ORAL ARGUMENT NOT YET SCHEDULED
No. 19-1240

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NUCLEAR ENERGY INSTITUTE,
Petitioner,

v.

UNITED STATES NUCLEAR REGULATORY COMMISSION and
UNITED STATES OF AMERICA,
Respondents.

On Petition for Review of Action by the
Nuclear Regulatory Commission

FINAL BRIEF OF FEDERAL RESPONDENTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

(A) **Parties and amici.** The parties are Petitioner, Nuclear Energy Institute, and Respondents, the United States of America and the United States Nuclear Regulatory Commission.

(B) **Rulings Under Review.** The ruling under review is a letter dated September 16, 2019, from John Lubinski, Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission; to Ellen C. Ginsberg, Vice President, General Counsel and Secretary, Nuclear Energy Institute. No citation for the letter is available.

(C) **Related Cases**. There are no related cases, and the case on review was not previously before this court or any other Court.

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TABLE OF AUTHORITIES

Cases

*Authorities upon which we chiefly rely are marked with an asterisk.

Statutes

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GLOSSARY

APA	Administrative Procedure Act
AEA	Atomic Energy Act
NEI	Nuclear Energy Institute
NRC	Nuclear Regulatory Commission
RCRA	Resource Conservation and Recovery Act
Section 20.2002	10 C.F.R. § 20.2002

INTRODUCTION

A longstanding safety regulation of the U.S. Nuclear Regulatory Commission ("NRC"), 10 C.F.R. § 20.2002 ("Section 20.2002"), requires NRC licensees to apply "to the Commission" for approval when they seek to dispose of low-level radioactive waste using methods that have not otherwise been authorized by the agency through notice-and-comment rulemaking. In 2012, the NRC publicly communicated its view that Section 20.2002 requires NRC approval when NRC licensees seek to use these alternative methods to dispose of such waste even in "Agreement States"—those states that have entered agreements under the Atomic Energy Act ("AEA") to regulate certain forms of radiological hazards, including the disposal of low-level waste. In 2016, the NRC reiterated to the regulated community that Section 20.2002 requires nuclear power plant licensees—which are regulated exclusively by the NRC—to seek NRC approval before pursuing an alternative disposal method in an Agreement State under Section 20.2002. And in November 2019, in response to a request by Petitioner Nuclear Energy Institute ("NEI") that the agency "rescind" its 2016 interpretation, the NRC issued a one-page letter (the "2019 Letter") declining NEI's request based upon the same rationale underlying its 2012 and 2016 communications.

Only the 2019 Letter is the subject of this Petition for Review. But it does not constitute final agency action reviewable by the Court under the Hobbs Act. It

merely restates the NRC's interpretation of its regulatory authority—an interpretation the NRC has held since 2012 and that, to the extent it is directly challengeable in court at all, could have been challenged years ago. Moreover, neither the 2019 Letter nor the prior interpretations it restates has legal consequences upon licensees, who remain free to dispute the NRC's interpretation of its regulation in the event that the agency takes enforcement action against them for noncompliance.

To the extent the NRC's interpretation of Section 20.2002 is reviewable by this Court at this time, it is fully consistent with the text of the regulation and the existing regulatory framework, under which *all* methods of disposal of waste generated by NRC licensees must be approved by the Commission. And contrary to NEI's assertions, it fully preserves Agreement States' authority to determine whether and under what conditions low-level radioactive waste may be disposed of within their own borders. Accordingly, the Petition for Review should be dismissed or, in the alternative, denied.

JURISDICTIONAL STATEMENT

Under the AEA, 42 U.S.C. § 2239(a), (b), and the Hobbs Act, 28 U.S.C. § 2342(4), the NRC must issue a "final order" before this Court may exercise jurisdiction over a petition challenging the result of an NRC "proceeding." For an agency order to be final under the Hobbs Act and under *Bennett v. Spear*, 520

U.S. 154 (1997), the action must (1) mark the consummation of the agency's decisionmaking process; and (2) result in legal consequences. *Id.* at 177-78.

The 2019 Letter is an informational, workaday letter declining NEI's unsolicited request for the NRC to rescind its prior guidance that had been previously articulated in both 2012 and 2016. The 2019 Letter has no legal effect, does not bind the agency, is not related to any enforcement action, and does not order anyone to take any action. While the 2019 Letter, in repeating the agency's settled view, is not tentative or interlocutory in nature, its lack of legal or practical consequences fails to satisfy the second prong of *Bennett*. Accordingly, this Court should dismiss the Petition for Review for lack of jurisdiction.

STATEMENT OF THE ISSUES

1. Whether the NRC's 2019 Letter constitutes final agency action that is reviewable under the Hobbs Act, when it imposed no new obligations, declined NEI's request to rescind the agency's previously issued position, and reiterated an interpretation of Section 20.2002 that would be reviewable if the agency took enforcement action against a licensee.

2. Whether, if the 2019 Letter constitutes final agency action, the NRC's interpretation of the plain meaning of Section 20.2002 is contrary to law on the ground that it usurps state authority under the AEA to regulate the disposal of low-

level radioactive waste, when states retain the authority to dictate the conditions under which low-level waste can be disposed of within their borders.

STATUTES AND REGULATIONS

The text of pertinent statutes and regulations is set forth in the addendum to this brief.

STATEMENT OF THE CASE

I. Statutory and regulatory background.

A. Federal regulation of power plant operations and handling of wastes at facility sites.

The AEA empowers the NRC to issue licenses for the possession of certain nuclear materials, *see* 42 U.S.C. §§ 2071-2114; 10 C.F.R. Pts. 30, 40, 70, and the construction and operation of nuclear power plants, *see* 42 U.S.C. §§ 2131-2133; 10 C.F.R. Pts. 50, 52. While the AEA permits states to regulate certain activities related to nuclear materials, regulatory authority over the licensing and operation of nuclear power plants (which are referred to as "utilization facilities") is within the exclusive purview of the NRC. 42 U.S.C. § 2021(c)(1); *see also* 10 C.F.R. § 50.2.

10 C.F.R. Part 20 establishes standards, applicable to all NRC licensees, for protection against ionizing radiation resulting from NRC-licensed activity. 10 C.F.R. §§ 20.1001, 20.1002. As part of this comprehensive set of rules, NRC licensees are responsible for the disposal of low-level radioactive waste—including

items that have become contaminated with radioactive material or have become radioactive through exposure to radiation—created in the course of operations. *See* 10 C.F.R. § 20.1003 (definition of "waste"); *id*. Subpt. K ("Waste Disposal"). An NRC licensee seeking to dispose of low-level waste generated during operation is subject to 10 C.F.R. Part 20, Subpart K, which sets forth the acceptable methods, approved by the Commission through notice-and-comment rulemaking, by which NRC licensees may dispose of licensed material. These NRC-approved methods for disposal of waste include transfer to an authorized recipient (i.e., a facility licensed by the NRC or an Agreement State, as applicable, to receive and dispose of low-level radioactive waste), 10 C.F.R. §§ 20.2001(a)(1), 20.2006[1]; decay in storage, *id.* § 20.2001(a)(2); or, under certain carefully prescribed limits, release in effluents, *id*. §§ 20.2001(a)(3), 20.1301; release into sanitary sewers, *id*. §§ 20.2001(a)(4), 20.2003; and incineration, *id*. §§ 20.2001(a)(4), 20.2004.

Should an NRC licensee wish to dispose of waste using a method not specified in Subpart K (and, as a result, not approved by the Commission through notice-and-comment rulemaking), NRC's regulations provide an avenue for seeking approval of alternative methods—namely, Section 20.2002. This provision allows NRC licensees to apply "to the Commission for approval of

[1] NRC regulations in 10 C.F.R. Part 61 specify the requirements for low-level waste disposal facilities licensed by the NRC.

proposed procedures . . . to dispose of licensed material generated in the licensee's activities." 10 C.F.R. § 20.2002. The provision further specifies the contents of such an application, including a description of the waste to be disposed of and procedures to ensure that the radiation dose to which affected persons may be exposed as a result of such disposal complies with applicable limits and is as low as reasonably achievable (referred to as "ALARA"). *Id.* § 20.2002(a)-(d). Such an approval is distinct from any necessary authorization from the regulator of a disposal facility, including, as discussed below, from an Agreement State.

B. State regulation of offsite waste disposal.

States have a role in the regulation of some radiological hazards, including waste disposal, through the Agreement State program. Under Section 274 of the AEA, Agreement States may enter into agreements with the NRC whereby the NRC may "discontinue" its regulatory authority over certain aspects of its jurisdiction, and states may assume this responsibility (though even in Agreement States, the AEA requires the NRC to maintain exclusive regulatory authority over nuclear power plants with respect to radiological hazards). 42 U.S.C. § 2021(b), (c)(1). Thus, in Agreement States that have assumed regulatory responsibility for such subject matters, low-level waste disposal facilities are subject to the licenses and regulations issued under state law, and disposal may only proceed subject to those state requirements. *See id.* § 2021(b).

State authority over such facilities is generally circumscribed by the NRC's requirements. As a precondition to the discontinuance of its regulatory authority pursuant to Section 274, the NRC must certify that the state's program for regulation is "adequate" to protect the public health and safety and is "compatible" with the NRC's program. *Id.* § 2021(d)(2).[2] In addition, the NRC conducts periodic reviews of each Agreement State program to ensure that actions taken by the state are consistent with the AEA. *Id.* § 2021(j)(1).

II. The NRC's interpretation of Section 20.2002 and communication of its interpretation to the public.

At issue in this case is the application of Section 20.2002 to those instances when NRC licensees (most often, nuclear power plants) that have generated low-level waste seek to employ alternative disposal procedures at offsite facilities that are not already licensed to receive and dispose of such waste. Licensees typically

[2] The NRC has placed each element of its regulatory program into "compatibility" categories. These categories range from those program elements for which Agreement State standards must be "essentially identical" to those of the NRC (Category A), through program elements for which Agreement State standards may be more restrictive than NRC standards as long as they "embody the essential objective of the corresponding NRC program elements" (Category C), to program elements that are not required to be adopted by the state for purpose of compatibility (Category D). *See generally* Agreement State Program Policy Statement; Correction, 82 Fed. Reg. 48,535, 48,538-39 (Oct. 18, 2017); Regulation Toolbox: Review Summary Sheets for Regulation Adoption for New Agreement States/Programs (10 CFR Part 20), available at https://scp.nrc.gov/regulationtoolbox/10cfr20.pdf.

seek approval of this type in order to dispose of waste at a municipal landfill or a Resource Conservation and Recovery Act (RCRA)[3] disposal facility (referred to collectively, for the purposes of this brief, as "unlicensed facilities").

The fact that these unlicensed facilities are not already licensed by federal or state regulators to receive and dispose of low-level radioactive waste raises a potential safety concern because, unlike each of the other methods that have been authorized in Subpart K following notice-and-comment rulemaking, the method of disposal will not have been approved by the Commission. Put differently, if the disposal facility *was* licensed to receive and dispose of low-level radioactive waste under either NRC or Agreement State-equivalent regulations, then the procedure or method of disposal would already be permitted under 10 C.F.R. § 20.2001(a)(1), and there would be no need to seek Commission approval of an *alternative* disposal procedure under Section 20.2002.

