

ORAL ARGUMENT NOT YET SCHEDULED**No. 19-1240**

**United States Court of Appeals
for the District of Columbia Circuit**

NUCLEAR ENERGY INSTITUTE,**Petitioner,****v.****U.S. NUCLEAR REGULATORY COMMISSION
and the UNITED STATES OF AMERICA,****Respondents.**

**On Petition for Review of an Action of the
United States Nuclear Regulatory Commission**

PETITIONER NUCLEAR ENERGY INSTITUTE'S OPENING BRIEF

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September 30, 2020

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certifies the following:

A. Parties and Amici

Petitioner: Nuclear Energy Institute (“NEI”), on behalf of its members.

Respondents: United States Nuclear Regulatory Commission (“NRC”) and the United States of America.

There are no intervenors or amici in this case to date.

B. Ruling Under Review

Petitioner seeks review of NRC’s adherence to and substantive and material alteration of Regulatory Issue Summary 2016-11 (“RIS 2016-11”) without notice, as expressed in NRC’s September 16, 2019 letter to NEI. NRC’s September 16, 2019 letter indicates that NRC intends to rely on RIS 2016-11 as a basis for enforcement actions going forward.

C. Related Cases

This case was not previously before this Court or any other court. NEI is not aware of any other related cases.

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CORPORATE DISCLOSURE STATEMENT

As required by Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioner NEI submits the following corporate disclosure statement. NEI is a nonprofit organization founded in 1994 and incorporated in the District of Columbia. NEI is a “trade association” as that term is defined in Rule 26.1(b). NEI has no parent company, and no publicly held company has any ownership interest in NEI. NEI represents the policy interests of its members in the nuclear power industry, including nuclear power plant licensees, reactor designers and advanced technology companies, architect and engineering firms, fuel suppliers and service companies, consulting services and manufacturing companies, companies involved in nuclear medicine and nuclear industrial applications, radionuclide and radiopharmaceutical companies, universities and research laboratories, law firms, labor unions, and international electric utilities.

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

1986 Information Notice	NRC, Information Notice No. 86-90, Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.302 (Nov. 3, 1986)
2016 Issue Summary	Regulatory Issue Summary 2016-11
2019 Letter	September 16, 2019 letter from NRC to petitioner Nuclear Energy Institute
AEA	Atomic Energy Act
AEC	Atomic Energy Commission
APA	Administrative Procedure Act
EPA	Environmental Protection Agency
Legal Opinion	NRC, Jurisdiction Over Low Level Waste Management at Reactor Sites in Agreement States (Sept. 13, 1985)
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
Public Meeting Summary	NRC, Summary of September 6, 2019 Public Meeting (Oct. 2, 2019)
South Texas	STP Nuclear Operating Company
South Texas Letter	Aug. 14, 2018 Letter from STP Nuclear Operating Company to NRC

JURISDICTIONAL STATEMENT

This petition seeks review under the Administrative Procedure Act (“APA”) of the Nuclear Regulatory Commission’s (“NRC”) final agency action contained in a September 16, 2019 letter to petitioner Nuclear Energy Institute (“NEI”) (“2019 Letter”) (JA__). *See* 5 U.S.C. §§ 551, 702. This Court has jurisdiction under 42 U.S.C. § 2239(b)(1) and 28 U.S.C. § 2342(4) to review NRC’s final agency order, which effects a “modification of rules and regulations dealing with the activities of licensees.” 42 U.S.C. § 2239(a)(1)(a). NEI timely filed the petition for review on November 15, 2019, within sixty days of NRC’s 2019 Letter. *See* 28 U.S.C. § 2344.

STATEMENT OF ISSUES

1. Do “direct and appreciable legal consequences” flow from the 2019 Letter such that it constitutes reviewable final agency action? NEI answers yes.
2. NRC’s 2019 Letter states that the agency will now apply an informal guidance document titled “Regulatory Issue Summary 2016-11” (“2016 Issue Summary”) in enforcement actions against reactor licensees that do not obtain a previously unnecessary approval from NRC for disposal of very low-level radioactive waste. 2019 Letter 1 (JA__). But NRC provided no notice or opportunity to comment on the 2019 Letter (or the 2016 Issue Summary to which the 2019 Letter ascribes new meaning and legal effect). Did NRC violate the APA

by failing to provide any notice or opportunity to comment before imposing a new regulatory obligation on nuclear power licensees? NEI answers yes.

3. NRC's 2019 Letter relied upon a single statement in the 2016 Issue Summary asserting that NRC's prior interpretation of the Atomic Energy Act ("AEA") and NRC regulations was incorrect. *See* 2019 Letter 1 (JA__). But neither the 2019 Letter nor the 2016 Issue Summary provides any explanation or supporting rationale for NRC's new position that the AEA precludes transfer of regulatory jurisdiction over disposal of very low-level waste to "Agreement States." Did NRC violate the APA by failing to provide the required reasoned explanation for its changed interpretation? NEI answers yes.

4. A foundational NRC regulation known as the "Backfitting Rule" requires the agency to conduct an analysis before imposing new or amended regulations or interpretations on reactor licensees. The 2016 Issue Summary stated that because it "require[d] no action or written response" and was "strictly voluntary," no "backfitting" analysis was required. 2016 Issue Summary 3 (JA__). But then, without any backfit analysis and without even addressing the Backfitting Rule, NRC's 2019 Letter stated, for the first time, that nuclear licensees must follow the 2016 Issue Summary or else face enforcement action. Was NRC's failure to perform a backfitting analysis arbitrary and capricious, an abuse of discretion, or

otherwise a violation of law, as well as inconsistent with its own regulation? NEI answers yes.

5. The AEA allows NRC to transfer authority to regulate nuclear waste disposal to the states unless NRC determines by “regulation or order” that for reasons of public safety it must maintain that authority. 42 U.S.C. § 2021(c)(4). In 1962, NRC determined by regulation that states may regulate low-level waste disposal, and accordingly entered into agreements transferring this authority to many Agreement States. Decades later, without issuing any “regulation or order” as required by the AEA, NRC reasserted jurisdiction over the disposal of very low-level waste. Does NRC’s new claim of authority contravene both the AEA and NRC’s own regulations? NEI answers yes.

STATUTES AND REGULATIONS

Applicable statutes and regulations are contained in the separate addendum filed herewith at ADD67-75. *See* Fed. R. App. P. 28(f); D.C. Cir. R. 28(a)(5).

INTRODUCTION

This case tests basic principles of fair administrative process and NRC’s own “Principles of Good Regulation.”¹ Upending decades of settled agency practice on

¹ *See* NRC, *Values: Principles of Good Regulation* (last updated Apr. 19, 2019), <https://www.nrc.gov/about-nrc/values.html#principles> (stating that “[t]he public must be informed about and have the opportunity to participate in the regulatory processes as required by law,” and that “[a]gency positions should be readily understood and easily applied.”).

which members of NEI had come to rely, NRC altered the relative roles of the federal and state governments in regulating disposal of low-level radioactive waste. NRC's decision, conveyed in its 2019 Letter, expanded its own regulatory authority and imposed new obligations on owners and operators of nuclear power reactors (NRC "licensees"). NRC mandated that licensees obtain NRC approval for the land disposal of certain low-level waste—*i.e.*, "very low-level waste," and concluded that existing state disposal authorizations are no longer sufficient.

NRC thus abandoned its longstanding position that states exercising authority transferred to them from NRC under AEA Section 274, 42 U.S.C. § 2021, so-called "Agreement States," have control over the land disposal (*i.e.*, burial) of very low-level waste. NRC's new policy is both procedurally defective and substantively untenable, in violation of the APA, the AEA, and NRC's own regulations. In short, NRC failed to: (1) give NEI's members fair notice or opportunity to comment on the policy change; (2) provide any legal analysis, factual basis, or reasoned decisionmaking to justify the change in position; (3) perform a backfit analysis as required by its own regulations; and (4) comply with AEA Section 274 and NRC's implementing regulations. The 2019 Letter therefore has both legal and practical consequences for the nuclear industry.

NEI recognizes that, in passing the AEA, Congress "enact[ed] a regulatory scheme, which is virtually unique in the degree to which broad responsibility is

reposed in the administering agency, free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives.” *Siegel v. Atomic Energy Comm’n*, 400 F.2d 778, 783 (D.C. Cir. 1968). But that discretion is not unbounded. There are areas where Congress has prescribed how NRC is to exercise its authority. Ignoring those constraints, NRC changed the regulatory rulebook governing very low-level waste disposal. It did so by fiat—without adhering to settled principles of administrative law as well as applicable statutory and regulatory requirements.

This Court should not permit NRC to shortcut required processes by using a mere letter to express its decision, and then use those procedural shortcuts to avoid NEI’s challenge. Indeed, NRC’s 2019 Letter should have taken the form of—not substituted for—a regulation or order under the AEA, *and* the agency should have complied with the APA’s notice-and-comment and reasoned decisionmaking requirements, *and* its own regulations governing the imposition of such policy changes. This case requires vacatur of NRC’s unlawful action, and remand for further agency consideration of relevant issues—this time with full participation by the industry and other stakeholders, as required by law.

STATEMENT OF THE CASE

A. The Atomic Energy Act and the Regulation of Low-Level Radioactive Waste

In generating approximately 20% of the nation’s electrical power and much of its carbon-free energy, nuclear plants produce certain types of radioactive waste.

That waste presents risks of varying degrees depending primarily on the radioactivity level of the given type of waste. 10 C.F.R. § 61.55. The AEA distinguishes among different types of radioactive waste, including high-level and low-level waste.² Low-level radioactive waste includes items that have become contaminated with radioactive material or have become radioactive through exposure to radiation (*e.g.*, old reactor parts, used protective clothing, or everyday equipment and tools). At issue here is the disposal of very low-level radioactive waste, which is waste with some residual radioactivity, but at the lowest end of the low-level waste spectrum.

NRC regulations provide several pathways for disposing of low-level waste. Those include, for example, transferring the material to an NRC-licensed disposal facility, or releasing it in effluents within regulatory limits. 10 C.F.R. § 20.2001(a)(1), (3). NRC regulations also allow licensees to obtain approval of alternative procedures for low-level waste disposal, such as disposal in hazardous or municipal solid waste landfills that, while strictly regulated, are not licensed under the AEA. 10 C.F.R. § 20.2002. For decades, power reactor licensees located in so-called “Agreement States” have obtained approval for such alternative disposal procedures from the states, not NRC.

² Low-level waste is radioactive waste not considered high-level waste, spent nuclear fuel, transuranic waste, or byproduct material. 42 U.S.C. § 2021b(9).

B. NRC's Agreement State Program

While NRC has jurisdiction over most civilian uses of nuclear materials, AEA Section 274 authorizes NRC to transfer regulatory authority over specific categories of nuclear materials to the states. 42 U.S.C. § 2021. Thus, NRC may cede some of its regulatory authority by “enter[ing] into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the [NRC]” and the assumption of the authority by the state. *Id.* § 2021(b). These “Agreement States” then assume “authority to regulate the materials covered by the agreement.” *Id.*; *see also* 10 C.F.R. § 150.10.

Before transferring such authority, NRC must find that the Agreement State's proposed regulatory regime is “compatible with the [NRC's] program” and “adequate to protect the public health and safety.” 42 U.S.C. § 2021(d)(2). Thereafter, through its “Integrated Materials Performance Evaluation Program,” NRC provides oversight of Agreement State programs to ensure they remain compatible with NRC's program, and that public health and safety are adequately protected. Section 274 also allows NRC to reclaim its regulatory authority when necessary to protect public health and safety, or when an Agreement State fails to meet its regulatory obligations. *See id.* § 2021(j). Neither circumstance, however, is present or alleged to apply here.

C. Limitations on NRC’s Delegation Authority: Plant “Operation” vs. “Waste Disposal”

The AEA places some limitations on NRC’s ability to delegate authority to Agreement States. *See* 42 U.S.C. § 2021(c). Section 274(c) states that a transfer of NRC’s authority to Agreement States may not extend to “the *construction* and *operation* of any production or utilization facility or any uranium enrichment facility.” 42 U.S.C. § 2021(c)(1) (emphasis added). Thus, NRC’s jurisdiction over construction and operation of nuclear power plants (which are utilization facilities) is unaffected by NRC’s transfer of other regulatory authority to an Agreement State. Regulation of nuclear power plant construction and operation (and likewise that of enrichment and certain other complex nuclear facilities) lies at the core of NRC’s regulatory mission and expertise and thus is exclusive to NRC. The AEA also prevents NRC from delegating authority over disposal of certain nuclear waste materials “as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed without a license from the Commission.” *Id.* § 2021(c)(3); *see also id.* § 2021(c)(4).

In promulgating the AEA’s implementing regulations, NRC’s predecessor, the Atomic Energy Commission (“AEC”), determined that it could delegate authority over low-level waste disposal to Agreement States. In the preamble to that final rule, the AEC explained that many comments on the proposed rule questioned whether the Commission should maintain control “of the commercial land burial of

byproduct, source, or special nuclear wastes.” 27 Fed. Reg. 1351, 1351 (Feb. 14, 1962). Upon considering such comments, the AEC “decided against blanket reservations of control over land burial of waste.” *Id.* The agency clarified that “[c]ontrol over the handling and storage of waste at the site of a reactor, including effluent discharge, will be retained by the Commission as a part of the control of reactor operation.” *Id.* But the Commission stated unequivocally that, “[t]he states will have control over land burial of low level wastes.” *Id.* (emphasis added).

Thus, the Commission clearly distinguished between the “storage and handling” of nuclear waste, which it viewed as “part of the control of reactor operation,” and the “disposal” of low-level waste. This distinction makes logical sense. *See id.* Disposal refers to the “permanent isolation” of the waste (and not its temporary storage). 42 U.S.C. § 2021b(7). As a practical matter, “storage” usually refers to the temporary holding of waste prior to treatment or disposal.

NRC’s current regulations implementing AEA Section 274, at 10 C.F.R. Part 150, reinforce the basic distinction between the agency’s regulatory jurisdiction over nuclear power plant operation and its jurisdiction over low-level waste disposal. Section 150.15(a)(1) of NRC’s regulations provides that persons in Agreement States “are not exempt from the Commission’s licensing and regulatory requirements with respect to . . . [t]he construction and operation of any production [*i.e.*, nuclear fuel] or utilization [*i.e.*, nuclear reactor] facility.” 10 C.F.R.

§ 150.15(a)(1). The regulation further provides that “operation of a facility,” as that term is used in that subparagraph, “includes, but is not limited to (i) the *storage and handling* of radioactive wastes at the facility site by the person licensed to operate the facility, and (ii) the discharge of radioactive effluents from the facility site.” *Id.* (emphasis added). That is unremarkable, as storage and handling, and likewise controlled discharges of plant effluents, are all considered part of the nuclear power plant *operation*. Disposal of low-level waste is not.

D. NRC Has Long Interpreted Its Regulations to Provide Jurisdiction Over Low-Level Waste Disposal to Agreement States

Consistent with the foregoing framework, NRC for decades interpreted 10 C.F.R. §§ 150.10 and 150.15 to provide for Agreement State jurisdiction over very low-level waste disposal procedures. Consequently, NRC licensees in Agreement States have long sought, and routinely obtained, state approvals of their waste disposal procedures—not NRC approval under 10 C.F.R. § 20.2002, which NRC now claims is necessary.

NRC articulated the jurisdictional dichotomy outlined above in a 1985 opinion by its Office of Executive Legal Director. *See* Office of Executive Legal Director, NRC, Jurisdiction Over Low Level Waste Management at Reactor Sites in Agreement States (Sept. 13, 1985) (“Legal Opinion”) (JA__-__). It concluded, consistent with the language of the AEA and its implementing regulations, that NRC retained jurisdiction over *handling* and *storage* of low-level waste at the reactor site

under 10 C.F.R. § 150.15, but delegated authority over waste *disposal* to Agreement States. *Id.* The Legal Opinion reflected explicit consideration of the relevant statutory and regulatory provisions as well as the Part 150 preamble. *Id.* at 2 (JA__). The Legal Opinion further observed that “the NRC is not at liberty to vary the clear meaning given to this regulation by the [AEC] *without a rulemaking proceeding, or by issuance of appropriate orders*, pursuant to Section 274c. of the [AEA].” *Id.* (emphasis added).

NRC incorporated this Legal Opinion into an NRC “Information Notice”³ distributed to all NRC reactor licensees. *See* Office of Inspection Enforcement, NRC, Information Notice No. 86-90, Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.302 (Nov. 3, 1986) (“1986 Information Notice”) (JA__). The 1986 Information Notice informed “nuclear reactor licensees of the authority of Agreement States in reviewing and approving disposals of waste that in the past might have been reviewed by the NRC” under 10 C.F.R. § 20.302(a) (since re-designated as Section 20.2002(a)). *Id.* at 1 (JA__). It explained that when a “reactor facility was in an Agreement State, *the NRC did not have a legal basis for performing the reviews and granting approvals*” for low-level waste disposal. *Id.*

³ NRC uses “information notices” to communicate operating experience to the nuclear industry. It expects licensees to review the notice for applicability and consider appropriate actions. *See* NRC, Information Notices, <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/> (last updated Sept. 17, 2020).

(emphasis added). Citing the Legal Opinion, the Information Notice further stated “that in Agreement States NRC approval is not necessary for *disposal* within or outside of the exclusion area of low-level radioactive waste from a reactor facility” because “[s]uch approval is within the jurisdiction of the Agreement State.” *Id.* Here again, NRC treated Section 20.2002 as addressing low-level waste *disposal*.

E. NRC’s Puzzling Change in Position, and Its Consequences for Reactor Licensees

For the next three decades, licensees in Agreement States accordingly sought approval to dispose of very low-level waste from Agreement States, not NRC. And Agreement States provided such approvals. Licensees have relied on those state approvals, as reflected in the NEI member declarations filed in this case. But thirty years after NRC’s 1986 Information Notice stated that NRC approval is not necessary for the *disposal* of very low-level waste from reactor facilities located in Agreement States, *see* 1986 Information Notice 1 (JA__)—and with no changes in law or other circumstance—NRC apparently began to reverse course. The breadth and regulatory import of NRC’s rewrite of the regulatory history would not be fully revealed until its 2019 Letter.

NRC’s 2016 Issue Summary cryptically asserted that NRC’s 1986 Information Notice was a thirty-year mistake that “incorrectly stated that in cases where a nuclear reactor facility is located in an Agreement State, the NRC does not have the legal basis for performing the reviews and granting approvals.” 2016 Issue

Summary 1 (JA__). It also stated that “any licensee’s request for approval to dispose of licensed material under 10 CFR 20.2002, or the equivalent Agreement State regulations, must be submitted to the regulatory authority that issued the license for use of the radioactive material.” *Id.* at 2 (JA__). But NRC provided no legal analysis or policy justification for these assertions. In particular, the 2016 Issue Summary failed to mention the jurisdictional issues discussed in NRC’s 1985 Legal Opinion, and offered no alternative interpretations of the AEA’s relinquishment provisions or Section 150.15 to justify its conclusion. 2016 Issue Summary 1-3 (JA__-__); *see also* 42 U.S.C. § 2021(c); 10 C.F.R. § 150.15(a). It also overlooked that Section 20.2002 on its face applies solely to the “disposal” of “waste containing licensed material”—not “storage and handling” of such waste or any other aspect of reactor “operation.” 2016 Issue Summary 1-3 (JA__-__); *see also* 10 C.F.R. § 20.2002.

Those shortcomings aside, the 2016 Issue Summary lacked any apparent regulatory force or legal effect. By its terms, the 2016 Issue Summary imposed no legal consequences on licensees. Importantly, it did not state that licensees who had secured Agreement State approvals for very low-level waste disposal could no longer rely on them and needed to seek new, duplicative approvals from NRC. To the contrary, the 2016 Issue Summary stated clearly that it “*does not represent a departure from current regulatory requirements and practice.*” *Id.* at 3 (JA__)

(emphasis added). It further stated that it “require[d] no action or written response” from industry. *Id.* Nor did NRC invite comment.

NRC’s 2016 Issue Summary also expressly stated that it did not impose a “backfit” on the nuclear industry. *Id.* Significantly, “backfitting” occurs when NRC adopts new or amended regulations or imposes new or different interpretations of regulations on reactor licensees. 10 C.F.R. § 50.109(a). The associated “backfitting” analysis requires NRC to demonstrate that the new or amended regulation or interpretation will result in a “substantial increase” in safety or security, “and that the . . . costs of implementation . . . are justified in view of this increased protection.” *Id.* § 50.109(a)(3); *see also id.* § 50.109(c). This analysis is used to determine whether such changes can justifiably be imposed on licensees. *Id.* § 50.109(c). The Backfitting Rule reflects sound regulatory policy and is critical to ensuring that the imposition of new or amended regulations or interpretations will yield demonstrable safety benefits and are justified in light of their costs. By stating that the 2016 Issue Summary imposed no backfit, NRC further confirmed that the Issue Summary did *not* alter the regulatory status quo. 2016 Issue Summary 3 (JA__). Licensees took NRC’s plain statements at face value and continued to rely on existing Agreement State approvals. *See, e.g.,* Aug. 14, 2018 Letter from STP Nuclear Operating Company to NRC 2 (“South Texas Letter”) (JA__).

