provided as a regulatory backstop for licensees that do not choose a performance-based justification. The commenter stated that the guidance could retain prescriptive expectations for inexperienced applicants as specific examples of measures that may assist in meeting the performance objectives (IDNL-0014).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that performance-based objectives support the implementation of target set requirements. Refer to the NRC's response to Comment Bin 5.1.B for additional information related to the addition of a physical security performance objective that is used to identify target sets. Regarding key attribute level expectations that center on attributes rather than specific locations, NRC guidance documents already provide this option. Specifically, while identification of target sets does focus on specific component and location identification, the physical protection program and protective strategy can protect each target set in its entirety or protect a set of equipment that includes one element from each target set.

The NRC disagrees that RGs create prescriptive expectations. RG 5.97 (formerly DG-5076), like all RGs, describes methods and approaches that the NRC considers acceptable for meeting the requirements, but it does not preclude applicants or licensees from using other methods.

Accordingly, the NRC did not change the rule language or guidance in response to this comment.

Comment Bin 8.5.E: A commenter recommended that objective and measurable security performance standards be kept in DG-5076 to allow for an adaptable implementation that would not require a formal rulemaking to update guidance. The commenter added that this would align with the NRC's broader approach to security rulemaking. The commenter also suggested that other necessary revisions to DG-5076, including updates to terminology, be implemented to ensure applicability to 10 CFR Part 53 while maintaining consistency with existing security frameworks (SCWG-0008).

NRC Response: The NRC agrees with the comment.

The NRC agrees that performance standards should be identified in guidance to support the physical security requirements. In addition, the NRC agrees that consistent terminology should be used.

Accordingly, the NRC did not change the rule language and guidance in response to this comment.

Comment Bin 8.5.F: A commenter stated that DG-5076 should be published as an RG to support 10 CFR Part 53, including the proposed requirements in 10 CFR 53.440(f), “Security by Design” (NEI3-0023).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees that DG-5076 should be published as an RG to support 10 CFR Part 53. RG 5.97 (formerly DG-5076) includes guidance for the requirement in 10 CFR 53.440(f).

Accordingly, the NRC did not revise the rule language or the guidance in response to this comment.

Comment Bin 8.5.G: A commenter recommended that the NRC include a suggestion for applicants in section C 1 in DG-5076 to consider the implementation of onsite and offsite preventative or mitigating strategies to respond to adversary actions, in conjunction with the concepts of the security bounding time and adversary interference preclusion time, in the security by design of the facility to comply with proposed 10 CFR 53.240-53.250. The commenter proposed the following language be included in the bulleted list in section 1.2: “Consideration of SSCs and procedures facilitated by on-site and offsite response organizations to return the facility to a safe state following a security event, inclusive and in addition to those considered to respond to very-unlikely event sequences” (IDNL-0010).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the concepts raised by the commenter are important and should be discussed in guidance. The NRC has already addressed these concepts separately in RG 5.81 (formerly DG-5071). However, the NRC disagrees that additional changes are necessary in RG 5.97 (formerly DG-5076).

Accordingly, the NRC did not change the rule language or the guidance in response to this comment.

Comment Bin 8.5.H: A commenter requested that the phrase “minimizing obstructions for lines of sight for neutralization functions” in section C 1.2 of DG-5076 be revised to incorporate technology-inclusive language, such as, “configuring site layout and facility structures to maximize neutralization functions, such as defensive fighting positions overlapping fields of fire, and minimizing obstructions for lines of sight, or to funnel adversaries to defined engagement

zones.” The commenter also suggested clarifying which plant personnel, such as control room operators or security personnel, are referred to in the phrase “designing for personnel protection or survivability against hazards” and whether personnel protection should be achieved using installed systems or with personal protective equipment.

Additionally, the commenter suggested that the section reference IAEA NSS 8-G Rev. 1, “Preventive and Protective Measures Against Insider Threats,” be included to provide additional guidance in support of insider threat mitigation approaches and that all references be updated to add complete titles, revision numbers, and dates (IDNL-0011).

NRC Response: The NRC agrees with the comment and made the noted changes to RG 5.97 (formerly DG-5076).

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.97 (formerly DG-5076) as described above.

Comment Bin 8.5.I: A commenter discussed section C 2.1.3 in DG-5076, stating that some radiological sources can be excluded from analysis for not constituting an unreasonable risk to public health and safety, such as sources below exempt quantities or meeting discharge limits. The commenter recommended that the NRC revise the section to clarify that the analysis of sources should be consistent with the development of target sets and with the screening criteria described in draft RG 5.81, Revision 2 (IDNL-0012).

NRC Response: The NRC agrees with the comment.

Specifically, the NRC moved guidance from RG 5.97 (formerly DG-5076) to RG 5.81 (formerly DG-5071) to ensure consistent development of target sets. In addition, guidance to identify radiological sources has been added to RG 5.81 (formerly DG-5071) to ensure that only those sources that could result in an unreasonable risk to public health and safety are assessed.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.97 (formerly DG-5076) and RG 5.81 (formerly DG-5071) as described above.

Comment Bin 8.5.J: A commenter expressed concern that section C 2.1.6 in DG-5076 may be burdensome for the many iterations of equipment combinations associated with target sets, adding that the necessary SSCs to prevent release would be included within target sets. The commenter recommended that this section point to existing screening documentation methods in RG 5.81, Revision 2, section 6.3 (IDNL-0013).

NRC Response: The NRC agrees with the comment.

The NRC moved the analysis in RG 5.97 (formerly DG-5076) referred to by the commenter into the target set process in RG 5.81 (formerly DG-5071), consistent with the NRC’s response to Comment Bin 8.5.I.

Accordingly, the NRC did not change the rule language or the guidance in response to this comment.

Comment Bin 8.5.K: A commenter requested that the NRC clarify guidance described in section C 4.1.1.4.C in DG-5076, including whether applicants are required to use the shortest amount of time for the conservative breach mechanism and whether applicants model the fence delay time using the uncertainty distribution of the shortest possible time. The commenter suggested that the NRC instruct applicants to model either possible breach modes probabilistically and assign probabilistic timing to each breach mode, allowing for realistic modeling of attack vectors, or to delay time using the uncertainty distribution of the fastest breach vector to achieve a compromise between conservatism and realism. The commenter suggested that such guidance similarly apply for the security response time.

Additionally, the commenter requested that the NRC replace the statement "Account for the safety and security interfaces in the design to mitigate effects on manual operator actions necessary for public health and safety" with the following language: "Considering the design and operation of the facility and the necessity of operator actions that may be interrupted by an adversary, and plan delay features in accordance with guidance on the crediting of operator actions found in RG 5.81 rev. 2 to support necessary functions." The commenter further suggested that the NRC consider adding language to the security by design portion of the guidance document to protect operators from adversary interference (IDNL-0016).

NRC Response: The NRC agrees, in part, with the comment.

The NRC revised the guidance in RG 5.97 (formerly DG-5076) regarding manual operator actions and the safety and security interface to recommend applicants and licensees design and implement delay features consistent with the guidance for crediting operator actions in RG 5.81 (formerly DG-5071).

The NRC disagrees that additional guidance is needed related to protecting operators from adversary interference and, specifically, finds guidance related to delays and response in RG 5.97 (formerly DG-5076) sufficient to support determining credible operator actions in RG 5.81 (formerly DG-5071).

The NRC disagrees that additional clarification is necessary in a publicly available document regarding the barrier delay times that applicants and licensees should use to design their facility physical protection programs and protective strategies. The NRC considers the guidance in section 3.7.5 of Revision 1 to RG 5.54, "Standard Format and Content of Safeguards Contingency Plans for Nuclear Power Plants," section 6.1 of RG 5.81 (formerly DG-5071), and other nonpublicly available guidance documents to be sufficient for applicants and licensees to know to credit only the shortest delay times based on DBT attributes and capabilities, adversary path strategies, breaching methods most advantageous to the adversary, and other site-specific factors described in those guidance documents.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.97 (formerly DG-5076) as described above.

Comment Bin 8.5.L: A commenter discussed section C 4.1.1.2 of DG-5076, stating that no guidance or requirement for two independent and diverse cameras for each alarm zone for interior zones could be found in existing DOE orders. The commenter expressed concern that additional camera coverage could lead to increased equipment, maintenance protocol, and

costs with minimal improvements to the effectiveness of the physical protection system. The commenter suggested that it is important to focus on closed-circuit television (CCTV) positioning in the monitored area to support proper identification of shapes and assessment of intrusions, and that overlapping CCTV coverage could be used in areas with extended distances or dim lighting. The commenter explained that a redundancy hardware expectation would not be required, as it could be conservatively assumed that there is an intrusion requiring assessment by security personnel and possible contingency or armed response if a CCTV fails following an alarm. The commenter stated that it should not be necessary to require a second or third diverse CCTV, and requested that the NRC allow performance-based flexibility to the applicant in design to ensure that adequate assessment is in place at entry points into protected and vital areas and along credible pathways (IDNL-0018).

NRC Response: The NRC disagrees with the comment.

Applicants and licensees establish and implement risk-informed compensatory measures for security equipment degradations or failures, and the NRC does not make assumptions about whether an applicant or licensee will design its physical protection program or protective strategy to automatically consider alarm assessment equipment failures as unauthorized intrusions. Recommending assessment cameras (redundant or not) along all credible pathways could result in the same significant costs and minimal security benefit that the commenter is concerned about. The guidance in section C.4.1.1.2.A. regarding the design of an alarm assessment system focuses on redundancy for two types of locations: (1) the critical detection point and (2) any alarmed areas inside a facility (e.g., vital areas). The NRC expects applicants and licensees to consider redundant assessment cameras for those locations because effectively assessing threats there will likely be important to the initial or evolving security response. For example, some applicants and licensees may want to design their physical protection programs and protective strategies with fewer armed security responders than potential contingency response positions; increasing the likelihood of accurate intrusion assessments at the critical detection point and any interior alarmed area could enable effective responder deployment during the initial response, as well as during any subsequent redeployment(s) that may be necessary. Additionally, licensees and applicants may always propose alternative methods for meeting the NRC's regulations that differ from those described in guidance.

Accordingly, the NRC did not change the rule language or the guidance in response to this comment.

Comment Bin 8.5.M: A commenter stated that section 4.1.3.2 of DG-5076 seems to expect an operator to perform thorough vehicle searches at the owner-controlled area (OCA) boundary, but suggested that discussion instead focus on performance-based and design/facility-specific vehicle searches at the boundary of the vehicle barrier(s), in consideration of standoff distance and facility design differences between smaller advanced reactors and traditional large LWRs (IDNL-0026).

NRC Response: The NRC disagrees with the comment.

The first paragraph in section 4.1.3. of RG 5.97 (formerly DG-5076) indicates that individual, vehicle, and material searches need to occur at each access control point or portal. Therefore, if an applicant or licensee's physical protection program design requires OCA searches, they

would be performed at the OCA access control point (e.g., at a vehicle barrier boundary). The OCA access control point may or may not be located at the OCA boundary.

Accordingly, the NRC did not change the rule language or the guidance in response to this comment.

Comment Bin 8.5.N: A commenter discussed that DG-5076 presents conflicting guidance regarding a bounding analysis for a DBT attack, including that scenarios should both assume the loss of systems (with no consideration for methods or materials used by an adversary) (described in section C 2.1.1) and also consider target sets with adversary actions to enable radionuclide release (described in section C 2.1.5). The commenter recommended that section C 2.1.1 in DG-5076 be revised to provide clarity to applicants and regulatory consistency across advanced reactor technologies.

The commenter also suggested that the guidance in RG 5.81 better informs the crediting of operator actions than the rule language proposed in 10 CFR 53.560[860](a)(2)(ii) (IDNL-0007).

NRC Response: The NRC agrees with the comment.

As described in the response to Comment Bin 3.6.3.3.C, the NRC has removed the requirement for a consequence analysis in 10 CFR 53.860(a)(2)(ii) from the final rule and instead has included a general performance objective that will inform the identification of target sets in 10 CFR 73.100 in response to Comment Bin 5.1.B. RG 5.81 (formerly DG-5071) identifies assumptions a licensee can consider during a DBT attack to perform the target set analysis.

Accordingly, the NRC did not change the rule language or the guidance in response to this comment.

Comment Bin 8.5.O: A commenter stated that the guidance on security by design in DG-5076 does not appear to address the function of safety system design in line with the 2008 Commission Policy on the Regulation of Advanced Reactors. The commenter suggested that the NRC revisit section C1 of DG-5076 to include a bullet with language similar to the following: “incorporation of security goals into the design of engineered safety systems and operational programs to reduce vulnerabilities or increase resistance to the design basis threat of radiological sabotage, and consider safety capabilities to prevent or mitigate consequences from adversary actions….” The commenter suggested that such language could help integrate security with safety in reactor system and associated facility design and support a full implementation of security by design from the target identification level to the implementation of security and the application of security SSCs and programs to close remaining gaps not addressed by design features (IDNL-0009).

NRC Response: The NRC agrees with this comment and updated RG 5.97 (formerly DG-5076).

Accordingly, the NRC did not change the rule language in response to this comment but updated the guidance as noted above.

Comment Bin 8.5.P: A commenter suggested that additional guidance is needed to address graded approaches for EP and security programs under 10 CFR Part 53. The commenter stated that revisions should be made to DG-5076 and RG 1.242 to clarify that the spectrum of events should be categorized to potential offsite impacts and evaluated against protective actions, as appropriate. The commenter additionally requested that updated guidance clarify that the existence of sequences with the potential for offsite consequences is not a direct indicator that a reduced-size emergency planning zone (EPZ) is inappropriate, as a reduced-size EPZ is not based on a strict dose threshold, and that significant security events be considered relative to protective actions for risk insights and defense in depth (BI1-0024).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees with establishing clear rule language and guidance on addressing interactions between the graded approaches for emergency planning and security programs. As described in proposed rule FRN section VI, "Specific Requests for Comments" (Part 53, Subpart F—Emergency Preparedness and Security Programs 89 FR 86985), the NRC is planning to issue a draft revision of RG 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities," for public comment. The NRC plans to issue this draft revision after the publication of the 10 CFR Part 53 final rule.

The planned revision to RG 1.242 will add guidance for 10 CFR Part 53 applicants and licensees to address interactions between graded approaches for emergency planning and security programs. During the development of the revision to RG 1.242, the NRC will consider categorization of the spectrum of events with potential offsite impacts and evaluation against protective actions. Additional guidance describing that each of the criteria in 10 CFR 50.33(g)(2)(i)(A) and (B) are to be considered holistically (none as a "strict limit"); that the existence of sequences with the potential for offsite consequences is not a direct indicator that a reduced-size EPZ is inappropriate, as a reduced-size EPZ is not based on a strict dose threshold; and that significant security events be considered relative to protective actions for risk insights and defense in depth will also be considered.

The NRC agrees that the existence of sequences that have the potential for offsite consequences is not a direct indicator that a reduced-size EPZ is not appropriate and a reduced-size EPZ is based on risk insights and the potential for protective actions to mitigate consequences, not based on a strict dose threshold.

The NRC disagrees that the spectrum of events should be categorized in RG 5.97 (formerly DG-5076) for offsite release. RG 5.81 (formerly DG-5071) provides guidance for licensees on how to use postulated security events to assess potential offsite consequences.

Accordingly, the NRC did not change the rule language or guidance in response to this comment.

8.6. DG-5078, "Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53"

No comments are associated with this issue.

8.7. DRO-ISG-2023-01, “Operator Licensing Programs”

Comment Bin 8.7.A: For criterion 2.3 on page 8 of DRO-ISG-2023-01, a commenter stated that “instructional designer” and “human factors specialist” are not defined and requested clarification on whether an instructor who develops training meets the intent of the criterion (NEI2-0156).

NRC Response: The NRC agrees with the comment. The terms “instructional designer” and “human factors specialist” were not defined in DRO-ISG-2023-01 as proposed.

The intent of criterion 2.3 is for someone with the necessary expertise and/or education regarding design of the overall training program and not development of the technical training content per se. An instructor who develops the technical content for a given training and delivers that training content would not necessarily have the required expertise.

Accordingly, the NRC updated DRO-ISG-2023-01 to define the terms “instructional designer” and “human factors specialist” in response to this comment.

Comment Bin 8.7.B: For the acceptance criteria in DRO-ISG-2023-01, a commenter requested that the NRC explain the purpose of a requirement to provide information on content excluded from the test method and examination. Additionally, for both criterion 2.7 on page 11 and criterion 9.3 on page 26, the commenter suggested the requirements be removed if there is no value added or no compelling regulatory reason to increase the administrative burden (NEI2-0157).

NRC Response: The NRC disagrees with the comment.

The NRC needs to verify that the information determined to be excluded from the examination is appropriate for that exclusion and that none of that information should actually be included in the examination. In other words, the NRC needs to verify that there is no information that needs to be tested that was inappropriately excluded from testing. The way for the NRC to verify this is for the NRC to be provided with the information that was excluded from testing so that the NRC can review this information and verify that the information is not required to be tested to ensure operator competence.

Accordingly, the NRC did not change the guidance in response to this comment.

Comment Bin 8.7.C: For the statement regarding the sampling content domain found in the third bullet on page 13, criterion 2.18 on page 14, and criterion 2.18 on page 34 of DRO-ISG-2023-01, a commenter proposed that the language “and explain how examination security concerns related to predictability are addressed” be removed from the statement, as predictability is a desirable examination condition which ensures no knowledge, skills, and abilities gaps (NEI2-0158).

NRC Response: The NRC disagrees with the comment.

Although it is true that, if there is no sampling, the applicant will know the scope of the examination, there are other aspects to predictability that would still need to be met to prevent

the applicant from just memorizing patterns rather than mastering the necessary knowledge. An example of unacceptable predictability would be the same questions with the same answers in the same order repeated on every examination. This would be an unacceptable level of predictability because the applicant could just memorize the answers in order and not learn any of the material. Therefore, the expectation is that the submitter would discuss methods to reduce this kind of predictability (e.g., overlap restrictions, restrictions on the use of bank questions, requiring variations in the ordering of questions and answers).

Accordingly, the NRC did not change the guidance in response to this comment.

Comment Bin 8.7.D: A commenter stated that the DRO-ISG-2023-01 does not acknowledge whether an operator licensing or general licensing training program accredited by the National Nuclear Accrediting Board (NNAB) would be considered a "Commission-approved training program." The commenter proposed that the NRC provide clarification, such as by defining "Commission-approved training program" or by incorporating relevant language from NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," into the guidance. Additionally, the commenter discussed that the guidance is applicable to operator licenses, including the reactor operator, senior reactor operator, and general licensed operator, and that it would not include the proposed general personnel training requirements from 10 CFR 53.830 (NEI2-0155, NEI2-0077, NEI2-0082).

NRC Response: The NRC disagrees with these comments.

The Commission has not had the opportunity to review an NNAB accreditation program for training licensed operators at advanced reactor facilities or an opportunity to determine if such a program is sufficient to warrant Commission approval. Once such a program is provided to the Commission, the NRC will review the program and, if warranted, provide such approval at that time. For facilities that plan to use the current NNAB accreditation process, Commission approval of that process is already documented as discussed in the comment and additional approval is not required.

Accordingly, the NRC did not change the guidance in response to these comments.