NEI seeks to challenge the NRC's interpretation of Section 20.2002, and, in particular, the agency's conclusion that NRC licensees must obtain approval from the NRC for the approval of procedures for alternative methods of disposal under

[3] RCRA provides a framework for the regulation of solid waste disposal. *See* 42 U.S.C. § 6901 *et seq*. In the context of 10 C.F.R § 20.2002 requests, "RCRA disposal facilities" are typically those regulated under Subtitle C of RCRA—meaning that they are authorized for the disposal of hazardous waste (but not radioactive material). *See* 40 C.F.R. Pts. 260-271.

Section 20.2002 in addition to any necessary Agreement State approvals. To provide context for this conclusion, which the NRC articulated in both 2012 and 2016 and declined to disturb in the 2019 Letter, this section summarizes: (A) the NRC's interpretation of Section 20.2002; and (B) the NRC's communications to the licensed community about that interpretation.

A. The NRC interprets Section 20.2002 to require approval of alternate disposal procedures by the jurisdiction that authorized the use of the radioactive material.

The approval process for offsite disposal pursuant to an alternative method entails two separate regulatory actions—first, the approval for the *generator* of the waste to use alternate procedures for disposal; and, second, approval for the *recipient* of the waste to receive the material and dispose of it.

The NRC has determined that for waste generators that are nuclear reactor licensees, the first approval must be granted by the NRC (and by not Agreement States). The NRC has reached this conclusion because the AEA confers *exclusive* authority on the NRC over regulation of nuclear power plant operations, *see* 42 U.S.C. § 2021(c)(1), and, as NRC licensees, plant operators are subject to the requirements of 10 C.F.R. Part 20.

The conclusion that NRC licensees must apply to the NRC for approval of procedures for a method of disposal not already contemplated in NRC regulations does not require or impose anything beyond what is already specified in the

regulation itself. *See* 10 C.F.R. § 20.2002 (requiring NRC licensees to "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") (emphasis added). Indeed, the requirement that the NRC approve these alternate procedures is consistent with the requirements for other methods by which NRC licensees can comply with Subpart K, *all* of which permit disposal through methods that have themselves been approved (through notice-and-comment rulemaking) by the Commission itself. *See* 10 C.F.R. §§ 20.2001(a)(1)-(4), 20.2003, 20.2004. 20.2005, 2.2008.

NEI disputes the NRC's interpretation, asserting that the approval for a reactor licensee to employ an alternate method of disposal can be made by an Agreement State, even though the NRC licenses the material and facility at issue, even though the authority to regulate such material or facility is exclusively reserved to the NRC under the AEA, and even though Agreement States do not regulate reactor licensees.

B. NRC communications to the public regarding its interpretation of Section 20.2002.

The NRC has communicated its interpretation of Section 20.2002 in several public documents. As relevant here, the first interpretation was publicly communicated in 1986, when licensees primarily sought Section 20.2002 approvals as a means to dispose of low-level waste by onsite land burial. At that

time, the NRC issued an "Information Notice" (JA9) advising nuclear power plant operators that Agreement States had jurisdiction to approve disposal of low-level radioactive waste by NRC licensees under the equivalent of what today is Section 20.2002.

Over time, licensees increasingly used Section 20.2002 as a means of securing approval for offsite (rather than onsite) disposal, prompting the NRC to reassess its understanding of the provision in light of the jurisdictional issues that this practice had created and the agency's own inconsistent treatment of such requests.[4] In particular, the NRC became concerned that Agreement States were authorizing disposal of waste at out-of-state unlicensed facilities, i.e. Agreement State A was authorizing its licensees to dispose of waste in Agreement State B.

[4] NEI asserts that the agency's current insistence upon considering Section 20.2002 requests from reactor licensees located in Agreement States "upends decades of settled agency practice." Br. 3; *see also id.* at 6 ("For decades, power reactor licensees located in so-called 'Agreement States' have obtained approval for such alternative disposal procedures from the states, not NRC."). But its suggestion of a uniform practice in the wake of the Information Notice is inaccurate. Numerous NRC licensees (including reactor licensees in Agreement States) applied directly to, and obtained approval from, the NRC, to employ alternate disposal methods. *See, e.g.*, Environmental Assessment and Finding of No Significant Impact Related to Exemption of Material for Proposed Disposal Procedures for the Humboldt Bay Power Plant, Unit No. 3, License DPR-007, Eureka, CA, 75 Fed. Reg. 69,138 (Nov. 10, 2010); Environmental Assessment and Finding of No Significant Impact Related to Exemption of Material in Accordance With 10 CFR 20.2002 for Proposed Disposal Procedures for the Yankee Atomic Electric Company; License DPR-003, Rowe, MA, 70 Fed. Reg. 24,124 (May 6, 2005).

The NRC addressed this concern in a March 2012 letter to Agreement States (the "2012 Letter," JA12). In that letter, the NRC clarified that the NRC's or an Agreement State's approval for an unlicensed disposal facility to *receive* low-level radioactive waste does not by itself permit the generator to *send* the waste to that unlicensed facility for disposal. Rather, if the generator obtained its license from the NRC (as is necessarily the case for reactor licensees), it must obtain the NRC's approval of procedures to dispose of licensed material at an unlicensed facility in a manner not otherwise authorized by 10 C.F.R. Subpart K, in addition to Agreement State or NRC approval to receive and dispose of the material.

The 2012 Letter illustrated that *two* regulatory actions are needed to accomplish offsite disposal of low-level radioactive waste at an unlicensed facility. First, the generator of the waste must receive approval from its regulator of alternative procedures for disposal because disposing of low-level waste at an unlicensed facility is not a method of disposal already contemplated in NRC or Agreement State-equivalent regulations. Second, the unlicensed recipient of the waste must in turn obtain approval from its own regulator to receive and dispose of the waste. JA12-13.

The 2012 Letter provided guidance reflecting the allocation of authority for these two regulatory actions in five different jurisdictional scenarios, depending on whether (1) the generator held a license from the NRC or an Agreement State; and

(2) whether the generator sought to dispose of material in an Agreement State or a non-Agreement State. Across all scenarios, the driver of the need for NRC approval was whether the generator's license to possess the material at issue had been issued by the NRC. The 2012 Letter explained that when the generator of the waste is an NRC licensee (Scenarios 4 and 5), NRC approval would be required under Section 20.2002. By contrast, in situations involving Agreement State licensees (Scenarios 1, 2, and 3), approval for use of an alternative methodology would be required under "the Agreement State's [Section] 20.2002-equivalent regulation." Of particular note here, the 2012 Letter examined Scenario 4, when "[a]n NRC licensee [such as a nuclear power plant] requests authorization under [Section] 20.2002 to dispose of material at an unlicensed facility in an Agreement State." It explained that "the NRC would need to approve the disposal of the material under [Section] 20.2002" *and* that "[t]he unlicensed facility would then need to obtain a license or an exemption from the Agreement State prior to accepting the material for disposal." JA13.

In November 2016, the NRC issued Regulatory Issue Summary[5] 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR

[5] Regulatory Issue Summaries are one means that the NRC uses to communicate with stakeholders concerning issues affecting nuclear licensees and the nuclear industry. *See* https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/.

20.2002" ("2016 Issue Summary," JA16). In that document, which it circulated to all NRC licensees and Agreement States, the NRC reiterated the interpretation of Section 20.2002 announced in the 2012 Letter and formally "supersede[d]" the 1986 Information Notice (which, it stated, had "incorrectly" concluded that the NRC lacked a legal basis to review approval requests for alternate methods of waste disposal). JA16. The agency did not provide an opportunity for public comment, explaining that the summary was "informational and pertains to [an NRC] staff position" that, inasmuch as it was consistent with the 2012 Letter and the text of Section 20.2002, "does not represent a departure from current regulatory requirements and practice." JA18.

Consistent with the 2012 Letter, the 2016 Issue Summary expressed the agency's view that a "licensee's request for approval to dispose of licensed material under § 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." JA17. The 2016 Issue Summary confirmed that for licenses issued under 10 C.F.R. Parts 50 or 52 (i.e., operators of nuclear power plants who are subject to exclusive NRC authority), the licensee's request for approval of procedures for an alternate method of disposal, again distinct from authorization

for the disposal facility itself to receive the material, "should be made to the NRC." JA17. [6]

III. Events following the NRC's announcement of its interpretation of 20.2002.

Neither NEI nor any licensee nor any Agreement State challenged the 2012 Letter or the 2016 Issue Summary. Nonetheless, NEI now contends that events beginning in 2018 reflect a new agency position that, ostensibly for the first time, constitutes final agency action with respect to Section 20.2002.

As NEI recounts, during a 2018 inspection, an NRC inspector discovered that the licensee operating the South Texas Project, a two-unit nuclear power plant, had been disposing of low-level radioactive waste without receiving NRC approval of procedures for this alternative method of disposal under Section 20.2002. In an October 2018 letter (JA31), the NRC acknowledged that the South Texas Project has an agreement with the State of Texas (an Agreement State) to allow for the disposal of this waste at unlicensed facilities, but the NRC informed the licensee that, because it was licensed by the NRC, it needed to obtain NRC authorization under Section 20.2002 before disposing of low-level radioactive waste at

[6] The 2016 Issue Summary correspondingly explained that, for materials licenses issued by NRC under Parts 30, 40, or 70 (i.e., licenses other than those to construct and operate nuclear power plants), the licensee's request should be submitted to the NRC; and that, for analogous licenses issued by Agreement States, the request should be made directly to the Agreement State regulatory authority. JA17.

unlicensed facilities. The agency explained that, as an exercise of its enforcement discretion, it would excuse the licensee's past non-compliance with that provision and that "[g]oing forward," it would "continue to exercise enforcement discretion for [the licensee's] existing process for disposal of low-level waste while the NRC evaluates regulatory options to address this issue." JA32.

In February 2019, NEI sent a letter to the NRC (JA34) citing to the NRC's correspondence with the operator of the South Texas Project and requesting that the NRC rescind the 2016 Issue Summary. NEI raised a series of legal arguments related to the position that the NRC had adopted and requested that the agency, "in accordance with 10 [C.F.R.] § 2.804(f), treat [its] letter as a post-promulgation comment on the agency's new interpretation in [the 2016 Issue Summary], and publish a statement in the *Federal Register* rescinding [the Issue Summary] and reinstating" the position set forth in the Information Notice. JA43. NEI's letter also prompted other stakeholders to submit letters (JA44, 45) to the NRC about Section 20.2002.

Due to stakeholder interest in this issue, the NRC held a September 2019 public meeting to discuss the issue in accordance with its public meeting policy.[7]

[7] The NRC has a longstanding policy to open meetings between the agency staff and one or more outside persons to public observation and participation, to the extent possible. Enhancing Public Participation in NRC Meetings; Policy Statement, 67 Fed. Reg. 36,920 (May 28, 2002).