Two years later, however, NRC abruptly changed course. It took enforcement action against NEI member STP Nuclear Operating Company (“South Texas”), which had a longstanding state approval for its very low-level waste disposal. After South Texas was informed during a routine safety inspection in 2018 that NRC was “considering issuing a minor violation” for relying on an approval from the State of Texas for very low-level waste disposal, South Texas promptly sought clarification from NRC. *See* South Texas Letter (JA__-__). South Texas pointed out that Texas is an Agreement State, South Texas had a state approval, and the 2016 Issue Summary required “no action or written response” from licensees and was not a backfit. *See id.* at 1-2 (JA__-__).

In response, NRC took the position that *its* approval, not that of Texas or any other Agreement State, was required for very low-level waste disposal. NRC thus took the position—for the first time—that an existing, otherwise sound Agreement State approval could not be relied upon by a licensee. At the same time, however, NRC conceded that South Texas had “raised issues with the [2016 Issue Summary] and with prior guidance,” stating that it “is evaluating the issue generically to provide further clarity.” Oct. 31, 2018 NRC Letter to South Texas 2 (JA__). Given NRC’s response, it appeared at that time that NRC might well change course and withdraw its enforcement action against South Texas, especially given the clear incongruity between NRC’s new position, its explicit statements that the 2016 Issue Summary

merely maintained the regulatory status quo, and the previous thirty years of regulatory history and industry practice.

NEI supported NRC's proposed reconsideration of its new stance, and challenged any suggestion that the 2016 Issue Summary could be understood to unwind previous Agreement State approvals. *See* Feb. 28, 2019 Letter from NEI to NRC (JA__-__). NEI also highlighted NRC's statements that the 2016 Issue Summary was "strictly voluntary" and imposed no backfit. *Id.* at 9-10 (JA__-__).

Responding to stakeholder comments, NRC held a public meeting on September 6, 2019, attended by industry and Agreement State representatives, to address concerns about NRC's possibly-evolving position on the 2016 Issue Summary and discuss, in NRC's words, a "path forward," including a possible "update" to the 2016 Issue Summary. *See* NRC, Summary of September 6, 2019 Public Meeting (Oct. 2, 2019) 1-2 ("Public Meeting Summary") (JA__-__). At the meeting's end, NRC indicated it would "issue the response letters by the end of September," *id.* at 3 (JA__), leaving open the possibility that NRC would clarify that it did not intend to unwind existing Agreement State regulatory jurisdiction over very low-level waste disposal after all.

Confoundingly, however, in September 2019 NRC did not merely double down on its new position regarding approval requirements, it drastically *changed* the meaning and reach of the 2016 Issue Summary, a mere informational document.

Specifically, NRC stated it had “reviewed the information [NEI] provided and the history of this issue and determined that [the 2016 Issue Summary] correctly stated that any licensee’s request for approval to dispose of licensed material [under Section 20.2002] must be submitted to the regulatory authority that issued the license for use of the radioactive material.” 2019 Letter 1 (JA__).

NRC expressed a completely new legal theory for this regulatory change—albeit in one conclusory sentence. In its 2019 Letter, NRC stated—contrary to its own long-established interpretation of the AEA, Part 150, and Section 20.2002—that “this requirement is based on NRC’s jurisdiction over the *operation of* nuclear power plants, which cannot be delegated to an Agreement State.” *Id.* (emphasis added). Again, the agency offered no citation or analysis to support its stark new position that very low-level waste disposal is somehow subsumed in the “operation of nuclear power plants.” *Id.*

Contrary to the 2016 Issue Summary’s plain terms, NRC also indicated that its *reinterpretation* of Sections 20.2002 and 150.15 was an enforcement matter after all. For those licensees that had relied on “Agreement State approvals in the past in lieu of an NRC 10 C.F.R. § 20.2002 approval,” NRC said it would “consider” enforcement discretion, but only on a “case-by-case basis.” *Id.* Since this case was filed, however, NRC has brought enforcement action against another licensee that already has Agreement State approval—and NRC has not granted enforcement

discretion. *See* Hedges Decl. ¶¶ 15, 19-21 (ADD7, 10-12).⁴ And another licensee fears the same possibility. Weber Decl. ¶ 24 (ADD47-48). NRC's new position—expressed nowhere but in NRC's 2019 Letter—neither followed nor reflected any rulemaking or other established public process. It is also devoid of any apparent factual basis, supporting legal analysis, or policy rationale.

NEI timely petitioned for judicial review on November 15, 2019. On February 10, 2020, NRC filed a motion to dismiss, claiming that the September 2019 Letter merely restates a prior agency position and is not a final agency order subject to judicial review. *See* Resp'ts' Mot. to Dismiss (Feb. 10, 2020). NEI opposed the motion, and this Court ultimately referred the motion to the merits panel, directing the parties to address the final agency action issue in their merits briefs. *See* Opp. to Mot. to Dismiss (Mar. 11, 2020); Order (June 2, 2020) (*per curiam*).

SUMMARY OF ARGUMENT

NRC's September 16, 2019 Letter finally altered the requirements for nuclear power plants to dispose of very low-level waste under the AEA. In promulgating these new requirements, NRC failed to comply with the notice and comment requirements of the APA, failed to give a reasoned explanation for its new policy, and failed to perform a backfitting analysis as required by its own regulations. But

⁴ NEI submits declarations in support of standing in the separate addendum filed herewith at ADD1-66. *See* D.C. Cir. R. 28(a)(7).

even if NRC had not completely failed to comply with these procedural requirements, the 2019 Letter cannot stand substantively, as it exceeds NRC's authority under the AEA and its implementing regulations.

Because the 2019 Letter subjects NEI's members to new approval requirements and enforcement risks, it is a final reviewable agency action. An agency action is final and reviewable when it "imposes an obligation" and marks "the consummation of an administrative process." *Adenariwo v. Fed. Mar. Comm'n*, 808 F.3d 74, 78 (D.C. Cir. 2015) (citation omitted). NRC's 2019 Letter meets both of these requirements. The 2019 Letter was the first time that NRC "adopted an unequivocal [policy]" under which federal approval would be required for the disposal of very low-level waste by plants already operating with valid state approvals, and thus marked the agency's final decision regarding this new requirement. *See CropLife America v. EPA*, 329 F.3d 876, 884 (D.C. Cir. 2003) (rejecting agency's argument that petitioners could not bring their claim because agency made similar equivocal arguments in the past).

That NRC published this decision in a letter does not undermine the final nature of that decision. Whereas the 2016 Issue Summary had indicated that "no action or written response" was required for regulated entities, and that it did "not represent a departure from current regulatory requirements and practice," 2016 Issue Summary 3 (JA__), the 2019 Letter stated that federal approval was now mandatory,

see 2019 Letter 1 (JA___). The non-obligatory nature of the 2016 Issue Summary was confirmed by NRC’s statement in that document that it did not require any “backfitting” analysis or evaluation, which would have been required if the agency were imposing new or different interpretations of existing regulations. And while the 2016 Issue Summary referred to developments that were explicitly “voluntary,” the 2019 Letter was the first time that NRC imposed its new federal approval requirement on the regulated community.

The 2019 Letter has “direct and appreciable legal consequences” for the regulated community because it requires plants relying on Agreement State very low-level waste disposal approvals to obtain federal approval for the first time. Agency action has a reviewable legal effect if it creates requirements that states or industry must follow, *see Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2005), exposes regulated parties to the possibility of an enforcement action, enhanced fines, or penalties, *see Sackett v. EPA*, 566 U.S. 120, 126 (2012); *see also Barrick Goldstrike Mines, Inc. v. Browner*, 215 F.3d 45, 50 (D.C. Cir. 2000), or has “a *practical* effect on regulated parties even if it has no formal legal force,” *Valero Energy Corp. v. EPA*, 927 F.3d 532, 537 (D.C. Cir. 2019).

The 2019 Letter does all three. Under the 2019 Letter, reactor licensees must now obtain federal approval, even though numerous licensees have been disposing of very low-level waste pursuant to valid Agreement State approvals for decades.

Failing to obtain NRC approval opens these licensees to the risk of enforcement action. Alternatively, licensees can avoid the new requirement only by significantly altering their procedures for disposing of very low-level waste—a costly “practical effect.” Weber Decl. ¶ 27 (ADD49-50).

NRC’s claim that it may exercise enforcement discretion does not negate these adverse impacts. Even if NRC exercised discretion, plants would still be left open to the risk of enforcement action unless they either obtained NRC approval or changed their very low-level waste disposal procedures. In practice, however, since providing this assurance to consider enforcement discretion, NRC has already levied a violation against another NEI member, Energy Northwest. *See* Hedges Decl. ¶¶ 19-21 (ADD10-12). Clearly, NRC’s 2019 statement that it will “consider” enforcement discretion in certain cases does not mean that licensees can ignore the new requirements. Reactor licensees must either comply with the 2019 Letter’s obligations or else risk enforcement action. The 2019 Letter, therefore, was a final and reviewable agency action. *See Rhea Lana, Inc. v. Dep’t of Labor*, 824 F.3d 1023, 1030 (D.C. Cir. 2016).

Turning to the merits, NRC’s promulgation of the 2019 Letter violated several procedural requirements under the APA, the AEA, and its own rules.

First, by imposing these new licensing requirements without undertaking the notice-and-comment process, NRC violated the APA. *See* 5 U.S.C. § 553. Before

the 2019 Letter, longstanding regulations permitted the disposal of very low-level waste with only state approval. *See* 10 C.F.R. § 150.15(a). To amend these regulations, NRC was required by the APA to publish notice in the *Federal Register*, explain the proposal's basis and purpose, and respond to public comments, all in the service of developing a factual record sufficient to justify a new rule. 5 U.S.C. §§ 551(5), 553(b)-(d); *see also Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015) (agencies must “use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance”). It is uncontested that NRC did none of these things.

Second, the 2019 Letter fails to give a reasoned explanation for the change in NRC's policy and therefore violated the APA's prohibition against arbitrary and capricious policy changes. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009). The 2019 Letter (and likewise the 2016 Issue Summary) provides no legal or factual analysis supporting NRC's new approval requirement, or any justification for upending the longstanding reliance of the regulated community on NRC's prior determinations recognizing Agreement State regulation of very low-level waste disposal. *See* Sterling Decl. ¶ 12 (ADD23-24) (South Texas received an exemption concurrence from the Texas Commission on Environmental Quality in 2008); Weber Decl. ¶ 15 (ADD42) (Arizona Public Service Company received a permit from the Arizona Department of Environmental Quality in 2003); Hedges

Decl. ¶ 15 (ADD7-8) (Washington Energy Facility Site Evaluation Council issued Energy Northwest a disposal permit by Resolutions in 1995 and 2001).

Third, by failing to do a “backfitting” analysis for the 2019 Letter, NRC violated the backfitting requirement in its own regulations. Under NRC’s Backfitting Rule, before it can apply a new rule or a new interpretation of an existing rule to licensees, NRC is required to prepare either “a systematic and documented analysis” to determine whether imposing the prospective new rule is justified considering its benefits and costs, or a documented evaluation justifying an exception to such an analysis. 10 C.F.R. § 50.109(a)(2)-(4). Here too, it is uncontested that NRC did neither.

Finally, even if NRC had not failed to comply with the requirements of the APA and its own regulations, NRC’s new policy cannot stand because it is inconsistent with the plain language of AEA Section 274 and NRC’s longstanding interpretation of that provision. AEA Section 274 empowers NRC to transfer regulatory authority over low-level waste disposal to Agreement States by entering “into agreements with the Governor of any State providing for *discontinuance* of the regulatory authority of the [NRC]” and the assumption of the authority by the state. 42 U.S.C. § 2021(b) (emphasis added). That is precisely what NRC has done by entering into numerous Section 274 agreements with states and promulgating its Part

150 regulations. NRC’s attempt to take back this authority through the 2019 Letter fails as an *ultra vires* agency action.

NRC’s contrary arguments lack merit. NRC posits that it alone has authority to regulate reactor low-level waste disposal—despite existing state agreements long acknowledged by NRC—because under the AEA, NRC may not give up authority over the “operation” of nuclear power plants. *See* 2019 Letter 1 (JA__); 42 U.S.C. § 2021(c)(1) (prohibiting NRC from delegating authority over the “construction and operation” of nuclear power plants). But this claim is inconsistent with the agency’s previously settled, well-reasoned position. That position is based on both the language of the AEA and its implementing regulations, which explicitly distinguish between the *construction and operation* of nuclear plants, on the one hand, and the *disposal* of low-level waste, on the other hand. *See, e.g.,* 42 U.S.C. § 2021(c); 10 C.F.R. § 150.15(a)(1) (distinguishing regulatory jurisdiction over power plants from jurisdiction over waste disposal); *see also* 27 Fed. Reg. at 1351 (“Control over the handling and storage of waste at the site of a reactor, including effluent discharge, will be retained by the Commission as a part of the control of reactor operation,” meanwhile, “states will have control over land burial of low level wastes.”).

Given that distinction, NRC’s new stance that Section 274 somehow *prevents* NRC from transferring authority of low-level waste disposal to the states makes no

sense. Indeed, the position implies that NRC has violated its organic statute for thirty years. But NRC properly transferred its authority over low-level waste to Agreement States under the AEA, and in doing so, discontinued its own authority over low-level waste disposal so long as state programs are compliant with federal law. 42 U.S.C. § 2021(j). NRC no longer has authority over low-level waste disposal in Agreement States, absent a finding by NRC that the authority it has already transferred to the Agreement States is inconsistent with public health and safety. *Id.* Again, it is undisputed that NRC has made no such finding.

Accordingly, and for the reasons that follow, this Court should vacate the agency action at issue and remand to NRC for further consideration.

STANDING

NEI has standing to bring this suit. NEI is the policy organization of the nuclear technologies industry. Its members include companies that own or operate nuclear power plants and fuel service companies, among others. This Court has recognized NEI as a proper entity to represent the collective interests of the nuclear power industry. *See, e.g., NEI v. EPA*, 373 F.3d 1251, 1278-80 (D.C. Cir. 2004) (holding that NEI had associational and prudential standing to challenge EPA ground water standards on behalf of its members). NEI has associational standing to bring suit in this case because at least one of its members would have standing to sue in its own right, the interests NEI seeks to protect are germane to its purposes,

and neither the claims asserted nor the relief requested requires that an individual NEI member participate in this suit. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 342 (1977); *Sierra Club v. FERC*, 827 F.3d 59, 65 (D.C. Cir. 2016).

NEI's members have suffered, or will suffer, tangible injuries caused by NRC's decision embodied in the 2019 Letter that reactor licensees must obtain NRC approval of requests to use alternate disposal procedures for very low-level waste, even if they already have state authorizations. Without properly invoking its rulemaking or adjudicatory authority—and contrary to its own rules and regulations as well as the AEA and APA—NRC's 2019 Letter rendered once compliant licensees out of compliance.

NEI's standing is supported by the Declarations of T. Weber (Arizona Public Service Company) (¶¶ 22-28 (ADD45-50)); L. Sterling (South Texas) (¶¶ 17, 23-29 (ADD26, 30-34)); and T. Hedges (Energy Northwest) (¶¶ 19-25 (ADD10-15)). Simply put, NEI members wish to continue to dispose of very low-level waste in Agreement States using their valid state approvals, but now must expend additional resources to obtain duplicative NRC approvals and alter their waste disposal procedures, or face NRC enforcement action. The tangible result is additional compliance costs and increased regulatory risk with no discernible safety benefit. A favorable decision here would redress those concrete injuries by preserving the status quo that existed before NRC determined in the 2019 Letter that the new

position set forth in the 2016 Issue Summary is binding on licensees who had already obtained Agreement State approval, and the basis for NRC enforcement action.

NEI's interests in this litigation—to clarify NRC rules and regulations and ensure NRC follows proper procedure before enacting new, enforceable rules—are germane to NEI's purpose of advancing the nuclear power industry's policy interests. *Cf. NEI*, 373 F.3d at 1279 (finding that “pursuing litigation to speed the licensing of a permanent repository [for nuclear waste] is ‘germane to [NEI’s] purpose’” (citation omitted)). NEI's petition for review seeks to vacate NRC's determination that compliance with the agency's new very low-level waste disposal requirement is mandatory for all NRC licensees. Neither NEI's claims nor the relief requested require the participation of any individual NEI member in this lawsuit.

STANDARD OF REVIEW

This Court reviews agency action challenged under the Hobbs Act for compliance with the APA. *See* 42 U.S.C. § 2239(b); *Honeywell Int'l, Inc. v. NRC*, 628 F.3d 568, 575-76 (D.C. Cir. 2010); *see also Bhd. of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, No. 18-1235, 2020 WL 5079389, at *26 (D.C. Cir. Aug. 28, 2020) (“In reviewing final orders under the Hobbs Act,” this Court applies “‘the familiar standards [of review] set forth in the Administrative Procedure Act.’” (alteration in original) (citation omitted)). The APA “requires agencies to engage in reasoned decisionmaking,” and mandates that the Court set aside agency action that

is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 2020 WL 5079389, at *26 (citation omitted). Among other things, this “arbitrary and capricious” standard requires the agency to “provide a reasoned explanation for any failure to adhere to its own precedents.” *Honeywell*, 628 F.3d at 579 (citation omitted).

ARGUMENT

I. NRC’S 2019 LETTER CONSTITUTES REVIEWABLE FINAL AGENCY ACTION

In its motion to dismiss, NRC claimed that the 2019 Letter does not constitute final agency action subject to judicial review, because it is merely a “routine, informational document” that “simply reaffirms” a prior agency position. *See* Resp’ts’ Mot. to Dismiss 1-2 (Feb. 10, 2020). Not so. As explained below, the 2019 Letter articulates a new, final agency position with both legal and practical consequences for the regulated industry. NRC cannot be permitted to use the informal method in which it chose to express this final decision as a shield from judicial review.

The Hobbs Act permits review of a “final order,” 42 U.S.C. § 2239(b), which this Court has held is the equivalent of a “final agency action” for purposes of determining whether an order is sufficiently final to permit judicial review. *See Weaver v. Fed. Motor Carrier Safety Admin.*, 744 F.3d 142, 146 (D.C. Cir. 2014). An agency action or order is final where it “imposes an obligation, denies a right, or

fixes some legal relationship, usually at the consummation of an administrative process.” *Adenariwo v. Fed. Mar. Comm’n*, 808 F.3d 74, 78 (D.C. Cir. 2015) (quoting *Natural Res. Def. Council, Inc. v. NRC*, 680 F.2d 810, 815 (D.C. Cir. 1982)); *Honicker v. NRC*, 590 F.2d 1207, 1209 (D.C. Cir. 1978). Under the Supreme Court’s decision in *Bennett v. Spear*, an agency decision is considered final if it “mark[s] the ‘consummation’ of the agency’s decision-making process,” is not “merely tentative or interlocutory in nature,” and is “one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences flow.’” 520 U.S. 154, 177-78 (1997) (citation omitted).⁵

The 2019 Letter does both. First, it marks the first time NRC stated unequivocally and conclusively, and to the industry at large, that compliance with the new very low-level waste disposal requirement is mandatory for all NRC licensees. Second, it further makes clear that licensees cannot rely on existing, valid state authorizations, but must seek NRC approval in the absence of enforcement discretion. The 2019 Letter thus satisfies both prongs of the *Bennett* test for final agency action.

⁵ Although *Bennett* involved a challenge to an APA “final agency action,” this Court has applied the *Bennett* test in the Hobbs Act “final order” context. See, e.g., *Blue Ridge Envtl. Def. League v. NRC*, 668 F.3d 747, 753 (D.C. Cir. 2012).

A. The 2019 Letter Marks the Consummation of NRC's Decisionmaking

Final action communicates an agency determination that is “definitive,” not merely “tentative or interlocutory.” *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813-14 (2016) (citation omitted). There is nothing tentative or interlocutory about the 2019 Letter. NRC will attempt to make much of the fact that its final decision was expressed in a letter, but “the fact that the letter was a response to inquiries by [NEI] did not preclude the agency from expressing a final position in that document.” *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436-37 & nn.8-9 (D.C. Cir. 1986); *see also Barrick Goldstrike Mines*, 215 F.3d at 50 (“That the agency action is embodied in interpretative statements in a rulemaking preamble, in a guidance document, and in a letter from a branch chief is not disqualifying.”); *Her Majesty the Queen in Right of Ontario v. EPA*, 912 F.2d 1525, 1531 (D.C. Cir. 1990) (letters of subordinate agency official at EPA constituted final agency action). The 2019 Letter “represents the first time that the agency has adopted an unequivocal [policy].” *CropLife America v. EPA*, 329 F.3d 876, 884 (D.C. Cir. 2003) (rejecting agency's argument that petitioners are time-barred because agency made similar equivocal arguments in the past).

To be clear, NRC should have provided far more process than that reflected in a letter. But that is a separate defect in NRC's action. NRC cannot now use the fact that its change of position took the form of a short letter to avoid judicial review.

Nothing in the 2019 Letter suggests that NRC's position therein is "open to further consideration, or conditional on future agency action." *City of Dania Beach v. FAA*, 485 F.3d 1181, 1188 (D.C. Cir. 2007). Nor has NRC claimed this position is anything but final and conclusive. Indeed, since its issuance, NRC has initiated further enforcement action.