8.8. DRO-ISG-2023-02, "ISG Augmenting NUREG-1791, 'Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),' for Licensing Commercial Nuclear Plants under 10 CFR Part 53"

Comment Bin 8.8.A: A commenter expressed that DRO-ISG-2023-02 is not clear about the meaning of "on-shift support" for engineering expertise. The commenter requested that the NRC clarify that engineering expertise will frequently be located remotely and on-call and suggested that NUREG-0737 discussion about conditions necessitating the shift technical advisor (STA) be incorporated into the guidance to reflect recent experience of an advanced reactor design licensed under 10 CFR Parts 50 and 52 (NEI2-0160).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the guidance in DRO-ISG-2023-02 does not state where a person fulfilling the engineering expertise must be located. The regulatory framework of 10 CFR Part 53 is technology inclusive; as a result, neither the rule language in 10 CFR 53.730(f)(1) nor the guidance in DRO-ISG-2023-02 prescribe a location for engineering expertise. The NRC expects future applicants to explain how engineering expertise will be available to the on-shift operating personnel, including details of the position such as location, expected response time, access to plant status information, and methods of communication, as part of the staffing plan proposed for their design. This is evident in the staff review criteria in section 7.3 of DRO-ISG-2023-02, which acknowledges that personnel fulfilling the engineering expertise position may be located off site or on site.

The NRC disagrees that DRO-ISG-2023-02 needs to include information from NUREG-0737 about the intent for the STA to be an interim measure until long-term actions were complete. NUREG-0737 states that, “The need for the STA position may be eliminated when the qualifications of the shift supervisors and senior operators have been upgraded and the man-machine interface in the control room has been acceptably upgraded. However, until those long-term improvements are attained, the need for an STA program will continue.” Guidance and criteria specifying the level of upgrading required for licensed operators and the control room interfaces that would be acceptable to the NRC for eliminating the STA position were never promulgated and subsequent Commission policy statements affirmed the value of maintaining the STA position.

The requirement for engineering expertise in 10 CFR 53.730(f)(1) is not equivalent to the STA position at large LWRs. As explained in NUREG-0737, the original purpose of the STA, in the aftermath of the accident at Three Mile Island Unit 2, was to improve the ability of the on-shift operating crew to recognize, diagnose, and effectively respond to plant transients and abnormal conditions. With an increased reliance on automation and passive safety features, the staff expects that reactors licensed under 10 CFR Part 53 will have very few (if any) risk-significant operator actions during plant transients and abnormal events. The purpose of the engineering expertise requirement is for a qualified person to provide on-shift operators technical support if a situation arises that is not covered by operator training or operating procedures. The engineering expertise requirement is more aligned with the 1985 “Commission Policy Statement on Engineering Expertise on Shift,” published in the *Federal Register* (50 FR 43621). In this policy statement, the Commission stressed the importance of providing engineering and accident assessment expertise on shift and provided two options to satisfy this intent: a combined senior reactor operator/STA position or a dedicated STA position. The NRC added clarifying information to part II, section 1.4 of DRO-ISG-2023-02 where this Commission policy statement is listed in response to this comment.

The NRC agrees that DRO-ISG-2023-02 does not include a reference to a recent topical report, reviewed by the NRC, to eliminate the STA position for an SMR design certification applicant. Therefore, the NRC added a reference to SECY-21-0039, “Elimination of the STA for the NuScale Design,” to section 1.4 of DRO-ISG-2023-002 in response to this comment.

Accordingly, the NRC changed the guidance in response to this comment.

Comment Bin 8.8.B: A commenter recommended that response time as mentioned in the fourth bullet in section 7.2 on page 16 of DRO-ISG-2023-02 include the time required to arrive on site or to make communication with the control center (NEI2-0162).

NRC Response: The NRC agrees with the comment.

The NRC agrees that the guidance in DRO-ISG-2023-02 should include more information about response time.

Accordingly, the NRC revised the review criteria for staffing plan submittals in part II, section 1.3 of DRO-ISG-2023-02 to provide more information about response time based on the location of personnel fulfilling the engineering expertise requirement in response to this comment.

Comment Bin 8.8.C: A commenter wrote that the background section of DRO-ISG-2023-02 still discusses Frameworks A and B under 10 CFR Part 53 and proposed that the guidance be revised to align with the proposed regulatory language in 10 CFR Part 53 (NEI2-0159).

NRC Response: The NRC agrees with this comment.

DRO-ISG-2023-02 should not reference Frameworks A and B.

Accordingly, the NRC revised DRO-ISG-2023-02 by removing the noted reference in response to this comment.

Comment Bin 8.8.D: A commenter requested that the NRC remove “on shift” from the bullet on engineering expertise on shift on page 11 of DRO-ISG-2023-02, as use of the term is inconsistent with earlier guidance language involving staffing plans The commenter suggested that the discussion of the Commission Policy Statement on Engineering Expertise in DRO-ISG-2023-02 instead focus on what engineering expertise looks like (NEI2-0161). The commenter requested that the term “engineering expertise” with definition be provided in the glossary (NEI2-0163).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the recommendation to remove the term “on-shift” from DRO-ISG-2023-02. The use of the term “on-shift” is a technology-inclusive means of stating that the engineering expertise is available to the operating crew that is immediately responsible for monitoring or controlling the reactor unit(s). The NRC added this explanation of “on-shift” to part II, section 1.3 of DRO-ISG-2023-02 to clarify the reason for using the term “on-shift” in 10 CFR 53.730(f)(1).

The NRC agrees, in part, with the comment on the Commission Policy Statement on Engineering Expertise which is listed as a reference in part II, section 1.4 of DRO-ISG-2023-02. The NRC added a reference to “Commission Policy Statement on Engineering Expertise on Shift,” published in the *Federal Register* (50 FR 43621) on October 28, 1985, because it contains useful information about the Commission’s preference for the continued use of the STA position and the importance of having engineering and accident assessment expertise available to the operating crew at all nuclear power plants. The 10 CFR 53.730(f)(1) requirement for engineering expertise is based, in part, on this policy statement. Accordingly, the NRC revised the guidance in response to this comment. The NRC revised the bullet in DRO-ISG-2023-02 to explain why the Commission Policy Statement is listed as a reference.

The NRC disagrees with the request to define the term “engineering expertise” because the NRC wants to allow 10 CFR Part 53 applicants to determine how best to satisfy 10 CFR 53.730(f)(1) for their designs and a definition has the potential to introduce limitations and restrictions. Accordingly, the NRC did not change the guidance in response to this comment.

8.9. DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans”

Comment Bin 8.9.A: For the purpose section, the first paragraph of the rationale, and the first paragraph of the guidance overview in DRO-ISG-2023-03, a commenter stated that the use of the term “diversity” incorrectly implies the concept of “diversity and defense-in-depth” in discussion of differences in reactor technology that will be submitted for review. The commenter requested that “diversity” be replaced, but did not specify an alternative (NEI2-0164, NEI2-0166, NEI2-0169).

NRC Response: The NRC agrees with these comments.

The intent of this statement in DRO-ISG-2023-03 is to describe the need for flexibility in the human factors engineering (HFE) licensing reviews due to the differences in reactor technology and is not intended to imply the use of diversity as it relates to defense in depth.

Accordingly, the NRC revised DRO-ISG-2023-03 in response to these comments.

Comment Bin 8.9.B: A commenter discussed the applicability section of DRO-ISG-2023-03, including that the ISG is limited to applicants under 10 CFR Part 53 and that Division of Advanced Reactors and Non-Power Production or Utilization Facilities (DANU)-ISG-2022-05 is applicable to applicants under 10 CFR Parts 50 and 52. The commenter stated that DRO-ISG-2023-03 describes sampling methodology that could be used for any advanced reactor applicant and requested that the applicability of the guidance be expanded to include applicants under 10 CFR Parts 50 and 52 (NEI2-0167).

Relatedly, for the guidance overview section, the commenter stated that if the applicability of DRO-ISG-2023-03 is not expanded to include applicants under 10 CFR Parts 50 and 52, then the reference to DANU-ISG-2022-01 for guidance for preapplication engagement is not applicable and should be removed (NEI2-0170).

NRC Response: The NRC agrees with these comments.

DRO-ISG-2023-03, although developed for 10 CFR Part 53, may facilitate staff reviews for non-large-light-water power reactor applications when such applications are submitted under 10 CFR Part 50 or 52, as appropriate to the design challenges posed by new or novel facility designs. The Background section of DRO-ISG-2023-03 acknowledges that NUREG-0711, the guidance typically used for reviews of large light-water reactors, may result in reviews for non-LWRs that do not reflect the lower risk associated with these designs. Use of DRO-ISG-2023-03 to inform staff reviews of non-large-light-water power reactor applications under 10 CFR Part 50 or 52 may enable a streamlined review.

Accordingly, the NRC updated DRO-ISG-2023-03 in response to these comments.

Comment Bin 8.9.C: For the guidance on facility characterization in DRO-ISG-2023-03, a commenter requested that the NRC define how reviewers will determine “important” characteristics, as “important” is a subjective term and lacks a supporting definition or criteria (NEI2-0172).

Relatedly, for the subsection on safety analyses, methods, and results, the commenter requested that the NRC define how significance is determined, including clarifying whether this refers to safety significance or risk significance (NEI2-0173).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the need to define “important” in the context of the facility characterization section of this ISG. DRO-ISG-2023-03 is guidance to the NRC staff to aid it in appropriate scaling of the HFE review. The term “important” in the context of developing the facility characterization refers to what is important to the HFE of the design and its operation. Importance is based on the characteristics of the specific facility design and the human actions required to support plant safety or emergency response functions.

The NRC agrees that the term “significant” could be clarified in DRO-ISG-2023-03 to be consistent with 10 CFR 53.450(e)(4). The terms “risk significance” and “safety significance” are not defined in 10 CFR Part 53 to provide the applicants flexibility in defining these terms. The LWR PRA standard (American Society of Mechanical Engineers (ASME)/ American Nuclear Society (ANS) RA-Sa-2009 as endorsed in RG 1.200) and the non-LWR PRA standard (ASME/ANS RA-S-1.4-2021 as endorsed in trial RG 1.247) provide industry consensus definitions of risk-significance event sequences.

Accordingly, the NRC clarified DRO-ISG-2023-003 in response to these comments.

Comment Bin 8.9.D: For the acceptance criteria in DRO-ISG-2023-03, a commenter discussed that notes three through five are not used in table 1 and suggested they be removed (NEI2-0168).

NRC Response: The NRC agrees, in part, with the comment.

These notes are not used in table 1 but are used in tables 2 and 3.

Accordingly, the NRC clarified the use of the “notes” column in DRO-ISG-2023-03 in response to this comment.

Comment Bin 8.9.E: For the application acceptance review in DRO-ISG-2023-03, a commenter requested that the NRC remove the first paragraph and the first sentence of the second paragraph to avoid duplicating generic guidance statements across multiple documents (NEI2-0171).

NRC Response: The NRC agrees, in part, with the comment.

The first sentence of the first paragraph and a portion of the first sentence of the second paragraph duplicate generic guidance statements. However, other information within the first paragraph is not duplicative and contains important information for the reviewer and should be retained.

Accordingly, the NRC revised DRO-ISG-2023-03 in response to this comment.

Comment Bin 8.9.F: A commenter proposed that the NRC remove the phrase “and large commercial aircraft impacts” in the subsection on identification of human actions important to safety in DRO-ISG-2023-03, as these impacts will be considered in the safety analysis as an external hazard (NEI2-0174).

NRC Response: The NRC agrees with the comment.

This is consistent with the NRC’s removal of the requirements in proposed 10 CFR 53.440(j) which would have required applicants to provide design features to limit the release of radionuclides assuming the impact of a large, commercial aircraft. See also response to Comment Bin 3.3.2.1.C.

Accordingly, the NRC is making changes to the guidance document in response to this comment. Specifically, the NRC has removed the phrase “and large commercial aircraft impacts” in the noted section of DRO-ISG-2023-03.

Comment Bin 8.9.G: For appendix A-1 to DRO-ISG-2023-03, a commenter recommended that the NRC include figure A-1, which is referenced in the second paragraph of the appendix but is not presented in the guidance document (NEI2-0177).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that figure A-1 is referenced but not presented in the guidance. However, the NRC believes that the reference to the figure is unnecessary to include in DRO-ISG-2023-03, appendix A-1.

Accordingly, the NRC revised the guidance document in response to this comment to remove the reference to figure A-1.

Comment Bin 8.9.H: A commenter stated that the background section of DRO-ISG-2023-03 discusses limitations of reviews for advanced reactors under NUREG-0711 and NUREG-0800 chapter 18. The commenter added that DRO-ISG-2023-03 appears to rely on a NUREG-0711 HFE program but lacks guidance for reviewing HFE program elements and suggested that acceptance criteria for HFE program elements be provided (NEI2-0165).

NRC Response: The NRC disagrees with the comment.

The guidance provided in DRO-ISG-2023-03 allows for scaling of NRC review efforts, thus ensuring that the HFE review is informed by risk insights and scoped appropriately based upon the particulars of the design under review. Further, the objective of the fourth step, grading, is to select the HFE review standards and guidance documents that will be applied to the assessment of each target and the HFE activity to be included within the scope of the review. In the application, the applicant may identify the specific HFE standards and guidance documents that were applied, or will be applied, to the development and implementation of the design under review. This may or may not include the guidance and acceptance criteria for the HFE program elements in NUREG-0711.

Accordingly, the NRC did not change DRO-ISG-2023-03 in response to this comment.

Comment Bin 8.9.I: For the fourth paragraph in the section on the grading process and reviewer responsibilities in DRO-ISG-2023-03, a commenter stated that current guidance will result in a selective, inefficient, and unpredictable review process. The commenter suggested that the NRC develop a process in which applicants propose standards and guidance for developing the HFE program, which the NRC would review for acceptance (NEI2-0176).

NRC Response: The NRC disagrees with this comment.

The guidance provided in DRO-ISG-2023-03 allows for scaling of NRC review efforts, ensuring that the HFE review is informed by risk insights and appropriately scoped based upon the particulars of the design under review. The guidance provided in DRO-ISG-2023-03 reduces the effort needed to conduct license reviews for facilities licensing under 10 CFR Part 53 as compared to facilities licensing under 10 CFR Part 50 or 52. This is expected to expedite the time it takes to conduct technical reviews and lower costs by focusing on novel features and risk-important features of the design.

Further, the objective of the fourth step, grading, is to identify HFE review standards and guidance documents that will be applied to the assessment of each target and the HFE activity to be included in the scope of the review. In the application, the applicant may identify the specific HFE standards and guidance documents that were applied, or will be applied, to the development and implementation of the design under review. DRO-ISG-2023-03, Appendix D, “Grading,” addresses the process of reviewing the proposed use of standards or guidance documents not published or endorsed by the NRC.

Accordingly, the NRC did not change DRO-ISG-2023-03 in response to this comment.

Comment Bin 8.9.J: A commenter requested a process diagram demonstrating the overall design process for an HFE program, including required information and the responsible party for each step. The commenter stated the current process steps and the relationship between DRO-ISG-2023-03 and NUREG-0711 are confusing. The commenter specifically stated that the use of appendix C or NUREG-0711 is unclear if it is neither all-inclusive nor a minimum set of criteria (NEI2-0175).

NRC Response: The NRC disagrees with this comment.

Although NUREG-0711 is one potential design process the industry can use, it is not the only one nor is it required to be used and, therefore, adding a process diagram based upon NUREG-0711's design process would be unnecessarily prescriptive.

Accordingly, the NRC did not change DRO-ISG-2023-03 in response to this comment.

8.10. Other comments on accompanying guidance, including guidance published prior to the final rule

Comment Bin 8.10.A: A few commenters discussed that updates to existing RGs, standard review plans (SRPs), and other NRC guidance to reflect methodology acceptable under 10 CFR Part 53 would increase regulatory certainty (NEI2-0008, NEI3-0015, USNIC2-0018). Relatedly, a commenter requested updated NUREGs and RGs to include scalability guidance for smaller reactors with lower risk profiles, technology demonstrations, and risk-informed review examples (BI1-0017). A commenter stated that all current RGs should be acceptable for use for at least certain reactor types under 10 CFR Part 53 and provided a list of RGs requiring updates to support 10 CFR Part 53 applications.

The commenter listed the following guidance as the highest priority for updates:

- RG 1.233 for updated guidance on functional design criteria. The commenter suggested the NRC develop an addendum to NEI 18-04 to address LWRs in one guide to support regulatory clarity. The commenter also stated that NEI 18-04 could be updated if necessary to reference dose limits from 10 CFR 50.34 and 10 CFR 53.210 in support of updates to RG 1.233, but expressed belief that this would not be necessary.

- RG 1.253 and associated guidance for updated content of application guidance for both LMP and non-LMP applicants under 10 CFR Part 53. The commenter suggested that the NRC develop an addendum to NEI 21-07 to address LWRs and meet the Commission directive for flexibility for 10 CFR Part 53 applicants, in line with discussion in the proposed rule. Specifically, the commenter requested that the language "The level of detail in a [construction permit] CP PRA should be established using the process provided in Section 3 of ASME/ANS RA-S-1.4-2021, 'Risk Assessment Application Process.'" from RG 1.253 be extended to all LMP applicants.

- RG 1.232 for changes in scope to address LWRs. The commenter discussed a subset of the advanced reactor design criteria (ARDC) would meet the proposed functional design criteria requirements of 10 CFR Part 53, adding that the X-Energy Principal Design Criteria Topical Report provides details on ARDC considered functional design criteria and which criteria should be handled as special treatments (NEI2-0008, NEI3-0015).

A commenter provided detailed feedback on the design and analysis process under 10 CFR Part 53, with the goal of presenting a flexible framework for a technology-inclusive, risk-informed, and performance-based design and analysis process for assessing the safety adequacy of the design under 10 CFR Part 53. The commenter noted that while changes made to the proposed rule in response to SRM-SECY-23-0021 are a step in the right direction, RG 1.253 only allows flexibility for construction permit applicants following the LMP framework, and presumes an all-hazards, all-modes, all-sources PRA for operating license and combined license applicants. The commenter stated language in RG 1.253 will need to be updated to extend flexibility to all LMP applicants (NEI3-0003).

One commenter listed the following guidance as high priority for updates regarding the acceptability of PRA to support broader adoption of 10 CFR Part 53:

- RG 1.247 for lessons learned from the peer-review experience and to address comments provided by industry on the trial use regulatory guidance.

- RG 1.200 for consideration of stakeholder input regarding a method to combine full power internal events with bounding and screening approaches to achieve quantitative health objectives (NEI2-0008, NEI3-00015). A commenter added that while RG 1.247 could provide one acceptable approach to meet the proposed requirement 10 CFR 53.450(a), an updated RG 1.200 should provide a similar path for LWRs to meet the provision. The commenter further stated that an appropriately written DG-1413 and DG-1414, supplemented by traditional hazard analysis, would provide another approach (NEI3-0007). The commenter stated that DG-1413 and DG-1414 would require significant changes made after a series of workshops with industry stakeholders, or an alternative pathway would be endorsement of a methodology similar to NUREG-1537 (NEI3-0015).

- RG 1.174 for consideration of stakeholder input, to be provided in 2025, proposing a technology-inclusive risk metric and performance objectives to provide confidence quantitative health objectives will be met. The commenter added that NRC endorsement of this approach would be important in meeting proposed requirements in 10 CFR 53.220 and could also endorse core damage frequency and large early release frequency as a means to satisfy the proposed requirement for a comprehensive risk metric.

- RG 1.203 for being an acceptable means to meet the proposed DBA requirements in 10 CFR Part 53 (NEI2-0008, NEI3-0015, NEI3-0018).

- RG 1.183 and other guidance involving source term calculations for being potential means to meet the proposed DBA requirements in 10 CFR Part 53 (NEI2-0008).

The commenters also discussed required guidance changes to endorse the codes and standards from 10 CFR 50.55a for use in 10 CFR Part 53:

- RG 1.26, RG 1.28, and RG 1.33 endorsing Nuclear Quality Assurance (NQA)-1 standard (NEI2-0008).

- RG 1.84 endorsing ASME Section III Code Cases.

- RG 1.87 endorsing ASME Section 3 Division 5.

- RG 1.97 endorsing Institute of Electrical and Electronics Engineers (IEEE) 497-2025.

- RG 1.192 endorsing the ASME OM Code, or preferably a future update that endorses OM-2.

- RG 1.208 or RG 1.251 endorsing American Society of Civil Engineers (ASCE) 43 and ASCE 4 (NEI2-0008).