JA48. Shortly after the public meeting, the NRC issued the 2019 Letter responding to NEI. JA51. In one page of text, the NRC stated that it was adhering to its prior interpretation and rejected NEI's request that the agency rescind the 2016 Issue Summary. The agency noted that the Issue Summary "correctly stated that 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." The NRC stated that it "intend[ed] to provide updated guidance" to streamline the approval process for licensees that had previously (but improperly) obtained Agreement State, rather than NRC, approval. The NRC also noted that for reactor licensees that had received approval from Agreement States rather than the NRC, "the NRC staff will consider enforcement discretion on a case-by-case basis, as appropriate." JA51.

In November 2019, NEI filed this Petition for Review, challenging what it refers to as the NRC's "renewed adherence and substantive alteration" of the 2016 Issue Summary, as expressed in the 2019 Letter. Petition for Review, ECF Document No. 1816696 (Nov. 15, 2019), at 1. Federal Respondents moved to dismiss, arguing that the 2019 Letter does not constitute final reviewable agency action. This Court referred the motion to the merits panel and directed the parties

to address issues presented in the motion in their briefs. Order, ECF Document No. 1845358 (June 2, 2020).

SUMMARY OF ARGUMENT

The Petition for Review should be dismissed for lack of jurisdiction. The NRC's 2019 Letter responding to NEI's request to rescind the 2016 Issue Summary is not judicially reviewable because it does not constitute a "final order" under the Hobbs Act.

Specifically, the 2019 Letter fails to satisfy the second prong of *Bennett v. Spear*, 520 U.S. 154 (1997), because it has no practical or legal effect (and, at a minimum, has no effect that is not traceable to the agency's 2012 or 2016 articulations of its position). The 2019 Letter repeats the 2016 Issue Summary nearly verbatim—it treads no new ground, binds no one, orders nothing, and subjects no one to any penalties. NEI's Petition for Review, filed more than three years after the issuance of the Issue Summary and seven years after the 2012 Letter, is an untimely attempt to resurrect a challenge to the NRC's previously articulated position. And treating the 2019 Letter as final agency action would muzzle informal communications between agencies and their regulated communities.

In arguing to the contrary, NEI distorts the facts. It asserts that the 2019 Letter is a "new" position that makes compliance with Section 20.2002

mandatory, yet it wholly omits mention of the 2012 Letter, in which the NRC made it clear that under Section 20.2002, NRC-licensed waste generators must apply to the NRC to use an alternative method of disposal not already contemplated in NRC regulations. Fundamentally, NEI's attack on the 2019 Letter overlooks the fact that the agency's binding position is set forth in the regulation itself, the plain language of which requires NRC licensees to apply "to the Commission" when they seek to employ methods of disposal that have not already been approved by regulation. As a result, neither the 2019 Letter nor any of the NRC's prior interpretative statements have the force of law; any "violations" that the agency has identified or may identify in the future would be based on the text of the regulation. And if a licensee disagrees with the NRC's interpretation of that regulation, it is free to raise its arguments as a challenge to any enforcement action.

Further, NEI is not entitled to relief on the merits, largely because its argument misapprehends the consequences of the NRC's interpretation of Section 20.2002. Contrary to NEI's assertions, the NRC's Section 20.2002 approval process does not usurp Agreement State authority over low-level waste disposal. Rather, Section 20.2002 authorization constitutes a separate, distinct approval that an NRC-licensed waste generator must obtain before departing from the prescribed methods of disposal that have been approved and codified after notice-and-

comment rulemaking conducted by the agency. Agreement States retain the authority to decide the conditions under which low-level waste may be disposed of at unlicensed waste storage facilities within their borders, but they cannot authorize NRC licensees to depart from NRC regulations by approving alternative methods of disposal under Section 20.2002. The NRC's interpretation of its regulation preserves this division of authority.

To the extent NEI raises challenges arising under either the Administrative Procedure Act ("APA") or the agency's procedural requirements, its arguments fail for similar reasons. In particular, NEI attempts to suggest that the 2019 Letter constitutes a "new" rule requiring notice and comment, and that it imposes a new obligation requiring additional justification under both the APA and the agency's "backfit" requirements. But NEI ignores the fact that the 2019 Letter contains no new requirements or interpretations that have not been previously expressed, and that the underlying rationale for the agency's position stems from the text of the NRC's regulations and from the AEA, which provide for both Agreement State regulation of disposal of low-level radioactive waste *and* for NRC approval of all methods for disposal of waste generated by NRC licensees.

ARGUMENT

I. The 2019 Letter is not final agency action.

NEI challenges the 2019 Letter as a new agency position affecting the legal rights of its members. But it cannot be reviewed under the Hobbs Act because it is not a "final order." It simply restates the agency's interpretation of its regulatory authority that is susceptible to challenge, if need be, in the event that enforcement action is taken against a licensee for noncompliance with Section 20.2002.

A. The 2019 Letter is not final because it does not determine any legal rights.

Finality under the Hobbs Act is "narrowly construed." *Blue Ridge Envtl. Def. League v. NRC*, 668 F.3d 747, 753 (D.C. Cir. 2012). A Hobbs Act "final order" is one that "imposes an obligation, denies a right, or fixes some legal relationship, usually at the consummation of an administrative process." *Honicker v. NRC*, 590 F.2d 1207, 1209 (D.C. Cir. 1978). In determining the finality of an order under the Hobbs Act, courts have looked to the familiar framework established by the Supreme Court in *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).[8] To be "final," the order (1) "must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory

[8] *Bennett v. Spear* considered whether agency action was final under the APA. Although the Hobbs Act and the APA use different terminology—"final order" versus "final agency action"— they are "equivalent for the purposes of finality." *Weaver v. Fed. Motor Carrier Safety Admin.*, 744 F.3d 142, 146 (D.C. Cir. 2014).

nature"; and (2) "must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 177-78 (internal citations and quotation marks omitted).

While we do not dispute that the first prong of *Bennett v. Spear* has been satisfied here—the agency has articulated its interpretation of Section 20.2002 to the public and has declined to disturb it—there is no doubt that the second one has not. Indeed, this Court and others have long recognized that routine, informational letters from agencies reiterating agency policies and legal interpretations, such as the 2019 Letter, are not final agency actions subject to judicial review because they do not, in and of themselves, impose legal obligations on affected parties. *See*, *e.g.*, *Gen. Motors Corp. v. EPA*, 363 F.3d 442, 449 (D.C. Cir. 2004) (EPA letters did not constitute reviewable agency action where, "[i]n response to industry inquiries," the agency "repeated its regulatory interpretation" from a prior policy document issued years earlier); *Am. Iron & Steel Inst. v. EPA,* 886 F.2d 390, 398 (D.C. Cir. 1989) (agency did not "reopen" issue, and subject itself to new statute of limitations, where it "reaffirmed its previous position and at most briefly reiterated its prior reasoning" (alteration and internal quotation marks omitted)); *Menominee Indian Tribe of Wis. v. EPA*, 947 F.3d 1065, 1070 (7th Cir. 2020) ("Letters restating earlier interpretations likewise do not carry legal consequences for purposes of the 'final agency action' requirement."); *Clayton County, Ga. v. FAA*,

887 F.3d 1262, 1266-70 (11th Cir. 2018) (holding that agency letter that simply restated a previously articulated statutory interpretation was not final agency action and noting that "if the FAA brings an enforcement action in the future, Petitioners will be able to raise their claims then").

For example, in *Independent Equipment Dealers Association v. EPA*, 372 F.3d 420 (D.C. Cir. 2004), this Court held that it lacked jurisdiction to review an EPA letter responding to an industry trade association's letter, in which the agency stated that it did not concur in the trade association's proposed interpretation of certain emissions regulations. *Id.* at 422. This Court held that the EPA letter failed to satisfy the second prong of *Bennett* and therefore was not a final agency action. *Id*. at 425-29. This Court reasoned that the EPA letter "merely restated in an abstract setting—for the umteenth time—EPA's longstanding interpretation of the [relevant emissions] regulations." *Id*. at 427. Thus, the EPA letter was "the type of workaday advice letter that agencies prepare countless times per year in dealing with the regulated community." *Id*.

The reasoning behind these cases applies with full force to the 2019 Letter and precludes a finding of finality under prong two of *Bennett*. Barely exceeding one page, the 2019 Letter merely restates what the NRC already made clear in both the 2012 Letter and the 2016 Issue Summary—that "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."[9] JA51. In the 2019 Letter, the NRC reiterated that its interpretation of Section 20.2002 in the 2016 Issue Summary was "correct[]," quoted the Issue Summary's language and rationale nearly verbatim, and declined NEI's invitation to rescind it. Thus, like the EPA letter in *Independent Equipment Dealers*, the NRC's 2019 Letter covered "no new ground"; rather, it "left the world just as it found it, and thus cannot be fairly described as implementing, interpreting, or prescribing law or policy." 372 F.3d at 428; *see also Edison Elec. Inst. v. OSHA*, 411 F.3d 272, 282 (D.C. Cir. 2005) (directive that repeated agency's interpretation of regulatory standard was properly viewed as challenge to standard itself and not to directive). Because the 2019 Letter itself imposed no new legal consequences, it is not a final order under the Hobbs Act. *See Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 637-38 (D.C. Cir. 2019). And absent a final order, this Court lacks jurisdiction.

[9] NEI incorrectly asserts (Br. 30) that we are relying on the length of the letter to demonstrate that it cannot constitute final agency action. Neither the length of the letter nor its "informality" (*id.* 28) precludes a finding of finality. But its length and its invocation and incorporation of a previously expressed position do reflect the fact that it did not break new ground and therefore did not, in and of itself, have appreciable legal consequences.

B. The 2019 Letter did not reflect a change in the agency's position.

Trying to escape this Court's firm rejection of attempts to manufacture Hobbs Act jurisdiction by challenging previously resolved issues, NEI argues that "[u]ntil the 2019 Letter, NRC's policy related to very low-level waste disposal had not been settled and was not transparent." Br. 31. But this assertion flies in the face of the plain text of the 2019 Letter, which, by its terms, is a "respon[se]" to NEI's "request[]" that the NRC "rescind" the Issue Summary, and a decision not to do so. JA51. It would be difficult to conceive of a situation in which an agency more strictly adhered to the position that it had previously adopted than one where, as here, a party expressly invites the agency to revoke its prior position and the agency unequivocally declines to do so.

Undeterred by the context in which the agency declined its invitation, NEI nonetheless asserts that, embedded within the agency's two-sentence explanation for its conclusion not to rescind its legal interpretation is a "brand new—and still puzzling—legal theory." Br. 33. In so doing, NEI refers to the agency's statement in the 2019 Letter that, "In the case of 10 CFR Part 50 or 52 licensees, th[e] requirement [to seek NRC approval for alternate methods of disposal] is based on the NRC's jurisdiction over the operation of nuclear power plants, which cannot be delegated to an Agreement State." JA51. But this theory is neither new nor puzzling; the NRC made exactly the same point in the 2016 Issue Summary—that

with respect to nuclear power plants (i.e., Part 50 and 52 licensees), requests for approval of alternate methods of disposal "should be made to the NRC" because the NRC is the "regulatory authority that issued the license for use of the radioactive material." JA17.