B. The 2019 Letter Does Not Simply Restate a Prior NRC Position

The 2019 Letter does far more than reiterate a prior NRC position. The final action at issue in this case consists of "a series of steps taken by [NRC]' culminating in a letter from an [NRC] official stating the agency's position." *Barrick Goldstrike Mines*, 215 F.3d at 50 (citation omitted); *id.* at 49 (preamble, guidance document, and enforcement letter together "could crystallize an agency position into final agency action"). Until the 2019 Letter, NRC's policy related to very low-level waste disposal had not been settled and was not transparent.

Before the 2019 Letter was issued, NRC held a public meeting with Agreement States and industry participants explicitly to air concerns and devise a "proposed path forward" to resolve the regulatory confusion surrounding very low-level waste disposal. Public Meeting Summary 2 (JA__). Several parties expressed confusion about NRC's apparent new position that nuclear licensees could no longer rely on Agreement State approvals. *Id.* at 2-3 (JA__-__). NRC indicated that it "continues to develop its path forward" and "has not reached a decision of the

specific means to do so,” but would soon respond to the industry’s concerns, thus suggesting that its position on this matter was not yet settled. *Id.* at 1, 3 (JA__, __).

Shortly after the stakeholder meeting, NRC responded to NEI in the 2019 Letter. NRC’s “proposed path forward” only then took its final form. The 2019 Letter stated: “We have reviewed the information you provided and the history of this issue and determined that [the 2016 Issue Summary] correctly stated” that NRC licensees would need to seek approval from NRC to dispose of very low-level waste, or face enforcement action. 2019 Letter 1 (JA__). The 2019 Letter was the first time that NRC clearly stated that NRC rather than Agreement State approval for very low-level waste disposal was a mandatory, enforceable regulatory requirement—even for licensees with existing, valid Agreement State approvals.

NRC’s claim in its motion to dismiss that the 2019 Letter simply echoes a position made plain in its 2016 Issue Summary does not withstand scrutiny. *See* Resp’ts’ Mot. to Dismiss 12-13 (Feb. 10, 2020). The 2016 Issue Summary suggested that NRC’s policy with respect to very low-level waste disposal might be changing insofar as it seemed to disavow parts of the 1986 Information Notice. However, it also made several unequivocal and reassuring statements informing the industry that “no action or written response” was required, and that it did “not represent a departure from current regulatory requirements and practice.” 2016 Issue Summary 3 (JA__). Furthermore, because multiple NRC licensees had standing authorizations

from Agreement States to dispose of very low-level waste at the time of the 2016 Issue Summary, *see, e.g.*, South Texas Letter 2 & Attachments 1-2 (JA__, __-__); Weber Decl. ¶¶ 15-17 (ADD42-43); Hedges Decl. ¶ 15 (ADD7-8), the Backfitting Rule would have been triggered if the 2016 Issue Summary had required licensees to change their procedures. 10 C.F.R. § 50.109(a)(1). But it did not say state approvals were no longer legally valid; rather, it said there was no backfit. Thus, a reasonable observer would not have perceived a “very substantial risk” that NRC might several years later construe the “informational” 2016 Issue Summary to mean what NRC eventually specified in its 2019 Letter. *See Dominion Res., Inc. v. FERC*, 286 F.3d 586, 589 (D.C. Cir. 2002).

Moreover, the 2019 Letter also offered a brand new—and still puzzling—legal basis for NRC’s new approval requirement, stating for the first time that “this requirement is based on NRC’s jurisdiction over the operation of nuclear power plants, which cannot be delegated to an Agreement State.” 2019 Letter 1 (JA__). But this new interpretation contravenes the position NRC had long taken with respect to what authority it may and may not delegate under the AEA. While the AEA prohibits NRC from delegating authority over the “operation” of nuclear power plants, 42 U.S.C. § 2021(c)(1), NRC has never interpreted the disposal of very low-level waste to constitute part of the “operation” of the plant. *See* Legal Opinion 1-2 (JA__-__); 1986 Information Notice 1-2 (JA__-__). This position constitutes a

marked change in NRC's interpretation of the AEA and its regulations. In short, between issuance of the 2016 Issue Summary and the 2019 Letter, NRC changed its position concerning both the legal effect of the Issue Summary and the legal basis for the agency's new approval requirement, thereby altering the regulatory landscape for reactor licensees.

C. Direct and Appreciable Legal Consequences Flow from the 2019 Letter

Whether an agency action has "direct and appreciable legal consequences" is a "pragmatic" inquiry. *Hawkes Co.*, 136 S. Ct. at 1814-15 (citations omitted). Courts must consider "the concrete consequences an agency action has or does not have as a result of the specific statutes and regulations that govern it." *Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 637 (D.C. Cir. 2019). Agency action has a reviewable legal effect if it creates requirements that states or industry must follow, *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000), exposes regulated parties to the possibility of an enforcement action, enhanced fines, or penalties, *see Sackett v. EPA*, 566 U.S. 120, 126 (2012); *Barrick Goldstrike Mines, Inc. v. Browner*, 215 F.3d 45, 50 (D.C. Cir. 2000), or has "a *practical* effect on regulated parties even if it has no formal legal force," *Valero Energy Corp. v. EPA*, 927 F.3d 532, 537 (D.C. Cir. 2019). NRC's 2019 Letter does all three.

The 2019 Letter creates new enforcement risks and imposes new regulatory burdens on licensees. NRC's 2019 Letter imposed new requirements for disposal

approvals that industry must now follow, in stark contrast to the 2016 Issue Summary's explanation that "no action" is required because it "does not represent a departure from current regulatory requirements and practice." *See* 2016 Issue Summary 3 (JA__); *Appalachian Power Co.*, 208 F.3d at 1023 (guidance document constituted final agency action because "[i]t commands, it requires, it orders, it dictates"). Under NRC's previous interpretation of AEA Section 274 and its implementing regulations, licensees in Agreement States needed to seek very low-level waste disposal approval only from their Agreement State. Now, they must obtain NRC approval, even if they already have an Agreement State approval. 2019 Letter 1 (JA__).

The legal effect of this newly-mandatory requirement is further evident from NRC's initial statement that it "will consider" exercising enforcement discretion for licensees that have relied on existing Agreement State approvals, but "only on a case-by-case basis." *Id.* Enforcement discretion is cold comfort, however, and is necessary only where the agency finds a legal violation in the first place. *See generally* 42 U.S.C. § 2273(a), (c) (AEA civil and criminal penalties). This statement also implies there are cases in which enforcement discretion will not be exercised. *See Barrick Goldstrike Mines*, 215 F.3d at 50 (legal consequences flow from the position agency expressed because the regulated party must now "keep records and report to [the agency] unless it wishes to risk an enforcement action");

see also Sackett, 566 U.S. at 126 (order had legal effect where it exposed regulated parties to the possibility of an enforcement action and enhanced fines or penalties); *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1026 (D.C. Cir. 2016) (letter notifying petitioner of non-compliance constituted final agency action because although the letter merely restated petitioner's existing legal obligations, the notice potentially subjected petitioner to enhanced penalties for an enforcement action).

And indeed, despite NRC's suggestion that its reference to enforcement action was merely "hypothetical," *see Reply to Opp. to Mot. to Dismiss* 5 (Apr. 2, 2020), NRC has, since making that suggestion, invoked its new position as the basis for issuing another licensee a violation, which can only be remedied by complying with NRC's dictate of seeking a Section 20.2002 approval. *See Hedges Decl.* ¶¶ 19-21 (ADD10-12). This is no mere "hypothetical" exercise to that licensee, Energy Northwest.

The new requirement that licensees must seek NRC approval before disposing of very low-level waste has important implications for NEI's members beyond enforcement risks as well. It also implicates their internal compliance procedures, and creates costs associated with satisfying a new regulatory requirement. *See Sterling Decl.* ¶¶ 24-29 (ADD31-34) (estimating that compiling an application for NRC authorization, including added analysis of environmental impacts, other potentially affected facilities, and "specific procedures to ensure that doses are

maintained as low as reasonably achievable” would require 500-1,000 man hours); Weber Decl. ¶¶ 25-28 (ADD48-50) (similarly estimating that “approximately 500 hours of Palo Verde staff time would be needed to compile, review, and approve the Section 20.2002 application”); *see also CSI Aviation Servs., Inc. v. U.S. Dep’t of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011) (agency action was final where it “imposed an immediate and significant burden”).

Accordingly, because the 2019 Letter constitutes both the “consummation of [NRC’s] decision making” and has significant legal consequences for licensees, there should be no question that it is a “final order” subject to judicial review.

II. NRC FAILED TO COMPLY WITH REQUIRED NOTICE-AND-COMMENT RULEMAKING PROCEDURES

The 2019 Letter stated that the 2016 Issue Summary would have the force and effect of law in NRC enforcement actions. NRC thereby effectively repealed its published rules allowing Agreement States to regulate very low-level waste disposal pursuant to Agreement State requirements analogous to the requirements contained in 10 C.F.R. § 20.2002. In their place, NRC imposed a new substantive requirement that all reactor licensees obtain NRC approval to dispose of very low-level waste, regardless of existing state approvals. But NRC did not provide notice or an opportunity to comment in connection with these changes. In short, NRC created “a *de facto* rule or binding norm that could not properly be promulgated absent the notice-and-comment rulemaking required by § 553 of the APA.” *Ctr. for Auto*

Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 806 (D.C. Cir. 2006).

NRC therefore violated the APA. 5 U.S.C. § 553.

First, it is clear that the approval requirement articulated in the 2019 Letter is contrary to NRC's existing regulations regarding state jurisdiction over the disposal of very low-level waste. AEA Section 274 precludes NRC from transferring to Agreement States regulatory authority over disposal of nuclear wastes that "the Commission determines *by regulation or order* should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission." 42 U.S.C. § 2021(c)(4) (emphasis added). By prior regulation, NRC declined to make such a finding with respect to the disposal of all low-level waste, including waste generated by nuclear power plants. *See* 10 C.F.R. § 150.15(a). The exclusion of low-level waste disposal from Section 150.15(a)(1) was deliberate and unambiguous: NRC decided only to retain regulatory "[c]ontrol over the handling and storage of waste at the site of a reactor, including effluent discharge . . . as a part of the control of reactor operation," and determined that "states will have control over land burial of low level wastes." 27 Fed. Reg. 1351, 1351 (Feb. 14, 1962).

NRC has now effectively changed that rule's division of regulatory responsibility, reasserting jurisdiction over very low-level waste disposal, but without following required procedures. To be sure, NRC could, if it developed an appropriate record, alter these longstanding determinations governing very low-level

waste disposal. But to amend or repeal its current regulations, NRC must publish notice of its proposed action in the *Federal Register*, explain the proposal's basis and purpose, and respond to public comments to develop a sufficient supporting factual record. 5 U.S.C. §§ 551(5), 553(b)-(d); *see also Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015) (agencies must “use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance”). The notice-and-comment requirement “allow[s] interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process.” *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 530-31 (D.C. Cir. 1982). Otherwise, “the agency may operate with a one-sided or mistaken picture of the issues at stake in a rule-making.” *Id.* at 530.

NRC itself previously acknowledged the need for a rulemaking in order to modify Section 150.15(a) before it could reclaim from Agreement States regulatory authority over low-level waste disposal, including authority over the disposal of low-level waste generated at nuclear plants. NRC's 1985 Legal Opinion, for example, concluded “NRC is not at liberty to vary the clear meaning” of its regulations “without a rulemaking proceeding, or by issuance of appropriate orders, pursuant to Section 274c. of the [AEA].” Legal Opinion 2 (JA__).

In addition, NRC later published a proposed rule intended to do exactly what NRC did by letter in this case. In 1988, the Commission proposed a rule to reassert

NRC's jurisdiction over onsite disposal of low-level waste generated at reactor sites. *See* 53 Fed. Reg. 31,880 (Aug. 22, 1988). NRC later withdrew the proposed rule based in part on "the relatively low hazards associated with onsite disposal of this type of radioactive material, and current experience with disposals." *See* 61 Fed. Reg. 26,852, 26,853 (May 29, 1996). In other words, after considering public comments, evaluating the radiological hazards, and reviewing industry and Agreement State practices, NRC determined that "the Agreement States will maintain jurisdiction over the disposal of low-level radioactive waste on nuclear reactor sites," meaning NRC licensees in Agreement States need not obtain NRC Section 20.2002 approvals. *Id.*

NRC's previous use of notice-and-comment rulemaking in connection with its 1988 proposed rule on the same subject is striking. Whereas NRC in 1988 satisfied notice-and-comment procedures, its 2019 Letter wrought regulatory change without them. But because the 2019 Letter imposes new substantive obligations on licensees, the NRC decision it embodies is a legislative rule subject to notice-and-comment requirements. *See Sierra Club v. EPA*, 699 F.3d 530, 533-34 (D.C. Cir. 2012); *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1108-12 (D.C. Cir. 1993) (a rule has "'legal effect'" if "in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties," or "the rule effectively

amends a prior legislative rule”); *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (“A rule is legislative if it . . . adopts a new position inconsistent with existing regulations”).⁶ Because the 2019 Letter altered NRC’s existing regulations without following the notice and comment procedure required by law, it violates the APA. 5 U.S.C. §§ 553, 706(2)(A), (D).

III. NRC’S NEW INTERPRETATION IS ARBITRARY AND CAPRICIOUS FOR LACK OF REASONED EXPLANATION

The 2019 Letter is also arbitrary and capricious. The APA’s reasoned decisionmaking requirement “ordinarily demands that an agency acknowledge and explain the reasons for a changed interpretation.” *Verizon v. FCC*, 740 F.3d 623, 636 (D.C. Cir. 2014). “An agency may not, for example, depart from a prior policy sub silentio or simply disregard rules that are still on the books.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). When switching interpretations, an agency must always “show that there are good reasons for the new policy.” *Id.* And in certain circumstances—like those here—more is required. The Supreme Court has held that “the APA requires an agency to provide more substantial

⁶ Assuming, contrary to fact, that NRC’s 2019 Letter did not constitute a legislative rule, NRC still violated its own regulation requiring a 30-day post-promulgation comment opportunity for interpretative rules. See 10 C.F.R. § 2.804(e). “On their face, these rules admit no exception” and “having chosen to grant interested persons ‘additional procedural rights in the exercise of [its] discretion,’ the agency is bound by its own rules.” *Union of Concerned Scientists v. NRC*, 711 F.2d 370, 381-82 (D.C. Cir. 1983) (alteration original) (citations omitted).

justification when ‘its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account.’” *Perez*, 135 S. Ct. at 1209 (citation omitted). “[I]t is not that further justification is demanded by the mere fact of policy change[,] but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.” *Fox*, 556 U.S. at 515-16. Put another way, “[i]t would be arbitrary and capricious to ignore such matters.” *Id.* at 515.

The 2019 Letter does not come close to reflecting reasoned decisionmaking. The 1985 Legal Opinion and 1986 Information Notice conveyed NRC’s conclusion that it lacks authority over the disposal of low-level waste from a reactor facility located in an Agreement State. NRC based that conclusion on Section 274’s plain language and structure, subsequent Part 150 rulemaking determinations, and 10 C.F.R. § 20.2002’s plain language. *See supra* at 39-40. The 2019 Letter disregards all of that, stating only that NRC’s new approval requirement “is based on the NRC’s jurisdiction over the operation of nuclear power plants, which cannot be delegated to an Agreement State.” 2019 Letter 1 (JA__). In a single sentence, NRC thus upended decades of agency policy, but altogether failed to provide a “reasoned explanation” of the basis for this changed interpretation, in violation of one of the APA’s “fundamental” requirements. *See, e.g., Celcom Commc’ns Corp.*

v. FCC, 789 F.2d 67, 71 (D.C. Cir. 1986) (describing “reasoned decisionmaking” as a “fundamental mandate”).

Indeed, NRC provided no legal or factual analysis, not even a single citation, to support its contention that low-level waste disposal procedures are considered part of nuclear power plant “operation.” It did not acknowledge the extensive statutory and regulatory analysis in either the 1985 Legal Opinion or the 1986 Information Notice, much less explain how that prior analysis could be squared with its new conclusion. While “an agency may justify its policy choice by explaining why that policy ‘is more consistent with statutory language’ than alternative policies,” it violates the APA’s requirement for reasoned decisionmaking when it does “not analyze or explain why the statute should be interpreted” as the agency suggests. *Encino Motorcars., LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007)).

Not only was this departure from NRC’s longstanding position insufficiently explained, it remains unclear why such a change is necessary. NRC has not suggested, for example, that Agreement State regulation of very low-level waste disposal poses a safety issue. Indeed, nothing in the record indicates this is the case. NRC has ample tools to evaluate Agreement State regulation of low-level waste disposal. Specifically, under its Integrated Materials Performance Evaluation Program, NRC already provides comprehensive oversight of Agreement State

programs, including in particular low-level waste disposal programs. These reviews ensure that public health and safety are adequately protected from potential radiological hazards and that Agreement State programs are compatible with NRC's program. If NRC had concerns about Agreement State programs, the Integrated Materials Performance Evaluation Program provides a ready mechanism for identifying and addressing such concerns. But NRC has not identified a need to reverse its position and require reactor licensees to seek NRC approval of very low-level waste disposal procedures in Agreement States.

The industry's longstanding reliance on the previous status quo makes matters worse. *See* Sterling Decl. ¶ 12 (ADD23-24) (South Texas received an exemption concurrence from the Texas Commission on Environmental Quality in 2008); Weber Decl. ¶ 15 (ADD42) (Arizona Public Service Company received a permit from the Arizona Department of Environmental Quality in 2003); Hedges Decl. ¶ 15 (ADD7-8) (Washington Energy Facility Site Evaluation Council issued a disposal permit to Energy Northwest by Resolutions in 1995 and 2001). Licensees have developed procedures, entered into contracts, and secured Agreement State approvals for the disposal of very low-level waste in accordance with Agreement State processes. Requiring these licensees to adapt to NRC's new position will require significant changes to their low-level waste disposal processes and procedures. *See* Sterling Decl. ¶ 29 (ADD34); Weber Decl. ¶ 27 (ADD49-50); Hedges Decl. ¶ 24 (ADD14-

15). Licensees who do not seek NRC approval for their current practices risk enforcement action. *See* Sterling Decl. ¶¶ 23-24 (ADD30-31); Weber Decl. ¶ 25 (ADD48-49); Hedges Decl. ¶¶ 19-20 (ADD10-11). As the Supreme Court recently reiterated, such reliance interests must be taken into consideration when an agency reverses a prior policy position. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913-15 (2020). “A summary discussion may suffice in other circumstances, but here—in particular because of decades of industry reliance on the [NRC’s] prior policy—the explanation fell short of the agency’s duty to explain why it deemed it necessary to overrule its previous position.” *Encino Motorcars*, 136 S. Ct. at 2126.

In summary, “core principles of administrative law dictate that ‘an agency changing its course must supply a reasoned *analysis* indicating that prior policies and standards are being deliberately changed, not casually ignored.’” *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 647 (D.C. Cir. 2020) (quoting *Lone Mountain Processing, Inc. v. Sec’y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013)). Here, NRC departed from its prior position without citing the relevant statutory and regulatory provisions, without addressing the original rationales for NRC’s longstanding contrary interpretation, without providing any factual support for the new interpretation, and without considering the industry’s reliance on NRC’s prior interpretation. Accordingly, NRC’s 2019 Letter was arbitrary and capricious and an

abuse of discretion, violating the APA requirement for reasoned decisionmaking.

5 U.S.C. § 706(2)(A).

IV. NRC FAILED TO PERFORM A REQUIRED “BACKFITTING” ANALYSIS UNDER ITS OWN REGULATIONS

NRC also failed to perform the “backfitting” analysis required by its own regulations before imposing this new requirement on the regulated community. NRC’s “Backfitting Rule” requires it to conduct an analysis or evaluation before imposing certain new or amended regulations, or new or different interpretations of unchanged regulations, on licensees. *See* 10 C.F.R. § 50.109. The 2016 Issue Summary explicitly stated NRC was not “backfitting” any licensees because it required “no action or written response” and was “strictly voluntary.” 2016 Issue Summary 3 (JA__). Without addressing NRC’s Backfitting Rule, however, the 2019 Letter reversed course and said licensees “must” follow the Issue Summary and submit a 10 C.F.R. § 20.2002 application to NRC for approval of very low-level waste disposal procedures or risk enforcement action. *See* 2019 Letter 1 (JA__). NRC’s failure to perform a backfitting analysis violated agency regulations.

Under its Backfitting Rule, NRC is required to prepare “a systematic and documented analysis” to determine whether imposing a new regulatory requirement on reactor licensees is justified considering its benefits and costs, or else it must prepare a documented evaluation justifying invocation of a listed exception to the otherwise required systematic analysis. 10 C.F.R. § 50.109(a)(2)-(4); *see also Union*

of *Concerned Scientists v. NRC*, 824 F.2d 108, 118-19 (D.C. Cir. 1987) (explaining that the backfit rule derives from NRC’s authority under AEA Section 161 to “order plants to provide ‘extra-adequate’ protection,” but that the imposition of a new regulatory requirement is only appropriate “if the added protection to public health and safety resulting from the backfit justifies the costs of implementation”); *Consol. Edison Co. of N.Y. (Indian Point, Unit No. 2)*, No. CLI-85-6, 21 NRC 1043, 1066-67 (1985) (noting that backfits are permitted only when they offer “substantial, additional protection which is required for the public health and safety”).