- RG 1.246 endorsing ASME Section XI Division 2 (NEI2-0008, NEI3-0021). The commenter stated that applicability should be extended to LWRs (NEI2-0008). The

commenter added that additional guidance must be developed to support implementation of an integrity assessment program, if proposed 10 CFR 53.870 and associated requirements remain (NEI3-0021).

- Digital instrumentation and control RGs, including the following:
    - RG 1.152 endorsing IEEE 7-4.3.2 for digital system requirements.
    - RGs 1.168 through 1.173 endorsing standards for software lifecycle.
    - RG 1.250 endorsing NEI 17-06 for use of International Electrotechnical Commission 61508 Safety Integrity Level certified equipment (NEI2-0008).

A commenter discussed that they developed a white paper describing different approaches and methodologies to address the TI-RIPB 10 CFR Part 53 requirements (NEI3-0001, NEI3-0016). The commenter stated that NEI 18-04, endorsed in RG 1.233 for 10 CFR Parts 50 and 52, provides one approach, with the white paper outlining an additional three example approaches that also include a selection of LBEs, safety SSCs and associated risk-informed special treatments, and determination of defense-in-depth adequacy, each with varying reliance on deterministic safety analyses (NEI3-0001, NEI3-0017).

The commenter added that the white paper provides a roadmap identifying regulatory guidance that should be updated and the specific changes to the guidance needed to accommodate each licensing approach and to increase flexibility in meeting the proposed 10 CFR Part 53 requirements (NEI3-0001, NEI3-0016). The commenter additionally discussed that the white paper identifies regulatory guidance updates required to address PRA acceptability, allow for more traditional safety analysis approaches and bounding assessments, and provide regulatory clarity for licensing (NEI3-0006, NEI3-0017).

The commenter provided an overview of the four different licensing approaches presented in the white paper:

- Example A: A process that corresponds to that detailed in NEI 18-04, in which PRA plays a foundational role in informing various aspects of safety, with deterministic analyses playing essential complementary parts;
- Example B: A process similar to the one presented in NEI 18-04, except that the PRA plays a confirmatory role. The primary emphasis is on the use of deterministic analyses for the safety case, with insights from the PRA providing key considerations in the safety case;
- Example C: A process that utilizes standards and guidance developed by the IAEA, in which deterministic assessments, including a comprehensive assessment of defense in depth, are supplemented and confirmed by insights from the PRA (called a probabilistic safety assessment by the IAEA); and
- Example D: A process that focuses on the identification and deterministic analysis of a bounding accident (or, potentially, on a set of such accidents). In this example, PRA is used to a more limited extent to provide perspective on specific aspects of the plant's safety case, since the deterministic analyses are more bounding/conservative than in the other examples.

The commenter discussed that all these methodologies should be able to meet the intent of the 10 CFR Part 53 requirements, but with a need for additional guidance to be developed, including for implementing the IAEA approach (NEI3-0006, NEI3-0017). The commenter specified that proposed 10 CFR 53.210 through 53.250, 10 CFR 53.210 through 53.250, 10 CFR 53.450 through 53.460, and 10 CFR 53.480 would require different guidance depending on which of the four approaches would be applied (NEI3-0006).

The commenter added that testing via table-top exercises of the guidance would be beneficial to ensure that it is practical and effective and can evolve with 10 CFR Part 53 (NEI3-0017). The commenter stated that appendix B to the white paper lists the regulatory guidance expected to be followed to meet requirements in proposed subparts B and C in 10 CFR Part 53, as well as other guidance documents that should be updated to be more technology inclusive (NEI3-0006, NEI3-0018).

The commenter stated that the following guidance would require updates to meet proposed 10 CFR 53.440(c): RG 1.40, RG 1.73, RG 1.87, RG 1.89, RG 1.97, RG 1.100, RG 1.142, RG 1.152, RG 1.153, RG 1.156, RG 1.158, RG 1.180, RG 1.209, RG 1.210, RG 1.211, RG 1.213, and RG 1.243 (NEI3-0020). The commenter discussed other guidance and potential updates that could allow other proposed requirements in 10 CFR 53.440 as well as 10 CFR 53.450 to be met:

- An updated DANU-ISG-2022-05 to meet proposed requirements in 10 CFR 53.440(a)(2).
- An updated DANU-ISG-2022-06 to meet proposed requirements in 10 CFR 53.440(a) and 10 CFR 53.450(d) (NEI3-0018).
- An updated RG 1.205 with technology-inclusive risk metrics, RG 1.189, or DANU-ISG-2022-09 to meet proposed requirements in 10 CFR 53.440(e) (NEI3-0022). The commenter additionally stated that this would support meeting proposed requirements in 10 CFR 53.450(g)(1) (NEI3-0031).
- An updated RG 5.74 to meet proposed requirements in 10 CFR 53.440(f) (NEI3-0023).
- Updated RG 1.233 and RG 1.247 to meet proposed requirements in 10 CFR 53.440(g) and (h) (NEI3-0024).
- An updated RG 1.217 endorsing NEI 07-13 for meeting proposed requirements in 10 CFR 53.440(j) (NEI3-0026). The commenter additionally stated that this would support meeting proposed requirements in 10 CFR 53.450(g)(2) (NEI3-0032).
- A finalized draft guide on chemical hazards to meet proposed requirements in 10 CFR 53.440(k) (NEI3-0027).
- An updated DANU-ISG-2022-03 to meet proposed requirements in 10 CFR 53.440(l) (NEI3-0028). The commenter additionally stated that this would provide some support in meeting proposed requirements in 10 CFR 53.450(g)(3), but that additional guidance for an ODCM for non-LWRs similar to NUREGs 1301 and 1302 would be needed (NEI3-0033).
- An updated RG 3.71 to meet proposed requirements in 10 CFR 53.440(m) (NEI3-0029).

- An updated DANU-ISG-2022-05 to meet proposed requirements in 10 CFR 53.440(n) (NEI3-0030).

The commenter stated that the following guidance, which would inform how applicants meet hazard related requirements, would be essential to meet the proposed requirements in subpart D to 10 CFR Part 53 and require minimal technical updates: RG 1.23; RG 1.27, Revision 3; RG 1.29, Revision 6; RG 1.59, Revision 2; RG 1.76, Revision 1; RG 1.91, Revision 3; RG 1.102, Revision 1; RG 1.132, Revision 3; RG 1.198, Revision 0; RG 1.208, Revision 0; RG 1.221, Revision 0; RG 4.7, Revision 4; RG 4.26, Revision 1; RG 1.189; and RG 1.205. The commenter added that the Advanced Reactor Content of Application Project (ARCAP) series of guidance, including DANU-ISG-2022-01 through DANU-ISG-2022-09, should be updated to clarify that the guidance is equally applicable to 10 CFR Parts 50, 52, and 53 (NEI3-0015).

A commenter discussed that the proposed rule intends to add clarity and assist licensees, but that there is evidence of excessive new regulations, overly prescriptive requirements, and of de-facto submission, methodology, and acceptance criteria. The commenter stated that over 100 reports, letters, and other guidance are associated with the rulemaking, and that the roadmap in DANU-ISG-2022-01 provides an approximate 100 additional documents to consider for multiple specifications, plans, assessments, programs, and other requirements. The commenter expressed that for each of these specifications, plans, assessments, programs, and other requirements, the ISG references multiple NRC regulatory guides and NUREGs; NEI-issued guides, templates, and methodologies; other industry guidance issued by the American National Standards Institute (ANSI), ANS, ASME, and IEEE; and other memorandums or policy statements. The commenter stated that additional references include guidelines for content, methods, and submission formatting described in DANU-ISG-2022-02 through DANU-ISG-2022-09, RG 1.242, and RG 4.7.

The commenter stated that by being referenced or sub-referenced in the proposed rule, the hundreds of documents, guides, procedures, and reports become an integral part of the licensing process and review and require consultation and examination. The commenter expressed concern that the guidance is optional and informal in name only, and that deviations from the guidance must be identified, addressed, and justified or otherwise require further review or an allowable exception. The commenter requested that all guidelines and sub-references be withdrawn, reduced, and revised unless justified by data and PRA/RIDM analyses, verified as generically applicable and effective, and not prescriptive (RD-0030).

A commenter wrote that the NRC should follow the intent of SRM-SECY-20-0032 and work with stakeholders to identify and develop the necessary regulatory guidance and technical bases (BI1-0037).

NRC Response: The NRC agrees, in part, with the comments.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.253 and the standard review plan (SRP) (i.e., NUREG-0800), that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to RG 1.253 or development of companion guidance would be needed to ensure RG 1.253 and other guidance documents would be applicable under 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to these guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance but notes that an

update to RG 1.217 endorsing NEI 07-13 for meeting proposed requirements in 10 CFR 53.440(j) will not be necessary because those requirements have been removed in the final rule (see the NRC's response to Comment Bin 3.3.2.1.C).

The NRC agrees that 10 CFR Part 53 allows for a variety of different approaches to meet the requirements. Depending on the application, such approaches could potentially include those proposed in examples A, B, and C of the commenter's white paper. However, the NRC emphasizes that, as discussed in various other comment responses, the requirements in 10 CFR Part 53 do not accommodate the development of safety analyses that would involve, for example, the exclusive use of bounding assessments or that is based on the development of traditional, deterministic safety analyses similar to that developed for a 10 CFR Part 50 application and which is similar to the proposed example D in the commenter's white paper. Such approaches would not be able to meet certain requirements under 10 CFR Part 53 such as 10 CFR 53.450(b) and 10 CFR 53.450(e) related to the classifying SSCs based on safety significance and identifying significant event sequences. Suggested changes to 10 CFR Part 53 rule language provided in the white paper have been addressed in responses to comments related to the sections of the rule they are associated with and, accordingly, the NRC did not make additional changes to rule language in response to these comments.

The NRC disagrees that 10 CFR Part 53 contains excessive new regulations and overly prescriptive requirements. On the contrary, 10 CFR Part 53 adopts technology-inclusive approaches and uses risk-informed and performance-based techniques to ensure an equivalent level of safety to that of operating commercial nuclear plants while providing flexibility for licensing and regulating a variety of technologies and designs for commercial nuclear reactors. The NRC also disagrees that all guidance and references associated with 10 CFR Part 53 be withdrawn, reduced, and revised, as this would be counter to regulatory stability and certainty.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.B: A commenter suggested that if the scope of 10 CFR 53.440(b) is not limited to SR SSCs and continues to include NSRSS SSCs, then as a means of meeting proposed requirements in 10 CFR 53.440(c) the following guidance documents would need to be updated: RG 1.40, RG 1.73, RG 1.87, RG 1.89, RG 1.97, RG 1.100, RG 1.142, RG 1.152, RG 1.153, RG 1.156, RG 1.158, RG 1.180, RG 1.209, RG 1.210, RG 1.211, RG 1.213 and RG 1.243. The commenter stated that some documents may need technical updates to align the guidance with the changes to the traditional scope of "safety related" and the flexible requirements under 10 CFR Part 53 (NEI2-0009).

The commenter added that many applicants under 10 CFR Part 53 anticipate using commercial codes and standards not yet endorsed by the NRC but in line with NEI 18-04, as endorsed by RG 1.233, for NSRSS SSCs (NEI2-0005). The commenter recommended that the NRC endorse the following codes and standards: ISO-9001, ASME Section VIII, ASME B31.1 and B31.3, ASCE 7, American Institute of Steel Construction (AISC) 360, ACI 318, and any additional unendorsed codes and standards that may have been used or proposed for use for U.S. reactors (NEI3-0019). The commenter stated that guidance could provide the scope NSRSS SSCs for which the proposed requirements in 10 CFR 53.440(b), 10 CFR 53.440(e), and 10 CFR 53.875(b) are applicable (NEI2-0005).

A commenter addressed the proposed requirement in 10 CFR 53.880(a), stating that consensus codes and standards are more appropriately handled through guidance rather than the regulatory text. The commenter discussed that guidance appropriately understands and communicates intricacies in codes and standards. The commenter requested that implementation of 10 CFR 53.880 be conducted through updated guidance such as RG 1.246 endorsing ASME Section XI Division 2 or other guidance related to the surveillance frequency control program (NEI2-0118).

Further, the commenter discussed required guidance changes to endorse the codes and standards from 10 CFR 50.55a for use in 10 CFR Part 53:

- RG 1.26, RG 1.28, and RG 1.33 endorsing NQA-1 (NEI2-0008, NEI3-0019). The commenter stated that NQA-1 is arguably the only generally accepted consensus code or standard used for quality assurance during the design phase, as discussed in RG 1.28, and 10 CFR 53.440(b) may effectively require NQA-1 for SR and NSRSS SSCs in direct contradiction to proposed 10 CFR 53.460(b) (NEI2-0049).

- RG 1.84 endorsing ASME Section III Code Cases.

- RG 1.87 endorsing ASME Section 3 Division 5.

- RG 1.97 endorsing IEEE 497-2025.

- RG 1.192 endorsing the ASME OM Code, or preferably a future update that endorses OM-2.

- RG 1.208 or RG 1.251 endorsing ASCE 43 and ASCE 4 (NEI3-0019). The commenter stated that until ASCE 43-19 is endorsed in RG 1.251, then the use of DG-1410 as guidance in LMP submittals would require an exemption under 10 CFR Part 53 and increase regulatory burden (NEI2-0049).

- RG 1.246 endorsing ASME Section XI Division 2. The commenter stated that applicability should be extended to LWRs (NEI3-0019).

Relatedly, a commenter demanded that the NRC collaborate with standards-setting organizations to identify specific technical areas and incorporate the respective consensus-based codes and standards into the regulatory framework. The commenter stated that the framing around where codes and standards are applicable should be clarified to ensure that codes and standards for safety components are applied at least as stringently as they are in the current licensing frameworks, such as under 10 CFR Parts 50 and 52. The commenter stated that a list of approved codes and standards for certain NSRSS functions would benefit both industry and the NRC (BI1-0012). Another commenter expressed generally that the NRC should consider endorsing industry-developed guidance when appropriate to manage the burden to staff conducting safety reviews (USNIC2-0002).

NRC Response: The NRC agrees, in part, with the comments.

As addressed in the NRC's response to Comment Bin 3.3.2.1.A, the NRC has revised the rule language in 10 CFR 53.440(b) to specifically apply to SSCs classified as SR in the final rule. As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.87 and others that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or

development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53-related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Regarding the comment on NRC collaboration with standards development organizations, the NRC has established processes and mechanisms for interacting with such organizations as directed by and consistent with the National Technology Transfer and Advancement Act of 1995 and the Office of Management and Budget (OMB) Circular A-119-1, "Federal Register (Federal Participation in the Development of Use of Voluntary Consensus Standards and in Conformity Assessment Activities," issued February 1998. As such, the NRC will continue to engage with standards development organizations to address regulatory priorities related to the development of consensus codes and standards.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.C: A commenter proposed a potential need for new or updated guidance for the ODCM requirements in proposed 10 CFR 53.850, as existing ODCM focuses on pressurized-water reactor and boiling-water reactor LWRs licensed under 10 CFR Parts 50 and 52. The commenter added that ODCM guidance for advanced reactor types (high-temperature gas-cool reactor, molten salt reactor, sodium-cooled fast reactor) and updates to numerous Division 8 RGs would provide sufficient guidance to meet 10 CFR 53.850 (NEI2-0108).

Another commenter expressed support for this approach to comply with the proposed radiation protection requirements (NEX-0021).

NRC Response: The NRC agrees with the comments.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as the ODCM and other RGs that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.D: A commenter suggested that the proposed rule be amended to include discussion of functional design criteria in context of principal design criteria and that RG 1.232 be updated to allow use of a subset of the general design criteria (GDC) for LWRs and the ARDC for functional design criteria under 10 CFR Part 53 (NEI2-0014). The commenter discussed that guidance should provide clarity that the GDC and ARDC in RG 1.232 are valid means of identifying functional design criteria under 10 CFR Part 53 (NEI2-0033, NEI2-0045). The commenter added that applicants should have the option of developing design criteria in line with RG 1.232, RG 1.233, or the GDC (NEI2-0033). The commenter also cited the Xe-100

Licensing Topical Report Principal Design Criteria, Revision 3 (ML24047A310) as a resource providing precedent on which principal design criteria would be functional design criteria under 10 CFR Part 53 (NEI2-0045).

Additionally, the commenter stated that distinctions made in RG 1.233 and RG 1.253 between safety criteria and associated design criteria to meet DBA and non-DBA LBE requirements helps applicants understand different classifications of components and their associated requirements (NEI2-0045).

NRC Response: The NRC disagrees with these comments.

There are significant differences between the concepts of "principal design criteria" from 10 CFR Part 50 and "functional design criteria" used in 10 CFR Part 53. Principal design criteria are a key part of a largely deterministic methodology and define specific, prescribed design requirements and design rules against which the NRC reviews proposed reactor designs. Functional design criteria within 10 CFR Part 53 are derived as part of a risk-informed and performance-based methodology and an overall hierarchy that covers (1) plant-level safety criteria, (2) safety functions needed to demonstrate compliance with the safety criteria, (3) design features, human actions, and programmatic controls needed to fulfill the safety functions, and (4) functional design criteria defined for each design feature relied on to demonstrate the safety criteria are met. In terms of specificity of requirements for individual design features, functional design criteria would align more closely with the definition of "design bases" in 10 CFR 50.2.

As it relates to the use of RG 1.232, the ARDC could potentially be used as a guide or starting point for what functional design criteria could look like. However, consistent with the hierarchical nature of 10 CFR Part 53, the analyses supporting an application would still need to demonstrate that the functional design criteria support achieving the high-level safety functions and meeting the high-level safety criteria. As such, the use of RG 1.232 to inform the development of functional design criteria would be application-specific and reviewed by the NRC on a case-by-case basis.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.E: A commenter discussed required guidance changes to endorse the codes and standards from 10 CFR 50.55a for use in 10 CFR Part 53. The commenter proposed that DG-1410 be published as RG 1.251 to provide guidance for NSRSS SSCs and to support implementation of the flexible language in 10 CFR Part 53 (NEI2-0056). Further, the commenter suggested that NRC consider endorsement of ANS 2.26 as part of the endorsement of ASCE 43-19, in line with industry comments and justified by consequence analysis (NEI2-0182). The commenter stated that additional guidance building on the graded approach to site characterization discussed in ML24213A337 may be appropriate (NEI2-0056).

Additionally, the commenter discussed that the NRC's Nth-of-a-kind microreactor white paper (ML24268A310) provides a graded approach to site characterization but does not go far enough, adding that a true graded approach could use U.S. Geological Survey National Seismic Hazard Model and not require a site-specific Senior Seismic Hazard Analysis Committee. The commenter stated that RG 1.208 is the only currently approved methodology for establishing the design basis seismic hazard and does not allow such a flexible approach. The commenter

proposed that the NRC work with industry to endorse a graded approach to site characterization necessary and sufficient to establish the design basis seismic hazard (NEI2-0182).

Another commenter discussed that additional guidance may be needed to support applicants in demonstrating compliance through a graded approach to earthquake engineering. The commenter stated that items including U.S. Geological Survey seismic data and alternative sources provide examples of acceptable methods for seismic hazard assessment and could constitute new options for advanced reactor developers (SCWG-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC has a number of initiatives underway related to the evaluation of external hazards, including those mentioned on grading site characterization activities and risk-informed approaches to seismic design. However, the timing of the NRC's development and issuance of guidance may not comport with the suggested timing. The NRC will continue to engage stakeholders as guidance is developed in these areas. In addition, the NRC will engage with potential applicants during preapplication interactions regarding potential alternatives to the guidance.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.F: A commenter suggested that RG 1.253 should be updated to endorse RG 1.253 for 10 CFR Part 53 and that the commenter would support changes to NEI 21-07 to facilitate that endorsement. The commenter stated that similar guidance could inform other TI-RIPB methodologies for licensing basis development, and the commenter would work with the NRC to develop this guidance (NEI-2019-0062-0418-0208).