It is true that, in the Issue Summary, the agency did not expressly refer to the non-delegability of jurisdiction over nuclear power plants. But this limitation has existed since the Agreement State regime was enacted in 1959. *See* 42 U.S.C. § 2021(c)(1) ("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. . . ."). And the statements in the Issue Summary concerning the appropriate regulatory authority to issue Section 20.2002 approvals are premised on precisely this statutory limitation (and the consequence that power plants are necessarily NRC licensees). Pursuant to the directions set forth in the Issue Summary, Part 50 and Part 52 licensees (i.e., operators of nuclear power plants) seeking an alternate method of waste disposal must obtain approval from the NRC. JA17. But persons authorized to possess source, byproduct, or certain special nuclear material under Parts 30, 40, or 70 or their Agreement State equivalents—authority over which *can* be discontinued pursuant to an agreement under 42 U.S.C. § 2021(b))—should

obtain such approval either from the NRC (in non-Agreement States) *or* from Agreement States, as applicable. JA17. Thus, the 2019 Letter does not articulate a new legal theory; it simply refers to the underlying and widely known justification for the conclusion that the agency expressed three years earlier. NEI's suggestion that the 2019 Letter breaks ground that had not been plowed in 2016 fails.

In fact, the NRC articulated as far back as 2012 its conclusion that NRC licensees must apply to the NRC under Section 20.2002 to use an alternative method of disposal not already contemplated in NRC regulations. Indeed, the 2012 Letter (which NEI fails even to acknowledge in its brief) made clear that the approval process for alternate methods of offsite disposal entailed two regulatory approvals—one pursuant to Section 20.2002 or its Agreement State equivalent and one for the unlicensed facility—and that the jurisdiction responsible for the first approval was the one that had authorized possession and use of the material in the first instance. *Compare* JA12-13 (scenarios 1-3, which specify that an *Agreement State* licensee must obtain authorization for an alternate disposal method from the State "under the State's [Section] 20.2002-equivalent regulation") *with* JA13 (scenarios 4 and 5, which specify that *NRC* licensees must obtain approval from the NRC itself under Section 20.2002).

NEI's failure to acknowledge the 2012 Letter also reveals the flaw in its repeated assertion (Br. 19, 29, 32, 35) that the 2019 Letter somehow made the agency's position mandatory for the first time and thus effected some kind of change in the legal landscape. Indeed, NEI makes much of the fact that the 2016 Issue Summary, as part of its "backfit" analysis, stated that "no action or written response" was required by licensees.[10] But it ignores the reason that the agency was able to reach this conclusion—because the position it advanced "[did] not represent a departure from current regulatory requirements and practice" and that any action licensees might take in response would be undertaken only to "ensure[] compliance with current regulations." JA18. In other words, a backfit analysis was unnecessary because the NRC was reminding reactor licensees of their existing obligations under Section 20.2002.

Indeed, the Issue Summary referenced the 2012 Letter (cited as "FSME-12-25") and explained that, in that document, the agency had provided a "discussion of several situations where the NRC and an Agreement State or multiple Agreement States would be involved in reviewing requests for and authorizing alternate procedures to dispose of licensed material under [Section] 20.2002 (or the

[10] The agency has promulgated extensive regulations concerning whether the retroactive application of an interpretation of a requirement imposes a "backfit" on licensees and therefore requires additional justification. *See* 10 C.F.R. § 50.109.

equivalent Agreement State[] regulations)." JA17. Thus, the Issue Summary does not prove that the agency announced the mandatory nature of its interpretation for the first time in 2019; the Issue Summary merely stated, unremarkably, that licensees who were in compliance with existing regulatory requirements (as had been expressed in the 2012 Letter and was required by Section 20.2002) did not have to do anything because the position set forth in the Issue Summary had been articulated four years earlier and was already required.[11]

NEI makes a related argument by noting that the 2016 Issue Summary stated, in the "backfit" section, that any actions taken to comply with the information contained therein would be "strictly voluntary." Br. 20. But NEI misapprehends the meaning of this statement by failing to understand its context. The agency did not state in the Issue Summary that compliance with NRC's requirements, and specifically, the need for "the Commission" to provide approval under Section 20.2002, was "voluntary." Indeed, the Issue Summary specifically

[11] Further, contrary to its repeated assertion here that the agency's interpretation first became mandatory through issuance of the 2019 Letter, NEI previously asserted before the agency that this obligation was made clear in the Issue Summary itself. Indeed, in its February 2019 request that the agency rescind the Issue Summary, NEI deliberately emphasized the view that "the changed interpretation provided in the [2016 Issue Summary] *requires* licensees that have obtained approval from an Agreement State for alternative disposal of LLW to obtain approval from the NRC prior to continuing such disposals or risk enforcement action." JA42 (emphasis in original). Its selection of words and choice of emphasis belie the position it advances here.

states the NRC's previously articulated view that "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." JA17 (emphasis added). Rather, the agency merely observed that licensees were not compelled to take action as a result of the interpretation conveyed in the Issue Summary or the 2012 Letter because they could avoid the need to obtain any additional approvals altogether if they employed disposal methods already authorized by Section 20.2001.

In the end, NEI's focus on language in the Issue Summary only underscores the fact that NEI's true dispute is with a position conveyed in that document and the 2012 Letter (challenges to which would unquestionably be time-barred). *See Edison Elec. Inst.*, 411 F.3d at 282 ("What this argument makes manifest is that EEI's true quarrel is not with the 2003 Directive, but with the 1994 Standard and its preamble."). Indeed, NEI is unable to explain how the Issue Summary—a formal agency guidance document, applicable to all operating reactors, and shared widely with reactor licensees—is not final agency action, but an informational letter, sent only to NEI and rejecting NEI's invitation to rescind the Issue Summary, has legal effect that is challengeable before this Court. The 2019 Letter did not break new

ground, and NEI's attempt to characterize it as something other than an adherence to previously articulated positions is unpersuasive.[12]

C. Potential for future enforcement actions for noncompliance with Section 20.2002 does not render the 2019 Letter final agency action.

Next, NEI contends that both legal and "real and practicable" consequences flow from the 2019 Letter because it "creates new enforcement risks and imposes new regulatory burdens on licensees." Br. 34. This assertion is flatly incorrect for several reasons.

First, NEI makes no effort to explain how the 2019 Letter imposes finality-creating requirements that did not exist in 2012 or 2016. To the extent that NEI relies on regulatory burdens allegedly created by the NRC's licensing regime, those burdens were created years ago and did not somehow coalesce into final

[12] NEI's reliance on the fact that the agency discussed its interpretation of Section 20.2002 with affected stakeholders prior to issuing the 2019 Letter (Br. 31) does not alter this conclusion. As an initial matter, such discussions comply with NRC policy, s*ee* note 7 *supra,* and provide evidence only of the agency's transparency and good governance. They do not demonstrate the existence of an open policy question that required resolution. And while NEI suggests that the agency's position "was not yet settled" (Br. 31) at the time of the discussions because it had not yet developed a decision concerning the issuance of new guidance, it ignores the NRC's statement during the meeting—in the very paragraph it cites in its brief—reflecting that the agency was "affirm[ing] the position" explained in the 2016 Issue Summary that approval of alternative methods of disposal, as distinct from approval of the disposal itself, must be obtained from "the licensing authority of the generator of the waste." JA54.

agency action merely because the NRC sent a letter in 2019 reaffirming its prior interpretations.

Second, the NRC position set forth in the 2012 Letter and the 2016 Issue Summary—that NRC licensees must apply under Section 20.2002 to use a method of disposal not already contemplated in NRC regulations—requires nothing beyond what the regulation's plain text commands. Indeed, Section 20.2002 states that "[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" (emphasis added). Any enforcement action the agency may take for noncompliance with this provision would be (indeed, must be) based on noncompliance with the regulation itself—not the 2012 Letter, not the 2016 Issue Summary, and *certainly* not the 2019 Letter. *See Edison Elec. Inst.*, 411 F.3d at 282 (holding that an OSHA directive was not judicially reviewable and noting that "OSHA foreswears drawing any independent authority at all from the directive, contending that in an enforcement action, any finding of a violation must be predicated on the standard itself, 'just as if the [directive] had never been issued.'" (quoting *Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974)); *AT&T Co. v. EEOC*, 270 F.3d 973, 975 (D.C. Cir. 2001) ("The Commission has not inflicted any injury upon AT&T merely by expressing its

view of the law—a view that has force only to the extent the agency can persuade a court to the same conclusion."). Indeed, when the NRC notified the South Texas Project licensee that it would not take enforcement action based upon that licensee's failure to seek NRC approval for its use of alternative disposal methods, the agency explained that the violation it had identified was "non-compliance with 10 CFR 20.2002." JA32.

Although NEI attempts to compares the instant case to the circumstances in *Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45 (D.C. Cir. 2000), and *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), those cases are inapposite. In *Barrick*, this Court found that an enforcement letter, issued in concert with a guidance document, constituted agency action from which legal consequences flowed. 215 F.3d at 48-49. Here, the NRC had not commenced enforcement action against any licensee at the time that the Petition was filed, and in fact, it specifically informed the South Texas Project licensee, with which it had communicated about the issue, that it had "exercised enforcement discretion for past-noncompliance" and would continue to do so while it evaluated future regulatory options. JA32; *see Cmty. Fin. Servs. Ass'n of Am. v. FDIC*, 132 F. Supp. 3d 98, 121 (D.D.C. 2015) ("In this case however, none of the Defendants have issued any enforcement letters and *Barrick* is not relevant."); *see also Reliable Automatic Sprinkler Co. v. Consumer Prods. Safety Comm'n*, 324 F.3d

726, 731-32 (D.C. Cir. 2003) (agency's letter was not final agency action where agency "ha[d] not yet made any determination or issued any order imposing any obligation on [the petitioner], denying any right of [petitioner], or fixing any legal relationship" and where any enforcement action would require the agency to initiate a formal adjudication).

Further, the NRC concedes that it would not, and indeed *could* not, rely on the 2016 Issue Summary, and certainly not on the 2019 Letter, as a basis for enforcement action because neither of those documents has the force and effect of law. Unlike *Barrick*, any enforcement action would be taken based on a violation of Section 20.2002 itself (which requires application "to the Commission" for approval of procedures for alternative methods of disposal "of licensed material generated in the licensee's activities"). *See Edison Electric Inst.*, 411 F.3d at 282; *compare id. with Barrick*, 215 F.3d at 49 ("[I]f Barrick refuses to abide by the 1999 Guidance, the company will be subject to an enforcement action.").

Similarly, in *Appalachian Power v. EPA*, this Court, in holding that a nineteen-page EPA guidance document was judicially reviewable, noted that the guidance "reads like an ukase" and that "State authorities, with EPA's Guidance in hand, are insisting on [additional monitoring]." 208 F.3d at 1023. Unlike the guidance at issue in *Appalachian Power*, however, the 2019 Letter does not "command[]," does not "require[]," does not "order[]," and does not "dictate[]."

Id.; *see also Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 227-28 (D.C. Cir. 2007) (identifying factors that distinguished *Appalachian Power*, including that EPA "does not treat the [agency guidance document] as binding"). Rather, the 2019 Letter reflects the NRC's willingness to work with licensees, including through the exercise of enforcement discretion and the minimization of any undue regulatory burden, to address the need to comply with the binding requirements in Section 20.2002. JA51.