NRC did neither. Yet “having chosen to grant interested persons ‘additional procedural rights in the exercise of [its] discretion,’ the agency is bound by its own rules.” *Union of Concerned Scientists*, 711 F.2d at 381-82 (alteration in original) (citation omitted). Because NRC failed to follow its own regulations in promulgating the approval requirement in the 2019 Letter, NRC’s actions are not in accordance with law. 5 U.S.C. § 706(2)(A), (D).

V. NRC’S NEW ASSERTION OF AUTHORITY OVER LOW-LEVEL WASTE DISPOSAL CONTRAVENES THE ATOMIC ENERGY ACT AND ITS IMPLEMENTING REGULATIONS

Even if it had not failed to comply with the APA and agency procedural requirements, NRC still violated the AEA and its own regulations implementing relevant sections of the AEA. NRC’s 2019 Letter stated that reactor licensees must seek approval to dispose of very low-level waste from NRC—not Agreement

States—“based on the NRC’s jurisdiction over the operation of nuclear power plants, which cannot be delegated to an Agreement State.” 2019 Letter 1 (JA__). Given the brevity and lack of clarity of this language, one is left to guess what *precisely* such a statement means. But whatever it may mean, NRC has ignored the unambiguous language and structure of the AEA and its implementing regulations.

A. NRC Has Not Issued Any Valid Regulation or Order Precluding Agreement State Regulation of Low-Level Waste Disposal

NRC’s new basis to assert regulatory authority appears to be based on AEA Section 274(c)(1), which precludes the transfer to Agreement States of authority over the “operation” of reactor facilities. 42 U.S.C. § 2021(c)(1). Section 274(c)(1), however, does not cover “disposal” of waste, and thus provides no authority for NRC’s position that its exclusive jurisdiction over reactor operations precludes Agreement State regulation of very low-level waste disposal.

Section 274 must be read as a whole. Because disposal is clearly addressed in Section 274 subparagraphs (c)(3)-(4)—not in subparagraph (c)(1)—the term “construction and operation” in subparagraph (c)(1) cannot reasonably be read to include the “disposal” of nuclear waste, and thus cannot be read to preclude Agreement State authority over the disposal of very low-level waste from reactor facilities. Significantly, NRC has twice concluded, during separate rulemaking efforts conducted 26 years apart (in 1962 and 1988), that AEA Section 274 permits the Commission to transfer its regulatory authority over low-level waste disposal to

Agreement States. *See supra* at 8-9, 39-40. NRC’s instant attempt to casually discard those prior (and legally sound) determinations on the ground that very low-level waste disposal is tantamount to “the operation of nuclear power plants” over which NRC jurisdiction cannot be delegated to an Agreement State strains credulity.

Had Congress intended to impose a blanket limitation on the ability of Agreement States to regulate the disposal of low-level wastes from nuclear plants, it could have said so plainly. Instead, Congress provided NRC with the authority to determine, by regulation or order, which wastes present sufficient hazards such that NRC must retain regulatory jurisdiction over their disposal. 42 U.S.C. § 2021(c)(4). But NRC cannot, under the terms of the AEA, simply reclaim jurisdiction over very low-level waste disposal and displace settled approvals with Agreement States without a regulation or order referenced in subparagraph (c)(4). And NRC has never determined “by regulation or order” that it must retain authority over very low-level waste generated by power reactors. Indeed, for decades, NRC took the opposite position: that it may relinquish authority over the disposal of very low-level waste generated by power reactors to the Agreement States. *See supra* at 6-9.

Furthermore, NRC’s regulations implementing this provision of the AEA unambiguously contemplate Agreement State regulation of low-level waste disposal *from reactors*. That is, those regulations draw a distinction between the need for NRC to maintain authority to regulate reactor operations—which includes the

handling and *storage* of low-level waste at the reactor facility site—and the ability of the Agreement States to maintain authority to regulate low-level waste *disposal*. See 10 C.F.R. § 150.15(a)(1), (5). As explained above, this has long been the case: the AEC, in promulgating these implementing regulations, expressly classified “storage and handling,” as part of the “operation” of plant facilities, but treated “disposal” separately. See *supra* at 8-9. Had NRC endeavored to retain jurisdiction over the disposal of mere low-level waste generated by nuclear plant operators, even though the AEA’s Agreement State regime does not require NRC to do so, it could have said so in its regulations. It did not. By ignoring this critical distinction and taking the opposite view in the 2019 Letter, NRC acted contrary not only to AEA Section 274 but also its own regulations at 10 C.F.R. § 150.15(a).

B. NRC Regulations Unambiguously Treat “Disposal Procedures” as a Disposal Activity and Not as Reactor Operations

To eschew the plain language of Section 274 and NRC regulations at 10 C.F.R. § 150.15(a), NRC appears committed to the position that a different regulation, 10 C.F.R. § 20.2002, concerns nuclear power plant operations, not disposal. See 2019 Letter 1 (JA__). That is, NRC seems to contend that because Agreement States may not be delegated regulatory authority over nuclear power plant operations, plant operators must seek NRC approval under Section 20.2002 to dispose of very low-level waste within Agreement States. *Id.* But NRC’s apparent implication that Section 20.2002 is relevant to reactor operations rather than disposal

is contrary to *that* regulation's unambiguous language and thus entitled to no deference. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (“[A] court should not afford *Auer* deference unless the regulation is genuinely ambiguous.”).

By its plain terms, Section 20.2002 deals with “disposal procedures.” It is also found in Part 20, Subpart K, titled “Waste Disposal.” In addition, a Section 20.2002 application must address the risks and conditions for “waste disposal,” as well as the environment surrounding the disposal site and dose limits for disposal. *See* 10 C.F.R. § 20.2002(a)-(d). Similarly, NRC’s guidance for Section 20.2002 approvals directs applicants to evaluate the safety of disposal (*e.g.*, by performing disposal dose assessments). *See* 85 Fed. Reg. 19,966 (Apr. 9, 2020).

In addition, NRC has historically classified Section 20.2002 as a disposal regulation rather than one addressing reactor operations. For example, NRC’s 1986 Information Notice treated Section 20.2002 as dealing with disposal rather than reactor operations. *See* 1986 Information Notice 1 (JA__) (concluding that if a “reactor facility was in an Agreement State, the NRC did not have a legal basis for performing the [Section 20.2002] reviews and granting approvals”). Likewise, NRC considered Section 20.2002 a disposal regulation when it proposed, and then withdrew, the 1988 rule that would have reasserted NRC jurisdiction over low-level waste generated and disposed of at reactor sites in Agreement States. *See* 61 Fed. Reg. at 26,852-53. Indeed, NRC would not have needed to initiate a rulemaking

“reasserting” jurisdiction over the approval of reactor licensee low-level waste disposal procedures if Section 20.2002 applied to reactor operations because the AEA and NRC regulations *already* provide NRC with exclusive regulatory jurisdiction over reactor operations. *See* 42 U.S.C. § 2021(c)(1); 10 C.F.R. § 150.15(a)(1).

In short, nothing in Section 20.2002’s plain language, structure, history, or related guidance suggests that provision applies to nuclear reactor operations. Given the absence of any ambiguity over whether Section 20.2002 concerns disposal, the Court need not afford *Auer* deference to the agency’s apparent reinterpretation of that provision in the 2019 Letter. *See Kisor*, 139 S. Ct. at 2415. Allowing NRC to use the 2019 Letter as a vehicle to reinterpret Section 20.2002, an unambiguous regulation, “would be to permit the agency, under the guise of interpreting a regulation to create *de facto* a new regulation.” *Christensen v. Harris Cty.*, 529 U.S. 576, 588 (2000). Because Section 20.2002 unambiguously applies to disposal, the Court should vacate NRC’s action recasting that provision as one that regulates operations.

CONCLUSION

NRC’s 2019 Letter has direct and appreciable legal consequences on NEI’s members. In reversing decades of agency practice, NRC failed to provide notice and

an opportunity for comment, and its final decision lacked reasoned explanation. NRC also acted in contravention of its organic statute and regulations.

The Court should therefore vacate NRC's unlawful action, and remand the issue for further consideration. In the meantime, NRC must adhere to its prior interpretations of 10 C.F.R. §§ 20.2002, 150.10, and 150.15. Allowing NRC licensees to continue to rely on existing Agreement State approvals will not create any disruption; it would simply maintain the prior accepted practice pending NRC compliance with the AEA, APA, and agency regulations. For the reasons explained above, NEI respectfully requests that this Court vacate NRC's determination that compliance with the agency's new very low-level waste disposal requirement is mandatory for all NRC licensees, and remand to NRC for further consideration.

Dated: September 30, 2020

Respectfully submitted,

/s/ Steven P. Croley

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/s/ Steven P. Croley
Steven P. Croley

ORAL ARGUMENT NOT YET SCHEDULED**No. 19-1240**

**United States Court of Appeals
for the District of Columbia Circuit**

NUCLEAR ENERGY INSTITUTE,**Petitioner,****v.****U.S. NUCLEAR REGULATORY COMMISSION
and the UNITED STATES OF AMERICA,****Respondents.**

**On Petition for Review of an Action of the
United States Nuclear Regulatory Commission**

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September 30, 2020

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**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

NUCLEAR ENERGY INSTITUTE,

Petitioner,

v.

U.S. NUCLEAR REGULATORY
COMMISSION and the UNITED
STATES OF AMERICA,

Respondents.

Case No. 19-1240

DECLARATION OF TONY L. HEDGES

I, Tony Hedges, swear or affirm under penalty of perjury, the following:

1. I am the Chemistry/Radiological Services Manager at Columbia Generating Station (“Columbia”), a single-unit boiling water General Electric Type 5 nuclear reactor owned and operated by Energy Northwest. My business address is 76 N Power Plant Loop, Richland, WA 99354. Energy Northwest is a member of the Nuclear Energy Institute (“NEI”), a professional trade association that represents the nuclear energy industry on policy, regulatory, and other matters affecting the industry. NEI is the petitioner in this case.

2. I have worked in the commercial nuclear power industry for more than 28 years, initially as Radiation Protection Instructor with Constellation Energy. I began

my career at Energy Northwest in August 2017 in the Chemistry Department as the Chemistry/Radiation Protection Support Supervisor. In August 2019, I assumed my current role of Chemistry/Radiological Services Manager. I am responsible for the overall leadership, direction, and management of the Columbia Chemistry and Radiological Services organizations, including oversight of the disposal of very low-level radioactive waste (“VLLW”). I hold a B.S. degree in Information Technology.

3. I am providing this Declaration in support of NEI’s Petition for Review of the U.S. Nuclear Regulatory Commission’s (“NRC”) decision, in a September 16, 2019 letter to NEI,¹ to give new legal effect to a non-binding NRC guidance document, Regulatory Issue Summary 2016-11, “Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002” (Nov. 13, 2016) (“Issue Summary”).² Energy Northwest understands the September 16, 2019 letter to require NRC licensees to obtain NRC approval for the disposal of VLLW, even when their facilities are located in NRC Agreement States. Historically, Energy Northwest has disposed of certain VLLW pursuant to an approval from the State of Washington, issued in accordance with Washington’s status as an Agreement State under Section 274 of the Atomic Energy Act of 1954, as amended (“AEA”), 42

¹ Letter from John W. Lubinski, U.S. NRC, to Ellen C. Ginsberg, NEI at 1 (Sept. 16, 2019) (“September 2019 NRC Letter”), available at <https://www.nrc.gov/docs/ML1922/ML19224A774.pdf>

² Available at <https://www.nrc.gov/docs/ML1600/ML16007A488.pdf>.

U.S.C. § 2021, and related NRC regulations in 10 C.F.R. Part 150. VLLW is waste that contains some residual radioactivity that is a small fraction of the “Class A” limits specified in 10 C.F.R. Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste,” and which may be safely disposed of in hazardous or solid waste landfills that, while strictly regulated, are not AEA-licensed facilities and do not require the extensive controls specified in 10 C.F.R. Part 61 or equivalent Agreement State regulations.³

4. As explained below, the need to comply with NRC’s new regulatory position, which the agency has not tied to any safety concerns, will impose additional regulatory burden and substantial costs on Energy Northwest. In this Declaration, I provide information concerning: (1) Energy Northwest; (2) the management of waste at Columbia; (3) the State regulatory approvals that authorize the disposal of certain types of VLLW (including cooling tower and spray pond sediment containing trace amounts of radioactivity) in the Columbia sediment disposal cells; (4) the source of the State of Washington’s regulatory jurisdiction over VLLW disposal; and (5) the practical impacts of the NRC’s newly-asserted jurisdiction over VLLW by NRC reactor licensees on Columbia operations.

³ See U.S. NRC, “Very Low-Level Waste” (updated Apr. 30, 2020), <https://www.nrc.gov/waste/llw-disposal/very-llw.html>) (accessed Sept. 26, 2020).

A. Overview of Columbia Generating Station

5. Columbia is owned and operated by Energy Northwest, which is a municipal corporation and joint operating agency of the State of Washington. Energy Northwest operates a number of non-carbon emitting electrical generating facilities, including the approximately 1,200 megawatt electrical-rated Columbia nuclear power station, which provide electric service throughout the Pacific Northwest to over 1.5 million customers.

6. Columbia is located on the U.S. Department of Energy's Hanford Site in Benton County, Washington, roughly 10 miles north of Richland. Columbia began commercial operations in May 1984 and is authorized to operate through 2043 pursuant to the facility's NRC-renewed operating license. Columbia is the sole nuclear power station in the State of Washington and accounts for about 8 percent of the State's carbon-free electricity generation.

7. The Columbia site spans approximately 1,089 acres. The site infrastructure includes office buildings, two incomplete power plants that were abandoned during the construction process (referred to as WNP-1 and WNP-4), the electric generating unit and cooling towers, standby service-water spray ponds (open air concrete containment structures), plant operation and maintenance warehouses, and administration buildings.

8. The generating facility consists of one boiling water reactor, housed within the reactor building, and six cooling towers. The Columbia site also houses the Independent Spent Fuel Storage Installation, an above-ground concrete storage pad housing spent fuel storage dry casks surrounded by a security fence; railroad tracks and roadways; fire protection and security facilities; control room simulators and other training facilities; and emergency facilities.

9. Columbia's water system is supplied directly by the Columbia River, which bounds the Columbia site to the east. Once Columbia River water enters Columbia's circulating water system, it is supplemented with sodium hypochlorite and sodium bromide to retard biological growth; other chemical additives are used to control corrosion and scale.

10. Columbia also operates five lined evaporation ponds; two unlined standby service water spray ponds; and sediment disposal cells, which serve for the disposal of the spray pond and the cooling tower sediments that are contaminated with low levels of radioactivity.

B. Management of Radioactive and Nonradioactive Waste at Columbia

11. The operation of nuclear power plants produces radioactive materials. Radioactivity results primarily from the fission of uranium fuel. The radioactive materials produced by the fission of uranium fuel generally fall into two categories: fission products and activation products.

12. Under normal operating conditions, fission products are located in, and remain inside, the used uranium fuel rods. Activation products are located in the reactor coolant system. As a result, these activation products are more readily transported by the reactor coolant system to any support system that connects to the reactor coolant system. Activation products are the source of most radiological contamination at nuclear power plants, potentially including radiological contamination in cooling tower water. These activation products are released to the environment through the plant ventilation systems in accordance with NRC requirements and plant procedures. These controlled releases are monitored and the activity released is documented in various reports. This released activity is then recaptured through deposition on surfaces surrounding the plant.

13. Columbia's radioactive waste system collects, treats, and disposes of radioactive and potentially radioactive wastes that are byproducts of plant operations. Operating procedures for the radioactive waste system ensure that radioactive materials are safely processed and discharged from the plant as controlled releases or effluents within the limits set forth in NRC regulations in 10 C.F.R. Part 20, "Standards for Protection Against Radiation."

14. Columbia also generates solid wastes as part of routine plant maintenance, cleaning activities, and plant operations. Columbia generates solid waste that is classified as either nonhazardous or hazardous waste, as defined by the Resource

Conservation and Recovery Act (“RCRA”). The nonhazardous solid waste includes office trash, construction debris, kitchen waste, and other rubbish material from routine plant maintenance and operations and cleaning activities. One of these solid wastes is algae and other biological organisms present in the cooling towers and in the spray ponds; when the material is removed during cleaning, it is referred to as “sediment.” These sediments are slightly contaminated with very low levels of radionuclides and thus are designated as VLLW.

C. Source of the State of Washington’s Regulatory Jurisdiction Over VLLW Disposal

15. The State of Washington, through the Washington Energy Facility Site Evaluation Council (“Site Evaluation Council”), long has regulated the disposal of sediments from the Columbia cooling towers and spray ponds pursuant to Site Evaluation Council Resolutions, originally through Site Evaluation Council Resolution No. 278, which was adopted in May 1995 and was replaced by Site Evaluation Council Resolution No. 299 in August 2001. Resolution No. 278 permitted “the onsite disposal of slightly contaminated sediment cleaned from the Columbia Generating Station circulating cooling water system,” and Resolution No. 299 expanded “the scope of plant cooling water systems covered by the disposal authorization.” Copies of Site Evaluation Council Resolution Nos. 278 and 299 are available at <https://www.efsec.wa.gov/council-information/resolutions> (under “Resolutions – Columbia Generating Station”). Pursuant to these Resolutions, the

State of Washington has permitted Energy Northwest to dispose of certain sediments containing very low levels of radionuclides (i.e., VLLW) from the Columbia facility onsite since 1995.

16. It bears emphasis that in approving Resolution No. 299 in 2001, the Site Evaluation Council stated that “[t]he Departments of Health and Ecology have reviewed the Energy Northwest application and supplemental information and found that the proposed disposal plan for service water cooling system sediments provides sufficient protections for public health and the environment.”⁴ It further noted that “[t]his judgement is also based on a review of the five years of experience with onsite disposal of circulating cooling water system sediments.”⁵ Importantly, the Site Evaluation Council has limited the annual incremental dose directly attributable to disposal of cooling tower and service water spray pond sediments to 15 millirem per year (i.e., the maximum dose above background that an individual would receive spending 2000 hours at the disposal site).⁶ As the Site Evaluation Council noted, actual doses are maintained as low as reasonably achievable and thus are even lower than 15 millirem per year.⁷ To put this in perspective, Americans on average receive

⁴ Site Evaluation Council Resolution No. 299 at 1.

⁵ Id.

⁶ Resolution No. 299, Attachment 1 at 1-2.

⁷ Resolution No. 299, Attachment 1 at 1.

a total radiation dose of about 620 millirem each year from natural background radiation and man-made (e.g., medical, industrial) radiation sources combined.⁸ The NRC's total effective dose equivalent limit to individual members of the public from licensed plant operation is 100 millirem per year (exclusive of background and man-made radiation sources).⁹

17. The State of Washington's authority to regulate the onsite disposal of radiologically-contaminated sediment at Columbia stems from its status as an Agreement State under AEA Section 274. The State and the Atomic Energy Commission (NRC's predecessor) entered into a Section 274 Agreement in December 1966, with an effective date of December 31, 1966.¹⁰ The Section 274 Agreement was amended in March 1982.¹¹

18. Notably, when the NRC renewed the Columbia reactor operating license in 2012, it acknowledged Washington's jurisdiction over sediment disposal:

Periodic cleaning of the cooling tower basins and the standby service water ponds results in sediment that contains low levels of radioactivity. The sediment is disposed of onsite in a dedicated area south of the cooling towers. The State of Washington Energy Facility Site Evaluation Council allows the onsite disposal of the contaminated

⁸ See NRC, "Doses in Our Daily Lives" (updated Apr. 27, 2020) (<https://www.nrc.gov/about-nrc/radiation/around-us/doses-daily-lives.html>) (accessed on Sept. 27, 2020).

⁹ See 10 C.F.R. § 20.1301.

¹⁰ See 31 Fed. Reg. 16,375 (Dec. 22, 1966).

¹¹ See 82 Fed. Reg. 7061 (March 15, 1982).

sediment as long as the material meets specific concentration limits and monitoring requirements.¹²

D. Impacts of the NRC's Newly-Asserted Jurisdiction Over VLLW Disposal

19. Given the division of regulatory authority between the State of Washington and the NRC that has existed for decades regarding onsite sediment disposal at Columbia, Energy Northwest is very concerned by the position taken by NRC in its September 2019 letter to NEI. According to that letter, “any licensee’s request for approval to dispose of licensed material under . . . Section 20.2002, or the equivalent Agreement State regulations, must be submitted to the regulatory authority that issued the license for use of the radioactive material.”¹³ Thus, Energy Northwest understands this letter to require NRC reactor licensees to now seek disposal approval for VLLW from the NRC in addition to Agreement States, contrary to the decades of prior practice described above. Moreover, this letter states that the NRC will consider “enforcement discretion” on a case-by-case basis for those licensees who have relied on Agreement State approvals in the past.¹⁴ This necessarily implies that there are some instances in which the agency will not exercise enforcement

¹² NUREG-1437, Supplement 47, “Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Columbia Generating Station – Final Report,” at 2-7 (Mar. 2012), available at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1437/supplement47/>.

¹³ September 2019 NRC Letter at 1 (emphasis added).