In a comment related to 10 CFR 53.450, the commenter also recommended that RG 1.253 should be updated to allow supplemental evaluations for all licensing applications if justified in line with the non-LWR PRA Standard. The commenter noted that this is particularly important for LWRs where there is no consensus low power/shutdown standard (NEI2-0022).

In a comment related to 10 CFR 53.450(e), the commenter noted that the traditional approach of identifying DBAs should be sufficient to meet 10 CFR Part 53 and recommended that guidance such as the SRP could describe how traditional approaches meet the regulatory requirements of 10 CFR Part 53 (NEI2-0019).

NRC Response: The NRC agrees, in part, with these comments.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.253 and the SRP (i.e., NUREG-0800), that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to RG 1.253 or development of companion guidance would be needed to ensure RG 1.253 and other guidance documents would be applicable under 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to these guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.G: A commenter expressed that an update to RG 1.233 endorsing its use under 10 CFR Part 53 or other regulatory guidance addressing defense in depth could provide clarity in meeting the proposed defense-in-depth requirements (NEI2-0071).

NRC Response: The NRC agrees with this comment.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.233, which may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.H: A commenter stated that RG 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities" should be updated for emergency planning. The commenter also stated that this guidance is needed to develop a fully informed response to the NRC request for public comment related to Subpart F in the 10 CFR Part 53 rulemaking. The commenter suggested that the revision to RG 1.242 be made available for public comment prior to the 10 CFR Part 53 rule being finalized (NEI2-0011, NEI2-0203).

NRC Response: The NRC agrees with the comment.

As described in proposed rule FRN section VI, "Specific Requests for Comments" (Part 53, Subpart F—Emergency Preparedness and Security Programs 89 FR 86985) the NRC is planning to issue a draft revision of RG 1.242, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities," for public comment. The NRC plans to issue this draft revision after the publication of the 10 CFR Part 53 final rule. The planned revision to RG 1.242 would add guidance for 10 CFR Part 53 applicants and licensees to address interactions between graded approaches for emergency planning and security programs.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.I: In discussion of the proposed requirement in 10 CFR 53.1209(a), a commenter recommended that the NRC develop guidance and examples, potentially including tabletop exercises, to clarify implementation of the expectations for approving major portions of a standard design approval. The commenter added that the tabletop exercises could inform a significant reduction in the scope of standard design approval application requirements (NEI2-0125).

In context of the proposed requirements in 10 CFR 53.1209 and 10 CFR 53.1279, the commenter stated that guidance in RG 1.253 only requiring full-power internal events PRA CPs should be updated to allow flexibility for PRA scope to be determined by use of section 3 of the PRA standard for all applications under 10 CFR Part 53 (NEI2-0126, NEI2-0129).

NRC Response: The NRC agrees, in part, with the comments.

As discussed in the proposed and final rule FRNs, the NRC recognizes that guidance development to support 10 CFR Part 53 and advanced reactors is important. The development of guidance and interactions with external stakeholders will continue as the industry and NRC learn lessons from licensing reviews and operating experience and the NRC appreciates commenters' suggestions to that end.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.J: A commenter discussed that the guidance documents accompanying the 10 CFR Part 53 rulemaking do not appear to have similar counterparts associated with the existing 10 CFR Parts 50 and 52. The commenter expressed that the NRC is attempting to impose new requirements on applicants via these new documents, including requiring applicants to respond to staff review comments and explain not conforming to proposed methods and approaches. The commenter expressed concern that the guidance document rulemaking efforts do not align with congressional direction to modernize the licensing process and improve efficiency, and suggested that consensus industry codes and standards may address the issues contained in the guidance (HPT26-0001).

The commenter also asserted that guidance documents cannot be used to create requirements outside the law or be used to require applicants or licensees to explain deviations from the suggested methods contained in the guidance. The commenter added that NRC inquiries must be proportionate to the risk involved and that unimportant guidance documents should not be inflicted upon an applicant or licensee (HPT40-0006).

NRC Response: The NRC agrees, in part, with the comments.

RGs, along with other guidance documents issued by the NRC, are not regulations. Their purpose is to provide guidance on methods that are acceptable to the NRC for demonstrating compliance with NRC requirements. As such, the NRC disagrees that the guidance documents impose requirements because these documents are not mandatory unless a licensee has incorporated a specific RG into its licensing basis. The NRC relies on licensee and applicant compliance with 10 CFR. The NRC considers the licensee and applicant use of guidance documents as acceptable methods to satisfy regulatory requirements.

The NRC also uses guidance documents to endorse industry codes and standards, which are then acceptable for use by licensees and applicants. Applicants may refer to an industry code or standard, whether it has not been previously endorsed by the NRC, either in guidance or in a regulation, and the NRC will consider the referenced industry code or standard on an application-specific basis. The NRC agrees that the requests for information should be informed by and commensurate with the risk associated with a given matter; however, such requests allow the NRC to gain a better understanding of how a given requirement is met and therefore must always have a regulatory basis.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 8.10.K: A commenter stated that RG 1.217 should be updated to indicate that NEI 07-13 is acceptable guidance for meeting 10 CFR 53.440(j) and associated 10 CFR Part 53 requirements; the commenter further noted that the NEI is working on an addendum to NEI 07-13 to develop additional acceptance criteria for 10 CFR Part 53 (NEI2-0010).

For subpart D, the commenter stated that the following guidance documents should be updated and would require minimal technical work to do so (NEI2-0010):

- RG 1.23, “Meteorological Monitoring Programs for Nuclear Power Plants”
- RG 1.27, Revision 3, “Ultimate Heat Sink for Nuclear Power Plants”
- RG 1.29, Revision 6, “Seismic Design Classification [for Nuclear Power Plants]”
- RG 1.59, Revision 2, “Design Basis Floods for Nuclear Power Plants”
- Appendix K in DG-1290 (proposed by the commenter to be incorporated into the revision of RG 1.59 that supports 10 CFR Part 53)
- RG 1.76, Revision 1, “Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants”
- RG 1.91, Revision 3, “Evaluations of Explosions Postulated to Occur on Transportation Routes Near Nuclear Power Plants”
- RG 1.102, Revision 1, “Flood Protection for Nuclear Power Plants”
- RG 1.132, Revision 3, [“Geologic and Geotechnical Site Characterization Investigations for Nuclear Power Plants”] “Site Investigations for Foundations of Nuclear Power Plants”
- RG 1.198, Revision 0, “Procedures and Criteria for Assessing Seismic Soil Liquefaction at Nuclear Power Plant Sites”
- RG 1.208, Revision 0, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion”
- RG 1.221, Revision 0, “Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants”
- RG 4.7, Revision 4, “General Site Suitability Criteria for Nuclear Power Stations”
- RG 4.26, Revision 1, “Volcanic Hazards Assessment for Proposed Nuclear Power Reactor Sites
- RGs for fuels and materials facilities (Division 3) to support 10 CFR 53.620

For subpart F, the commenter proposed a potential need for new guidance and other updates to existing RGs or NUREGs as follows (NEI2-0010):

- Update RG 1.189 for guidance to meet the fire protection requirements in 10 CFR 53.440(e), 10 CFR 53.450(g)(1), and 10 CFR 53.875.

- Update Division 8 regulatory guidance to meet the radiation protection requirements in 10 CFR 53.850 and clarify the applicability to licensees under 10 CFR Part 53.

- New or updated guidance for the ODCM requirements in 10 CFR 53.850, as existing ODCM guidance (e.g., NUREG-1031 and NUREG-1302) focuses on pressurized-water reactor and boiling-water reactor LWRs licensed under 10 CFR Parts 50 and 52.

NRC Response: The NRC agrees with this comment.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as the various RGs cited in the comments and other guidance that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance but notes that an update to RG 1.217 endorsing NEI 07-13 for meeting proposed requirements in 10 CFR 53.440(j) will not be necessary because those requirements have been removed in the final rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.L: In discussion of the proposed requirement in 10 CFR 53.875, a commenter requested that the NRC update RG 1.189 and RG 1.205 in coordination with the National Fire Protection Association to facilitate implementation of 10 CFR Part 53, as National Fire Protection Association 805 (endorsed in RG 1.205) is not technology inclusive and relies on risk metrics which may not be applicable for non-LWRs (NEI2-0113).

NRC Response: The NRC agrees with this comment.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.189 and RG 1.205, that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.M: A commenter stated that the following guidance documents need to be updated to include references to 10 CFR Parts 52 and 53 in addition to 10 CFR Part 50:

RG 8.19, Revision 3; RG 8.25, Revision 1; and RG 8.27, Revision 0. The commenter added that RG 8.27, Revision 0 must also be updated to include non-LWRs.

The commenter discussed other necessary changes to guidance:

- The commenter stated that RG 1.160 requires significant technical updates to support the maintenance program under 10 CFR Part 53. The commenter proposed to submit a methodology for review by NRC in 2026.

- The commenter stated that RG 1.143 needs a revision to address waste streams not typically generated at an LWR in 10 CFR Parts 52 and 53.

- The commenter proposed two options to address updates to the safety evaluations for NEI 08-08 Contamination Control, NEI 07-08A ALARA [as low as reasonably achievable], NEI 07-03A Radiation Protection Program, and NEI 07-10A Process Control Program. In the first option, the commenter proposed that the documents would be revised to incorporate 10 CFR Part 53 and that the NRC could review and approve the revised templates. In the second option, the commenter proposed that a license applicant could choose to implement the industry guidance documents and identify any deviations applicable to reactor SSCs under 10 CFR Part 53.

The commenter recommended updates to the ARCAP series of guidance (DANU-ISG-2022-01 through DANU-ISG-2022-09) to clarify that guidance is equally applicable to 10 CFR Parts 50, 52, and 53 (NEI2-0012).

NRC Response: The NRC agrees with this comment.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.160 and others that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.N: A commenter discussed the proposed requirement in 10 CFR 53.1550, stating that experience from implementing 10 CFR 50.59 indicates that guidance is critical to understanding the application of change control criteria but that guidance for 10 CFR 50.59 took significant resources and years to develop. The commenter added that no guidance has been provided for 10 CFR 53.1550 and expressed concern that PRA-based criteria could be deemed undesirable by the time details are provided in guidance (NEI2-0142).

The commenter recommended that the NRC use the criteria in NEI 22-05: Technology-Inclusive Risk-Informed Change Evaluation, which the NRC seemingly deemed acceptable in a pre-decisional DG (ML24354A075), to inform an update to 10 CFR 53.1550(a)(2) criteria (NEI2-0142). Further, the commenter recommended that the pre-decisional draft regulatory guidance endorsing NEI 22-05 for change evaluation under LMP for 10 CFR Parts 50 and 52

should be updated as an acceptable means of meeting proposed 10 CFR 53.1550, once finalized (NEI2-0010).

The commenter also proposed that RG 1.187 with adjustments to account for additional criteria be updated as a means of meeting proposed 10 CFR 53.1550 and stated that workshops between the NRC and industry could resolve gaps in the language between existing guidance and the proposed language in 10 CFR Part 53 (NEI2-0142).

NRC Response: The NRC agrees, in part, with the comment.

As explained in the NRC's response to Comment Bin 3.9.1.F, the NRC has revised the rule text for 10 CFR 53.1550 to more closely align with the criteria for change evaluations in NEI 22-05. The NRC expects that additional meetings will be held during the development of guidance for implementing 10 CFR 53.1550.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.O: A commenter proposed that the NRC collaborate with industry to develop guidance on the licensing requirements of design changes for MLs and combined licenses using a manufactured reactor in context of safety significant impacts, with a framework potentially based on cask MLs and NEI 12-04 (NEI2-0209).

NRC Response: The NRC agrees with the comment.

The proposed and final rule FRNs address that the NRC recognizes that guidance development to support 10 CFR Part 53 and advanced reactors will continue as the industry and NRC learn lessons from licensing reviews and operating experience. As described in the NRC's response to Comment Bin 3.9.3.B, the NRC revised 10 CFR 53.1530 and 10 CFR 53.1550 in the final rule to provide additional flexibility for ML and combined license holders to make changes to the design and procedures associated with manufactured reactors.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.P: A commenter proposed that if 10 CFR 53.470 is retained in the final rule, then the NRC should develop supporting regulatory guidance providing information on the potential benefits gained by the optional requirement (NEI2-0055).

NRC Response: The NRC agrees with the comment.

The proposed and final rule FRNs address that the NRC recognizes that guidance development to support Part 53 and advanced reactors will continue as the industry and NRC learn lessons from licensing reviews and operating experience. However, as discussed in the NRC's response to Comment Bin 3.3.2.3.B, the NRC has removed 10 CFR 53.470 in the final rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 8.10.Q: A commenter expressed support for the industry-led LMP, Technology-Inclusive Content of Application Project, and Technology-Inclusive Risk-Informed Change Evaluation efforts. The commenter suggested that these efforts be endorsed as satisfying 10 CFR Part 53 requirements. The commenter appreciated the NRC's communication during the endorsement of RG 1.233 and RG 1.253 for applications under 10 CFR Parts 50 and 52 (SOU-0003).

NRC Response: The NRC agrees, in part, with the comment.

As discussed in the proposed and final rule FRNs, there is extensive guidance for 10 CFR Parts 50 and 52, such as RG 1.233 and RG 1.253, that may be considered in the development of all licensing applications and NRC reviews. The NRC acknowledges that updates to such guidance or development of companion guidance would be needed to ensure the applicability of those guidance documents for 10 CFR Part 53. The NRC will issue revisions or 10 CFR Part 53–related companions to guidance documents for public comment and finalize and issue the guidance documents following publication of the final 10 CFR Part 53 rule. The NRC appreciates commenters' suggestions for prioritization of such guidance.

Accordingly, the NRC did not change the rule language in response to this comment.

DG-5071, "Target Set Identification and Development for Nuclear Power Reactors" (from Alternative Physical Security Requirements for Advanced Reactors Proposed Rule)

Comment Bin 8.10.R: A commenter said that they have no comments on DG-5071, but that other comments the commenter had may necessitate changes (NEI4-0028).

NRC Response: This comment suggests no specific changes to the guidance, RG 5.81 (formerly DG-5071).

Accordingly, the NRC did not change the guidance in response to this comment.

DG-5072, "Guidance for Alternative Physical Security Requirements for Small Modular Reactors and Non-Light-Water Reactors" (from Alternative Physical Security Requirements for Advanced Reactors Proposed Rule)

Comment Bin 8.10.S: A commenter said that the text in section 7.2 of DG-5072 is vague regarding what is meant by offsite armed response being "not available" and that additional guidance would be appreciated to define what is meant by this term (e.g., providing some context regarding what percentage of force is out of service or what timeframe they are out to be considered unavailable). The commenter added that it would also be helpful to have guidance on when compensatory measures would be needed in place (WEST2-0005).

NRC Response: The NRC disagrees with the comment.

In the final rule, power reactor applicants and licensees that elect to implement the requirements in 10 CFR 73.100(b)(4)(iv) are required to provide timely response to interdict and neutralize threats up to and including the DBT at all times. The requirement "at all times" is aimed at

response readiness, meaning that that NRC requires licensees to always be ready to defend target sets against an attack from threats up to and including the DBT.

Applicants and licensees are responsible for determining whether and how to incorporate law enforcement or other offsite armed responders into their physical protection programs and protective strategies, including the degree to which they can rely on offsite responders to meet NRC security requirements. The performance-based standards the NRC has established in 10 CFR 73.100(b)(4)(iv) and 10 CFR 73.100(b)(4)(iv)(A)(*1*) are clear, and they ensure consistency across commercial nuclear plants.

When applicants and licensees elect to implement the requirement in 10 CFR 73.100(b)(4)(iv)(A) and rely on law enforcement or other offsite armed responders to interdict and neutralize threats up to and including the DBT, the applicants and licensees are responsible for ensuring that those offsite forces are always available and prepared to fulfill those duties. The NRC understands that there may be times when competing demands or other factors may adversely impact some offsite responders, particularly law enforcement responders, and prevent them from effectively responding to a licensee's call for assistance. Therefore, the NRC requires applicants and licensees to identify the criteria and measures they need to maintain the capability to perform the interdiction and neutralization functions when law enforcement or other offsite armed responders may be unable to provide effective support, and to implement those measures within the associated timeframes to ensure that the applicants and licensees always remain prepared to adequately interdict and neutralize threats up to and including the DBT.

Accordingly, the NRC did not change the guidance in response to this comment.

Comment Bin 8.10.T: A commenter said that the effort needed by a local law enforcement agency to support appendices A and B to DG-5072 is significant, highlighting the difference in the number of pages between a typical memorandum of understanding with an outside agency (i.e., 3-5 pages) and the information suggested in DG-5072 that a local law enforcement agency would have to agree to (i.e., more than 50 pages). The commenter said that these additional requirements are likely going to be burdensome and result in these options not being pursued (WEST2-0005).

NRC Response: The NRC agrees, in part, with this comment.

The reason there are different documentation requirements and recommendations for currently operating reactor licensees versus 10 CFR Part 53 applicants and licensees that elect to rely on law enforcement for interdiction and neutralization of threats up to and including the DBT is because of the differing roles, and the significance of those roles, that law enforcement responders play in licensees' physical protection programs and protective strategies. Currently operating reactors demonstrate reasonable assurance of adequate protection when they design, implement, and maintain physical protection programs and protective strategies that can defend against threats up to and including the DBT for 8 hours without outside (e.g., law enforcement) assistance. The NRC established the law enforcement liaison-related requirements in 10 CFR 73.55(k)(9) and section II.B.3.d in appendix C to 10 CFR Part 73, and related guidance (e.g., RGs 5.54 and 5.76), with the assumption that law enforcement support was not integral to a licensee's ability to adequately defend against threats up to and including the DBT. Because applicants and licensees that elect to implement the requirements in 10 CFR 73.100 can rely on law enforcement to interdict and neutralize threats up to and

including the DBT, the NRC concluded it is necessary to add the requirements in 10 CFR 73.100(b)(4)(iv)(A)(*1*)–(*5*) and provide related guidance to better ensure that when applicants and licensees rely on law enforcement or other offsite responders for interdiction and neutralization, those responders will be prepared at all times to effectively perform those critical security functions.

The NRC acknowledges that the effort needed from law enforcement or other offsite armed response organization(s) to support the NRC's expectations is significant, when applicants or licensees rely on law enforcement responders to protect against the DBT. Documentation and other requirements (e.g., information sharing, training, evaluation) associated with offsite responders for those 10 CFR Part 53 applicants and licensees will be greater than those that apply to currently operating power reactor licensees. The NRC anticipates that a 10 CFR Part 53 applicant or licensee's overall effort to establish, implement, and maintain the capabilities to interdict and neutralize threats will be similar to or less than the currently operating reactor licensees' effort, regardless of whether the 10 CFR Part 53 applicant or licensee elects to rely on onsite armed responders, law enforcement or other offsite armed responders, or a combination of onsite and offsite responders to perform those functions. A 10 CFR Part 53 applicant or licensee may expend less effort and resources when relying on law enforcement responders because unlike licensee or contracted security personnel, law enforcement organizations assume the responsibilities and costs associated with law enforcement responders' employment suitability and qualifications; duty and weapons training; and weapons, personal equipment, and maintenance. A 10 CFR Part 53 applicant or licensee would need to augment those responders' training and skills by providing applicable information and training related to the DBT and the reactor facility.