Finally, in asserting that the 2019 Letter constitutes final agency action, NEI relies (Br. 21) upon events that post-date its Petition for Review, specifically a minor violation that NRC identified to Energy Northwest, the reactor licensee for the Columbia Generating Station in Washington State. This Court, however, has stated that "[t]he question of justiciability must be decided on the facts in existence *at the time the suit was filed.*" *Fed. Express Corp. v. Air Line Pilots Ass'n*, 67 F.3d 961, 965 n.5 (D.C. Cir. 1995); *see AT&T Co.*, 270 F.3d at 976 (declining to consider, for purposes of ascertaining finality of agency action, events occurring after filing of complaint). NEI cannot establish finality based on events that post-date the filing of its Petition for Review.[13]

[13] The Petition for Review in this matter was filed on November 15, 2019. The declaration supporting NEI's assertions indicates that an inspection of the Columbia facility was performed "in November 2019" and that a minor violation was "subsequently issued." Separate Addendum of Petitioner Nuclear Energy

Even if the Court were to consider events that occurred after the filing of the Petition, the violation that the NRC brought to Energy Northwest's attention was based on its noncompliance with Section 20.2002, not the 2016 Issue Summary or the 2019 Letter. Moreover, Energy Northwest, like any licensee informed of the existence of a violation, had the opportunity to contest the conclusion that, by failing to obtain Commission approval of procedures for alternate methods of disposal, it was acting in violation of this provision. 10 C.F.R. §§ 2.201, 2.202, 2.205 (providing process for licensees to contest violations identified by agency); *see also* 42 U.S.C. § 2239(b) (providing for judicial review of certain enforcement actions taken against licensee); *id.* § 2282 (providing for *de novo* civil action, commenced by United States, to collect nonpayment of civil penalty assed by agency). It chose not to do so. But the mere fact that that the Commission may take or threaten enforcement action against licensees who act in contravention of its established regulatory requirements does not create a freestanding right, free of applicable statutes of limitations and jurisdictional prerequisites, for an industry

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Institute (Sept. 30, 2020), ADD10. In fact, the existence of the violation was conveyed orally to Energy Northwest in April 2020, and Energy Northwest voluntarily corrected the condition; no enforcement action was taken.

We further note that the addendum containing the information concerning Energy Northwest was provided to support NEI's claim of standing, in accordance with D.C. Rule 28(a)(7). Br. 18 n.4. It is not part of the administrative record of this case, and it is therefore not appropriately considered in reviewing the 2019 Letter.

group to invite the agency to change its interpretation and, upon a denial of that invitation, to challenge the agency's requirements in court.[14]

D. Treating the 2019 Letter as final agency action would chill agency communications with stakeholders.

The conclusion we ask the Court to draw here—that the 2019 Letter does not constitute final agency action—is not only correct as a matter of law but also promotes the sensible agency practice of being responsive to stakeholders. The NRC wrote the 2019 Letter in response to an informal inquiry from NEI—an organization that represents companies that the NRC regulates. Seeking to be responsive to NEI's request, the NRC agreed to discuss the issue with interested parties and stated that it was adhering to its preexisting views of Section 20.2002.

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[14] NEI also relies upon a declaration submitted by an employee of the Palo Verde Nuclear Generating Station in support of its standing (and specifically suggesting that the NRC's interpretation of Section 20.2002 will impose additional recordkeeping and compliance costs upon licensees) to suggest that the 2019 Letter has legal consequences. Br. 37. But this argument not only relies on information outside the administrative record, *see* note 13 *supra*, but also conflates the Article III injury-in-fact requirement with the legal consequences necessary to satisfy prong two of *Bennett*.

NEI also fails to note that no enforcement action of any kind has been taken concerning Palo Verde, and it glosses over its declarant's speculation that his company is "concerned that during a future inspection at Palo Verde, the NRC *might* allege a violation." ADD46 (emphasis added). Moreover, NEI fails to explain how any additional compliance costs it claims to incur flow from the 2019 Letter rather than the text of Section 20.2002 itself or the agency's 2012 or 2016 articulations of its positions, or why its constituent members could not present their legal arguments in the context of a live controversy.

Subjecting agencies such as the NRC to judicial review when they merely restate a regulatory interpretation in response to inquiries from the regulated community would chill future interactions. As this Court observed in *Independent Equipment Dealers*, "it is silly to permit parties to challenge an established regulatory interpretation each time it is repeated." 372 F.3d at 428. "Such a regime would quickly muzzle any informal communications between agencies and their regulated communities—communications that are vital to the smooth operation of both government and business." *Id*.

Such an undesirable result is precisely the situation this Court and others have warned against in refusing to find similar informational, workaday agency letters to be judicially reviewable. *See, e.g., Valero Energy Corp. v. EPA*, 927 F.3d 532, 538 (D.C. Cir. 2019) ("A contrary conclusion would have the undesirable consequence of discouraging agencies from issuing clarifying documents like this one."); *Clayton County,* 887 F.3d at 1269 ("If a court intervened now, it might mean that regulated parties could bring lawsuits whenever an agency advises a party of its already-existing obligations. Such a result would discourage agencies from offering advisory guidance which in turn would harm regulated parties who appreciate and rely on such guidance."). Adopting the approach NEI urges would mean that "every agency statement restating—let alone clarifying—existing

standards would constitute a new standard subject to immediate challenge." *Steel Erectors Ass'n of Am. v. OSHA*, 636 F.3d 107, 116-17 (4th Cir. 2011).

This Court has stressed that "when the agency merely responds to an unsolicited comment by reaffirming its prior position, that response does not create a new opportunity for review." *Kennecott Utah Copper Corp. v. U.S. Dept. of Interior*, 88 F.3d 1191, 1213 (D.C. Cir. 1996). This instruction applies with full force here, particularly given that any licensee who contests the NRC's position will have a full and fair opportunity to litigate the merits of the agency's interpretation of Section 20.2002, should it choose to do so. NEI should not be permitted to manufacture jurisdiction under the Hobbs Act merely by prodding the agency into repeating its settled views.

II. NEI's merits arguments rely on an incorrect understanding of the agency's interpretation of Section 20.2002.

Should the Court determine that the 2019 Letter is a final, reviewable order, it should reject NEI's merits arguments. NEI fundamentally misconstrues the NRC's interpretation of Section 20.2002. Properly understood, the NRC's interpretation is a rational and lawful exercise of its authority to protect the public health and safety, and NEI has provided no justification for the Court to disturb the NRC's conclusion.

A. Section 20.2002 does not usurp Agreement State authority over the regulation of low-level waste.

NEI makes a series of arguments contesting the validity of the agency's interpretation of Section 20.2002. While we address each in turn below, we note at the outset that NEI's various arguments are each premised on an incorrect reading of the provision and a misapprehension that the NRC is usurping Agreement State authority over low-level waste disposal. NEI's mistake appears to be based upon its conflation of a waste generator's disposal *procedures*, which must be approved by the authority that issued the license to possess the waste, and *actual disposal* at a waste disposal facility, which can be independently regulated by Agreement States.

The NRC agrees that Agreement States have jurisdiction over the disposal of low-level waste under the AEA, where the NRC has relinquished its authority over disposal of this waste in its Agreement with the State. But Section 20.2002 does not itself authorize disposal; it is merely a separate determination of whether NRC-licensed waste generators, who are themselves subject to 10 C.F.R. Part 20, can pursue a method of disposal not already contemplated by NRC regulations and approved after notice-and-comment rulemaking. Thus, in the case of NRC licensees seeking to dispose of low-level waste in Agreement States using an alternative disposal method, approval is required both from the NRC under Section

20.2002 *and*, to the extent necessary, from the applicable state authority in accordance with state requirements.

B. NRC was not required to provide notice and comment.

Beginning on page 37 of its brief, NEI asserts that the 2019 Letter ascribed the "force of law" to the 2016 Issue Summary without complying with the APA. For the reasons we have explained above, however, this is simply not the case. The agency did not assert in 2019 that the 2016 Issue Summary has the "force of law"; it has simply articulated its view in 2012, 2016, and now in 2019, that Section 20.2002—which does have the force of law, and could be the basis for an enforcement action—means what it says, and that *all* licensees of the NRC (whether power plant operators under Part 50 or 52; or materials licensees under Parts 30, 40, or 70) must apply "to the Commission" for approval of procedures should they seek to dispose of low-level waste using a method that is not otherwise provided for in NRC regulations (and thus already approved by the Commission). The APA does not require more. *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 95 (2015) (opportunity for notice and comment not required prior to issuance of interpretive rule).

NEI's arguments (Br. 38-41) suggesting that the agency has imposed a new obligation on licensees that must be accomplished through rulemaking are premised on its misapprehension that NRC's interpretation of Section 20.2002

usurps Agreement State authority over low-level waste disposal. Again, the NRC does not dispute, as NEI asserts, that states entering agreements with the NRC under Section 274 of the AEA can obtain jurisdiction over the disposal of low-level waste within their borders. And, as NEI correctly notes (Br. 38), a rulemaking or an order would be necessary for the agency to conclude otherwise. *See* 42 U.S.C. § 2021(c)(4).

But Section 20.2002 does not itself authorize disposal in Agreement States or prevent Agreement States from regulating or disapproving such disposal, and it does not "reclaim" (Br. 39) Agreement State authority; it merely sets forth the regulatory framework for NRC consideration of requests *by NRC licensees* to employ methods of disposal not already contemplated (and approved) by the NRC, distinct from separate approvals from Agreement States that may be necessary to actually accomplish the disposal. As NRC explained in 2012 and 2016 when it specified that the Section 20.2002 process entails two regulatory actions, Agreement States retain full authority to decide whether and under what conditions low-level waste generated by NRC licensees can be buried within their borders. JA13 (2012 Letter, Scenario 4, explaining that "[i]n this situation, both the Agreement State and the NRC would need to become involved. The NRC would need to approve the disposal of the material under [Section] 20.2002. The unlicensed facility would then need to obtain a license or an exemption from the

Agreement State's regulations prior to accepting the material for disposal.); JA17 (2016 Issue Summary, explaining that "Unlicensed disposal (or other) facilities that intend to take possession of licensed material must either obtain a license or an exemption from the requirement to have a license to possess the material. In Agreement States, this license or exemption must be obtained from the regulatory authority in the Agreement State."). Under the plain text of Section 20.2002, however, Agreement States do not have authority to unilaterally authorize *NRC* licensees to depart from NRC regulations by permitting an otherwise unapproved method of disposal, and the NRC was not required to seek provide an opportunity for notice and comment prior to reiterating that conclusion.[15]

C. The NRC has provided a reasoned explanation for its position.

NEI next asserts (Br. 41-46) that the NRC has acted arbitrarily and capriciously because the 2019 Letter did not provide an explanation for deviating from the Information Notice that had been issued by the agency in 1986 (based

[15] NEI asserts in the alternative that the 2019 Letter constituted an interpretive rule that required post-promulgation comment under NRC regulations. Br. 41 n.6 (citing 10 C.F.R. § 2.804(e)). But NEI fails to explain how the agency's denial of a letter requesting rescission of a position announced in 2012 and 2016 constitutes a new interpretive rule. Nor does it explain how it or other interested parties were deprived of an opportunity to comment on the agency's position when it submitted a ten-page, single-spaced letter to the agency on February 20, 2019, requesting rescission of the 2016 Issue Summary (JA34); individual licensees provided their views on the matter (JA44, 45); and the agency conducted a public meeting to discuss the issue (JA54).

upon a legal memorandum drafted in 1985). It asserts that, "[i]n 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." Br. 42 (quotation marks omitted).