¹⁴ Id.

discretion. Section 20.2002 of the NRC's regulations provides that licensees may seek NRC approval of proposed procedures, not otherwise authorized in 10 C.F.R. Part 20, "to dispose of licensed material generated in the licensee's activities."¹⁵

20. As noted above, Energy Northwest has long relied on Agreement State approval for its VLLW disposal activities. In November 2019, however, consistent with the NRC's newly stated regulatory position in the September 2019 NRC Letter, the NRC's Region IV conducted a Radiation Protection inspection at Columbia and subsequently issued a Minor Violation for Energy Northwest's disposal of the cooling tower and spray pond sediment without NRC approval pursuant to 10 C.F.R. § 20.2002. The NRC has not exercised enforcement discretion to date.

21. Minor Violations are "those that are less significant than a SL [Severity Level] IV violation."¹⁶ A Severity Level IV Violation is itself defined as a violation that "resulted in no or relatively inappreciable potential safety or security consequences," but which "created the potential of more than minor safety or security consequences."¹⁷ Thus, Minor Violations "do not warrant enforcement action and are not normally documented in inspection reports."¹⁸ Nevertheless,

¹⁵ 10 C.F.R. § 20.2002.

¹⁶ NRC Enforcement Policy, at 12, 82 (Jan. 15, 2020), available at <https://www.nrc.gov/docs/ML1935/ML19352E921.pdf>.

¹⁷ *Id.* at 12.

¹⁸ *Id.* at 12, 82.

despite having no or almost no appreciable safety significance, Minor Violations “must be corrected,” or more severe consequences for the licensee could result.¹⁹ Specifically, a licensee must enter the minor violation in its Corrective Action Program, i.e., its internal, procedurally-established process for tracking, evaluating, and resolving deficiencies.²⁰ The Corrective Action Program is both required by the NRC and subject to NRC inspection under 10 C.F.R. Part 50.²¹ Energy Northwest entered a Condition Report in its Corrective Action Program on April 14, 2020, and has been working to resolve the Minor Violation since that time.

22. Specifically, to address the Minor Violation, Energy Northwest is drafting an application to the NRC, requesting permission for onsite disposal of the VLLW at issue pursuant to 10 C.F.R. § 20.2002, even though it already has disposal approval from the State’s Site Evaluation Council, previously through Resolution No. 278 (closed), and now through Resolution No. 299 (current). Until Energy Northwest submits the application and the NRC authorizes the disposal, Energy Northwest is at risk of further NRC enforcement action on this issue. As the NRC’s Enforcement Policy states, “if a licensee refuses to correct a minor violation within

¹⁹ Id. See also NRC Enforcement Manual, Revision 11, at 87 (Oct. 1, 2019), available at <https://www.nrc.gov/docs/ML1927/ML19274C228.pdf> (noting that “[m]inor violations are, by their very nature, minor issues with little or no safety consequences”, but that “licensees must correct these minor violations”).

²⁰ Id. at 15, 81.

²¹ 10 C.F.R. Part 50, Appendix B, Criterion XVI (“Corrective Action”).

a reasonable time such that it willfully continues, the violation should be considered more than minor,” and “[l]icenses are expected to take significant remedial action in responding to willful violations commensurate with the circumstances.”²² Otherwise, significant enforcement action against the licensee could result. Furthermore, the NRC may refer willful violations of NRC requirements to the U.S. Department of Justice for a prosecutorial determination.²³ Thus, absent the NRC’s exercise of enforcement discretion, simply leaving the alleged Minor Violation unaddressed is not a viable option from Energy Northwest’s perspective.

23. Energy Northwest’s need to comply with the NRC’s new mandate has imposed additional regulatory and cost burdens. These additional burdens appear unwarranted as a health and safety matter given that: (1) Energy Northwest has relied on valid State authorizations for the disposal of the VLLW at issue for 25 years; (2) the NRC previously has acknowledged those authorizations and not identified any related safety or environmental concerns; and (3) a Minor Violation is by definition one that has no appreciable potential safety or security consequences. In preparing to obtain the newly-required Section 20.2002 disposal authorization from the NRC, Energy Northwest staff have needed to compile and review the technical information

²² NRC Enforcement Policy, at 11.

²³ See Memorandum of Understanding Between the Nuclear Regulatory Commission and the Department of Justice, 53 Fed. Reg. 50,317, 50,318 (Dec. 14, 1988).

necessary to support the application. As specified in Section 20.2002 and related NRC guidance, the application must include, at a minimum: (1) a description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; (2) an analysis and evaluation of pertinent information on the nature of the environment; (3) the nature and location of other potentially affected licensed and unlicensed facilities; and (4) quantitative analyses and specific procedures to ensure that doses are maintained as low as reasonably achievable.²⁴

24. I estimate that more than 200 hours of Energy Northwest staff time have been spent in preparing the Section 20.2002 application to date, and Energy Northwest has not yet submitted the application to the NRC. After the application is submitted, Energy Northwest likely will need to respond in writing to NRC requests for additional information and engage in other interactions with NRC staff. Energy Northwest has estimated a cost of \$150,000 for application preparation and review, inclusive of staff time and consultant costs. The company also will be required to pay the regulatory services fees charged by the NRC pursuant to

²⁴ 10 C.F.R. 20.2002(a)-(d). See also NRC, “Guidance for the Reviews of Proposed Disposal Procedures and Transfers of Radioactive Material Under 10 CFR 20.2002 and 10 CFR 40.13(a)” at 14-18 (Apr. 2020),” available at <https://www.nrc.gov/docs/ML1829/ML18296A068.pdf>.

10 C.F.R. Part 170 for the agency's detailed technical review of the application, which is estimated to require about 9 to 12 months. I would anticipate the NRC's application review fees to be comparable in amount (i.e., at least \$100,000) and possibly greater than Energy Northwest's estimated internal costs. Thus, I estimate that the total licensing-related costs incurred by Energy Northwest could exceed \$250,000. Assuming the NRC approves the Section 20.2002 disposal request, it still could impose additional technical or administrative conditions that would create additional regulatory burden and related costs for Columbia.

25. In lieu of seeking a Section 20.2002 approval, another option for Energy Northwest would be to dispose of cooling tower and spray pond sediments in a low-level radioactive waste disposal facility licensed under 10 C.F.R. Part 61 (or equivalent Agreement State regulations). However, the resulting increase in disposal costs would be substantial. Based on current Columbia contracts with offsite low-level radioactive waste disposal facilities, Energy Northwest estimates disposal costs alone (i.e., excluding labor, container, and transportation costs) to be approximately \$25,000,000 to ship the sediments currently disposed of in the sediment cells, and approximately \$700,000 per year moving forward for disposal of new sediments. This is not an economically viable option for Energy Northwest.


26. As the foregoing suggests, the new position taken by the NRC in its September 16, 2019 letter creates considerable regulatory uncertainty for Energy

Northwest. For decades, Energy Northwest has relied on authorization from the State of Washington's Site Evaluation Council to dispose of cooling tower and spray pond sediments that contain, or may contain, trace amounts of radioactive material. The NRC now evidently expects Energy Northwest to seek NRC approval under 10 C.F.R. § 20.2002 in addition to its current State authorization. Until this issue is resolved, Energy Northwest, in effect, is subject to dual regulation by the State of Washington and the NRC with regard to the disposal of VLLW in the Sediment Disposal Cells. This outcome is neither consistent with the State's and NRC's Section 274 Agreement nor commercially practicable for Energy Northwest.

* * *

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct. Further, I declare that I have personal knowledge regarding the facts set forth above and that I am competent and authorized to file this Declaration.

Executed on September 28, 2020.



Tony L. Hedges
Chemistry/Radiological Services Manager
Energy Northwest

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

NUCLEAR ENERGY INSTITUTE,

Petitioner,

v.

U.S. NUCLEAR REGULATORY
COMMISSION and the UNITED
STATES OF AMERICA,

Respondents.

Case No. 19-1240

DECLARATION OF LANCE STERLING

I, Lance Sterling, swear or affirm under penalty of perjury, the following:

1. I am the Regulatory Affairs Manager at South Texas Project Units 1 and 2 (“South Texas Project”), a two-unit pressurized water reactor nuclear power station operated by STP Nuclear Operating Company (“STPNOC”). My business address is South Texas Project, P.O. Box 289, Wadsworth, TX 77483. STPNOC is a member of the Nuclear Energy Institute (“NEI”), a professional trade association that represents the nuclear energy industry on policy, regulatory, and other matters affecting the industry. NEI is the petitioner in this case.

2. I have worked at South Texas Project for 27 years. From 1993 through 2006, I worked as a Power Plant Operator and a Licensed Senior Reactor Operator. From 2003 through 2008, I also served as an Operations Support Supervisor.

Subsequently, I held positions as Work Week Manager (2009-2011) and Procedure Group Supervisor (2012-2014). I served as Licensing Supervisor from February 2014 through February 2019. I served as Performance Improvement Manager until June 2019, at which time I began my current position as Regulatory Affairs Manager. In my current role, I am responsible for managing, directing, and developing Regulatory Affairs and Environmental personnel to ensure regulatory requirements (including waste disposal requirements) are adhered to at STP. I hold a B.S. degree in Nuclear Engineering Technology from Thomas Edison State University.

3. I am providing this Declaration in support of NEI's Petition for Review of the NRC's decision, in a September 16, 2019, letter to NEI,¹ to give new legal effect to a non-binding NRC guidance document, Regulatory Issue Summary 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002" (Nov. 13, 2016) ("Issue Summary").² Very low-level radioactive waste ("VLLW") describes the lowest end of the low-level waste spectrum. It is waste that contains some residual radioactivity, but at levels so low the waste may be safely disposed in hazardous or industrial solid waste landfills. That is, because VLLW possesses only a small fraction of the lowest (i.e., Class A) radionuclide

¹ Letter from John W. Lubinski, U.S. NRC, to Ellen C. Ginsberg, NEI at 1 (Sept. 16, 2019) ("September 2019 NRC Letter"), available at <https://www.nrc.gov/docs/ML1922/ML19224A774.pdf>.

² Available at <https://www.nrc.gov/docs/ML1600/ML16007A488.pdf>.

concentration limits specified in NRC regulations in 10 CFR Part 61 (“Licensing Requirements for Land Disposal of Radioactive Waste”), it does not require disposal in a Part 61-licensed low-level radioactive waste disposal facility.³

4. STPNOC understands the September 2019 NRC Letter to require NRC reactor (10 C.F.R. Part 50) licensees to obtain approval from the NRC for the disposal of VLLW, even when their facilities are located in NRC Agreement States. Historically, STPNOC has disposed of certain VLLW pursuant to an approval from the State of Texas, issued in accordance with Texas’s status as an Agreement State under Section 274 of the Atomic Energy Act of 1954, as amended (“AEA”), 42 U.S.C. § 2021, and related NRC regulations in 10 C.F.R. Part 150. As I explain below, NRC’s new regulatory position will impose substantial cost on STPNOC in terms of the staff hours and financial resources that STPNOC will need to expend to come into compliance.

5. Since 2008, STPNOC has shipped certain VLLW generated at South Texas Project to an industrial solid waste landfill in Texas pursuant to an exemption granted by the State of Texas. Although STPNOC received the Issue Summary in 2016, the NRC stated therein that it was not requiring any action or written response

³ See U.S. NRC, “Very Low-Level Waste” (updated Apr. 30, 2020), <https://www.nrc.gov/waste/llw-disposal/very-llw.html> (accessed Sept. 28, 2020).

from licensees or imposing a regulatory backfit.⁴ However, during a routine safety inspection performed less than two years later, the NRC issued a Minor Violation because, while STPNOC had a continuing exemption from the State of Texas, it did not have a separate NRC approval to dispose of the VLLW at an offsite industrial landfill. Although the NRC decided to exercise enforcement discretion at the time, STPNOC cannot simply presume that the NRC will exercise enforcement discretion indefinitely, especially given the NRC's determination in its September 16, 2019 letter to NEI that reactor licensees "must" seek NRC approval for the disposal of VLLW associated with NRC-licensed activities.⁵ Thus, STPNOC is concerned that it may now need to take additional actions (e.g., prepare a Section 20.2002 approval request) or risk further NRC enforcement action.

6. In this Declaration, I provide information concerning: (1) STPNOC and South Texas Project operations; (2) the State of Texas regulatory authorization for offsite disposal of VLLW from South Texas Project in an industrial solid waste landfill; (3) the source of Texas' regulatory jurisdiction over VLLW disposal; and (4) the cost and resource impacts on the South Texas Project of the NRC's newly-asserted jurisdiction over VLLW. This information is intended to help the Court

⁴ Issue Summary at 3.

⁵ September 2019 NRC Letter, at 1.

understand the nature of the current dispute and how its resolution directly affects STPNOC and South Texas Project.

A. Overview of STPNOC and South Texas Project Operations

7. The South Texas Project is located on 12,220 acres in Matagorda County, Texas, approximately 15 miles southwest of Bay City along the west bank of the Colorado River. The South Texas Project is owned by NRG South Texas LP, the City of Austin, and the City Public Service Board of San Antonio as tenants in common. Houston Lighting & Power Company was the original operator of the South Texas Project and was responsible for the engineering, design, licensing, construction, startup, and initial commercial operation of the two-unit facility. In 1997, STPNOC, the current NRC-licensed operator, assumed operational control of the South Texas Project.

8. The South Texas Project consists of two Westinghouse pressurized water nuclear reactors. Unit 1 commenced full commercial operation in August 1988, and Unit 2 began full commercial operation in June 1989. On September 28, 2017, the NRC approved the South Texas Project's request to extend the operating licenses for those units through 2047 and 2048, respectively. The two units currently produce approximately 2,700 megawatts of electricity in total. STPNOC is the largest employer and source of revenue for Matagorda County.

B. State of Texas Regulatory Approval for Offsite Disposal of VLLW from South Texas Project in an Industrial Solid Waste Landfill

9. South Texas Project uses liquid, gaseous, and solid waste processing systems to collect and treat, as needed, radioactive materials that are produced as by-products of plant operations. Radioactive materials in liquid and gaseous effluents (i.e., controlled releases from the station) are reduced to levels that ensure that they comply with NRC radiation protection regulations in 10 C.F.R. Part 20, and that doses are as low as is reasonably achievable in accordance 10 C.F.R. Part 50. Radioactive waste is stored within plant buildings (with restricted access and radiation shielding) until it is shipped offsite for further processing by a vendor or disposal, or both.

10. Among the nonhazardous solid wastes generated at South Texas Project during regular plant maintenance, cleaning activities, and normal operations are dewatered sludge or sanitary sludge removed from the station wastewater treatment systems, ion exchange media or other purification media used in water treatment, filter media used in ventilation systems, soil, and other similar waste streams. These wastes sometimes contain trace amounts of radioactive materials such as tritium and gamma-emitting radioisotopes and thus are considered VLLW. These wastes constitute the VLLW for which STPNOC has a standing State of Texas approval to dispose of in an industrial solid waste landfill.

11. In general, Resource Conservation and Recovery Act (“RCRA”) waste regulations govern the disposal of solid (nonhazardous) and hazardous waste. See generally 40 C.F.R. Parts 239 through 299. The Texas Commission on Environmental Quality administers the Texas Solid Waste Disposal Act and also the federal RCRA program in Texas. Texas regulations address the identification, generation, minimization, transportation, and final treatment, storage or disposal of hazardous and nonhazardous solid waste.⁶

12. Since 2008, STPNOC has shipped VLLW to the Blue Ridge Landfill in Fresno, Texas (which is just south of Houston) pursuant to a March 7, 2008, exemption granted by the Texas Commission on Environmental Quality.⁷ The Blue Ridge Landfill is permitted by the Texas Commission on Environmental Quality as a Type I municipal/industrial solid waste landfill that can accept Class 1, Class 2, and Class 3 non-hazardous industrial solid waste, including VLLW. The Texas Commission on Environmental Quality’s exemption concurrence requires STPNOC to sample the VLLW to verify that tritium and other radionuclide levels do not

⁶ See generally Title 30, Texas Administrative Code (“TAC”), Chapter 330 (“Municipal Solid Waste”) and Chapter 335 (“Industrial Solid Waste and Municipal Hazardous Waste”).

⁷ See Letter from Hans Weger, Texas Commission on Environmental Quality, to R. A. Gangluff, STPNOC (Mar. 7, 2008), appended as Attachment 2 to the Letter from Michael Murray, STPNOC, to Brian Holian, NRC (Aug. 14, 2018) (<https://www.nrc.gov/docs/ML1822/ML18226A352.pdf>).

exceed the limits found in applicable Texas regulations before sending the waste to the landfill.⁸

C. Source of the State of Texas' Regulatory Jurisdiction over VLLW Disposal

13. The Texas Commission on Environmental Quality oversees all aspects of industrial and municipal hazardous waste, nonhazardous industrial solid waste, sewage sludge, and low-level radioactive waste disposal activities in Texas. The State of Texas's authority to regulate low-level radioactive waste (including VLLW) stems from its status as an Agreement State under Section 274 of the Atomic Energy Act. Texas and the Atomic Energy Commission (NRC's predecessor agency) entered into a Section 274 Agreement in 1963, which was amended in 1982.⁹

14. Under Texas Health and Safety Code Chapter 401 and the State of Texas' Agreement State regulations, certain radioactive materials can be exempted from radioactive material licensing requirements as exempt-concentration or exempt-quantity materials. The authorization and requirement concerning exempt materials are found in Section 401.106(a) of the Texas Health and Safety Code. Texas regulations at 25 TAC § 289.251(e) establish exempt concentrations and quantity

⁸ See id.

⁹ See Notice of Agreement with the State of Texas, 28 Fed. Reg. 531 (Jan. 19, 1963); State of Texas; Discontinuance of Certain Regulatory Authority and Responsibility Within the State, 47 Fed. Reg. 15,186 (Apr. 8, 1982).

limits for radioactive material other than “source material.” Radionuclide concentrations and quantities below these limits do not represent a hazard to the public or environment, such that the materials may be deemed exempt from the State’s radioactive material licensing requirements. The criteria that materials containing radioactivity must meet to qualify for such an exemption are found mainly in 25 TAC §§ 289.251 and 289.259.

15. Due to their exempt status, these materials do not need to be sent to a facility that is specifically licensed for low-level radioactive waste disposal and, pursuant to Texas regulations, can be disposed of in an authorized solid waste disposal facility (i.e., a landfill that accepts Class 1 and Class 2 nonhazardous industrial waste) or a RCRA hazardous waste disposal facility. Texas issues these “exemption concurrences” pursuant to 30 TAC § 336.5 (“Exemptions”), an NRC-approved Agreement State regulation that addresses both materials exempted by rule and materials exempted on a case-by-case basis. The disposal facilities receiving such exempt concentrations or quantities of radionuclides (i.e., VLLW) also are subject to various Texas Commission on Environmental Quality permitting and approval requirements. As discussed in paragraph 12, supra, on March 7, 2008, the Texas Commission on Environmental Quality provided such an exemption concurrence to STPNOC for the specific South Texas Project VLLW streams described above.

D. The NRC's Change in Position and Related Enforcement Action Against STPNOC

16. During a 2018 NRC Radiation Safety team inspection at South Texas Project, NRC inspectors reviewed shipments of exempt-quantity waste that STPNOC had shipped to the Blue Ridge Landfill pursuant to the March 7, 2008, State exemption concurrence discussed above. The reviewed shipments had been included in STPNOC's 2017 Annual Radioactive Effluent Release Report submitted to the NRC on April 18, 2018. That report indicated that STPNOC had made four truck shipments of "Low Level Exempt Quantities" of waste "per [its] Texas Commission on Environmental Quality exemption to [an] industrial landfill."¹⁰

17. During the inspection, NRC personnel informed STPNOC that the NRC was considering issuing a Minor Violation because, while the State of Texas had concurred with STPNOC's method of disposal of the VLLW as exempt quantities, the NRC had not issued a separate approval. This caught STPNOC completely by surprise, because STPNOC had a valid exemption from the Texas Commission on Environmental Quality, which is authorized to grant such exemptions under 30 TAC § 336.5.

¹⁰ South Texas Project Units 1 and 2 2017 Radioactive Effluent Release Report, at 6-4 (Apr. 18, 2018), <https://www.nrc.gov/docs/ML1811/ML18115A137.pdf>.

18. As a result, STPNOC sent a letter to the NRC's Acting Director of the Office of Nuclear Reactor Regulation requesting that the NRC acknowledge the existing durable agreement STPNOC has with the State of Texas for disposal of exempt-quantity waste streams, and that the NRC's change in position not be applied retroactively to STPNOC's existing agreement with the State of Texas.¹¹ STPNOC also noted that the NRC's new position was contrary to the agency guidance provided in Information Notice 86-90, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.302" (Nov. 3, 1986).¹² Finally, STPNOC pointed out that the 2016 Issue Summary stated that it required "no action or written response from licensees and was not a backfit pursuant to any of the NRC's backfitting or issue finality provisions."¹³

19. By letter dated October 31, 2018, the NRC responded to STPNOC's August 14, 2018, letter, asserting—again to STPNOC's surprise—that, despite having an exemption concurrence to dispose of VLLW from the State of Texas, STPNOC

¹¹ See Letter from Michael Murray, STPNOC, to Brian Holian, NRC, at 1 (Aug. 14, 2018), available at <https://www.nrc.gov/docs/ML1822/ML18226A352.pdf>.

¹² Id. at 2 (citing Information Notice 86-90, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.302" (Nov. 3, 1986), available at <https://www.nrc.gov/docs/ML0312/ML031250358.pdf>).