The NRC elected to provide a significant amount of guidance related to tactical response drills and force-on-force exercises for applicants and licensees that elect to rely on law enforcement responders for interdiction and neutralization for two primary reasons. First, for longer than a decade, the NRC participated in an interagency effort that was designed to improve law enforcement tactical response to currently operating power reactor facilities. It is prudent to share knowledge from that effort so that applicants and licensees could consider the information while they are designing their physical protection programs and protective strategies. Second, relying on law enforcement or other offsite armed responders for interdiction and neutralization is a new method for securing power reactor sites. The NRC is responsible for determining the minimum security measures a power reactor licensee must satisfy to provide reasonable assurance of adequate protection of threats up to and including the DBT. Within the context of relying on law enforcement responders to interdict and neutralize such threats, the NRC considers the requirements in 10 CFR 73.100(b)(4)(iv)(A) and the remaining requirements in 10 CFR 73.100 to be the minimum necessary for achieving that objective of adequate protection of public health and safety. The methods recommended in RG 5.97 are one way to satisfy the requirements in 10 CFR 73.100(b). Applicants and licensees can use other methods, supported by a basis acceptable to the NRC, to comply with the requirements in 10 CFR 73.100(b)(4)(iv)(A), as well as the option of electing not to rely on law enforcement or other offsite armed responders to perform the required interdiction and neutralization functions.

Accordingly, the NRC did not change the guidance in response to this comment.

Comment Bin 8.10.U: A commenter had an editorial comment regarding DG-5072 (NEI4-0029):

- On pages 13 and 14, step 4.11 should also reference RG 1.249, “Use of ARCON Methodology for Calculation of Accident-Related Offsite Atmospheric Dispersion Factors.”

NRC Response: The NRC agrees with this comment.

The NRC agrees with adding a reference to RG 1.249. Guidance related to a site-specific dose analysis was moved from RG 5.97 (formerly DG-5076) to RG 5.81 (formerly DG-5071); there the NRC added a reference to RG 1.249 to RG 5.81 (formerly DG-5071) as an acceptable model to determine atmospheric dispersion.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.81 (formerly DG-5071) as described above.

Comment Bin 8.10.V: Commenters submitted multiple comments regarding DG-5072:

- A commenter stated that on page 12, steps 4.4, 4.5, and 4.6 provide minimal guidance on creating the DBT- and security-related event scenarios to analyze in accordance with the requirements in 10 CFR 73.55(s)(1)(ii) and (iv) and that this guidance is not sufficient for an applicant or licensee to develop the necessary event scenarios, or to understand what associated assumptions and analysis techniques are acceptable to the NRC. Given that this guidance is central to being able to understand and implement a key aspect of the final rule, the commenter recommended that the NRC develop additional guidance and make it available for public comment prior to sending the final rule to the Commission for approval. The commenter also recommended that on page 12, step 4.3 be revised to make clear how the applicant or licensee is to use the site’s security bounding time (SBT) when evaluating potential radiological releases from DBT- and security-related events. The commenter asked how the SBT-related information should be considered in this regard (NEI4-0029).

- A commenter stated that some communications and data transmissions between a site alarm station and an offsite secondary alarm station could contain SGI. Step 9.2 should instruct the applicant or licensee to consider these potential occurrences and ensure that appropriate controls and technologies, such as those supporting communications using encrypted data, are in place to prevent unauthorized access to SGI (page 27, step 9.2) (NEI4-0029).

- A commenter agreed that a “Safety Margin Time” factor is appropriate to account for uncertainties; however, the proposed 50 percent factor is excessive and will lead to unreasonable security bounding times (page 11 of appendix C, step 3.6). Similarly, the commenter agreed that a “safety margin” factor is appropriate to account for uncertainties; however, the proposed 50 percent factor is excessive and will lead to unreasonable AIPTs (page 13 of appendix C, step 5.3). The commenter recommended that both factors be changed to 25 percent (NEI4-0029). Another commenter suggested reducing the operation time-based safety margin requirements generally by half (e.g., for sites in operation less than 5 years, use a safety margin of 25 percent; for sites in operation at least 5 years, use a safety margin of 10 percent) (NUS3-0005).

- A commenter said that they agree that rounding up the sum of the four AIPT time elements (page 13 of appendix C, step 5.2) and the sum of the six SBT time elements

(page 2 of appendix C, step 2.3) is appropriate; however, the directed rounding "to the next full hour" is excessive for sums that include a number of minutes under 30. The commenter recommended that the minutes in a sum of AIPT time elements and a sum of SBT time elements be rounded up to the next 30-minute time increment (e.g., a sum of 4 hours and 15 minutes would be rounded up to 4.5 hours) (NEI4-0029). Another commenter said that rounding of the SBT value in section 2.3 of appendix C is not required because conservatism is accounted for within established safety margins (NUS3-0004).

NRC Response: The NRC agrees, in part, with the comments.

The NRC agrees that the NRC should provide additional guidance to enable applicants and licensees to better understand which radiological consequence analysis-related assumptions and techniques are acceptable in a security context. The NRC moved guidance from RG 5.97 (formerly DG-5076) to RG 5.81 (formerly DG-5071) and augmented the information to provide applicants and licensees with a fuller context for understanding how radiological consequence analyses apply to the identification and development of target sets.

The NRC agrees that RG 5.97 (formerly DG-5076) should acknowledge that some communications and data transmissions between an onsite central alarm station and an offsite secondary alarm station could contain safeguards or other controlled unclassified information. The NRC revised RG 5.97 (formerly DG-5076) to recommend methods and references that applicants and licensees can use to adequately protect verbal and written SGI and other sensitive signals being transmitted intermittently or continuously between a facility and an offsite secondary alarm station. RG 5.97 (formerly DG-5076) also recommends that the applicants and licensees ensure that they use appropriate controls and technologies, such as those supporting communications using encrypted data, to prevent unauthorized access to sensitive information.

The NRC decided that an AIPT concept aligns better than SBT with the target set identification and development process. Therefore, the calculation methodology in appendix C to RG 5.97 is for AIPT rather than SBT. The NRC concluded that a 25 percent safety margin should adequately account for the uncertainties associated with the elements that the methodology in appendix C to RG 5.97 uses to calculate site-specific AIPTs. Therefore, the NRC revised the guidance in appendix C to recommend that applicants and licensees use a 25 percent safety margin, regardless of how long their facilities have been operating.

The NRC disagrees with the recommendation to use a 10 percent safety margin for facilities that have been operating for longer than 5 years. The NRC acknowledges that some uncertainties associated with the AIPT elements can be reduced when a facility gains operating experience. For example, an applicant may need to use data from discussions and discussion-based events like tabletop exercises to estimate the AIPT elements (i.e., mitigation activities; law enforcement response, mission planning, and mission execution) because performance-based data may not be possible to obtain before an actual facility exists. The longer a facility operates, licensees will have an increasing number of opportunities to train and test their mitigation and law enforcement responders' capabilities. However, most of the examples of potential uncertainties identified in section 3.5.1 of appendix C to RG 5.97 are outside licensees' control, and the NRC considers a 10 percent safety margin to be too low to adequately account for those factors, even when facilities have been operating for longer than 5 or 10 years.

The NRC agrees that rounding the calculated AIPT up to the next 30-minute time increment is adequate for standardization and simplicity. The NRC revised the guidance in RG 5.97 (formerly

DG-5076) to indicate that AIPTs can be rounded up to the next 30-minute increment rather than the next full hour.

Accordingly, the NRC did not change the rule language in response to this comment but did revise RG 5.81 and RG 5.97 as described above based on the comments on DG-5072.

Comment Bin 8.10.W: A commenter asked what "independent from security program" means on page 9 of DG-5072 (NEI4-0029).

NRC Response: While the comment is specific to an analysis performed to comply with 10 CFR 73.55(s)(1)(ii) as proposed in the "Alternative Physical Security Requirements for Advanced Reactors" rulemaking (89 FR 65226), the concept of "independent from security program" is applicable to 10 CFR Part 53. To clarify this concept, the NRC revised both the rule language and guidance. Specifically, the NRC revised target set requirements in 10 CFR 73.100(b)(5) to state that the identification of target sets shall not assume the success of the security organization, except that licensees may consider delay provided by the security organization when assessing the availability of operator actions. RG 5.81 (formerly DG-5071) and RG 5.97 (formerly DG-5076) provide guidance related to what actions from the security program can be credited in different steps of the site-specific target set analysis.

Accordingly, the NRC made changes to both the rule language and guidance in response to this comment.

Comment Bin 8.10.X: A commenter stated that DG-5072 should include a discussion of an option for an advanced reactor designer (or other party) to propose a standard security plan template along with the geographic bounding conditions that must be met to support use by a facility applicant or licensee. Once approved by the NRC, the security plan template could be adopted by an applicant or licensee and submitted with site-specific information along with material demonstrating that the bounding conditions have been met. The NRC discusses this approach in enclosure 1 to Draft NRC Staff White Paper, "Nth-of-a-Kind Micro-Reactor Licensing and Deployment Considerations" (NEI4-0029).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees with the description of the draft NRC white paper referenced in the comment. However, the purpose of the guidance in RG 5.97, which was revised to include most of the physical security-related guidance from DG-5072, is to identify one NRC-acceptable method for complying with each of the physical security requirements in 10 CFR 73.100. Information pertaining to other topics, including the process for establishing a standardized security plan template for NRC review and potential endorsement, is outside the scope of this rulemaking and associated guidance.

Accordingly, the NRC did not change the guidance in response to this comment.

Comment Bin 8.10.Y: A commenter said that the draft guidance found in DG-5072 provides clear and comprehensive information to applicants and licensees for regulatory expectations in the execution of some aspects of performance-based physical security (ARRC-0001).

NRC Response: The NRC agrees with the comment. The comment did not recommend any changes to RG 5.97 (formerly DG-5072).

Accordingly, the NRC did not change the guidance in response to this comment.

Comment Bin 8.10.Z: A commenter responded to the NRC's specific request for comments (question (3)) in Section IV of the proposed Alternative Physical Security Requirements for Advanced Reactors rule [NRC-2017-0227] regarding whether the NRC's proposed requirements adequately address the uncertainties associated with reliance on law enforcement. The commenter stated that that the NRC has mostly addressed the uncertainties associated with the proposed requirements at 10 CFR 73.100(b)(4)(iv)(A)(1)–(5) and 73.100(b)(4)(iv)(B); however, they said that the NRC staff should carefully examine the following aspects within 10 CFR 73.100(b)(4)(iv)(A) in greater detail:

- Reliance on Offsite Responders (10 CFR 73.100(b)(4)(iv)(A)) – The commenter said that their core concern lies in the timeliness of offsite law enforcement response and how this will be consistently ensured, noting that the rule does not specify how response times will be guaranteed across different sites or scenarios. The commenter said that the NRC could offer clearer guidance for applicants on ensuring the performance of timely, reliable offsite responses while considering site-specific risks.

- "Adequate Delay" for Threats (10 CFR 73.100(b)(4)(iv)(A)(*2*)) – The commenter said that the proposed rule does not define what constitutes "adequate" or how to measure this delay. The term "adequate delay" is vague, making it difficult to ensure that the physical protection systems can truly delay attackers long enough for offsite responders to arrive and neutralize the threat. The commenter said that the NRC should provide more clearly defined, performance-based metrics for delay.

- Coordination and Specialized Training (10 CFR 73.100(b)(4)(iv)(A)(*3*)) – The commenter said that the proposed rule does not adequately address the complexity of coordination between nuclear facility staff and offsite responders during an actual attack. The commenter said that the reliance on offsite armed personnel introduces a layer of uncertainty in communication, tactical alignment, and real-time decision-making compared to an onsite-only approach, all of which could hinder a successful response. The commenter expressed concern about how the NRC will evaluate the sufficiency of this training and whether it truly prepares law enforcement for sophisticated, high-risk nuclear security events.

- Accountability and Degradation (10 CFR 73.100(b)(4)(iv)(A)(*5*)) – The commenter said that they question how the NRC will ensure that facilities have practical and sufficient compensatory strategies in place (e.g., local law enforcement is unavailable due to a large-scale event, in what timeframe is the licensee required to have alternative measures in place and does the NRC need to be notified of the degradation?). The commenter said that they advocate for tighter accountability measures that ensure both the licensee and law enforcement agencies have clear responsibilities and communication.

The commenter said that they firmly believe that the partial or entire reliance on external responders could offer significant benefits to advanced reactor security needs. However, the commenter said that the concerns laid out above should be thoroughly addressed (BI2-0004).

NRC Response: The NRC disagrees with the comment.

The NRC decided that an AIPT concept aligns better than SBT with the target set identification and development process. Therefore, the calculation methodology in appendix C to RG 5.97 is for AIPT rather than SBT. Regarding response time and adequate delay, the AIPT calculation methodology described in appendix C to RG 5.97 is designed to account for the uncertainties associated with offsite response-related elements, including response time. For several of the AIPT elements, the guidance recommends that applicants and licensees identify and use the longest (i.e., most conservative) times to account for the most time-consuming variables for the given element. The AIPT calculation methodology also includes a 25 percent safety margin element to account for uncertainties associated with a security event that are beyond licensees' control. After an applicant or licensee calculates a site-specific AIPT, they use that time to screen target sets and establish sufficient delay to enable offsite responders to effectively interdict and neutralize threats up to and including the DBT. The NRC thinks this performance-based approach ensures that eligible applicants and licensees will adequately address offsite response-related elements in their facilities' physical protection programs and protective strategies.

Regarding coordination and specialized training, the final rule does not relieve applicants and licensees from the communication requirements in 10 CFR 73.100(b)(4)(iii) or the performance evaluation program requirements in 10 CFR 73.100(g). The NRC expects eligible licensees to identify and correct any performance deficiencies associated with law enforcement or other offsite armed response, just as they're expected to do with onsite armed response. Licensees will train and evaluate law enforcement or other offsite armed responders to the same performance standards that they would for onsite armed responders who perform physical protection program functions, including interdiction and neutralization. Additionally, the NRC will evaluate the effectiveness of licensees' armed response, including law enforcement response that is integral to their physical protection programs, by conducting NRC-graded force-on-force exercises at least every 3 years and periodically observing licensee-conducted force-on-force exercises. Should a licensee or the NRC determine that law enforcement responders cannot reliably perform the function(s) that the licensee relies on, including interdicting and neutralizing threats, then the licensee would need to implement a different method for performing that function(s) to ensure the licensee can, at all times, adequately defend against threats up to and including the DBT.

The final rule, associated guidance, and the risk-informed compensatory measures described in applicants' and licensees' security plans, in combination with the NRC's licensing and oversight processes, provide reasonable assurance that any necessary law enforcement response will be available and reliable, enabling applicants and licensees to maintain, at all times, the capability to interdict and neutralize threats up to and including the DBT. Compensatory measures must provide an equivalent level of protection and be implemented within the timeframes needed to ensure that, in this context, the degradation or loss of offsite response capability cannot be exploited. NRC guidance identifies potential disruptions to offsite response capabilities (e.g., law enforcement budgetary constraints, competing demands for law enforcement resources under routine and emergency conditions) and the need to adequately account for them in applicants' and licensees' security plans and supporting documentation (e.g., memoranda of understanding with law enforcement response organizations, security implementing procedures). Before issuing a license, the NRC will verify the adequacy of the security posture, to include the timeliness of, and coordination with, offsite response. After a facility is constructed and before it begins operation, the NRC will confirm that the licensee correctly implemented the physical

protection program that was approved during the licensing process, and the licensee and NRC will evaluate the effectiveness of the armed response at the applicable frequencies.

Accordingly, the NRC did not change the rule language or guidance in response to this comment.

Comment Bin 8.10.AA: A commenter responded to the NRC's specific request for comments (question (3)) in Section IV of the proposed Alternative Physical Security Requirements for Advanced Reactors rule [NRC-2017-0227] regarding whether the NRC's proposed requirements adequately address the uncertainties associated with reliance on law enforcement. The commenter stated that the additional proposed requirements regarding offsite law enforcement represent the bare minimum necessary for addressing the uncertainties associated with this option. The commenter said that broad implementation of the performance testing requirements in 10 CFR 73.100(g) or Appendix B to Part 73 would be essential, including demonstrations that offsite resources will be able to respond effectively within the security bounding time under a variety of circumstances. The commenter said that for defense-in-depth purposes, zero onsite armed responders should not be a permissible option under any circumstances and that it is not credible for the NRC to assert that it will be able to assure that licensees can fulfill their obligations for interdiction and neutralization of the DBT by relying on offsite resources that are not under NRC regulatory jurisdiction, are not subject to NRC requirements, and cannot be compelled to participate in any training offered by licensees. The commenter said that since neither the NRC nor the licensees can require that offsite responders participate in such exercises, the proposed rule is fundamentally inconsistent and will not likely survive judicial review (UCS1-0005).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the requirements under 10 CFR 73.100(b)(4)(iv)(A) and (B) are the minimum necessary to provide reasonable assurance of adequate protection when an applicant or licensee relies on law enforcement or other offsite armed responders to interdict and neutralize threats up to and including the DBT. The NRC disagrees that applicants and licensees should not be permitted to rely on zero onsite armed responders under any circumstances. The final rule, associated guidance, and the risk-informed compensatory measures described in applicants and licensees' security plans, in combination with the NRC's licensing and oversight processes, provide reasonable assurance that any necessary armed response will be available and reliable, enabling applicants and licensees to maintain, at all times, the capability to interdict and neutralize threats up to and including the DBT, even when a facility relies on zero onsite armed responders. Should a licensee or the NRC determine that law enforcement or other offsite armed responders cannot reliably perform the function(s) that the licensee relies on, including interdicting and neutralizing threats, then, in accordance with 10 CFR 73.100(b)(4)(iv)(A)(*5*), the licensee would be required to implement a different method for performing that function(s) to ensure that the licensee can, at all times, adequately defend against threats up to and including the DBT.

Accordingly, the NRC did not change the rule language or guidance in response to this comment.

Comment Bin 8.10.BB: A commenter recommended that after a licensee's SGI program is established, the licensee and the NRC should engage early in preapplication meetings about the expectations for performing sensitivity analyses related to methods for interdicting and neutralizing threats up to and including the DBT (BE1-0004).

NRC Response: The NRC agrees with the comment.

Eligible applicants and licensees should engage the NRC as early as practical to discuss methods for interdicting and neutralizing threats up to and including the DBT. Those discussions should include the types of scenarios and sensitivity analyses an applicant or licensee should consider and evaluate.

Accordingly, the NRC did not change the rule language or guidance in response to this comment.

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9. Procedural Matters and Other Supporting Documents

9.1. Regulatory impact analysis, regulatory flexibility certification, and backfitting

9.1.1. Estimated costs of the proposed rule and alternatives

Comment Bin 9.1.1.A: A commenter expressed concern that the proposed rule would cause their firm serious financial harm. The commenter said that the NRC cannot provide an even-handed cost-benefit analysis and the commenter said that the agency has historically used this analysis to justify expanding regulations in a prescriptive fashion that provided no "particular graduated linkage" between the level of regulation and the public radiation risk, resulting in unrestrained interactions with applicants that incur staggering licensing costs. The commenter said that the NuScale licensing effort cost over $500 million and asserted that licensing under 10 CFR Part 53 would be even more expensive (HPT6-0001, HPT9-0003, HPT29-0004).

NRC Response: The NRC disagrees with these comments.

The NRC disagrees that future licensing efforts will be more expensive than NuScale, or that the proposed rule will cause financial harm. The NRC also disagrees that the agency cannot provide an even-handed cost-benefit analysis. The regulatory analysis (RA) process compared existing regulations within 10 CFR, such as Parts 50 and 52, and compared the burden on record in NRC financial systems and regulatory requirements to the proposed requirements in the proposed rule. The NRC developed the RA for the proposed and final rules following NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," which is based on both EO 12866, "Regulatory Planning and Review," and OMB Circular No. A-4, "Regulatory Analysis."