As an initial matter, this argument ignores the events of the last eight years. The agency did not wipe away "decades" of policy with a single sentence; it reiterated a conclusion that it communicated to the public in 2012, repeated in 2016, and declined to disturb in 2019. And the NRC expressly and unequivocally explained in the 2016 Issue Summary that the interpretation it had announced in 1986 was being "supersede[d]" because, in the agency's view, it "did not provide the correct information regarding regulatory approval to dispose of very low-level waste" and "incorrectly stated that in cases where a nuclear reactor facility is located in an Agreement State, the NRC does not have a legal basis for performing the reviews and granting approvals." JA16. Thus, to the extent NEI has a complaint that the agency has violated the APA by failing to provide a suitable explanation for its change in position, its argument comes years too late.[16]

[16] And, as noted *supra* note 4, the NRC had actually considered numerous Section 20.2002 requests from reactor licensees in Agreement States prior to 2012. Thus, the agency acted to achieve consistency in its regulatory approach and not, as NEI would have it, to upend it.

Nor is the agency's position a simple "policy" choice or the product of factual findings that contradict prior positions and require additional explanation. *See* Br. 42-44. As we explained above, and as the 2012 Letter, the 2016 Issue Summary, and the 2019 Letter illustrate, the conclusion is compelled by (1) the text of Section 20.2002, which requires approval by "the Commission" when NRC licensees—who are subject to Part 20, even if they are located in Agreement States—pursue disposal of low-level waste using methods not otherwise authorized by NRC regulations in 10 C.F.R. Part 20, Subpart K; and (2) Section 274(c)(1) of the AEA, which explicitly requires the NRC to retain regulatory authority over "the construction and operation of any production or utilization facility or any uranium enrichment facility," 42 U.S.C. § 2021(c)(1).

That the NRC must retain jurisdiction over the *methods* by which an NRC licensee may dispose of NRC-licensed material reflects the fact that from the time the waste is packaged and shipped from a reactor (or other NRC-licensed facility) until the moment it is accepted at the receiving facility for disposal in an Agreement State (which regulate the disposal facilities, not the NRC licensees), the waste is under the NRC's regulatory purview (including the requirements of 10 C.F.R. Part 20). The agency cannot (and, at a minimum, has reasonably determined that it should not) permit nuclear reactor operators or other NRC licensees to ship nuclear waste for disposal at unlicensed facilities if, unlike *all*

other methods identified in Subpart K, the method of ultimate disposal has not been assessed by the Commission. To do so would contravene the NRC's clear authority and mandate from Congress to ensure the safe operation of nuclear reactors. The agency's communications to the public and to NEI—which acknowledged the infirmity of the superseded 1986 analysis and are based upon the incontrovertible fact that Section 20.2002 imposes requirements upon *all* NRC licensees—derive from this recognition.

Finally, NEI cites to industry members' "longstanding reliance on the status quo." Br. 44-45. These concerns are not persuasive or dispositive here. As an initial matter, the regulated community has been aware of the requirements in Section 20.2002 since the NRC issued the regulation in 1957. *See* 22 Fed. Reg. 548, 552 (Jan. 29, 1957) (issuing 10 C.F.R. Part 20, including 10 C.F.R. § 20.302, which was subsequently renumbered to § 20.2002). More recently, the agency has been publicly communicating its interpretation of Section 20.2002 since 2012, and in 2016 it expressly acknowledged that the 1986 Information Notice had "incorrectly" evaluated the legal framework and stated that NRC licensees must obtain a separate approval of the alternative disposal procedures from the NRC, distinct from the state approval for the receiving facility to dispose of the material. JA16; *see also* note 4 *supra* (noting that industry practice prior to 2012 was not uniform). Neither NEI nor any licensee nor any Agreement State voiced a

challenge to the agency's interpretation in 2012 or 2016, and NEI's delayed invocation of equitable principles militates against its assertions of detrimental reliance. At a minimum, any reliance interests generated after 2012, when the agency announced its position, are not relevant to the Court's inquiry.[17]

Moreover, the agency has made clear that it will consider (and has in fact granted) enforcement discretion with respect to licensees who neglected to obtain the NRC approval required by Section 20.2002, and it stated in the 2019 Letter that it will issue guidance to provide a "streamlined approach for reviewing [Section] 20.2002 requests, particularly in cases where an Agreement State may have already approved or exempted a facility that would receive the [low-level waste] that is subject to the 20.2002 request." JA32, 51. It is thus simply not the case, as NEI asserts (Br. 45), that the agency has failed to consider any reliance interests of

[17] NEI does not argue, in support of its claim of standing, that requiring NRC approval for alternate disposal methods would impose burdens on licensees that exceed the cost of compliance with state requirements. Instead, it contends that certain of its members who were authorized to dispose of waste under state law must now obtain "duplicative" NRC approval. Br. 26. To the extent these members obtained state approvals after 2012 (when the NRC announced its current position), their injury is entirely self-inflicted and does not provide a basis for standing. And, while we stress that the relief NEI seeks (invalidation of the need for NRC approval of alternate disposal procedures under Section 20.2002 in Agreement States) is neither warranted nor necessarily consistent with public health and safety, it follows that any remedy that the Court issues to redress the injury NEI has identified should be confined to state approvals for alternate disposal methods granted before 2012.

affected parties. The agency has committed itself (and demonstrated its commitment) to working with licensees to minimize any burden associated with the need to obtain the approval required by Section 20.2002.

D. The NRC was not required to perform a backfit analysis.

NEI argues (Br. 46-47) that the NRC violated its "backfit" regulation at 10 C.F.R. § 50.109 by issuing the 2019 Letter without performing an analysis of whether, as a "new requirement," it is cost-justified. This argument is misguided. As we have previously explained, the 2019 Letter did not create a new agency position imposing a new requirement on licensees, as would be required to support invocation of the agency's backfit obligation. Rather, the NRC's position has been known to the regulated community since at least 2012, and the 2019 Letter was a response to NEI's request that the agency rescind the position.

Indeed, NEI itself acknowledged when it asked the agency to rescind the 2016 Issue Summary that, in its view, the agency's position had been made "mandatory" in 2016. JA42 ("[T]he changed interpretation provided in the [2016 Issue Summary] *requires* licensees that have obtained approval from an Agreement State for alternative disposal of LLW to obtain approval from the NRC prior to continuing such disposals or risk enforcement action." (emphasis in original)). Moreover, as the agency explained when it deemed the backfit rule inapplicable in 2016, JA18, any changes that licensees must make based on the agency's

interpretation are "necessary to bring a facility into compliance with . . . [a] rule[]. . . . of the Commission"—namely 10 C.F.R. § 20.2002. Under the terms of the NRC's rules, no backfit analysis is required in these circumstances. *See* 10 C.F.R. § 50.109(a)(4)(i).

E. The NRC's interpretation of Section 20.2002 is consistent with the AEA and NRC regulations.

NEI asserts in its final set of arguments (Br. 47-52) that the NRC's position "ignore[s] the unambiguous language and structure of the AEA and its implementing regulations" because it "precludes Agreement State regulation of very low-level waste disposal." Br. 48. These arguments fail largely for the reasons we have identified above. Specifically, the NRC is *not* asserting that states lack the right to regulate low-level waste disposal (and it acknowledges that Agreement States can approve of alternate methods of disposal when authorizing disposal by *their own* licensees). Rather, the NRC merely explained in 2012 and 2016 that under Section 20.2002, *NRC* licensees must separately obtain authorization from "the Commission" for approval of procedures to dispose of such waste in Agreement States when they seek to employ methods that are not otherwise authorized by NRC regulations in 10 C.F.R. Part 20, Subpart K. Agreement State regulation of low-level waste is not "precluded" by the NRC's position (Br. 48), and, as the agency has explained, states retain full authority to

regulate such disposal as they see fit within the confines of the Agreement State program.

The NRC's exercise of authority in this limited matter is fully consistent with the AEA and the NRC's implementing regulations. Indeed, the NRC exercises jurisdiction over a host of activities involving the possession or use of licensed material that would otherwise be subject to Agreement State authority but for the fact that the activities are undertaken by reactor operators. One such activity concerns the methods for the disposal of waste created in the course of the operations of NRC-licensed reactors. The agency has determined that, to comply with its statutory mandate, it must approve the methods by which its licensees intend to dispose of waste generated by reactor operations (either through notice-and-comment rulemaking, pursuant to which the Commission has approved certain designated methods of disposal, or through the Section 20.2002 alternate approval process). *See* 42 U.S.C. § 2021(c)(1); *Siegel v. AEC*, 400 F.2d 778, 783 (1968) (noting that the AEA "'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 objective'").

This arrangement is fully consistent with the Agreement State program, particularly in the context of requests for alternate methods of approval under Section 20.2002 (which, by definition, have not been previously evaluated by the

Commission). The agency could not (and, at a minimum, has reasonably determined that it should not) authorize the delivery of waste by a reactor licensee to an unlicensed facility under Section 20.2002 without at least ascertaining and approving the methods by which the licensee intends to dispose of its waste. Section 20.2002 does no more than require a reactor licensee to meet a threshold requirement and explain the procedures it intends to use when it seeks to dispose of waste generated pursuant to an NRC license in a manner that has not already been authorized by the agency. This requirement is not a usurpation of authority of Agreement States, which do not regulate NRC licensees, have the ability to approve alternate disposal requests for waste generated by their own licensees, and maintain full authority to (and, indeed, must) take steps to ensure that waste is disposed of safely under the separate authorizations they provide.[18]

NEI emphasizes the distinction between "operation" and "disposal" (Br. 50-51), and we do not contest that those are discrete activities. However, it incorrectly relies upon 10 C.F.R. § 150.15 to suggest that the NRC lacks authority to approve the methods by which reactor licensees seek to dispose of the waste they generate.

[18] We further observe that Section 20.2002 has been designated as compatibility Category D, meaning that Agreement States are not required to adopt an analogous provision. *See* note 2 *supra.* The consequence of this designation is that, contrary to NEI's repeated assertions, adoption of NEI's position could have the effect of *reducing* the options available to reactor licensees.

Nothing in the AEA or 10 C.F.R. § 150.15(a)—which defines operation in a non-exclusive way that "includes, but is not limited" to certain activities—precludes a conclusion by the agency that the NRC's Section 20.2002 review is an appropriate way to ensure protection of public health and safety with respect to handling of waste (including its packaging and transportation) when an NRC licensee proposes to dispose of waste in a manner that the agency has not previously authorized through notice-and-comment rulemaking. And if NEI's argument were correct, the NRC would have no authority to impose conditions upon NRC reactor licensees located in Agreement States with respect to their use of the *enumerated* methods of disposal set forth in Subpart K (i.e., those that the Commission has approved in 10 C.F.R. § 20.2001 after notice-and-comment rulemaking). The requirements of Part 20 apply to *all* NRC licensees, regardless of whether they are located in Agreement States, and, as a result, Commission approval of the method by which NRC licensees seek to dispose of the waste they generate—whether in the form of notice-and-comment rulemaking or approval under Section 20.2002—is required.