¹³ Id. (quoting Issue Summary at 3).

likewise needed to seek approval to dispose of VLLW from the NRC.¹⁴ This is contrary to the previous 10 years of NRC practice, in which STPNOC only needed authorization (i.e., the exemption concurrence) from Texas to dispose of VLLW in an industrial solid waste landfill.

20. In support of its position, the NRC cited the 2016 Issue Summary for the notion that “an Agreement State does not have the authority to grant permission to a nuclear power plant licensee for proposed procedures to dispose of low-level waste,” and that “the NRC is the regulatory authority to grant approvals for disposal procedures under 10 CFR 20.2002 for [South Texas Project].”¹⁵ STPNOC, however, never understood the Issue Summary to require NRC disposal approval for existing reactor waste streams that already are being disposed of pursuant to valid state authorizations. The RIS stated that it was “voluntary” and required “no specific action.”¹⁶ Therefore, STPNOC did not understand the RIS to require it to seek disposal approval from the NRC pursuant to 10 C.F.R. § 20.2002 or otherwise alter its state-approved VLLW disposal process.

¹⁴ See Letter from Craig G. Erlanger, NRC, to G. T. Powell, STPNOC, at 1 (Oct. 31, 2018), available at <https://www.nrc.gov/docs/ML1826/ML18260A250.pdf> (“October 2018 NRC Letter”).

¹⁵ *Id.* at 2.

¹⁶ Issue Summary at 1, 2.

21. The NRC stated that it was “evaluating generically” the issue STPNOC had raised in order to “provide further clarity” about whether NRC licensees with Agreement State approvals nevertheless need NRC approval to dispose of waste.¹⁷ NRC also stated that, given the low safety significance of the alleged non-compliance with 10 C.F.R. § 20.2002, it had decided to exercise enforcement discretion for past and ongoing non-compliance associated with this issue in accordance with Section 3.5 of the NRC Enforcement Policy.¹⁸

22. The NRC further noted that “[o]nce a resolution path is determined, the NRC will contact STPNOC to provide additional information.”¹⁹ Now, nearly two years later, the NRC has stated in the September 2019 Letter that NRC licensees—like STPNOC—“must” seek disposal approval from NRC, and that the NRC will only exercise enforcement discretion on a case-by-case basis.²⁰ Given the determination in the September 2019 NRC Letter that compliance with the Issue Summary is both mandatory and an enforcement matter, and the previously-issued Minor Violation, STPNOC is concerned that it could lose the enforcement discretion NRC previously

¹⁷ October 2018 NRC Letter at 2 (“STPNOC has raised issues associated with the [2016 Issue Summary] and with prior guidance. The NRC is evaluating the issue generically to provide further clarity.”)

¹⁸ Id.

¹⁹ Id.

²⁰ September 2019 Letter at 1.

granted it on this issue. Even if the NRC does not issue a written Notice of Violation (see 10 C.F.R. § 2.201) to STPNOC, a Minor Violation still requires timely corrective action by a licensee. The failure to correct a Minor Violation within a reasonable time may be viewed by the NRC as a willful violation, for which “[l]icenses are expected to take significant remedial action . . . commensurate with the circumstances.”²¹

E. Practical Impacts of the NRC’s Newly-Asserted Jurisdiction Over Offsite Disposal of VLLW by STPNOC

23. When the NRC first apprised STPNOC of the alleged Minor Violation, STPNOC suspended its practice of shipping exempt-quantity waste offsite for disposal, and began storing the material at issue onsite pending resolution of this matter. However, South Texas Project had sufficient storage capacity available to accommodate exempt-quantity waste (i.e., VLLW) only until October 2018, at which point it needed to obtain extra storage capacity or begin shipping exempted quantity waste to a Part 61 LLW disposal facility. The cost of temporary storage was approximately \$1350. This cost was associated with rental of storage containers for sewage sludge. Accordingly, when the NRC decided to exercise enforcement discretion, STPNOC resumed shipments of the exempt-quantity waste streams for

²¹ NRC Enforcement Policy, at 11 (Jan. 15, 2020), available at <https://www.nrc.gov/docs/ML1935/ML19352E921.pdf>.

offsite disposal at the Blue Ridge Landfill, as authorized by its State of Texas exemption concurrence.

24. The NRC's exercise of enforcement discretion, however, is only a temporary measure, and does not obviate the practical problems STPNOC now faces in light of the NRC's conclusion in the September 2019 Letter that compliance with the Issue Summary is an enforcement matter. Thus, in order to avoid a possible enforcement action, STPNOC's present options appear very limited, and will result in increased regulatory burden and additional monetary costs for STPNOC.

25. One option would be to prepare and submit a Section 20.2002 disposal authorization request to the NRC. This is not a small undertaking, insofar as Section 20.2002 requires that an application include, at a minimum: (1) a description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; (2) an analysis and evaluation of pertinent information on the nature of the environment; (3) the nature and location of other potentially affected licensed and unlicensed facilities; and (4) quantitative analyses and specific procedures to ensure that doses are maintained as low as reasonably achievable and within the dose limits specified in 10 C.F.R. Part 20.²² In addition, as part of its application review, the NRC typically issues requests for additional information that

²² 10 C.F.R. § 20.2002(a)-(d).

require written responses from, and related discussions with, the applicant. The NRC uses this information, in addition to that contained in the application, to prepare its Safety Evaluation Report.

26. Based on my experience as both a Licensing Supervisor and Regulatory Affairs Manager, I estimate that internally preparing, reviewing, and approving the Section 20.2002 application before its submittal to the NRC could require 500 – 1,000 South Texas Project personnel hours. This would include tasks (not all inclusive) for data collection and review, any necessary studies/surveys, dose evaluations or other technical analyses in addition to application preparation, review and approval. These activities require participation and coordination by multiple departments, including, for example, Licensing, Chemistry, Environmental, and Health Physics. This also may require the help of outside entities (contractors) to aid in conducting and evaluating the tasks mentioned above. STPNOC also would need to respond in writing to any NRC requests for additional information.

27. Notably, when the NRC issued updated guidance earlier this year concerning its review of Section 20.2002 “alternative” disposal requests,²³ it also issued a regulatory analysis document that assesses the relative benefits and costs of

²³ See NRC, “Guidance for the Reviews of Proposed Disposal Procedures and Transfers of Radioactive Material Under 10 CFR 20.2002 and 10 CFR 40.13(a)” (Apr. 2020),” <https://www.nrc.gov/docs/ML1829/ML18296A068.pdf>.

issuing the updated guidance document.²⁴ In the regulatory analysis, the NRC staff assumes that applicants' preparation of alternative disposal requests would take on average about 1,262 hours, and that preparing responses to NRC requests for additional information would require more than 270 hours.²⁵ As discussed above, STPNOC estimates that it would take 500 – 1000 staff hours to prepare an application for a reactor site of STPNOC's size. In addition, STPNOC estimates another 250 – 300 hours to respond to NRC's requests for follow-up information, depending on the number of requests. This would cost approximately \$72,000 – \$126,000 based on the range of hours listed above.

28. Moreover, the costs of preparing the application for an applicant like STPNOC are in addition to the fees charged by the NRC to the applicant for licensing and regulatory services. Those services may include, for example, performing an acceptance review of the application for docketing; providing public notice of the request; conducting a technical review of the request, including issuing requests for additional information and reviewing responses thereto; preparing a Safety Evaluation Report and Environmental Assessment; coordinating with State regulatory agencies and disposal site operators, as needed; and conducting public

²⁴ See NRC, "Regulatory Analysis for Issuing a Guidance Document for the Review of Proposed Disposal Procedures and Transfers of Radioactive Material under 10 CFR 20.2002 and 10 CFR 40.13(a)" (Apr. 2020), available at <https://www.nrc.gov/docs/ML2007/ML20072L323.pdf>.

²⁵ See id. at 12, 17.

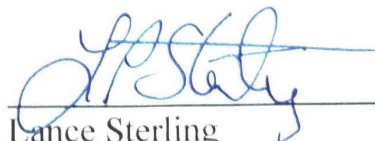
meetings or other outreach. A projected cost, to STP, for fees charged by the NRC would be roughly \$250,000. In total, the cost to prepare the application, together with the licensing and regulatory costs, would be roughly \$322,000 to \$376,000.

29. Another potential option for STPNOC would be to begin shipping exempt-quantity wastes to a low-level radioactive waste disposal facility licensed under 10 C.F.R. Part 61 or equivalent Agreement State regulations. However, this option would present substantial logistical and financial hardship to the station. Based on the historical data for a typical year of shipments, I estimate that shipping the exempt-quantity wastes to a disposal facility licensed under 10 C.F.R. Part 61 or equivalent Agreement State regulations (as opposed to an industrial landfill) would increase STPNOC's disposal costs for those wastes by roughly \$163,000 per year.

* * *

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct. Further, I declare that I have personal knowledge regarding the facts set forth above and that I am competent and authorized to file this Declaration.

Executed on September 28, 2020.



Lance Sterling
Regulatory Affairs Manager
South Texas Project Units 1 and 2

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

NUCLEAR ENERGY INSTITUTE,

Petitioner,

v.

U.S. NUCLEAR REGULATORY
COMMISSION and the UNITED
STATES OF AMERICA,

Respondents.

Case No. 19-1240

DECLARATION OF THOMAS N. WEBER

I, Thomas N. Weber, swear or affirm under penalty of perjury, the following:

1. I am the Nuclear Regulatory Affairs Director at Palo Verde Nuclear Generating Station (“Palo Verde”), a three-unit pressurized water nuclear reactor power station co-owned and operated by Arizona Public Service Company (“APS”). My business address is 5801 S. Wintersburg Rd, Tonopah, AZ 85354. APS is a member of the Nuclear Energy Institute (“NEI”), a professional trade association that represents the nuclear energy industry on policy, regulatory, and other matters affecting the industry. NEI is the petitioner in this case.

2. I have worked in the commercial nuclear power industry for more than 40 years, initially as a design engineer and field construction engineer for an Engineering firm. I began my career at APS in 1986 in the Engineering Department.

I transferred to the Nuclear Regulatory Affairs Department in 1993 where I have assumed positions of greater responsibility. I have been in my current role of Nuclear Regulatory Affairs Director since 2018. In this capacity, I oversee Palo Verde interactions with the U.S. Nuclear Regulatory Commission (“NRC”) associated with Licensing, Compliance, and Environmental activities. I serve as a member of the site Corrective Action Review Board, the Plant Review Board, and the 10 CFR Part 21 Review Board. I hold a B.S. degree in Physics and an M.S. degree in Mechanical Engineering.

3. I am providing this Declaration in support of NEI’s Petition for Review of the NRC’s decision, in a September 16, 2019, letter to NEI,¹ to give new legal effect to a non-binding NRC guidance document, Regulatory Issue Summary 2016-11, “Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002” (Nov. 13, 2016) (“Issue Summary”).² APS understands the September 16, 2019 letter to require NRC licensees to obtain NRC approval for the disposal of very low-level radioactive waste (“VLLW”), even when their facilities are located in NRC Agreement States. Historically, Agreement States, including Arizona, have

¹ Letter from John W. Lubinski, U.S. NRC, to Ellen C. Ginsberg, NEI at 1 (Sept. 16, 2019) (“September 2019 NRC Letter”), available at <https://www.nrc.gov/docs/ML1922/ML19224A774.pdf>.

² Available at <https://www.nrc.gov/docs/ML1600/ML16007A488.pdf>.

regulated VLLW disposal pursuant to their written agreements with the NRC under Section 274 of the Atomic Energy Act of 1954, as amended (“AEA”), 42 U.S.C. § 2021, and NRC regulations in 10 C.F.R. Part 150. VLLW is waste that contains some residual radioactivity that is a small fraction of the “Class A” limits specified in 10 C.F.R. Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste,” and which may be safely disposed of in hazardous or solid waste landfills without the need for the extensive controls specified in Part 61 or equivalent state regulations.³

4. NRC’s new regulatory position will impose substantial cost on APS in terms of the staff hours and financial resources that APS will need to expend to come into compliance. In this Declaration, I provide information concerning: (1) APS and the major Palo Verde facilities; (2) the management of waste at Palo Verde; (3) the State regulatory approvals that authorize the disposal of certain types of sludge (including cooling water sludge that may contain trace amounts of radioactivity) in the Palo Verde Sludge Disposal Landfill; (4) the source of Arizona’s regulatory jurisdiction over VLLW disposal; and (5) the practical impacts of the NRC’s newly-asserted

³ See U.S. NRC, “Very Low-Level Waste” (updated Apr. 30, 2020), <https://www.nrc.gov/waste/llw-disposal/very-llw.html> (accessed Sept. 26, 2020).

jurisdiction over VLLW disposal by NRC reactor licensees on Palo Verde operations.

A. Overview of APS and Palo Verde Facilities

5. APS is a wholly-owned subsidiary of Pinnacle West Capital Corporation, an investor-owned electric utility holding company based in Phoenix, Arizona. As a vertically-integrated electric utility, APS provides either retail or wholesale electric service to most of the State of Arizona, about 1.2 million customers in total. APS owns a 29.1 percent tenant-in-common interest and holds both operating and possession rights in the NRC licenses for Palo Verde Units 1, 2, and 3. Thus, APS is the NRC-licensed operator and a licensed co-owner of all three units.

6. Palo Verde is located in Maricopa County, Tonopah, Arizona, approximately 50 miles west of the City of Phoenix. Palo Verde began commercial operations between January 1986 (Unit 1) and January 1988 (Unit 3), and is authorized to operate well into the 2040s pursuant to the facility's NRC-renewed operating licenses. As the largest nuclear power station in the United States by net generation (nearly 4,000 megawatts-electric total), Palo Verde is the largest producer of clean-air energy in the nation, serving more than 4 million people in the Southwest, generating more than 32 million megawatt-hours of electric power annually, and accounting for about 70 percent of the State of Arizona's carbon-free electricity generation.

7. The Palo Verde site spans approximately 4,280 acres. The site buildings and adjacent developed areas occupy approximately 720 acres. There are roughly 780 surface acres of water on the site in various large ponds. The facility comprises electric generating units and cooling towers, solid waste handling and storage facilities, wastewater containment facilities (i.e., surface impoundments) for cooling tower blowdown and other plant effluents, a package wastewater treatment plant, an advanced water treatment plant (referred to as the Water Reclamation Facility or Water Resources Facility), water storage reservoirs, plant operation and maintenance warehouses, and administration buildings.

8. The generating facility consists of three separate, identical pressurized water reactors each equipped with three cooling towers. The Palo Verde site also includes hazardous waste storage areas; low-level radioactive waste interim storage facilities; railroad and road facilities; fire protection and security facilities; control room simulators and other training facilities; and emergency facilities.

9. Palo Verde's water systems are supplied by two sources. The main source is wastewater effluent, which is acquired through agreements with two Phoenix area wastewater treatment plants. Once it reaches the Palo Verde site, this effluent undergoes additional treatment at the Water Reclamation Facility to meet the station's water quality requirements. The main function of the Water Reclamation Facility, which also treats industrial process wastewater from plant operations, is to

provide makeup cooling water. The other, secondary source of water at Palo Verde is several onsite production wells, which supply groundwater for use in plant fire protection, demineralized, and domestic water systems, as well as for dust control.

10. APS operates numerous onsite surface impoundments at Palo Verde, including three lined Evaporation Ponds and two lined Water Storage Reservoirs. It also operates a Rubbish Landfill and a Sludge Disposal Landfill on site, the latter of which is described further below.

B. Management of Radioactive and Nonradioactive Waste at Palo Verde

11. The operation of nuclear power plants produces radioactive materials. Radioactivity results primarily from the fission of uranium fuel. The radioactive materials produced by the fission of uranium fuel generally fall into two categories: fission products and activation products.

12. Under normal operating conditions, fission products are located and remain inside the used uranium fuel rods. In contrast, activation products are located in the reactor coolant system. Because these activation products are located in the reactor coolant system, they are more readily transported by the reactor coolant system to any support system that connects to the reactor coolant system. Activation products (including tritium) are the source of most radiological contamination at nuclear plants, potentially including radiological contamination in cooling tower water.

13. Palo Verde's radioactive waste system collects, treats, stores, and disposes of radioactive and potentially radioactive solid, liquid, and gaseous wastes that are byproducts of plant operations. Operating procedures for the radioactive waste system ensure that any radioactive materials are safely processed, such that any liquid and gaseous effluents discharged from the station as controlled releases comply with the regulatory limits set forth in NRC regulations in 10 C.F.R. Part 20, "Standards for Protection Against Radiation."

14. Palo Verde also generates solid wastes as part of routine plant maintenance, cleaning activities, and plant operations. Palo Verde generates solid waste that is classified as either nonhazardous or hazardous, as defined by the Resource Conservation and Recovery Act ("RCRA"). The nonhazardous solid waste includes office trash, construction debris, kitchen waste, and other rubbish material from routine plant maintenance, operations and cleaning activities. It also includes sludge material, including wastewater treatment process sludge and cooling tower sludge that are disposed of in the onsite Sludge Disposal Landfill. Given the potential presence of activation products in cooling tower water, the cooling tower sludge also may contain trace quantities of radioactive material. For that reason, APS has obtained State of Arizona approval to dispose of the cooling tower sludge as VLLW in the Sludge Disposal Landfill.

C. State Regulatory Authorizations for the Palo Verde Sludge Disposal Landfill

15. Palo Verde's operation of certain surface impoundments, the Sludge Disposal Landfill, and the Rubbish Landfill is authorized by area-wide Aquifer Protection Permit No. P-100388 ("Aquifer Protection Permit") issued by the Arizona Department of Environmental Quality in December 2003, as subsequently amended. Relevant excerpts from the Aquifer Protection Permit are provided in Attachment 1 hereto. The Aquifer Protection Permit addresses the design, construction, operation, and closure requirements for the permit-regulated facilities, including the Sludge Disposal Landfill. The monitoring and compliance activities required by the Permit to protect the aquifer near Palo Verde are documented in annual reports to the Arizona Department of Environmental Quality that include the results of groundwater monitoring, impoundment monitoring, sludge monitoring, and compliance status, and document maintenance and repair activities for the surface impoundments over the past year.

16. The 213-acre Sludge Disposal Landfill is located on the east-central portion of the Palo Verde Site and operated in accordance with Arizona Revised Statutes ("A.R.S.") § 49-762.07(E) and (F). It is an active, unlined solid waste disposal facility used for the surface drying and landfilling of sludge from the Water Reclamation Facility and the cooling towers. The sludge is deposited by the area-

fill method and covered with one foot of soil with each application. The sludge from the cooling towers is physically set apart from the sludge from the Water Reclamation Facility, so there is no mixing of the two types of sludge. Based on the last 10 years of data, APS places (on average) about 800 cubic yards of cooling tower sludge in the Sludge Disposal Landfill each year.

17. Given the potential presence of radionuclides in the cooling tower sludge from normal station operations, APS possesses Special Approval License No. 07-368 (“Special Approval License”), Attachment 2 hereto, originally issued by the Arizona Radiation Regulatory Agency. On December 31, 2017, the Agency was transitioned into the Arizona Department of Health Services by state legislation and renamed the Bureau of Radiation Control. Thus, the current version of Special Approval License No. 07-368 (Amendment 11 issued on March 15, 2018) was issued by the Bureau of Radiation Control.

18. The Aquifer Protection Permit and Special Approval License issued by the Arizona Department of Environmental Quality and Bureau of Radiation Control, respectively, provide for the comprehensive State regulation of sludge deposited in the Sludge Disposal Landfill, including the disposal of cooling water sludge that may contain trace amounts of radioactive material. The Aquifer Protection Permit

limits the types of materials that can be deposited in the landfill and restricts the landfill to non-hazardous sludge that meets Permit requirements.⁴

19. The Aquifer Protection Permit requires, among other things, that cooling tower sludge samples be analyzed for radiological constituents in accordance with Special Approval License No. 07-368.⁵ The Special Approval License authorizes APS to dispose of sediment and sludge containing trace amounts of radioactive material in accordance with APS landfill operation procedures, and as described in the Aquifer Protection Permit.⁶ The Special Approval License provides that the average aggregate concentration of radioactive materials in sediments and sludge disposed of in the Sludge Disposal Landfill may not exceed certain concentration limits that are codified in Arizona's radiation protection regulations.⁷

D. Source of the State of Arizona's Regulatory Jurisdiction Over VLLW Disposal

20. The State of Arizona, through the Arizona Department of Environmental Quality and Bureau of Radiation Control (and its predecessor agency), long has regulated the disposal of sludge from the Palo Verde Units 1, 2, and 3 cooling towers pursuant to the Aquifer Protection Permit and Special Approval License. The scope

⁴ See Aquifer Protection Permit at 33-35 (Attachment 1).

⁵ See *id.*

⁶ See Special Approval License, ¶ 7 (Attachment 2).