The vast majority of requirements in the 10 CFR Part 53 proposed rule were either the same or similar to existing requirements, and where differences existed the costs or averted costs were carefully evaluated. While there are new requirements in the proposed rule, the costs of these were also estimated, along with the averted costs of the many requirements in 10 CFR Parts 50 and 52 that were simplified in the proposed rule or not included at all. The RA lists all of the requirements of the proposed rule, compared to existing requirements, in its appendices. The

NRC considers the RA, which discusses incremental costs (not net costs such as what the comment mentions for NuScale), to be a reasonable estimate of expected averted costs.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 9.1.1.B: A commenter said that it is unclear what burden 10 CFR 73.100 would impose on applicants under 10 CFR Part 53. The commenter said that the NRC should demonstrate that 10 CFR Part 53 would not impose serious adverse burdens on passive fail-safe designs (HPT40-0004).

NRC Response: The NRC disagrees with the comment.

The RA conforms to NRC RA guidelines, EO 12866, “Regulatory Planning and Review,” issued September 1993, and OMB Circular A-4, “Regulatory Analysis,” issued September 2023, and demonstrates that the proposed rule provides many averted costs relative to the current regulatory framework. The proposed 10 CFR 73.100 is a new requirement that was determined by the staff to require the same level of effort as the existing 10 CFR 73.55.

Accordingly, the NRC did not change the rule language or the RA in response to this comment.

9.1.2. Estimated benefits of the proposed rule and alternatives

No comments are associated with this issue.

9.1.3. Other comments on the regulatory analysis

Comment Bin 9.1.3.A: A commenter addressed the estimated cost savings under the proposed rule and asked how the NRC accounted for potential uncertainties like the possibility of more applicants than anticipated or other unforeseen regulatory challenges (LM-0002).

NRC Response: The NRC agrees with the comment’s description of the RA.

The RA includes an uncertainty analysis that uses a three-point estimate of cost and averted cost input variables. By appropriate choices of the low and high estimates for these inputs, the RA can account for potential higher costs or lower averted costs as a result of unforeseen regulatory challenges. The RA states that one applicant was considered in order to simplify the analysis and not present potentially nonconservative results by possibly overestimating the number of applicants, because there are net averted costs to each applicant. The NRC does not expect there to be a negative impact on these estimated averted costs due to a large number of applications being submitted within a relatively short period of time.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 9.1.3.B: A commenter requested that the NRC perform a cost-benefit analysis that assesses each change individually under 10 CFR Part 53 compared to 10 CFR Parts 50 and 52. The commenter highlighted several aspects of the rule that they felt would not provide a net benefit to the NRC or industry, including the integrity assessment program, any changes to ALARA requirements, the two independent physical mechanisms to prevent criticality, and extension of SR requirements to NSRSS SSCs (NEI2-0247, NEI2-0216).

NRC Response: The NRC disagrees with the comments.

The RA for the proposed rule was performed by assessing each change compared to the existing regulatory framework precisely as described in the comment. The results of the individual analysis of each proposed rule requirement are provided in the appendices of the RA. Each significant cost was analyzed to determine whether it was necessary to include in order to have a complete, functional, new framework. The NRC identified and removed unnecessary proposed requirements that added significant costs before publication of the proposed rule for public comment, and has also considered other such requirements that could have been determined to be unnecessarily burdensome as a result of public comments.

Accordingly, the NRC did not change the rule language or the RA in response to these comments.

Comment Bin 9.1.3.C: A commenter discussed that the NRC has historically enjoyed broad discretion to interpret its own authority without being subject to regulatory planning and review requirements established by EOs including EO 12866 and EO 13563, “Improving Regulation and Regulatory Review,” issued January 2011. The commenter stated that instead of developing a robust cost-benefit analysis, the NRC developed its own regulations based on its Principles of Good Regulation. The commenter expressed that these regulations reflect NRC-defined qualities such as “efficiency,” but added that the NRC’s treatment of “efficiency” substantively differs from EOs and other guidance.

The commenter further discussed that the NRC adopted an amended mission statement in January 2025 in response to direction in the ADVANCE Act, but that the NRC has neither incorporated this mission statement into 10 CFR Part 53 nor has the NRC addressed how the proposed rule provides an efficient approach to licensing and avoids imposing unnecessary limits on nuclear energy or technology. The commenter said that prior to *Loper Bright Enterprises v. Raimondo*, courts have interpreted statutes mandating “efficiency” to require cost-benefit analysis, as demonstrated by Judge Ginsburg’s opinion in *Business Roundtable v. SEC*. The commenter added that in the post-Loper Bright period, courts’ interpretations of statutory terms like “efficiency” determine their meaning and support a requirement for cost-benefit analysis.

The commenter wrote that, to avoid legal challenges that the rule is arbitrary and capricious, the NRC must show it has considered the efficiency of each portion of the proposed rule alongside benefits to society. Additionally, the commenter stated that the proposed rule cites a regulatory impact analysis prepared in 2023 containing a five-page cost-benefit analysis. The commenter expressed concern that the analysis does not demonstrate that nuclear energy or technology is not unnecessarily limited, as required by the ADVANCE Act (UL-0005).

NRC Response: The NRC agrees, in part, with the comment.

The NRC has historically not been required to follow EO 12866 and 13563, but the NRC also disagrees that the agency did not develop a robust cost-benefit analysis for 10 CFR Part 53. To the contrary, the NRC wrote NUREG/BR-0058, which governed the development of the RA for the proposed rule, specifically to follow the spirit of these EOs. In addition, the NRC has been continually working to improve RAs and to revise its cost benefit guidance to be more in line with these EOs, OMB Circular A-4, and best practices such as those covered in the U.S. Government Accountability Office (GAO) audit (GAO-15-98, "Nuclear Regulatory Commission—NRC Needs To Improve Its Cost Estimates by Incorporating More Best Practices," Report to Congressional Requesters, dated December 12, 2014.

The NRC agrees with the characterization of the mission statement and that the mission statement is not explicitly incorporated into 10 CFR Part 53. However, that is because the Commission had already voted to approve the proposed rule for public comment when the ADVANCE Act passed.

Nevertheless, the NRC has been mindful of efficiency principles throughout this rulemaking process, and the revised mission statement adopted under the ADVANCE Act in finalizing this rule (see the NRC's response to Comment Bin 1.3.B). Thus, the NRC has worked extensively with external stakeholders to ensure that 10 CFR Part 53 provides a workable framework for licensing that also appropriately protects public health and safety and the common defense and security. As a result of those interactions, the NRC has made a number of changes to the rule that increase its flexibility, remove unnecessary requirements, and provide greater efficiencies for potential applicants and licensees.

The NRC disagrees that it failed to conduct a cost-benefit analysis of the 10 CFR Part 53 proposed rule or that it failed to adequately quantify costs or explain why those costs could not be quantified. The NRC agrees that cost-benefit analysis is required but disagrees that the scope of the RA should be expanded to consider some benefits of nuclear energy technology to society and the potential of nuclear energy to improve the general welfare, because the NRC expects these applications would proceed with or without the issuance of this final rule.

The RA provides sufficient support for the final rule because it has already concluded that the benefits from this rulemaking to the agency and industry would greatly exceed the costs and that among the realistic options considered by the NRC for this rulemaking, the recommended option is the most cost-beneficial.

Accordingly, the NRC did not change the rule language or the RA in response to this comment.

Comment Bin 9.1.3.D: A commenter said that EOs 12866 and 13563 would require a more substantial cost-benefit analysis than is included in the proposed rule. For example, the commenter said that under EO 13563, the NRC would need to show that it has analyzed alternative regulatory approaches and chosen the approach that would maximize net benefits by considering each approach's impact on the economy, environment, public health and safety, distribution, equity, and other such impacts. The commenter added that the proposed rule as written does not make any such considerations. The commenter said that although the NRC could wait to comply with EO 13563 as it is reviewed by Federal courts, this could lead the agency to retrofit a cost-benefit analysis to justify the agency's decision. The commenter asked the NRC to revisit the cost-benefit analysis now to avoid a serious impact on the timeline for publishing the final rule (UL-0006).

NRC Response: The NRC disagrees with the comment.

The NRC disagrees that the requirements of EO 12866 and EO 13563 would require a more substantial analysis of costs and benefits than in the RA or that the RA did not show the agency chose the regulatory approach that maximizes net benefits. The development of an entirely new framework necessitates evaluation of alternatives with consideration to the fact that developing multiple alternative frameworks for comparison is not practical or realistic, to the extent the agency has no basis to conclude that such alternate frameworks would provide an appropriate level of safety. The existing frameworks serve as alternatives to the new framework, and the RA compared those alternatives, in addition to providing a full analysis of each new or modified requirement.

Requirements that resulted in costs were evaluated in terms of their necessity in enabling other requirements that resulted in averted costs and were not included in the proposed rule where such costly requirements were deemed unnecessary. Furthermore, the NRC did develop a second regulatory framework as another alternative for consideration, but ultimately the agency decided to present only one framework in the 10 CFR Part 53 proposed rule. The cost estimation process used in development of the RA is consistent with EO 12866, which the agency has incorporated into its RA guidelines, and the agency has worked with Office of Information and Regulatory Affairs to ensure that all of the newly applicable requirements are met. The NRC has analyzed the final rule in accordance with these requirements and assessed the rule, along with any changes that resulted from this public comment process.

Accordingly, the NRC did not change the rule language in response to this comment.

9.1.4. Regulatory flexibility certification

Comment Bin 9.1.4.A: A commenter said that 10 CFR Part 53 would not comply with the Regulatory Flexibility Act and would have a significant adverse economic impact on their small business by increasing licensing costs, which will make competing with larger entities more difficult. The commenter expressed concern that they would not receive adequate funding support from DOE grants. The commenter said that reducing the complexity of 10 CFR Part 53 could help reduce the cost burden on small entities (HPT28-0001, HPT28-0002, HPT28-0003, HPT28-0004). Conversely, the commenter also stated that the proposed rule would provide cost savings on the order of 50 percent and would significantly reduce the cost burden (HPT28-0002).

NRC Response: The NRC agrees, in part, with the comments.

The NRC disagrees with the comments regarding the disproportionate impact to small entities because of their size, and that the proposed rule would increase costs for any applicants when compared to the existing regulatory framework. The regulation in 10 CFR Part 53 is an optional licensing framework: therefore, small entities may continue to use the existing framework for licensing if it is more advantageous from a business standpoint. Consequently, 10 CFR Part 53 will not have a significant adverse impact on small entities. Moreover, there are no provisions in 10 CFR Part 53 that disproportionally impact businesses based on the magnitude of their financial assets. Section “Regulatory Flexibility Certification” of the proposed rule and final rule FRNs further discusses the NRC’s consideration of the impact of this rulemaking on small entities.

The NRC agrees with the comment that the proposed rule would significantly reduce costs to applicants and licensees, which is at odds with the assertion that the rule will increase licensing costs. The comment correctly identifies the DOE as the agency appropriately able to provide assistance to small entities in designing and constructing nuclear reactors.

In addition to the identified averted costs of the proposed rule for any future applicant, the NRC assesses that the overall costs of licensing, constructing, and operating smaller, safer reactors will be significantly less than that of large LWRs. This reduced cost is not captured in the RA because it does not result from the proposed rule language; regardless, this means that by design, small entities will have reduced costs under the NRC's regulatory framework.

Accordingly, the NRC did not change the rule language in response to these comments.

9.1.5. Backfitting and issue finality

No comments are associated with this issue.

9.2. Paperwork Reduction Act (including comments on OMB draft supporting statements)

Comment Bin 9.2.A: A commenter expressed concern that it would take 200 8-hour working days for 143 full-time staff members to meet the estimated total number of hours necessary to comply with the proposed rule's information collection requirements, which they stated could exceed the operational and security staffing for a nuclear facility and is excessive even with auto-reporting systems. The commenter said the NRC should reduce the information collection burden by focusing only on essential items, limiting the additional new information collection requirements and demonstrating reductions from present reporting requirements, excluding collection for routine data, and by consulting with technical experts on meaningful information reporting methods, technology, and streamlining (RD-0033).

NRC Response: The NRC disagrees with this comment.

In the 10 CFR Part 53 supporting statement accompanying the proposed rule, the NRC estimated that there would be two applicants under 10 CFR Part 53 – one for a construction permit and one for a combined license. The burden described by the commenter reflects the burden on these two applicants and is consistent with previously estimated preapplication and application burdens under 10 CFR Part 50 and 10 CFR Part 52. In constructing the supporting statements, the NRC calculates that all one-time reporting and recordkeeping burdens are incurred in the first year of the clearance period (when they may in fact be incurred in many years leading up to application submission). Accordingly, the actual burden on any one applicant in any one year will likely be less than 230,244 hours, which is equivalent to the 200 8-hour working days (i.e., full time for 143 staff) as mentioned by the commenter, and far less than that once operations begin. The detailed breakdown of estimated information collection burdens and supporting assumptions is available in the burden tables that are part of the supporting statements associated with the 10 CFR Part 53 final rule (ML26050A253, package).

Accordingly, the NRC did not change the rule language or supporting statements in response to this comment.

Comment Bin 9.2.B: A commenter said that the proposed rule fails to comply with the Paperwork Reduction Act (HPT27-0006, HPT27-0008).

The commenter expressed concern that their small business would be unfairly and significantly burdened by the proposed information collection requirements. The commenter said that the proposed information collection activities and forms would be overly complex such that they do not support the NRC's claim that the proposed rule would offer greater operational flexibility through enhanced safety margins (HPT27-0001). The commenter discussed that the proposed information collection would not be necessary for the proper performance of the functions of the NRC and that the link between risk-informed NRC responsibilities and the depth of information required in the proposed forms and information collections is difficult to ascertain (HPT27-0002). The commenter further stated that information collection under the proposed rule would require applicants to engage in complex thought and analysis that is not automated (HPT27-0005).

The commenter also said that section XIV of the proposed rule FRN does not support determining whether the estimated information collection burden is accurate or reasonable. The commenter asked NRC to provide a breakdown of the information collection activities associated with the estimated 220,801-hour burden. The commenter suggested that NRC could enhance the quality, utility, and clarity of information collected under the proposed rule by reducing the number of unnecessary items and the activity scope associated with the use of overly burdensome forms and collections (HPT27-0003, HPT27-0004).

Additionally, the commenter stated that it is unclear what "practical utility" refers to in the NRC's request for comment (HPT27-0002).

NRC Response: The NRC disagrees with these comments.

The burden for proposed information collection activities and forms associated with 10 CFR Part 53, including for event reporting, recordkeeping, the application process, and preapplication activities, is comparable to the burden associated with 10 CFR Part 50 and Part 52, and the proposed information collection activities and forms are compliant with the Paperwork Reduction Act. Since the health and safety consequences of improper design, manufacture, construction, or operation of commercial nuclear plants depend on the characteristics of the facility design and not the size of the applicant business, it is not possible to reduce the burden on small businesses by requiring less frequent or less complete reporting, recordkeeping, or accounting and control procedures. The proposed information collection activities are necessary for the adequate protection of public health and safety and support the proper performance of the functions of the NRC.

The detailed breakdown of estimated information collection burdens and supporting assumptions is available in the burden tables accompanying the 10 CFR Part 53 supporting statements (ML26050A253, package).

The NRC's request for comment applies the term "practical utility" as defined in 5 CFR 1320.3(l) to mean the actual usefulness of information to or for the agency to carry out its functions or make information available to third-parties or the public.

Accordingly, the NRC did not change the rule language or supporting statements in response to these comments.

9.3. Environmental assessment

Comment Bin 9.3.A: A commenter said that the proposed rule should require applicants to submit a comprehensive environmental impact assessment and added that such an assessment would increase the regulatory process's credibility. The commenter said that an environmental impact assessment is necessary since nuclear reactors can impact wildlife, contribute to water pollution, or disrupt habitats. The commenter said that both the IAEA and the NRC have issued guidance to facilitate environmental impact assessments for nuclear reactors (NA-0002).

NRC Response: The NRC disagrees with the comment.

As stated in the Environmental Assessment for this rulemaking, there is no physical action under the 10 CFR Part 53 rulemaking, such as the physical construction, operation, and decommissioning of a new reactor. This is because there is no actual new reactor design or siting information that is a part of this rulemaking. However, the NRC is concurrently developing in a separate rulemaking a GEIS for new reactors (NUREG-2249) that assesses the potential new reactor environmental impacts such as air resources, water resources, and biological resources. (See the new reactor GEIS rulemaking at https://www.regulations.gov under Docket No. NRC-2020-0101 and the NRC's new reactor GEIS public website at https://www.nrc.gov/reactors/new-reactors/advanced/modernizing/rulemaking/advanced-reactor-generic-environmental-impact-statement-geis.html.)

NUREG-2249 would support not only 10 CFR Part 50 and 52 licensing applications but also 10 CFR Part 53 license applications once both the 10 CFR Part 53 and the new reactor GEIS rules are finalized. Regardless of when the new reactor GEIS rulemaking is finalized, an appropriate environmental evaluation in accordance with the current version of 10 CFR Part 51 would occur once a license application under 10 CFR Part 53 has been submitted to the NRC. After the submission of the application, the appropriate environmental issues and resources would be assessed and disclosed to the public as specified by NRC regulations in 10 CFR Part 51.

While the IAEA may have its own guidance for environmental evaluations, the NRC's guidance for environmental reviews regarding NEPA has been written with respect to the regulations of 10 CFR Part 51 in RG 4.2, Revision 3, "Preparation of Environmental Reports for Nuclear Power Stations," issued September 2018 (ML18071A400), for applicants and NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants" (see https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1555/index.html) for the NRC. Further information on the NRC's NEPA review guidance for meeting the NRC's NEPA obligations can be found at https://www.nrc.gov/about-nrc/regulatory/licensing/ecoe/nepa-environment-analysis/guidance.html.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 9.3.B: A commenter discussed that the proposed rule could be considered arbitrary and capricious as it does not assess the environmental and climate benefits of nuclear energy in its regulatory impact analysis (e.g., reduced emissions from using nuclear energy

rather than carbon forms of energy). The commenter said that neither the regulatory cost-benefit analysis nor 10 CFR Part 53 address climate change, greenhouse gas emissions, or carbon dioxide.

The commenter requested that the NRC acknowledge and address climate and other environmental impacts in the rulemaking and explain any insignificant findings, adding that this would be consistent with congressional direction in the ADVANCE Act and NEPA. The commenter wrote that the regulatory impact assessment finds that environmental considerations will not be affected and that the NRC's finding of no significant impact does not identify or acknowledge potential impacts on greenhouse gas emissions. The commenter stated that the NRC cannot avoid estimating or quantifying climate impacts merely because of the complexity of the calculations and also recommended that the NRC specifically account for these impacts in future rulemakings (UL-0008).

Another commenter said that the NRC did not consider accounting for the potential effects of climate change on advanced reactors and suggested that the NRC consider including some type of mitigation against natural disasters that are becoming more prevalent. The commenter expressed that this is in line with an April 2024 report from the Government Accountability Office (GAO-24-106326) that recommended that the NRC take action to fully consider the potential effects of climate change (NYS2-0017). Another commenter wrote that the NRC should make it easier to build nuclear power in order to combat the danger posed by anthropogenic climate change (MM-0001).

NRC Response: The NRC disagrees with the comments.

This rulemaking is not authorizing the actual construction and operation of a new reactor. Therefore, assessing any adverse or beneficial impacts of this rulemaking focuses on whether a regulatory action under a finalized 10 CFR Part 53 would be significantly different from the existing regulations. Additionally, any benefit from the actual construction and operation of a nuclear power plant is very much dependent on several factors that cannot be accurately known until an actual application for a selected site is submitted for approval under 10 CFR Part 53.

Under the NRC's regulatory process, issues such as climate change can be assessed during review of an application to construct and operate a nuclear power plant. The NRC did prepare an EA to support the 10 CFR Part 53 rulemaking, which focused on the differences between 10 CFR Part 53 and the current regulatory infrastructure. However, there is no physical action, such as the construction, operation, and decommissioning of a new reactor, under the 10 CFR Part 53 rulemaking. Thus, there is no need to assess the environmental impact for such a new reactor licensing action at this time. An appropriate environmental evaluation in accordance with 10 CFR Part 51 and related guidance would occur once a license application is submitted to actually construct, operate, and eventually decommission a nuclear power plant under 10 CFR Part 53. That is when the issues mentioned in the comments (e.g., climate change) could be assessed by the applicant and the NRC. As stated in several locations in 10 CFR Part 53, the applicant must provide an environmental report under the appropriate licensing process.