Finally, NEI's last-gasp efforts to find inconsistencies in the agency's position by citing to various agency publications are unconvincing. NEI points to the NRC's guidance for Section 20.2002 approvals to assert that the NRC "directs applicants to evaluate the safety of disposal (e.g., by performing disposal dose assessments)." Br. 51 (citing 85 Fed. Reg. 19,966 (Apr. 9, 2020)). But the

guidance document referenced in the *Federal Register*—published after the filing of the Petition for Review and not part of the administrative record—specifically acknowledges the dual nature of the approval process for Section 20.2002 requests and references both the 2012 Letter and the 2016 Information Summary. *See* 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), available at https://www.nrc.gov/docs/ML1929/ML19295F109.html, at 7. And the 2020 guidance only underscores the fact that the approval of the methods by which a reactor licensee may dispose of NRC-licensed material necessarily involves the *handling* of waste by the licensee before it becomes subject to Agreement State authority, including the question of how waste should be packaged for shipment and transport. *Id.* (noting need for licensees to comply with 10 C.F.R. Part 71, governing packaging and transportation of radioactive material).

NEI's citation to a 1988 notice of proposed rulemaking that was ultimately withdrawn (Br. 51) is likewise unavailing. Simply put, NEI's citation to an over-thirty-year old proposed rule that was ultimately withdrawn by the agency does nothing to change NEI's misapprehension of the plain language of Section 20.2002 itself and the respective responsibilities of the NRC and Agreement States under the AEA. And NEI's reliance on the distinction between power plant operation and disposal yet again fails to acknowledge that Section 20.2002 does not

authorize the disposal *itself*, but approval only of procedures for an alternative disposal *method*. The NRC maintains authority to approve the procedures through which its own licensees propose to dispose of the waste they generate, and, before it can authorize delivery of waste to an Agreement State disposal facility, it must have approved the methods of disposal either by notice-and-comment rulemaking or through the alternate means set forth in Section 20.2002.

CONCLUSION

This Court should dismiss this Petition for Review for lack of jurisdiction, or in the alternative, the Petition should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 28(b) and 32(g)(1), I hereby certify:

The foregoing Final Brief of Federal Respondents complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Circuit Rule 32(e) because, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Circuit Rule 32(e)(1), the Brief contains 12,994 words, as calculated by the word processing software program with which the Brief was prepared.

The Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it was prepared in 14-point Times New Roman, a proportionally spaced font.

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ADDENDUM OF PERTINENT STATUTES AND REGULATIONS

28 U.S.C. § 2342

Jurisdiction of court of appeals

The court of appeals (other than the United States Court of Appeals for the Federal Circuit) has exclusive jurisdiction to enjoin, set aside, suspend (in whole or in part), or to determine the validity of--

(1) all final orders of the Federal Communications Commission made reviewable by section 402(a) of title 47;

(2) all final orders of the Secretary of Agriculture made under chapters 9 and 20A of title 7, except orders issued under sections 210(e), 217a, and 499g(a) of title 7;

(3) all rules, regulations, or final orders of--

(A) the Secretary of Transportation issued pursuant to section 50501, 50502, 56101-56104, or 57109 of title 46 or pursuant to part B or C of subtitle IV, subchapter III of chapter 311, chapter 313, or chapter 315 of title 49; and

(B) the Federal Maritime Commission issued pursuant to section 305, 41304, 41308, or 41309 or chapter 421 or 441 of title 46;

(4) all final orders of the Atomic Energy Commission made reviewable by section 2239 of title 42;

(5) all rules, regulations, or final orders of the Surface Transportation Board made reviewable by section 2321 of this title;

(6) all final orders under section 812 of the Fair Housing Act; and

(7) all final agency actions described in section 20114(c) of title 49.

Jurisdiction is invoked by filing a petition as provided by section 2344 of this title.

42 U.S.C. § 2021

Cooperation with states

(a) Purpose

It is the purpose of this section--

(1) to recognize the interests of the States in the peaceful uses of atomic energy, and to clarify the respective responsibilities under this chapter of the States and the Commission with respect to the regulation of byproduct, source, and special nuclear materials;

(2) to recognize the need, and establish programs for, cooperation between the States and the Commission with respect to control of radiation hazards associated with use of such materials;

(3) to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials;

(4) to establish procedures and criteria for discontinuance of certain of the Commission's regulatory responsibilities with respect to byproduct, source, and special nuclear materials, and the assumption thereof by the States;

(5) to provide for coordination of the development of radiation standards for the guidance of Federal agencies and cooperation with the States; and

(6) to recognize that, as the States improve their capabilities to regulate effectively such materials, additional legislation may be desirable.

(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.

(d) Conditions

The Commission shall enter into an agreement under subsection (b) of this section with any State if--

> (1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and
>
> (2) the Commission finds that the State program is in accordance with the requirements of subsection (o) and in all other respects compatible with the Commission's program for the regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed agreement.

(e) Publication in Federal Register; comment of interested persons

(1) Before any agreement under subsection (b) is signed by the Commission, the terms of the proposed agreement and of proposed exemptions pursuant to subsection (f) shall be published once each week for four consecutive weeks in the Federal Register; and such opportunity for comment by interested persons on the proposed agreement and exemptions shall be allowed as the Commission determines by regulation or order to be appropriate.

(2) Each proposed agreement shall include the proposed effective date of such proposed agreement or exemptions. The agreement and exemptions shall be published in the Federal Register within thirty days after signature by the Commission and the Governor.

(f) Exemptions

The Commission is authorized and directed, by regulation or order, to grant such exemptions from the licensing requirements contained in subchapters V, VI, and VII, and from its regulations applicable to licensees as the

Commission finds necessary or appropriate to carry out any agreement entered into pursuant to subsection (b) of this section.

(g) Compatible radiation standards

The Commission is authorized and directed to cooperate with the States in the formulation of standards for protection against hazards of radiation to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible.

(h) Consultative, advisory, and miscellaneous functions of Administrator of Environmental Protection Agency

The Administrator of the Environmental Protection Agency shall consult qualified scientists and experts in radiation matters, including the President of the National Academy of Sciences, the Chairman of the National Committee on Radiation Protection and Measurement, and qualified experts in the field of biology and medicine and in the field of health physics. The Special Assistant to the President for Science and Technology, or his designee, is authorized to attend meetings with, participate in the deliberations of, and to advise the Administrator. The Administrator shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. The Administrator shall also perform such other functions as the President may assign to him by Executive order.

(i) Inspections and other functions; training and other assistance

The Commission in carrying out its licensing and regulatory responsibilities under this chapter is authorized to enter into agreements with any State, or group of States, to perform inspections or other functions on a cooperative basis as the Commission deems appropriate. The Commission is also authorized to provide training, with or without charge, to employees of, and such other assistance to, any State or political subdivision thereof or group of States as the Commission deems appropriate. Any such provision or assistance by the Commission shall take into account the additional expenses that may be incurred by a State as a consequence of the State's entering into an agreement with the Commission pursuant to subsection (b).

(j) Reserve power to terminate or suspend agreements; emergency situations; State nonaction on causes of danger; authority exercisable only during emergency and commensurate with danger

(1) The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State with which an agreement under subsection (b) has become effective, or upon request of the Governor of such State, may terminate or suspend all or part of its agreement with the State and reassert the licensing and regulatory authority vested in it under this chapter, if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of this section. The Commission shall periodically review such agreements and actions taken by the States under the agreements to ensure compliance with the provisions of this section.

(2) The Commission, upon its own motion or upon request of the Governor of any State, may, after notifying the Governor, temporarily suspend all or part of its agreement with the State without notice or hearing if, in the judgment of the Commission:

> (A) an emergency situation exists with respect to any material covered by such an agreement creating danger which requires immediate action to protect the health or safety of persons either within or outside the State, and
>
> (B) the State has failed to take steps necessary to contain or eliminate the cause of the danger within a reasonable time after the situation arose.

A temporary suspension under this paragraph shall remain in effect only for such time as the emergency situation exists and shall authorize the Commission to exercise its authority only to the extent necessary to contain or eliminate the danger.

(k) State regulation of activities for certain purposes

Nothing in this section shall be construed to affect the authority of any State or local agency to regulate activities for purposes other than protection against radiation hazards.

(l) Commission regulated activities; notice of filing; hearing

With respect to each application for Commission license authorizing an activity as to which the Commission's authority is continued pursuant to subsection (c), the Commission shall give prompt notice to the State or States in which the activity will be conducted of the filing of the license application; and shall afford reasonable opportunity for State representatives to offer evidence, interrogate witnesses, and advise the Commission as to the application without requiring such representatives to take a position for or against the granting of the application.

(m) Limitation of agreements and exemptions

No agreement entered into under subsection (b), and no exemption granted pursuant to subsection (f), shall affect the authority of the Commission under section 2201(b) or (i) of this title to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material. For purposes of section 2201(i) of this title, activities covered by exemptions granted pursuant to subsection (f) shall be deemed to constitute activities authorized pursuant to this chapter; and special nuclear material acquired by any person pursuant to such an exemption shall be deemed to have been acquired pursuant to section 2073 of this title.

(n) “State” and “agreement” defined

As used in this section, the term “State” means any State, Territory, or possession of the United States, the Canal Zone, Puerto Rico, and the District of Columbia. As used in this section, the term “agreement” includes any amendment to any agreement.

(o) State compliance requirements: compliance with section 2113(b) of this title and health and environmental protection standards; procedures for licenses, rulemaking, and license impact analysis; amendment of agreements for transfer of State collected funds; proceedings duplication restriction; alternative requirements

In the licensing and regulation of byproduct material, as defined in section 2014(e)(2) of this title, or of any activity which results in the production of byproduct material as so defined under an agreement entered into pursuant to subsection (b), a State shall require--

(1) compliance with the requirements of subsection (b) of section 2113 of this title (respecting ownership of byproduct material and land), and

(2) compliance with standards which shall be adopted by the State for the protection of the public health, safety, and the environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose, including requirements and standards promulgated by the Commission and the Administrator of the Environmental Protection Agency pursuant to sections 2113, 2114, and 2022 of this title, and

(3) procedures which--

(A) in the case of licenses, provide procedures under State law which include--

(i) an opportunity, after public notice, for written comments and a public hearing, with a transcript,

(ii) an opportunity for cross examination, and

(iii) a written determination which is based upon findings included in such determination and upon the evidence presented during the public comment period and which is subject to judicial review;

(B) in the case of rulemaking, provide an opportunity for public participation through written comments or a public hearing and provide for judicial review of the rule;

(C) require for each license which has a significant impact on the human environment a written analysis (which shall be available to the public before the commencement of any such proceedings) of the impact of such license, including any activities conducted pursuant thereto, on the environment, which analysis shall include--

(i) an assessment of the radiological and nonradiological impacts to the public health of the activities to be conducted pursuant to such license;

(ii) an assessment of any impact on any waterway and groundwater resulting from such activities;

(iii) consideration of alternatives, including alternative sites and engineering methods, to the activities to be conducted pursuant to such license; and

(iv) consideration of the long-term impacts, including decommissioning, decontamination, and reclamation impacts, associated with activities to be conducted pursuant to such license, including the management of any byproduct material, as defined by section 2014(e)(2) of this title; and

(D) prohibit any major construction activity with respect to such material prior to complying with the provisions of subparagraph (C).