⁷ See *id.* ¶ 8.

of this regulatory authority includes sludge with “trace amounts of radioactive material,” i.e., sludge that is considered VLLW.⁸ Importantly, the Special Approval License distinguishes between the ultimate disposal of such VLLW, over which the State has authority, and the temporary storage of radiologically-contaminated sludge that does not meet the State’s concentration-based disposal criteria, over which the NRC has regulatory jurisdiction.⁹

21. The State’s authority to regulate radiologically-contaminated sludge stems from its status as an Agreement State under AEA Section 274. Arizona and the Atomic Energy Commission (NRC’s predecessor) entered into a Section 274 Agreement in April 1967.¹⁰

E. Impacts of the NRC’s Newly-Asserted Jurisdiction Over VLLW Disposal

22. Given the division of regulatory authority between the State of Arizona and the NRC that has existed for decades, including with regard to onsite sludge disposal at Palo Verde, APS is very concerned about the position taken by NRC in its September 16, 2019, Letter to NEI. According to that letter, “any licensee’s request for approval to dispose of licensed material under . . . Section 20.2002, or the

⁸ See id. ¶ 7.

⁹ See id. ¶¶ 7, 8, 10.

¹⁰ See Agreement Between [Atomic Energy Commission] and Arizona; Discontinuance of Certain Commission Regulatory Authority and Responsibility, 32 Fed. Reg. 6103 (Apr. 18, 1967).

equivalent Agreement State regulations, must be submitted to the regulatory authority that issued the license for use of the radioactive material.”¹¹ Thus, APS understands this letter to require NRC reactor licensees to now seek disposal approval for VLLW from the NRC rather than Agreement States, contrary to the decades of prior practice described above. Moreover, this letter states that NRC will consider “enforcement discretion” on a case-by-case basis for those licensees who have relied on Agreement State approvals in the past—indicating that there are some instances in which the agency will not exercise enforcement discretion.¹² Section 20.2002 of NRC’s regulations provides that licensees may seek NRC approval of proposed procedures, not otherwise authorized in 10 C.F.R. Part 20, “to dispose of licensed material generated in the licensee’s activities.”¹³

23. As noted above, APS has long relied on Agreement State approval for its VLLW disposal activities. APS is concerned that during a future inspection at Palo Verde, the NRC might allege a violation against APS on the ground that its disposal of cooling tower sludge potentially containing trace amounts of radiological material requires NRC approval pursuant to 10 C.F.R. § 20.2002. Indeed, I understand that

¹¹ September 2019 NRC Letter at 1 (emphasis added).

¹² Id.

¹³ 10 C.F.R. § 20.2002.

this situation already has occurred at other nuclear power stations located in the same NRC region (Region IV) as Palo Verde.

24. Even if the NRC were to issue only a “minor violation” or exercise enforcement discretion, alleged violations are an undesirable outcome that APS, like other NRC licensees, diligently seeks to avoid. Moreover, even minor violations, which the NRC defines as those that are less significant than a Severity Level IV violation, and which do not normally warrant enforcement action or documentation in inspection reports, “must be corrected.”¹⁴ Specifically, a licensee must enter the minor violation in its Corrective Action Program and address it through its NRC-inspected corrective action processes. NRC regulations require licensees to take corrective actions to ensure that conditions adverse to quality, safety, and security are promptly identified and corrected.¹⁵ A licensee’s Corrective Action Program is its formal process for tracking, evaluating, and resolving deficiencies.¹⁶ As the NRC’s Enforcement Policy makes clear, “if a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation

¹⁴ NRC Enforcement Policy, at 12, 14, 82 (Jan. 15, 2020), available at <https://www.nrc.gov/docs/ML1935/ML19352E921.pdf>. A Severity Level IV violation is defined as one that “resulted in no or relatively inappreciable potential safety or security consequences”, but which “created the potential of more than minor safety or security consequences.” *Id.* at 12.

¹⁵ See 10 C.F.R. Part 50, Appendix B, Criterion XVI (“Corrective Action”).

¹⁶ See NRC Enforcement Policy at 81.

should be considered more than minor,” and “[l]icenses are expected to take significant remedial action in responding to willful violations commensurate with the circumstances.”¹⁷ Otherwise, significant enforcement action against the licensee could result, because “[a]ll violations are subject to consideration for civil enforcement action [and] some violations may also be considered for criminal prosecution by the U.S. Department of Justice.”¹⁸

25. Any effort by APS to comply with the NRC’s new mandate would impose additional (and, in APS’s view, unnecessary) regulatory burden. To obtain a Section 20.2002 disposal authorization from the NRC, Palo Verde staff would need to compile the technical information necessary to support the application. The application must include, at a minimum: (1) a description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; (2) an analysis and evaluation of pertinent information on the nature of the environment; (3) the nature and location of other potentially affected licensed and unlicensed facilities; and (4) quantitative analyses and specific procedures to ensure

¹⁷ Id. at 11.

¹⁸ Id. at 9

that doses are maintained as low as reasonably achievable and within the dose limits specified in 10 C.F.R. Part 20.¹⁹

26. Based on informal benchmarking performed by reviewing relevant information in the NRC's public document system (e.g., relevant NRC guidance, previous Section 20.2002 disposal requests/approvals) and obtaining feedback from other licensees, I conclude that this is not a minor task. I estimate that approximately 500 hours of Palo Verde staff time would be needed to compile, review, and approve the Section 20.2002 application prior to its submittal to the NRC. After the application is submitted, APS likely would need to respond in writing to NRC requests for additional information and engage in other interactions with NRC staff. APS also would be responsible for paying the regulatory services fees charged by the NRC for its review of the application pursuant to 10 C.F.R. Part 170. Based on input provided by APS licensing personnel and my own professional experience, I estimate that the total licensing-related costs (inclusive of NRC fees) would be on the order of \$200,000. Furthermore, assuming the NRC approves the Section 20.2002 disposal request, it still could impose additional technical or administrative conditions that create additional regulatory burden and related costs for APS.

27. Another option for APS would be to dispose of cooling tower sludge in a low-level radioactive waste disposal facility licensed under 10 C.F.R. Part 61 (or

¹⁹ See 10 C.F.R. § 20.2002(a)-(d).

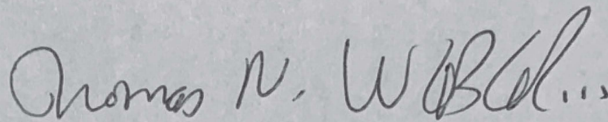
equivalent Agreement State regulations) pending resolution of the jurisdictional issues described above. However, the resulting increase in disposal costs would be substantial. Based on current APS contracts with offsite low-level radioactive waste disposal facilities, the disposal costs alone (excluding labor, container, and transportation costs) are estimated to be about \$1,000,000 per year for the cooling tower sludge.

28. Finally, as the foregoing suggests, the new agency position taken in the September 2019 NRC Letter creates considerable regulatory uncertainty for APS. For decades, APS has relied on authorizations from the Arizona Department of Environmental Quality and Bureau of Radiation Control (or its predecessor) to dispose of cooling tower sludge that contains, or may contain, trace amounts of radioactive material. The NRC now evidently expects APS to seek NRC approval under 10 C.F.R. § 20.2002 in addition to, or in lieu of, its current State authorizations. Until this issue is resolved, APS, in effect, is subject to dual regulation by the State of Arizona and the NRC with regard to the disposal of potential VLLW (i.e., cooling tower sludge) in the Sludge Disposal Landfill. This outcome is neither consistent with the State's and NRC's Section 274 Agreement nor commercially practicable for APS.

* * *

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct. Further, I declare that I have personal knowledge regarding the facts set forth above and that I am competent and authorized to file this Declaration.

Executed on September 29, 2020.

A handwritten signature in dark ink, appearing to read "Thomas N. Weber", is written over a horizontal line.

Thomas N. Weber

Nuclear Regulatory Affairs Director
Arizona Public Service

ATTACHMENT 1

Excerpts from Arizona Department of Environmental Quality

“Area-wide Aquifer Protection Permit No. 100388” (Jan. 2018)

for the Palo Verde Nuclear Generating Station



PERMIT

www.azdeq.gov

AREA-WIDE AQUIFER PROTECTION PERMIT NO. P-100388 PLACE ID 3507, LTF 64999, Significant Amendment

1.0 AUTHORIZATION

In compliance with the provisions of Arizona Revised Statutes (A.R.S.) Title 49, Chapter 2, Articles 1, 2 and 3, Arizona Administrative Code (A.A.C.) Title 18, Chapter 9, Articles 1 and 2, A. A. C. Title 18, Chapter 11, Article 4 and amendments thereto, and the conditions set forth in this permit, the Arizona Department of Environmental Quality (ADEQ) hereby authorizes **Arizona Public Service Company**, as a joint owner and the operating agent for the other joint owners:

1. Salt River Project Agricultural Improvement and Power District
2. Southern California Edison Company
3. El Paso Electric Company
4. Public Service Company of New Mexico
5. Los Angeles Department of Water & Power
6. Southern California Public Power Authority

to operate the discharging facilities listed in this permit at the **Palo Verde Nuclear Generating Station** (Facility) located in Tonopah, Arizona, approximately 50 miles west of downtown Phoenix in Maricopa County over groundwater of the Lower Hassayampa groundwater basin, within the Phoenix Active Management Area, in all or portions of Township 1 North, Range 6 West, Sections 26, 27, 28, 33, 34 and 35 and Township 1 South, Range 6 West, Sections 2, 3, 4, 9 and 10, of the Gila and Salt River Baseline and Meridian.

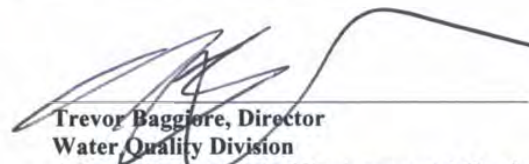
This permit becomes effective on the date of the Water Quality Division Director's signature and shall be valid for the life of the facility (operational, closure, and post-closure periods), unless suspended or revoked pursuant to A.A.C. R18-9-A213. The permittee shall construct, operate and maintain the permitted facilities:

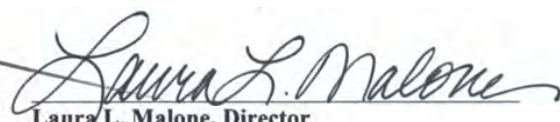
1. Following all the conditions of this permit including the design and operational information documented or referenced below, and
2. Such that Aquifer Water Quality Standards (AWQS) are not violated at the applicable point(s) of compliance (POC) set forth below, or if an AWQS for a pollutant has been exceeded in an aquifer at the time of permit issuance, that no additional degradation of the aquifer relative to that pollutant, and as determined at the applicable POC, occurs as a result of the discharge from the facility.

1.1 Permittee Information

Facility Name:	Palo Verde Nuclear Generating Station	
Annual Registration Fee Flow Rate:	Greater than 10 Million Gallons per Day (gpd)	
Permittee:	Mailing Address:	Facility Street Address:
APS – Palo Verde Nuclear Generating Station	P.O. Box 52034, M.S. 7626 Phoenix, Arizona 85072-2034	5801 South Wintersburg Road Tonopah, Arizona 85354-7529
Facility Contact:	Environmental Department Leader	623-393-4972
Emergency Telephone Number:	Water Reclamation Facility Shift Supervisor	623-393-3002
Latitude:	33° 22' 40" North	
Longitude:	112° 51' 34" West	
Legal Description:	See Section 14.0 of this permit	

1.2 Authorizing Signature


Trevor Baggione, Director
Water Quality Division
Arizona Department of Environmental Quality
Signed this 4 day of January, 2018


Laura L. Malone, Director
Waste Programs Division
Arizona Department of Environmental Quality
Signed this 26 day of December, 2017

THIS PERMIT AMENDMENT SUPERSEDES ALL PREVIOUS AMENDMENTS TO THIS PERMIT



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2.0 SPECIFIC CONDITIONS [A.R.S. §§ 49-203(4), 49-241(A)]

2.1 Facility / Site Description [A.R.S. § 49-243(K)(8)]

The Palo Verde Nuclear Generating Station (PVNGS) began operations in 1985 and at this time is expected to have an operational life of at least 60 years. The PVNGS is an existing electric generating baseload plant, utilizing nuclear fission for generation of electrical power. The 4,280-acre Facility is located west of Phoenix, Arizona.

The generating Facility consists of three, separate, identical, generating units/reactors, each equipped with three cooling towers. Each generating unit (also referred to in this permit as Unit) is capable of independent operation. These units have a nominal net electrical output of approximately 1,346 megawatts (MW) each for a total plant capacity of about 4,038 MW. Each Unit also includes associated structures: auxiliary building; radioactive waste (radwaste) building; fuel building; control building; diesel generator building; main steam support structure; access building; spray ponds and cooling towers; and an oil/water separator.

Major common installations serving all three Units include: administrative offices; maintenance, fire protection and security facilities; control room simulators and other training facilities; emergency facilities; a Water Reclamation Facility (WRF); a re-engineered 85-acre water storage reservoir (WSR) (formerly known as the 80-acre WSR) for storing treated effluent reused for cooling water; a 45-acre water storage reservoir (WSR); a sewage treatment plant for domestic sewage; three double-lined evaporation surface impoundments; two unlined stormwater sedimentation basins; a rubbish landfill; a sludge disposal landfill; a concrete/inert landfill; hazardous waste accumulation/storage facilities; low-level radioactive waste interim storage facilities including an above-ground spent fuel cask storage area located on a concrete pad; warehouses; and railroad and road facilities. A 500-kilovolt (KV) switchyard is also located at the PVNGS site and is managed and operated by Salt River Project (SRP). This switchyard is not regulated under the Aquifer Protection Permit (APP) program. Exempt facilities are listed in the Fact Sheet accompanying this permit.

The site includes the following permitted discharging facilities:

Facility	Latitude (North)	Longitude (West)
85-acre Water Storage Reservoir	33° 23' 30"	112° 51' 00"
45-acre Water Storage Reservoir	33° 23' 45"	112° 50' 48"
Evaporation Pond 1 (Cells 1A, 1B, 1C)	33° 22' 00"	112° 52' 08"
Evaporation Pond 2 (Cells 2A, 2B, 2C)	33° 22' 00"	112° 51' 30"
Sludge Disposal Landfill (Cooling Tower and WRF sludge)	33° 23' 47"	112° 51' 00"
Rubbish Landfill	33° 23' 06"	112° 51' 00"
Evaporation Pond 3 (Cells 3A and 3B)	33° 21' 29"	112° 52' 08"

The site includes the following clean-closed facilities:

Facility	Latitude (North)	Longitude (West)
Unlined Sedimentation Basin 1 (including ditches)	33° 22' 25"	112° 52' 20"
Unlined Sedimentation Basin 2 (including ditches)	33° 22' 21"	112° 51' 21"

2.1.1 APP Annual Registration Fee [A.R.S. § 49-242 and A.A.C. R18-14-104]

The annual registration fee for this permit is payable to ADEQ each year. The permitted flow for fee calculation is more than 10 million gallons per day (MGD). If the facility is not yet constructed or is incapable of discharge at this time, the permittee may be eligible for reduced fees under the rule.



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- Polynuclear Aromatic Hydrocarbons (PAHs) – Only analyzed if observable staining.

Analytical results for Sedimentation Basins 1 and 2 and associated ditches did not detect exceedances for respective minimum Groundwater Protection Levels (GPLs) for any of the analytes. Because no staining was observed, PAHs were not analyzed from any of the samples collected.

Two POC wells, APP-18 and PV-195A, are associated with Sedimentation Basins 1 and 2. Groundwater results did not indicate any violations of the Aquifer Quality Limits (AQLs) in each POC well. Clean closure has been obtained and Sedimentary Basins 1 and 2 and their associated ditches have been removed as discharging facilities from within this permit. Groundwater monitoring at the two associated POC wells is no longer required.

6.0 SLUDGE LANDFILL

PVNGS operates and maintains a surface drying Sludge Disposal Landfill that is approximately 213 acres in size. The Sludge Landfill is located on the east and south side of the WRF. The Sludge Landfill is an active, unlined solid waste disposal facility used for surface drying and land-filling of sludge from the WRF and the cooling towers. Sludge is deposited by the area-fill method and covered with 1 foot of soil with each application.

STP sludge is not deposited in the Sludge Disposal Landfill. The STP sludge is cycled back to the trickling filters of the WRF.

6.1 Sludge Landfill BADCT [A.R.S. § 49-243(B) and A.A.C. R18-9-A202(A)(5)]

The permittee shall operate and maintain a surface drying Sludge Disposal Landfill that is approximately 213 acres in size to receive cooling tower sludge and sludge from water treatment processes. The Sludge Landfill is located in a flat desert area and shall be filled to the prescribed elevation and capped with a layer of liner dirt. Alternately, the sludge may be disposed at an offsite permitted solid waste facility subject to applicable Federal and State Solid Waste Regulations. The Sludge Landfill is operated as a private solid waste landfill in accordance with Arizona Radiation Regulatory Authority (ARRA) Special Approval License No.7-368 and amendments and in accordance with A.R.S. § 49-762.07 (E) and (F). Sludge disposed in this landfill shall be characterized in accordance with requirements below and Section 13.2, Table 13.2-4, WRF and Cooling Tower Sludge Disposal Landfill Sludge Sampling Parameters. Operations shall include routine characterization in accordance with this permit.

6.2 Sludge Landfill Operational Requirements and Methods

Sludge shall be deposited by the area-fill method and covered with 1 foot of soil after placement. The landfill shall be maintained according to the requirements in Table 13.2-1 Surface Impoundment and BADCT Performance Standard Inspections and Alert Monitoring.

6.3 Sludge Landfill Discharge Limitations [A.R.S. §§ 49-201(14), 49-243 and A.A.C. R18-9-A205(B)]

The Sludge Disposal Landfill shall be operated, maintained, designated and authorized to receive the following materials only:

1. Sludge produced by the two-stage lime treatment process from the WRF. The sludge shall be dewatered before it is placed in the landfill.
2. Sodium carbonate and sodium sulfate from the following sources:
 - (a) Spills at the unloading and silo stations;
 - (b) Spills and leaks from the chemical feed and transport lines; and
 - (c) Neutralization materials and products from the neutralization of small sulfuric acid spills.
3. Lime grits from slaker stations and lime waste from the following sources:
 - i. Spills at the unloading and silo transfer stations;
 - ii. Spills and leaks from the lime feed and transport lines;
 - iii. Neutralization materials and products from the neutralization of small sulfuric acid spills; and
 - iv. Clean out from the recalcination furnace
4. Groundwater or WSR water sprayed in limited quantities to remove residual sludge from the bed of the trucks.
5. Cooling tower sludge, which meets the following requirements;
 - (a) Concentrations of each isotope in the cooling tower sludge shall not exceed the limits imposed by ARRA Special Approval License No. 7-368, and amendments/revisions made to that license issued by ARRA;

**AQUIFER PROTECTION PERMIT NO. P-100388**
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- (b) The sludge shall not meet the definition of hazardous waste as defined in 40 CFR Part 261; and
- (c) The sludge shall not contain free liquids.

Failure to comply with these DLs shall be reported in accordance with Section 10.3, Permit Violation and Alert Level Status Reporting and appropriate corrective actions taken in accordance with Section 9.4, Emergency Response and Contingency Requirements for Unauthorized Discharges and Section 9.5 Corrective Actions.

6.4 Sludge Landfill Sampling and Monitoring Requirements [A.R.S. § 49-243(K)(1), A.A.C. R18-9-A206(A)]**6.4.1 Cooling Tower Sludge**

The permittee shall sample cooling tower sludge prior to disposal in the Sludge Disposal Landfill on a per disposal event basis. The samples shall be collected and evaluated according to Section 13.2, Table 13.2-4, WRF and Cooling Tower Sludge Disposal Landfill Sludge Sampling Parameters and conformance with ARRA Special Approval License 7-368 requirements and restrictions.

1. Samples shall be a composite representing the horizontal and vertical distribution of the sludge from each accumulation area.
2. Samples for radiological analysis shall be collected and evaluated in accordance with ARRA Special Approval License No. 7-368, and subsequent amendments to the ARRA license for this Facility.
3. The samples for radiological analysis shall be analyzed by equipment capable of detecting the presence of principal gamma-ray emitting isotopes.
4. The Radiological Environmental Monitoring Program Report shall be included in the Annual Monitoring and Compliance Report, submitted in accordance Section 10.4.1, Annual Reporting Requirements.
5. Exceeded ALs in Section 13.2 Table 13.2-4, WRF and Cooling Tower Sludge Disposal Landfill Sludge Sampling Parameters, shall be reported in accordance with Section 10.3, Permit Violation and Alert Level Status Reporting.
6. In accordance with Section 10.4.1, Annual Reporting Requirements, the Annual Monitoring and Compliance Report shall contain summary table(s) of all analytical results for sludge testing performed for disposal of cooling tower sludge and WRF sludge in the Sludge Disposal Landfill during the calendar year. The report shall also contain a description of the estimated volumes disposed during the previous year. Certified analytical laboratory reports (CARs) shall be maintained at the Facility APP files and presented to an ADEQ inspector or representative within 30 calendar days of request.

6.4.2 WRF Sludge Sampling

The permittee shall sample the WRF sludge deposited in the Sludge Disposal Landfill in accordance with Section 13.2, Table 13.2-4, WRF and Cooling Tower Sludge Disposal Landfill Sludge Sampling Parameters. The disposal of sludge materials shall be in accordance with Section 6 of this permit and shall be limited to those materials listed as authorized for disposal in Discharge Limitations, Section 6.3, Sludge Landfill Discharge Limitations.