While the NRC defers a rigorous evaluation of the environmental impacts of reactor construction and operation to the licensing stage, the RA does recognize some of the societal benefits of nuclear power that may be facilitated by this rule, should it result in more efficient or effective reactor licensing. However, as noted in the NRC's response to other comments, such as Comment Bin 1.3.A and Comment Bin 9.1.3.D, because the RA already establishes that the recommended option is the most cost-beneficial option among the realistic options considered

by the agency, no further purpose would be served by a more detailed discussion of benefits in the RA called for by the comment.

Additionally, the design and siting regulations in 10 CFR Part 53, Subparts B, C, and D, require that plant SSCs important to safety be designed to withstand the effects of natural phenomena, such as flooding, without loss of capability to perform safety functions. These regulations would require applicants to use the best available data to project the expected impacts from these hazards during the operating period. Further, after the licensing process is complete, nuclear power plants are required to operate within technical safety specifications in accordance with the NRC operating license and periodically update the final safety analysis report to assure that it contains and is based on the latest information, including information related to the occurrence of and ability to cope with natural phenomena hazards.

Accordingly, the NRC did not change the rule language or the RA in response to these comments.

9.4. Other comments on procedural matters (e.g., plain writing, criminal penalties, voluntary consensus standards)

Comment Bin 9.4.A: A commenter suggested that the NRC use two methods to address comments on the proposed rule, with the first method being the "ordinary method used by the US NRC" and the second method being the use of artificial intelligence (AI). The commenter suggested that the NRC then compare the results of these two methods for addressing comments (TG25-0001).

NRC Response: The NRC disagrees with this comment.

The NRC received 152 unique comment submissions on the 10 CFR Part 53 proposed rule, with 915 individual comments. Processing and responding to these comments by two different methods, one of which is through "the use of AI," even if possible, would have added unnecessary complexity and significantly added to the resources needed to complete the already complex task of processing and considering this large volume of substantive comments.

In order to meet the NRC's obligations under the Administrative Procedure Act, the agency does use information technology tools, but the individual comment submissions are read and responded to by the NRC.

The comment suggests no changes to the proposed rule. Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 9.4.B: A commenter said that if the NRC forces applicants to use 10 CFR Part 53 as proposed, it will have the unintended consequence of causing the demise of new U.S. nuclear energy. The commenter said that reactors will not be competitive due to needlessly complex and expansive NRC regulations that contravene congressional direction (HPT29-0003).

NRC Response: The NRC disagrees with this comment.

As explained in both the proposed and final rule FRNs, 10 CFR Part 53 is an optional licensing framework; therefore, no applicants will be forced to use it if it does not suit their needs. Moreover, as also expressed in the rules, 10 CFR Part 53 provides many important design flexibilities to potential future applicants that may facilitate the licensing and deployment of some reactor technologies, as directed by Congress in NEIMA.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 9.4.C: A commenter addressed the Plain Writing Act of 2010 and said the NRC should reduce and clarify language complexity in the proposed rule as the language used in the proposed rule is not clear or concise and includes unnecessarily complex words. The commenter said that references to other regulations, guidance, and documents outside the proposed rule impose an undue burden on the reader by limiting the rule's cohesiveness and clarity. The commenter also said that such readability issues also present a challenge for those with a learning disability or other disability and said the NRC should contact disability groups to address these issues (NYS2-0025).

NRC Response: The NRC disagrees with this comment.

As noted in the proposed rule, the NRC attempted to write 10 CFR Part 53 in as clear and concise a manner as possible. However, given the complexities inherent to nuclear regulation, at times some longer words and sentences were unavoidable. In addition, references were used to improve the clarity and conciseness of the rule, where useful, so as to balance the competing priorities of completeness and simplicity. The comment did not propose any specific changes to simplify the rule language.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 9.4.D: A commenter said that 10 CFR Part 53 as proposed will cause severe adverse impacts on the cumulative effects of regulations (CERs) due to its complexity and provided a table of earlier comment submissions by the commenter, which included suggested changes for the proposed rule on a variety of topics. The commenter also said that the NRC should provide a sound, logical, and quantifiable analysis demonstrating that the proposed rule would not impose serious adverse burdens to support section XII on the cumulative effects of regulation (HPT29-0006, HPT29-0005, HPT40-0004).

In response to questions in the proposed rule related to CER, the commenter suggested that the NRC use a workshop style for future public engagements and not limit time available for public comments during meetings (HPT29-0001). The commenter further stated that the effective date of the rule is immaterial because applicants are unlikely to use 10 CFR Part 53 due to its complexity (and will instead use 10 CFR Parts 50 or 52) (HPT29-0002).

NRC Response: The NRC disagrees with these comments.

The NRC seeks to minimize any potential negative consequences resulting from CER. The CER process describes the challenges that licensees, or other impacted entities, may face during implementation of any new requirements. However, as explained in both the proposed and final rule FRNs, 10 CFR Part 53 is an optional licensing framework. Consequently, if implementation

of the rule will impose significant CER on individual applicants or licensees, they may use the existing licensing frameworks instead. In addition, the effective date of the rule is not immaterial because NEIMA requires the NRC to issue the final 10 CFR Part 53 rule by December 2027. The comment does not contain any specific suggestions for ways that the agency could mitigate the impact of implementation of 10 CFR Part 53 on applicants or licensees, should they choose to utilize it.

Additionally, the NRC has prepared a detailed RA that demonstrates that in many cases, the flexible licensing approach reflected in 10 CFR Part 53 will yield substantial savings for the applicant and agency.

Accordingly, the NRC did not change the rule language in response to these comments.

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10. Rulemaking Timeline and Implementation (e.g., requests to extend comment period, public engagement/stakeholder outreach, rulemaking/implementation timeline)

Comment Bin 10.A: Several commenters requested a 60-day extension to the comment period from December 30, 2024, to February 28, 2025, to allow for sufficient time following the holiday season to conduct a thorough review of the proposed rule and to develop detailed comments (NEI1-0001; NIA1-0001; NYS1-0001; USNIC1-0001; USNIC1-0003; HPT1-0001). One commenter expressed concern that a 60-day comment period fails to comply with the public participation requirements in NEIMA (HPT1-0001).

Two commenters discussed that an extension would allow time to coordinate an industry response to support straightforward comment resolution (NEI1-0003; USNIC1-0003). Another commenter said that an extension would support the development of responses to the specific requests for comments and enable broader stakeholder engagement to incorporate diverse input and build public confidence in a new rule (NIA1-0001).

In another submission to the docket, a commenter requested an additional 60-day extension to the comment period from February 2025 to April 2025 to allow for more time to review guidance documents which may impose new requirements on applicants and to comply with NEIMA (HPT26-0001).

The same commenter also requested a 30-day extension to the comment period beyond February 2025 to review the proposed changes to 10 CFR Part 26 and 10 CFR Part 73 and ensure compliance with NEIMA and congressional directives regarding licensing efficiency (HPT14-0001).

NRC Response: The NRC agreed to extend the comment period for the proposed rule from December 30, 2024, to February 28, 2025, for a total of a 120-day comment period, as requested by several commenters to allow more time for members of the public to develop and submit their comments and for the NRC to engage with stakeholders on the proposed rule language. This extension of the comment period was published in the *Federal Register* on November 22, 2024 (89 FR 92609).

The NRC did not agree to further extend the comment period past the 120-day comment period, as requested by one commenter, as NEIMA requires the NRC to issue the final 10 CFR Part 53

rule by December 2027, and the NRC is committed to meeting this congressionally mandated deadline.

These comments suggest no changes to the proposed rule. Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 10.B: A commenter discussed ways that the NRC could apply its Management Directive (MD) 5.2, "Cooperation with States at Commercial Nuclear Power Plants and Other Nuclear Production or Utilization Facilities," dated September 29, 2016 (DT-17-129), to the 10 CFR Part 53 rulemaking and implementation planning.

The commenter stated that MD 5.2 establishes a robust framework for engaging State and local governments in the NRC's reactor program and that the directive is directly applicable to the policy objectives presented in NEIMA and the rulemaking. However, the commenter expressed concern that the NRC neglected to consider how MD 5.2 might be used to fulfill NEIMA requirements and recommended that MD 5.2 be updated and expanded to fit the needs of current and future rulemakings. The commenter suggested that the NRC consider reviewing MD 5.2 and Directive Handbook 5.2 for use as a base framework to build a collaborative environment between States and the NRC. The commenter expressed that the regulatory language mentions the potential use of "[S]tate consultation" in proposed 10 CFR 53.1515, but requested that the NRC consider additional State involvement and established defined roles and responsibilities by utilizing MD 5.2 as a resource or direct reference in the rule. The commenter added that the NRC's Community Advisory Board (CAB) Report similarly fails to consider MD 5.2, and that an "instrument of cooperation" would ideally take the form of a CAB (UT1-0004; UT1-0005).

The commenter discussed that the NRC should engage its Agreement State program, consisting of 39 States, as a resource to assist in developing and implementing MD 5.2, the CAB program, and the Non-Light Water Reactor Near-Term Implementation Action Plans (NTIAP). The commenter expressed that MD 5.2 lacks specific action plans and methods to leverage expertise of State-trained personnel, and that both MD 5.2 and proposed 10 CFR Part 53 lack expertise-based requirements for "[S]tate consultation" or delegated authorities other than the "Governor-appointed" State Liaison Officer. The commenter recommended that the NRC utilize the Agreement State program to its advantage in developing 10 CFR Part 53.

The commenter further explained that the Organization of Agreement States (OAS) provides a mechanism for Agreement States to work with each other and the NRC on directly delegated programs, and suggested that expanding that OAS to address the policies and objectives of MD 5.2 could be advantageous. The commenter also proposed that the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations Council could inform the development of the NRC's CAB program, consistent with MD 5.2 and in support of the NRC's mission.

The commenter proposed that, to implement the policy objectives of NEIMA in collaborative ways, robust State radiation control programs be applied to the NRC's civilian nuclear reactor program. The commenter stated that the scope of the existing Agreement State program should be expanded to include topics in MD 5.2 and to provide guidance for State programs. The commenter discussed that utilization of the Agreement State program would incorporate

State-specific interests and support the projected increase in licensing under 10 CFR Part 53. The commenter suggested that State radiation control managers could serve as a natural bridge between the NRC's civilian nuclear reactor program and State and local government leaders, consistent with MD 5.2 (UT1-0006).

The commenter stated that the NTIAP (ML17165A069) should be updated to incorporate MD 5.2, CABs, Agreement States, and highly aligned organizations such as the OAS, CRCPD, and Energy Communities Alliance to support communication functions in 10 CFR Part 53 in line with NEIMA. The commenter discussed that communication is a foundational priority of the planning process, but that the NRC's current draft NTIAP lack details and actionable plans. The commenter stated that NTIAP strategy 6 regarding communication with stakeholders for non-LWR technologies consists of less than one page of simplistic concepts with no specific plan strategy (UT1-0007).

NRC Response: The NRC disagrees with these comments.

The commenter's recommendations on how to effectively engage with states and the public and on updating other guidance documents do not propose specific changes to the rule language and are outside the scope of this rulemaking. Although the NRC notes that it did recently update MD 5.2 (ML24362A140, dated April 23, 2025), the NRC disagrees with revising the rule language to reference MD 5.2. Management Directives already provide expectations and guidelines applicable to the NRC; therefore, codifying them is not necessary.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.C: A commenter suggested additional "aggressive" regulatory changes that they said would allow the NRC to meet direction from Congress and the President. The commenter said that the NRC could achieve this more aggressive approach on the existing rulemaking timeline as (NEI2-0248)—

- most of the work related to these suggestions has already been completed,
- eliminating pursuit of a proposed 10 CFR Part 56 rulemaking would free up resources for 10 CFR Part 53,
- stakeholders have provided the input necessary to incorporate this more aggressive approach, and
- the NRC can use public workshops to perform a systematic search for more aggressive changes.

Relatedly, another commenter expressed support for more aggressive regulatory changes, including to meaningfully address licensing framework needs that support business models for factory production and testing and implementing quality assurance measures. The commenter discussed that industry has invested significant resources in participating in public meetings and reviewing and commenting on the proposed 10 CFR Part 53 regulatory language to support an inclusive and efficient rulemaking. The commenter suggested that workshops preceded by information collection through a regulatory information summary response would be beneficial in resolving some of the business model-related comments on the proposed rule (BWXT-0001).

A commenter proposed that additional workshops and industry engagement is necessary to further develop guidance to permit the use of more traditional safety analysis approaches and bounding assessments under 10 CFR Part 53 (NEI3-0017).

NRC Response: The NRC acknowledges these comments.

To the extent the comments relate to the processes used to develop the proposed and final rules, the comments are outside the scope of this rulemaking and do not propose specific changes. To the extent the comments suggest additional regulatory provisions would facilitate development of microreactor technologies, the NRC notes that it is pursuing such a rulemaking in response to EO 14300.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.D: A commenter suggested that the NRC establish a priority system to efficiently review public and stakeholder comments on the proposed rule. The commenter stated that the highest priority should be assigned to comments with the greatest importance to overall safety and that meet the requirements of NEIMA and the ADVANCE Act. The commenter discussed that establishing fundamental general criteria first and following with more detailed requirements is an efficient strategy, previously used by both the Atomic Energy Commission and IAEA, that could help to minimize repetitive, contradictory, or incomplete implementation documents. The commenter referenced ML24366A097 (which is comment submission MU1) as an example comment that should be assigned a high priority for review given the discussion of a new regulatory tool that could replace the Linear No-Threshold (LNT) model (MU2-0001).

NRC Response: The NRC acknowledges this comment.

In accordance with the Administrative Procedure Act, the NRC considers all relevant and timely submitted comments. The agency's responses to those specific comments are contained within this document, and this comment response document will be included in the final rulemaking package. The comment suggests no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.E: A commenter asked the NRC to consider the staff recommended changes in SECY-24-0049, "Proposed Rule: Reporting Requirements for Nonemergency Events at Nuclear Power Plants," prior to or at the same time as when the 10 CFR Part 53 rulemaking is being finalized to coordinate and reconcile changes (NEI2-0146).

Further, the commenter recommended that proposed 10 CFR 53.1630(b)(2)(iii), 10 CFR 53.1630(b)(2)(v), 10 CFR 53.1630(b)(3)(ii), 10 CFR 53.1630(b)(3)(iii), 10 CFR 53.1630(b)(3)(iv), and 10 CFR 53.1630(b)(3)(v) be removed and conforming changes implemented, in line with recommendations in SECY-24-0049 to remove comparable requirements in 10 CFR 50.72(b)(2) and (3) (NEI2-0147).

NRC Response: The NRC agrees with these comments.

Accordingly, the NRC revised the rule language in response to these comments. Specifically, the NRC revised 10 CFR 53.1630 to be consistent with the changes to 10 CFR 50.72 proposed to the Commission in SECY-24-0049, “Proposed Rule: Reporting Requirements for Nonemergency Events at Nuclear Power Plants (RIN 3150-AK71; NRC-2020-0036),” dated June 10, 2024. The NRC has also revised NRC Form 361S with conforming changes.

Comment Bin 10.F: A commenter discussed the chronological sequence of events in the rulemaking, stated that the NRC did not resolve individual comments during the 2022 public comment periods, and asserted that the taxpayer costs associated with the rule development are not publicly available and therefore the effort’s efficiency is unknown. The commenter also discussed the role of industry during the rulemaking development, including that industry advice to incrementally implement expeditious and cost-effective regulatory updates to 10 CFR Parts 50 and 52 rather than develop a new 10 CFR Part 53 was ignored.

The commenter expressed concern that new nuclear plant energy costs are about two and one-half times that of similarly sized conventional power plants, and that the domestic nuclear industry will struggle if the NRC does not address extensive and unnecessary overregulation. The commenter stated that the NRC should organize a special taskforce to simplify proposed 10 CFR Part 53, and that a revised rule should be re-issued for public comment (HPT43-0001).

NRC Response: The NRC agrees, in part, with the comment.

The NRC agrees that the timeline discussed in the comment is approximately correct. While the NRC did not resolve and respond to individual comments provided during many public meetings and engagements on 10 CFR Part 53 held during the 2020 through 2022 timeframe, the feedback provided by stakeholders during this timeframe was used by the agency to ultimately inform the development of the proposed Part 53 rule.

The NRC disagrees that the costs associated with the development of this rule are not publicly available. In the draft RA published along with the proposed rule (ML24095A166), in section 5.3, “NRC Implementation,” the analysis includes a $6.2 million (undiscounted) cost for developing the final rule. The costs for the development of the proposed rule were not included in the RA, because once those resources have been expended by the agency, they are sunk costs, which cannot be recovered.

The NRC also disagrees that incremental revisions to 10 CFR Parts 50 and 52 were preferred over a new technology-inclusive risk-informed regulatory framework. NEIMA 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.” Since 10 CFR Parts 50 and 52 evolved primarily for large light-water and nonpower reactors they could not fully consider the variety of designs for advanced nuclear reactors without considerable modification and added complexity for applicants and licensees. The NRC’s rationale for developing a separate framework within 10 CFR Part 53 is provided in SECY-20-0032 and the Commission’s direction in the related staff requirements memorandum.

The NRC disagrees with proposing a significantly simplified 10 CFR Part 53, as doing so would not be in alignment with the NRC principles of good regulation, in particular the principles of efficiency, clarity, and reliability. See also the NRC’s response to Comment Bin 3.12.A.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.G: A commenter stated that right now is the time to work with stakeholders to create a transformational rule that sets the stage for domestic nuclear energy deployment for the next 50 years. The commenter discussed that the NRC could improve the proposed rule by considering detailed stakeholder feedback that accounts for different approaches, pathways, and methodologies to support rapid licensing. The commenter added that the NRC should continue to think about how a final rule would actually be used by industry and the agency (CP-0010).

NRC Response: The NRC agrees with this comment.

10 CFR Part 53 is a technology-inclusive, performance-based approach that in many ways transforms the regulatory paradigm for reactors. The NRC has considered stakeholder feedback throughout the development of the proposed rule, and has continued to do so with the receipt, consideration, and response to 152 unique comment submissions to develop the final rule. This comment suggests no specific changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.H: A commenter commended the NRC for its efforts to consider public comments and direction from Congress and the Commission to support predictable, achievable requirements in proposed 10 CFR Part 53 (CP-0003).

Two commenters discussed that industry has invested significant resources in participating in public meetings and reviewing and commenting on the proposed 10 CFR Part 53 regulatory language to support an inclusive and efficient rulemaking. The commenters added that industry is ready to provide additional input, including by supporting guidance development (SOU-0004; RAD-0016).

NRC Response: The NRC agrees with these comments.

The comments suggest no changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 10.I: A commenter expressed that the NRC must develop or refine processes and procedures to implement the proposed rule, including by incorporating lessons learned from ongoing reviews, improving licensing audits, maximizing the use of “core teams,” incorporating project management best practices, and by considering phased approaches to licensing decisions (CP-0008).

NRC Response: The NRC agrees with the comment.

As explained in the proposed and final rules, some guidance was developed, and additional guidance will be developed to support the implementation of 10 CFR Part 53. The NRC considers lessons learned from related activities when developing guidance and will solicit feedback from stakeholders as the guidance is being prepared.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.J: A commenter expressed concern that no public input was received and no public meetings were held to provide awareness, review, or engagement with stakeholders before DG-5073 was published, inconsistent with the NRC's practice of early engagement with stakeholders. The commenter requested that the draft guidance be rescinded and that any future guidance development occur in an open setting with several public meetings and stakeholder engagement, similar to NRC-endorsed industry guidance on construction site FFD programs (AN11-0001).

NRC Response: The NRC disagrees with this comment.

As part of developing the 10 CFR Part 53 proposed and final rules, the NRC held dozens of public meetings, at which FFD topics were frequently discussed. The NRC notes that the new FFD provisions accompanying the 10 CFR Part 53 rule are optional, and applicants and licensees may choose to reference the existing provisions and accompanying guidance. Nevertheless, the NRC has not issued RG 5.94 (formerly DG-5073) as part of this final rule. The NRC plans to issue RG 5.94 after the publication of the final Part 53 rulemaking. At that time, there may be additional opportunities for stakeholder engagement.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.K: A commenter recommended that the NRC continue to engage with stakeholders and consider the unique characteristics of advanced reactors like SMRs and microreactors to promote safety, innovation, and an accessible framework that remains adaptable to new technologies without imposing unnecessary constraints (BI1-0013).

NRC Response: The NRC agrees with this comment.

The NRC does engage stakeholders at all appropriate points in the rulemaking process and during other regulatory processes. For this rulemaking, following the close of the public comment period on February 28, 2025, on the proposed rule, the NRC did not conduct any stakeholder engagements that would have directly impacted the content of the final 10 CFR Part 53 rule. However, the NRC does have a periodic stakeholder meeting on the topic of advanced reactors and believes that maintaining ongoing stakeholder engagement is key to all regulatory activities.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 10.L: A commenter discussed NEIMA's public involvement requirement in context of the rulemaking, stating that the comment-posting period is unnecessarily long and has truncated the time for stakeholders to collectively and thoroughly understand the proposed rule by reviewing other public comments. The commenter expressed concern that the posting lag to regulations.gov may involve "slow-walking" of issues to "run-out-the-clock" on the comment period. The commenter discussed that the automated process on regulations.gov to

immediately post comments and deliver email notifications has seemingly not been implemented for the rulemaking.

Additionally, the commenter expressed concern that no reasoned public stakeholder comments and subsequent discussions were possible during time-constrained public meetings, and suggested that the current comment resolution process will lead to lawsuits. The commenter requested that the NRC immediately post comments on regulations.gov and amend the FRN to state that an additional 30-day period will be used for public workshops to resolve major issues (HPT11-0001).

NRC Response: The NRC agrees, in part, with this comment.

The NRC agrees that there is a delay between the submission of comments and the posting of comments through regulations.gov, and agrees that the NRC does not post comments immediately. This is because the comment submissions go through an internal NRC process before they are posted publicly to ensure the material posted is appropriate (e.g., not obscene, does not contain personal information). It may be possible that improvements to the comment posting process may be made by the agency in the future as suggested by the comment, but that is outside of the scope of this rulemaking.

The NRC disagrees that the public meetings held during the public comment period specifically did not allow time for the submission of stakeholder comments. The two public meetings were designed to inform stakeholders of the complex and large proposed rule content and to help the stakeholders understand the rule to better inform their written comment submissions. The public meetings related to proposed rules are, in general, not designed to accept public comments during the meetings, and this was made clear to the participants during each meeting. If participants did have comments on the proposed rule during the public meetings, the NRC staff strongly encouraged them to submit those comments in writing through regulations.gov. Given the status of this rulemaking at that time, public workshops to further develop the rule would have been inappropriate.

Accordingly, the NRC did not change the rule language in response to this comment.

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11. Out of Scope

Comment Bin 11.A: A commenter said that the NRC should not allow looser nuclear energy regulations. The commenter suggested focusing on renewable energy development until nuclear fusion becomes viable as a public utility energy source (AN1-0001).

NRC Response: The NRC acknowledges this comment.

The NRC considers this comment to be out of the 10 CFR Part 53 rulemaking scope.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.B: A commenter said that nuclear power is inherently safe, with rare accidents and minimal offsite health impacts over decades of global operation. The commenter said that early or latent radiation fatalities are nearly impossible under current plant design,

operational standards, natural mitigating forces, and emergency response protocols. The commenter also said that even the most severe accidents, like Chernobyl and Fukushima, did not result in widespread offsite fatalities while modern safety measures would likewise prevent widespread fatalities in similar accidents today. The commenter said that the NRC's continued reliance on the LNT model overstates low-dose risks and lacks scientific support, particularly for doses under 100 millisieverts (mSv) where health effects are undetectable. Instead, the commenter said the LNT model should be replaced with a new "Safe Area" regulatory tool that uses dose and dose-rate thresholds to assess public health risk. The commenter said that this approach would align better with the AEA's adequate protection mandate and NEIMA's requirements for a risk-informed, performance-based, and technology-inclusive framework. The commenter said a Safe Area tool would enable consequence-focused evaluations that prioritize high-impact scenarios, support smarter emergency planning, and streamline regulatory decision-making across all reactor types (MU1-0001).

NRC Response: The NRC acknowledges this comment.

Efforts to review the LNT model are outside the scope of this rulemaking and the comment did not propose specific changes to the rule language. However, the NRC notes that it will review the LNT model as part of its response to EO 14300. The results of that review may lead to changes to other regulations, some of which 10 CFR Part 53 references, such as 10 CFR Part 20.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.C: A commenter said NRC's method for calculating latent fatalities from radiation exposure is inadequate, specifically its reliance on the collective dose approach and the cancer mortality risk coefficient of 5.8×10^{-4} per person-rem. The commenter said that this method, which combines individual radiation doses to estimate collective risk, leads to exaggerated and unrealistic results, especially for low-dose exposures. The commenter said that calculating nearly 60,000 latent fatalities annually from medical radiation alone is absurd based on this model and addressed how such calculations conflict with real-world data. The commenter said that radiation from medical procedures and natural background sources contributes negligibly to cancer deaths, contrary to what the model suggests. The commenter also addressed findings from a National Institute for Occupational Safety and Health study which implied that there is a significant risk of cancer from low-level radiation exposure. The commenter said that these findings need to be rechecked for accuracy. The commenter concluded that using such flawed methodologies to assess radiation risk undermines scientific credibility and indicates exaggerated risks for nuclear energy (MU1-0011).

NRC Response: The NRC acknowledges this comment.

The NRC's method for calculating latent fatalities from radiation exposure is not within the scope of this rulemaking. This comment did not propose any specific changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.D: A commenter said that the NRC's Backfit Rule, which uses cost-benefit analysis to justify nuclear safety improvements, should be updated. The commenter expressed concern with the use of collective dose in these analyses saying that it results in misleading conclusions due to the large uncertainties in applying the LNT model, particularly for low radiation levels. The commenter referred to the International Commission on Radiation Protection's concerns about the biological and statistical uncertainties of collective dose calculations. The commenter suggested that NRC should exclude accident radiation exposures under 100 mSv from the Backfit Rule, as health effects below this threshold are undetectable.

The commenter also recommended that the use of the ALARA principle should align with the Backfit Rule and not involve collective doses for exposures below 100 mSv. The commenter said that ALARA actions should only be required if there is a demonstrable reduction in health effects, adding that some dose reductions may not yield meaningful health benefits. Lastly, the commenter said that the use of both the Backfit Rule and ALARA is infrequent due to the low risk of radiation exposure today and proposed modernizing these processes by focusing on situations where health benefits can be proven (MU1-0005).

NRC Response: The NRC acknowledges this comment.

The NRC's backfit and ALARA regulations are not generally within the scope of this rulemaking. However, to the extent the commenter identifies concerns with these regulations based on their reliance on the LNT model, the NRC notes that it will reconsider that model in response to EO 14300. This comment did not propose any specific changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.E: A commenter discussed various data and analyses including dose rates and cumulative doses related to radiation health effects followed by an adaptation of radiation incidents compiled by Devanney. The commenter said that Devanney observed an inconsistency in the LNT model that certain high doses over extended periods did not result in detectable cancer, specifically referencing "dial painters" who received high doses but showed no increase in bone cancers. The commenter also discussed a hypothetical terrorist attack analysis at the Indian Point nuclear plant where terrorists were assumed to breach the containment building and cause a meltdown. The commenter said that the study focused on site-specific evacuation scenarios, with different traffic models and meteorological data, and calculated radiation exposure for evacuees. The commenter said that the study's results showed zero early fatalities for most terrorist scenarios, even in mass evacuation situations, highlighting that evacuation speed and route precision played a significant role in minimizing exposure. The commenter said that the study suggested that sheltering could be a better option than evacuation in certain high-density areas due to road congestion during mass evacuations. The commenter said that this analysis also showed that conventional evacuation models might underestimate the severity of radiation health effects by not accounting for more complex evacuation dynamics. The commenter concluded that nuclear power plants are highly unlikely to result in early fatalities from accidents, with the health effects from such events likely being limited to stress from fear which they said is similar to the impacts of "dirty bombs." The commenter said that while high-dose epidemiological studies are valuable scientifically, they are less relevant for regulatory purposes given the low likelihood of such extreme events at nuclear plants (MU1-0009).

NRC Response: The NRC acknowledges this comment.

The NRC's analysis of security vulnerabilities at the Indian Point facility is not within the scope of this rulemaking. To the extent the comment identifies concerns with the LNT model, the NRC notes that it will reevaluate that model as part of its response to EO 14300. This comment did not propose any specific changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.F: A commenter discussed the NRC's decision to require PRAs after the Three Mile Island accident. The commenter briefly gave an overview of the history of PRA (TG22-0003). Another commenter requested the NRC undertake a study of health effects surrounding the Three Mile Island facility before authorizing restart of that plant and that the NRC consider lowering the annual permissible dosage for workers (JH-0001).

NRC Response: The NRC acknowledges these comments.

The NRC considers these comments to be out of scope of the 10 CFR Part 53 rulemaking. The comments do not suggest specific changes to the proposed rule.

Accordingly, the NRC did not change the rule language based on this comment.

Comment Bin 11.G: A commenter said they were pleased with the results of the staff evaluation report and individual plant examination for Nine Mile Point Unit I (TG22-0005).

NRC Response: The NRC acknowledges this comment.

The NRC considers this comment to be out of scope of the 10 CFR Part 53 rulemaking. The comment does not suggest changes to the proposed rule.

Accordingly, the NRC did not change the rule language based on this comment.

Comment Bin 11.H: A commenter expressed concern with the environmental risks of nuclear power, including the damage caused by uranium mining, the long-term dangers of radioactive waste, and contamination from routine leaks of materials like tritium. While acknowledging nuclear energy's low carbon emissions, the commenter questioned whether the proposed rule would effectively reduce pollution and protect public health. The commenter urged the NRC to require stricter waste management, better monitoring, and focus on long-term environmental sustainability in nuclear regulations (LM-0001, LM-0003).

Another commenter said that fears about nuclear waste are largely unfounded from a technical standpoint. The commenter said that the safe disposal of high-level nuclear waste is achievable such as using Yucca Mountain for waste storage. The commenter said that radiation from nuclear waste decreases significantly over time with spent fuel becoming less dangerous after just a few decades. Additionally, the commenter said that concerns with the long half-lives of certain radioactive materials are overstated since these materials pose minimal health risks

when stored properly. The commenter said education on nuclear waste risks should be improved since public misunderstanding of nuclear waste risks hinders the success of nuclear waste disposal programs (MU1-0008).

Another commenter said that the proposed rule does not emphasize long-term storage of radioactive waste, including storage, transportation, and disposal of radioactive waste in a manner that provides long-term protection of human health and the environment. The commenter suggested that the NRC requires facilities to develop and submit a waste management plan describing how radioactive materials will be handled, disposed, and treated during the life of the reactor and added that a good waste management plan is necessary to ensure the safety of the environment and the public (NA-0004).

NRC Response: The NRC acknowledges these comments.

The environmental impacts of this rulemaking were fully discussed in the accompanying environmental assessment to this rule. Concerns related to the uranium fuel cycle beyond those discussed in the environmental assessment are not within the scope of this rulemaking. These comments did not propose any specific changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 11.I: A commenter said that “we” need more large scale nuclear power (JSM-0001).

NRC Response: The NRC acknowledges this comment.

The NRC considers this comment to be out of scope of the 10 CFR Part 53 rulemaking. The comment does not suggest changes to the proposed rule.

Accordingly, the NRC did not change the rule language based on this comment.

Comment Bin 11.J: A commenter said that the NRC must be more transparent in addressing concerns from stakeholders (HPT32-0002).

NRC Response: The NRC acknowledges this comment.

The NRC’s procedures for conducting public meetings and engaging with the public are not within the scope of this rulemaking. This comment did not propose any specific changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.K: A commenter submitted text from 10 U.S.C. 8300. The commenter referenced a letter on 10 CFR 53.440, but it was not attached (HPT12-0001).

NRC Response: The NRC acknowledges this comment.

The NRC did not change the rule language in response to this comment.

Comment Bin 11.L: A commenter stated that building a reactor in a factory would be a new challenge for the NRC and asked how the NRC will oversee factory-built reactors that are made in the states and overseas in places like China (AN10-0003).

NRC Response: The NRC disagrees with this comment.

NRC regulations in 10 CFR Part 52 already permit factory manufacture of a reactor, and the NRC has historically observed manufacture of important safety components overseas. Additionally, the oversight of factory-built reactors is outside of the scope of this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.M: A commenter wrote that they are disappointed with the NRC's approach to digital common cause failure (TG17-0008).

NRC Response: The NRC acknowledges this comment.

This comment did not propose any specific changes to the rule language in 10 CFR Part 53.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.N: A commenter said that it will take more than an approved application or licensing process to actually regulate nuclear plants, and that the NRC should look to advice readily available in "Laying the Foundation for New and Advanced Nuclear Reactors in the United States" by the National Academies of Science, Engineering, and Medicine. The commenter asked the NRC to confirm that each of the 24 "Regulatory Matters" listed on pages 126 and 127 have been assigned to an NRC supervisor by name and that supervisor's manager by name, by an even higher level of NRC management. Additionally, the commenter asked the NRC to read lines 30 and 31 on page 128 and lines 1 and 2 on page 129 (TG23-0001).

NRC Response: The NRC acknowledges the comment.

Specific personnel assignments for follow-on activities are outside the scope of this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.O: A commenter said that NEPA review process should be streamlined to be more timely and should be strengthened to preclude frivolous challenges, such as by ensuring that challenges are relevant to the issue being addressed and by clearly specifying timelines and deadlines for introduction of new information (NEX-0002).

NRC Response: The NRC acknowledges this comment.

This comment is out of scope of the 10 CFR Part 53 rulemaking.

As stated in several public meetings, the NRC has been and continues to work toward a more streamlined and efficient environmental review process in meeting the agency's NEPA obligations. Several of the items made by the commenter are currently being considered by the NRC. To this end, the NRC has a public website specifically on all of the actions the agency has taken and is in the process of implementing for modernizing environmental reviews at https://www.nrc.gov/about-nrc/regulatory/licensing/ecoe/modernizing.html. From this website, the Environmental Center of Expertise present 22 items regarding streamlining and efficiencies the NRC is pursuing.

Additionally, the NRC sent the Commission and received their Staff Requirements Memorandum on the NEPA amendments in the Fiscal Responsibility Act (SECY-24-0046). Congress also gave specific directions to the NRC for streamlining the agency's environmental review processes in section 506 of the ADVANCE Act and the required report to Congress was delivered on time in January 2025. With respect to actions under the ADVANCE Act, the NRC has established a website to keep the public aware of related actions and continues to hold public meetings on the same. Additionally, the NRC will consider further changes to streamline its NEPA processes in response to EO 14300.

Regarding the idea of precluding frivolous challenges, the NRC regulations regarding contested hearings for an NRC action are contained in 10 CFR Part 2. The regulations in Part 2 are designed to focus litigation on material, supported issues within the scope of the proceeding. The NRC will also evaluate ways to streamline its hearing processes in response to EO 14300. However, considerations related to economizing the NRC's NEPA and hearings processes are outside the scope of this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.P: Citing research and data and using the Fukushima-Daiichi incident as an example, a commenter warned against over-evacuating in response to an emergency. The commenter proposed a new multi-step approach for developing an offsite emergency plan. The commenter added that in the event of an accident outside the spectrum of accidents, emergency planners should advise the public to take shelter or evacuate the innermost one mile from the site boundary. The commenter also advised that during an emergency it may be necessary for the emergency response team to modify the response plan in an ongoing manner, but this should not lead to massive evacuations and relocations.

The commenter added that, overall, this would provide a risk-informed and performance-based approach, and that they supported the continued use of the 50-mile EPZ (MU1-0002, MU1-0010).

NRC Response: The NRC acknowledges this comment.

The NRC understands that Section 12, "Appendix E - Present Emergency Planning Defects," in the comment submittal MU1 is the commenter's understanding of how evacuations are currently addressed by the NRC and how the commenter believes they should be addressed with regards to a significant radiological release from a nuclear power plant. The NRC understands that

Section 5, “Modernizing Emergency Planning,” in the comment submittal MU1 is how the commenter believes the development of offsite emergency plans could be modernized. As the scope of the 10 CFR Part 53 rulemaking and the supporting guidance documents do not include offsite evacuation emergency planning or the development of offsite emergency plans, these comments are out of scope of the proposed rule.

Accordingly, the NRC did not change the rule language in response to these comments.

Comment Bin 11.Q: A commenter recommended that the staff incorporate to the maximum extent practicable updates to its licensing processes and procedures that recognize and leverage license reviews performed by non-U.S. regulators (e.g., the Canadian Nuclear Safety Commission).

NRC Response: The NRC acknowledges this comment.

The NRC routinely evaluates and addresses regulatory priorities associated with the identification of and update to licensing processes and procedures and will continue to do so as the regulatory environment evolves. However, these updates are outside of the scope of this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.R: A commenter said that New York State is developing a plan that would establish a framework for in-depth examination of key issues necessary to implement advanced nuclear technologies in New York State. The commenter said that the plan will address regulatory, safety, and siting concerns, as New York places a strong policy focus on nuclear safety, public health and the environment (NYS2-0002).

NRC Response: The NRC acknowledges this comment.

The NRC appreciates being informed of stakeholder plans with respective to issues of interest to the agency, however, those stakeholder plans are beyond the scope of this rulemaking.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.S: A commenter discussed that, in 2024, they suggested that industry codes and standards be included as a discussion topic in one of the periodic stakeholder meetings regarding advanced reactors. The commenter said that they provided a presentation slide deck and that the NRC scheduled the topic for a public meeting, but that the NRC removed the topic from the agenda 2 days before the meeting. The commenter stated that their email access was blocked when attempting to communicate with the NRC regarding the meeting topic change (HPT8-0002).

NRC Response: The NRC acknowledges the comment.

NRC meeting agendas are not within the scope of this rulemaking, and the comment does not suggest any changes to the proposed rule.

Accordingly, the NRC did not change the rule language in response to this comment.

Comment Bin 11.T: Referring to 10 CFR 140.[1]3, a commenter asked if $1,000,000 is enough (TG17-0002).

NRC Response: The NRC acknowledges the comment.

The NRC understands the comment to be referring to 10 CFR 140.13 and asking about the amount of financial protection required of certain holders of construction permits and combined licenses. Because this amount is already established in 10 CFR 140.13 and the only change in this rulemaking is to make the requirement applicable to licensees under 10 CFR Part 53, the NRC considers the question to be outside the scope of this rulemaking activity.

Accordingly, the NRC did not change the rule language in response to this comment.

Comments received after closure of the comment period

Comment Bin 11.U: A commenter initially submitted comments on the 10 CFR Part 53 proposed rule, attaching the report “Modernizing the Nuclear Regulatory Commission.” After the closure of the proposed rule comment period, the commenter submitted a supplemental commentary with additional information contained in the attachment titled “Modernizing the NRC-Supplemental Analyses.”

This comment submission was sent after the closure of the 10 CFR Part 53 proposed rule comment period and has not been addressed by the NRC as part of this rulemaking activity.