6.4.3 Methane Gas Monitoring

1. A semiannual monitoring program shall be implemented for a 3-year period to ensure that methane gas concentrations remain below five (5) percent (%) by volume. If methane is not detected during the 3-year period, monitoring may be discontinued with ADEQ approval. In order to assess the effectiveness of the methane monitoring, the results of each monitoring event shall be submitted to ADEQ within 60 days after each event.
2. The permittee shall operate and maintain methane gas monitoring equipment to ensure that the standards of 40 CFR § 257.3-8 are met. Such routine methane monitoring shall include monitoring the gas probes installed around the landfill footprint as shown on Figure 1 Methane Monitoring Locations of the *Methane Monitoring Plan* dated March 31, 2017.
3. The permittee must ensure, in accordance with 40 CFR § 257.3-8, that the concentration of methane gas does not exceed:



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- a. Twenty-five percent (25%) of the lower explosive limit for the gases in facility structures (excluding gas control or recovery system components), and
 - b. The lower explosive limit for the gases at the property boundary.
4. If a methane gas exceedance occurs at facility structures or at the facility property boundaries, as described above, the permittee shall immediately report the exceedance to ADEQ Solid Waste Unit as specified in Sections 10.3.1 and 10.5.
5. The permittee shall initiate an investigation followed by corrective actions to resolve any problems identified by the investigation that may have led to an LEL exceedance. To implement any corrective action the permittee shall obtain prior approval from ADEQ.

6.5 Sludge Landfill Contingency Plan Requirements

If a sludge AL set in Section 13.2, Table 13.2-4, WRF and Cooling Tower Sludge Disposal Landfill Sludge Sampling Parameters has been exceeded, the permittee shall take the following actions:

1. Conduct verification sampling using Toxicity Characteristic Leaching Procedure (TCLP) extraction procedures and analytical methods within 5 business days of becoming aware of an AL being exceeded. Submit analytical results of verification sampling to ADEQ within 30 calendar days of the sampling date.
2. Within 5 business days of discovery, notify the ADEQ Groundwater Section in writing and in accordance with Section 10.3, Permit Violation and Alert Level Status Reporting to determine the appropriate action(s).
3. If sludge monitoring and disposal results require ARRA notification per the ARRA Special Approval License No. 7-368, and amendments due to specified limits being exceeded, the permittee shall notify the ADEQ Groundwater Section in writing within 5 business days of becoming aware of the condition or ARRA license exceedance.
4. A scope of work that addresses corrective actions shall be submitted to the Department for review and comment within 60 calendar days of becoming aware of the exceeded level.
5. A corrective action plan for response to future exceedances and meeting ADEQ standards must be submitted to the Department for review within 180 calendar days after the limit(s) have been exceeded. Upon approval, ADEQ may amend the permit to include the corrective action plan.

6.6 Sludge Landfill Closure Plan [A.R.S. §§ 49-243(K)(6), 49-252 and A.A.C. R18-9-A209(B)]

Within 90 calendar days following notification of closure, the permittee shall submit for approval to the Groundwater Section, a detailed Closure Plan which meets the requirements of A.R.S. § 49-252 and A.A.C. R18-9-A209(B)(3)(a). At the conclusion of site operations the permittee shall cap the Sludge Disposal Landfill and leave all materials in place. The Sludge Disposal Landfill shall be capped with 3 feet of low permeability soils, compacted and capped to facilitate drainage and prevent standing water from accumulating above the cap. The closure plan shall include Hydrologic Evaluation of Landfill Performance (HELP) or subsequent modeling to demonstrate that no fluids will infiltrate and reach the shallow aquifer after closure and clean closure has been achieved. The landfill shall be closed in a manner that demonstrates that the landfill shall not cause or contribute to post-closure violation of AWQS at the applicable POC. Closure reports shall include grading and draining plans sealed by an Arizona-registered Professional Engineer and cross-sections and as-builts of the landfill cap.

Closure activities shall include construction of stormwater run-on diversion structures as necessary to ensure that the landfill cap is protected from erosion and standing water does not infiltrate the land-filled materials.

If the closure plan achieves clean closure immediately, ADEQ shall issue a letter of approval to the permittee. If the closure plan contains a schedule for bringing the facility to a clean closure configuration at a future date, ADEQ may incorporate any part of the schedule as an amendment to this permit.

7.0 RUBBISH LANDFILL

The facility is an active, unlined solid waste disposal facility that receives PVNGS solid waste. Waste is deposited into trenches and covered with soil. The landfill is located on the east-central portion of the PVNGS site, east of the switchyard and south of the WSR, and is approximately 100 acres in size.



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- a. Identification and description of the permit condition for which there has been a violation and a description of its cause.
- b. The period of violation including exact date(s) and time(s), if known, and the anticipated time period during which the violation is expected to continue.
- c. Any corrective action taken or planned to mitigate the effects of the violation, or to eliminate or prevent a recurrence of the violation.
- d. Any monitoring activity or other information which indicates that any pollutants would be reasonably expected to cause a violation of an AWQS.
- e. Proposed changes to the monitoring which include changes in constituents or increased frequency of monitoring.
- f. Description of any malfunction or failure of pollution control devices or other equipment or processes.
- g. Copies of CARs, chain of custody forms, and a description of any sampling and monitoring methods used to determine, verify or assess compliance status.
- h. For exceeded ALs and AQLs in an APP monitoring well listed in tables in Section 8.1 or 8.2, the 45 day report submitted to ADEQ shall also contain the most recent contour maps for the appropriate aquifer.

For any condition lasting more than 90 calendar days, the permittee shall commence quarterly status reporting to keep ADEQ informed of the status of investigations, assessments, repairs, and corrective actions. Status reports shall be submitted to the Groundwater Section. The status reports shall provide an update on all response actions and a schedule for completing response actions. These reports shall be submitted until such time as the condition is corrected.

10.3.1 Methane Gas Exceedance Reporting

The following notifications are required if there is a methane gas exceedance:

1. Within twenty-four (24) hours or one (1) business day of any methane gas exceedance where the gas concentration in facility structures exceeds twenty-five percent (25%) of the lower explosive limit or gas concentrations at the landfill boundary exceed the lower explosive limit, the permittee shall notify the ADEQ Solid Waste Unit.
2. Within seven (7) days of detection, the permittee shall place in the operating record a description of the steps taken to protect human health. A copy of this description shall be sent to the ADEQ Solid Waste Unit.

Within sixty (60) days of detection of any methane gas exceedance, a remediation plan shall be implemented and a copy of the plan placed in the operating record. A copy of the plan, accompanied by a notification that the plan has been implemented, shall be sent to the ADEQ Solid Waste Unit.

10.4 Operational, Other or Miscellaneous Reporting

10.4.1 Annual Reporting Requirements

The goal and purpose of annual reporting requirements are to allow the permittee and ADEQ to keep current the status of the permit compliance and performance under this permit to assure the public that human health and the environment including future and foreseeable drinking water uses of groundwater are protected through implementation of all provisions of this permit. The secondary purpose is to allow constant assessment of the adequacy of this permit in achieving the primary goal and to allow rapid determinations to be made regarding the potential need for revision or amendment of the permit and more specifically, the monitoring provisions of this permit. Appropriate components of the report required by this Section shall be sealed by an Arizona-registered Geologist or Professional Engineer, in accordance with Arizona Board of Technical Registration (BTR) requirements.

A. Annual Monitoring and Compliance Report

Each year the permittee shall submit a report to the Groundwater Section summarizing the results of the facility's performance and include a copy of the Radiological



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Environmental Monitoring Program annual report. The report shall be divided into Groundwater Monitoring, Impoundment Monitoring, Sludge Monitoring, and Compliance Status under this permit. The report shall also include identification and discussion of any laboratory results that fall outside of the laboratory's QA/QC criteria and the detection levels required by this permit. The report shall contain the following sections with the specified information:

1. Groundwater Monitoring

This section of the report shall contain the following information:

- a. Semiannual shallow groundwater maps.

Groundwater contouring may be performed by hand or by using an accepted computer program/ model. All calculations for contouring shall be included in the submittal.

2. Impoundment Monitoring

This section of the report shall contain the following information:

- a. LCRS sump monitoring results;
- b. Summaries of analytical results;
- c. Summary of maintenance and repair activities;
- d. Summary of the results of all liner leakage; and,
- e. Summary tables of all basin, impoundment and reservoir data which allows data to be readily compared to leakage and discharge quality ALs and previous data.

3. Sludge Monitoring

This section of the report shall contain the following information:

- a. WRF sludge monitoring analytical results;
- b. Cooling Tower analytical results;
- c. Summary of any exceedances of permit limits for sludge quality;
- d. Description of any violations of the ARRA Special License for sludge radioisotope limits; and,
- e. The Radiological Environmental Monitoring Program Report (REMP).

4. Methane Monitoring

This section of the report shall contain the following information:

- a. Methane monitoring results

10.4.2 Ambient Groundwater Monitoring Reports

An Ambient Groundwater Monitoring Report is required for each new well installed that is incorporated into the monitoring program of this permit.

10.4.2.1 Reporting Requirements

The Ambient Groundwater Monitoring Report is due 45 calendar days from the conclusion of the ambient groundwater monitoring period (no less than 8 quarterly rounds) for each well. This report shall be accompanied by a request for permit amendment and fees to establish ALs and AQLs for the new well, a spreadsheet of the groundwater data for the well and calculations used to evaluate the data statistically, and ALs and AQLs based on statistical assessment of 8 rounds of groundwater data. Appropriate components of the report shall be sealed by an Arizona-registered Geologist or Professional Engineer, in accordance with Arizona BTR requirements.

The Ambient Groundwater Monitoring Report shall also include groundwater elevation measurements, groundwater flow calculations and semiannual groundwater contour maps prepared by hand or using an accepted computer program/ model for each round of samples using elevations collected for all on-site monitoring wells in the same aquifer as the new well. The Ambient Groundwater Monitoring Report shall include an assessment of groundwater flow, the adequacy



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13.0 TABLES OF MONITORING REQUIREMENTS

13.1 Pre-operational Monitoring (or Construction) Requirements

None

13.2 Compliance (or Operational) Monitoring

Table 13.2-1 – Surface Impoundment and BADCT Performance Standard Inspection & Alert Monitoring

Table 13.2-2 – Evaporation Ponds and Water Storage Reservoirs Flow Rate and LCRS Fluid Level

Monitoring Points

Table 13.2-3 – WSR and Evaporation Pond LCRS Monitoring Alert Levels

Table 13.2-4 – WRF and Cooling Tower Sludge Disposal Landfill Sludge Sampling Parameters

Table 13.2-5 – POC Well PV-R2AR, Semiannual Groundwater Monitoring

13.3 Contingency Monitoring

Table 13.3-1 – Contingency LCRS Monitoring, 85-acre WSR and 45-acre WSR

Table 13.3-2 – Contingency Plant Upset and Overtopping Releases to Unlined Facilities Sampling

Table 13.3-3 – Evaporation Ponds Contingency Wastewater Sampling Locations for Overtopping of the Surface Impoundment

Table 13.3-4 – Evaporation Pond Contingency Wastewater and LCRS Fluid Sampling



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Table 13.2-4 Water Reclamation Facility (WRF) Sludge and Cooling Tower Sludge Sampling Parameters				
Parameter	Units	AL (RCRA TCLP)	Monitoring Frequency¹	Reporting Frequency
pH	SU	<2,>12.5	Semi-annually	Annually
Arsenic	mg/L	5.0	Semi-annually	Annually
Barium	mg/L	100.0	Semi-annually	Annually
Cadmium	mg/L	1.0	Semi-annually	Annually
Chromium (Total)	mg/L	5.0	Semi-annually	Annually
Lead	mg/L	5.0	Semi-annually	Annually
Mercury	mg/L	0.2	Semi-annually	Annually
Selenium	mg/L	1.0	Semi-annually	Annually
Silver	mg/L	5.0	Semi-annually	Annually
Free Liquid ²	--	Pass/Fail	Semi-annually	Annually

1 The WRF sludge shall be characterized, including paint filter test or equivalent test method, through representative sampling on a semi-annual basis (2 times per year) in accordance with requirements in this permit. Cooling tower sludge shall be characterized on a per disposal event basis.

2 Characterization shall include the paint filter test or an equivalent test method.

SU = standard units

mg/L = milligram per liter

-- = Unitless

RCRA TCLP = Resource Recovery and Conservation Act Toxicity Characteristic Leaching Procedure

SMRF Reporting is not necessary under this table.

ATTACHMENT 2

Arizona Department of Health Services – Bureau of Radiation Control
Special Approval License No. 07-368, Amendment No. 11 (Mar. 15, 2018)
for the Palo Verde Nuclear Generating Station

ARRA-3

Page 1 of 1

ARIZONA DEPARTMENT OF HEALTH SERVICES
BUREAU OF RADIATION CONTROL**SPECIAL APPROVAL LICENSE**

Pursuant to Chapter 4, Title 30, Arizona Revised Statutes, and Title 12, Chapter 1 of the Arizona Administrative Code, and in reliance on statements and representations made to the Department by the applicant, an approval is hereby issued authorizing the release to unrestricted areas, of the radioactive material listed in this special approval LICENSE for the purposes and at the places specified. This special approval LICENSE does not authorize the possession or use of radioactive materials. This special approval LICENSE is subject to all applicable rules and Department orders now or hereafter in effect and to the conditions specified. **In accordance with AAC R12-1-434 A, and A.A.C. R12-1-435, and letter dated January 31, 2018 signed by Michael DiLorenzo, the following Special Approval License is issued: ALL CHANGES ARE IN BOLD**

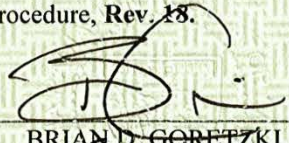

LICENSEE

1. **LICENSEE:** Arizona Public Service Company
Palo Verde Nuclear Generating Station
2. **ADDRESS:** P.O. Box 52034
Phoenix, AZ 85072-2034
3. a. **LICENSE NUMBER:** 07-368
b. **AMENDMENT NO.:** 11
4. **EXPIRATION DATE:** April 30, 2023
5. **CATEGORY:** D18

CONDITIONS

6. This Special Approval License supersedes Special Approval License, **Amendment No. 10**, issued **May 20, 2013**. This Special Approval License is equivalent to the Special Permit required by A.R.S. § 49-762.06.
7. The Licensee listed in 1. above may dispose of sediment and sludge containing trace amounts of radioactive material in accordance with the procedures submitted with the application, and as described in the Palo Verde Nuclear Generating Station, Aquifer Protection Permit Number 100388, as amended, issued by the ADEQ.
8. As provided in 5.8 and 5.9 of PVNGS station procedure No. WROP-8ZZ04, as submitted with letter dated **January 31, 2018**, the average aggregate concentration of radioactive materials in the sediment and sludge disposed of pursuant to this Special Approval License shall not exceed the concentrations listed in Table III, Appendix B, Article 4. The maximum individual sample concentration of radioactive materials may not exceed ten times the concentrations listed in said Table III per accumulation area. Where multiple radioactive isotopes are involved, the "Rule of Unity" as described in footnote 4. of such Appendix shall apply.
9. This Special Approval License is subject to the provisions of A.R.S. 30-681 through 30-689 as amended.
10. In the event radioactive materials are found in the sediment and sludge in concentrations greater than specified in Condition 8. above, the Licensee shall control the sludge at a suitable storage location, pursuant to the authority granted in a License issued by the U.S. Nuclear Regulatory Commission, until decay reduces the concentration to below such level or the material is disposed of by transfer to a licensed waste processor.
11. The licensee may follow procedures in attachments to letter dated **January 31, 2018**.

A. PVNGS Procedure WROP-8ZZ04, WRF Landfill Operation Procedure, **Rev. 18**.


BRIAN D. GORETZKI, BUREAU CHIEF
COLBY BOWER, ASSISTANT DIRECTOR

DATE ISSUED: **MAR 15 2018**
PRK:BDG:mjk

POST IN ACCORDANCE WITH R12-1-1002

Addendum Pursuant to Federal Rule of Appellate Procedure 28(f)

42 U.S.C. § 2021**§ 2021. Cooperation with States**

* * *

(b) Agreements with States

Except as provided in subsection (c), the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under subchapters V, VI, and VII of this division, and section 2201 of this title, with respect to any one or more of the following materials within the State:

- (1) Byproduct materials (as defined in section 2014(e) of this title).
- (2) Source materials.
- (3) Special nuclear materials in quantities not sufficient to form a critical mass.

During the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards.

(c) Commission regulation of certain activities

No agreement entered into pursuant to subsection (b) shall provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of—

- (1) the construction and operation of any production or utilization facility or any uranium enrichment facility;
- (2) the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
- (3) the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission
- (4) the disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

The Commission shall also retain authority under any such agreement to make a determination that all applicable standards and requirements have been met prior to termination of a license for byproduct material, as defined in section 2014(e)(2) of this title. Notwithstanding any agreement between the Commission and any State pursuant to subsection (b), the Commission is authorized by rule, regulation, or order to require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear

material shall not transfer possession or control of such product except pursuant to a license issued by the Commission.

* * *

10 C.F.R. § 20.2001**§ 20.2001 General requirements.**

(a) A licensee shall dispose of licensed material only—

(1) By transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter;

(2) By decay in storage; or

(3) By release in effluents within the limits in § 20.1301; or

(4) As authorized under §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.

(b) A person must be specifically licensed to receive waste containing licensed material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed under part 61 of this chapter; or

(5) Disposal at a geologic repository under part 60 or part 63 of this chapter.

10 C.F.R. § 20.2002**§ 20.2002 Method for obtaining approval of proposed disposal procedures.**

A licensee or applicant for a license may apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

- (a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and
- (b) An analysis and evaluation of pertinent information on the nature of the environment; and
- (c) The nature and location of other potentially affected licensed and unlicensed facilities; and
- (d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this part.

10 C.F.R. § 50.109**§ 50.109 Backfitting.**

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985;

(ii) Six (6) months before the date of docketing of the operating license application for the facility for facilities having construction permits issued before October 21, 1985;

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses;

(iv) The date of issuance of the design approval under subpart E of part 52 of this chapter;

(v) The date of issuance of a manufacturing license under subpart F of part 52 of this chapter;

(vi) The date of issuance of the first construction permit issued for a duplicate design under appendix N of this part; or

(vii) The date of issuance of a combined license under subpart C of part 52 of this chapter, provided that if the combined license references an early site permit, the provisions in § 52.39 of this chapter apply with respect to the site characteristics, design parameters, and terms and conditions specified in the early site permit. If the combined license references a standard design certification rule under subpart B of 10 CFR part 52, the provisions in § 52.63 of this chapter apply with respect to the design matters resolved in the standard design certification rule, provided however, that if any specific backfitting limitations are included in a referenced design certification rule, those limitations shall govern. If the combined license references a standard design approval under subpart E of 10 CFR part 52, the provisions in § 52.145 of this chapter apply with respect to the design matters resolved in the standard design approval. If the combined license uses a reactor manufactured under a manufacturing license under subpart F of 10 CFR part 52, the provisions of

§ 52.171 of this chapter apply with respect to matters resolved in the manufacturing license proceeding.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (c) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (c) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriated documented evaluation for its finding, either:

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

* * *

10 C.F.R. § 150.10**§ 150.10 Persons exempt.**

Except as provided in §§ 150.15, 150.16, 150.17, 150.17a, and 150.19, any person in an Agreement State who manufactures, produces, receives, possesses, uses, or transfers byproduct material, source material, or special nuclear material in quantities not sufficient to form a critical mass is exempt from the requirements for a license contained in Chapters 6, 7, and 8 of the Act, regulations of the Commission imposing licensing requirements upon persons who manufacture, produce, receive, possess, use, or transfer such materials, and from regulations of the Commission applicable to licensees. The exemptions in this section do not apply to agencies of the Federal government as defined in § 150.3.

10 C.F.R. § 150.15**§ 150.15 Persons not exempt.**

(a) Persons in agreement States are not exempt from the Commission's licensing and regulatory requirements with respect to the following activities:

(1) The construction and operation of any production or utilization facility. As used in this subparagraph, operation of a facility includes, but is not limited to (i) the storage and handling of radioactive wastes at the facility site by the person licensed to operate the facility, and (ii) the discharge of radioactive effluents from the facility site.

(2) The export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility.

(3) The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials, as defined in regulations or orders of the Commission. For purposes of this part, ocean or sea means any part of the territorial waters of the United States and any part of the international waters.

(4) The transfer, storage or disposal of radioactive waste material resulting from the separation in a production facility of special nuclear material from irradiated nuclear reactor fuel. This subparagraph does not apply to the transfer, storage or disposal of contaminated equipment.

(5) The disposal of such other byproduct, source, or special nuclear material as the Commission determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

(6) The transfer of possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from licensing and regulatory requirements of the Commission under Parts 30 and 40 of this chapter.

(7) The storage of:

(i) Spent fuel in an independent spent fuel storage installation (ISFSI) licensed under part 72 of this chapter,

(ii) Spent fuel and high-level radioactive waste in a monitored retrievable storage installation (MRS) licensed under part 72 of this chapter, or

(iii) Greater than Class C waste, as defined in part 72 of this chapter, in an ISFSI or an MRS licensed under part 72 of this chapter; the GTCC waste must originate in, or be used by, a facility licensed under part 50 of this chapter.

(8) Greater than Class C waste, as defined in part 72 of this chapter, that originates in, or is used by, a facility licensed under part 50 of this chapter and is licensed under part 30 and/or part 70 of this chapter.

(b) Notwithstanding any exemptions provided in this part, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.