If any State under such agreement imposes upon any licensee any requirement for the payment of funds to such State for the reclamation or long-term maintenance and monitoring of such material, and if transfer to the United States of such material is required in accordance with section 2113(b) of this title, such agreement shall be amended by the Commission to provide that such State shall transfer to the United States upon termination of the license issued to such licensee the total amount collected by such State from such licensee for such purpose. If such payments are required, they must be sufficient to ensure compliance with the standards established by the Commission pursuant to section 2201(x) of this title. No State shall be required under paragraph (3) to conduct proceedings concerning any license or regulation which would duplicate proceedings conducted by the Commission. In adopting requirements pursuant to paragraph (2) of this subsection with respect to sites at which ores are processed primarily for their source material content or which are used for the disposal of

byproduct material as defined in section 2014(e)(2) of this title, the State may adopt alternatives (including, where appropriate, site-specific alternatives) to the requirements adopted and enforced by the Commission for the same purpose if, after notice and opportunity for public hearing, the Commission determines that such alternatives will achieve a level of stabilization and containment of the sites concerned, and a level of protection for public health, safety, and the environment from radiological and nonradiological hazards associated with such sites, which is equivalent to, to the extent practicable, or more stringent than the level which would be achieved by standards and requirements adopted and enforced by the Commission for the same purpose and any final standards promulgated by the Administrator of the Environmental Protection Agency in accordance with section 2022 of this title. Such alternative State requirements may take into account local or regional conditions, including geology, topography, hydrology and meteorology.

42 U.S.C. § 2239

Hearings and Judicial Review

(a)(1)(A) In any proceeding under this chapter, for the granting, suspending, revoking, or amending of any license or construction permit, or application to transfer control, and in any proceeding for the issuance or modification of rules and regulations dealing with the activities of licensees, and in any proceeding for the payment of compensation, an award or royalties under sections 2183, 2187, 2236(c) or 2238 of this title, the Commission shall grant a hearing upon the request of any person whose interest may be affected by the proceeding, and shall admit any such person as a party to such proceeding. The Commission shall hold a hearing after thirty days' notice and publication once in the Federal Register, on each application under section 2133 or 2134(b) of this title for a construction permit for a facility, and on any application under section 2134(c) of this title for a construction permit for a testing facility. In cases where such a construction permit has been issued following the holding of such a hearing, the Commission may, in the absence of a request therefor by any person whose interest may be affected, issue an operating license or an amendment to a construction permit or an amendment to an operating license without a

hearing, but upon thirty days' notice and publication once in the Federal Register of its intent to do so. The Commission may dispense with such thirty days' notice and publication with respect to any application for an amendment to a construction permit or an amendment to an operating license upon a determination by the Commission that the amendment involves no significant hazards consideration.

(B)(i) Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a combined construction permit and operating license under section 2235(b) of this title, the Commission shall publish in the Federal Register notice of intended operation. That notice shall provide that any person whose interest may be affected by operation of the plant, may within 60 days request the Commission to hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria of the license.

(ii) A request for hearing under clause (i) shall show, prima facie, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(iii) After receiving a request for a hearing under clause (i), the Commission expeditiously shall either deny or grant the request. If the request is granted, the Commission shall determine, after considering petitioners' prima facie showing and any answers thereto, whether during a period of interim operation, there will be reasonable assurance of adequate protection of the public health and safety. If the Commission determines that there is such reasonable assurance, it shall allow operation during an interim period under the combined license.

(iv) The Commission, in its discretion, shall determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under clause (i), and shall state its reasons therefor.

(v) The Commission shall, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by clause (i) or the anticipated date for initial loading of fuel into the reactor, whichever is later. Commencement of operation under a combined license is not subject to subparagraph (A).

(2)(A) The Commission may issue and make immediately effective any amendment to an operating license or any amendment to a combined construction and operating license, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. Such amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. In determining under this section whether such amendment involves no significant hazards consideration, the Commission shall consult with the State in which the facility involved is located. In all other respects such amendment shall meet the requirements of this chapter.

(B) The Commission shall periodically (but not less frequently than once every thirty days) publish notice of any amendments issued, or proposed to be issued, as provided in subparagraph (A). Each such notice shall include all amendments issued, or proposed to be issued, since the date of publication of the last such periodic notice. Such notice shall, with respect to each amendment or proposed amendment (i) identify the facility involved; and (ii) provide a brief description of such amendment. Nothing in this subsection shall be construed to delay the effective date of any amendment.

(C) The Commission shall, during the ninety-day period following the effective date of this paragraph, promulgate regulations establishing (i) standards for determining whether any amendment to an operating license or any amendment to a combined construction and operating license involves no significant hazards consideration; (ii) criteria for providing or, in emergency situations, dispensing with prior notice and reasonable opportunity for public comment on any such determination, which criteria shall take into account the exigency of the need for the amendment involved; and (iii) procedures for consultation on any such determination with the State in which the facility involved is located.

(b) The following Commission actions shall be subject to judicial review in the manner prescribed in chapter 158 of title 28 and chapter 7 of title 5:

(1) Any final order entered in any proceeding of the kind specified in subsection (a).

(2) Any final order allowing or prohibiting a facility to begin operating under a combined construction and operating license.

(3) Any final order establishing by regulation standards to govern the Department of Energy's gaseous diffusion uranium enrichment plants, including any such facilities leased to a corporation established under the USEC Privatization Act [42 U.S.C. 2297h et seq.].

(4) Any final determination under section 2297f(c) of this title relating to whether the gaseous diffusion plants, including any such facilities leased to a corporation established under the USEC Privatization Act [42 U.S.C. 2297h et seq.], are in compliance with the Commission's standards governing the gaseous diffusion plants and all applicable laws.

42 U.S.C. § 2282

Civil Penalties

(a) Violations of licensing requirements

Any person who (1) violates any licensing or certification provision of section 2073, 2092, 2093, 2111, 2112, 2131, 2133, 2134, 2137, 2139, or 2297f of this title or any rule, regulation, or order issued thereunder, or any term, condition, or limitation of any license or certification issued thereunder, (2) violates any provision of section 2077, or (3) commits any violation for which a license may be revoked under section 2236 of this title, shall be subject to a civil penalty, to be imposed by the Commission, of not to exceed $100,000 for each such violation. If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty. The Commission shall have the power to compromise, mitigate, or remit such penalties.

(b) Notice

Whenever the Commission has reason to believe that a person has become subject to the imposition of a civil penalty under the provisions of this section, it shall notify such person in writing (1) setting forth the date, facts, and nature of each act or omission with which the person is charged, (2) specifically identifying the particular provision or provisions of the section, rule, regulation, order, or license involved in the violation, and (3) advising of each penalty which the Commission proposes to impose and its amount. Such written notice shall be sent by registered or certified mail by the Commission to the last known address of such person. The person so

notified shall be granted an opportunity to show in writing, within such reasonable period as the Commission shall by regulation prescribe, why such penalty should not be imposed. The notice shall also advise such person that upon failure to pay the civil penalty subsequently determined by the Commission, if any, the penalty may be collected by civil action.

(c) Collection of penalties

On the request of the Commission, the Attorney General is authorized to institute a civil action to collect a penalty imposed pursuant to this section. The Attorney General shall have the exclusive power to compromise, mitigate, or remit such civil penalties as are referred to him for collection.

10 C.F.R. 2.201

Notice of violation.

(a) In response to an alleged violation of any provision of the Act or this chapter or the conditions of a license or an order issued by the Commission, the Commission may serve on the licensee or other person subject to the jurisdiction of the Commission a written notice of violation; a separate notice may be omitted if an order pursuant to § 2.202 or demand for information pursuant to § 2.204 is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation and may require that the licensee or other person submit, within 20 days of the date of the notice or other specified time, a written explanation or statement in reply if the Commission believes that the licensee has not already addressed all the issues contained in the notice of violation, including:

(1) Corrective steps which have been taken by the licensee or other person and the results achieved;

(2) Corrective steps which will be taken; and

(3) The date when full compliance will be achieved.

(b) The notice may require the licensee or other person subject to the jurisdiction of the Commission to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the Commission may issue an order or a demand for information as to why the license should

not be modified, suspended or revoked or why such other action as may be proper should not be taken.

10 C.F.R. § 2.202

Orders.

(a) The Commission may institute a proceeding to modify, suspend, or revoke a license or to take such other action as may be proper by serving on the licensee or other person subject to the jurisdiction of the Commission an order that will:

(1) Allege the violations with which the licensee or other person subject to the Commission's jurisdiction is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the proposed action, and specify the action proposed;

(2) Provide that the licensee or other person must file a written answer to the order under oath or affirmation within twenty (20) days of its date, or such other time as may be specified in the order;

(3) Inform the licensee or any other person adversely affected by the order of his or her right, within twenty (20) days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the licensee or other person has consented in writing to the order;

(4) Specify the issues for hearing; and

(5) State the effective date of the order; if the Commission finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

(b) A licensee or other person to whom the Commission has issued an order under this section must respond to the order by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order, and shall set forth the matters of fact and law on which the licensee or other person relies, and, if the order is not consented to, the reasons as to why the order should not have been issued.

Except as provided in paragraph (d) of this section, the answer may demand a hearing.

(c) If the answer demands a hearing, the Commission will issue an order designating the time and place of hearing.

(1) If the answer demands a hearing with respect to an immediately effective order, the hearing will be conducted expeditiously, giving due consideration to the rights of the parties.

(2)(i) The licensee or other person to whom the Commission has issued an immediately effective order in accordance with paragraph (a)(5) of this section, may, in addition to demanding a hearing, at the time the answer is filed or sooner, file a motion with the presiding officer to set aside the immediate effectiveness of the order on the ground that the order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. The motion must state with particularity the reasons why the order is not based on adequate evidence and must be accompanied by affidavits or other evidence relied on.

(ii) Any party may file a motion with the presiding officer requesting that the presiding officer order live testimony. Any motion for live testimony must be made in conjunction with the motion to set aside the immediate effectiveness of the order or any party's response thereto. The presiding officer may, on its own motion, order live testimony. The presiding officer's basis for approving any motion for, or ordering on its own motion, live testimony shall be that taking live testimony would assist in its decision on the motion to set aside the immediate effectiveness of the order.

(iii) The NRC staff shall respond in writing within 5 days of the receipt of either a motion to set aside the immediate effectiveness of the order or the presiding officer's order denying a motion for live testimony. In cases in which the presiding officer orders live testimony, the staff may present its response through live testimony rather than a written response.

(iv) The presiding officer shall conduct any live testimony pursuant to its powers in § 2.319 of this part, except that no subpoenas, discovery, or referred rulings or certified questions to the Commission shall be permitted for this purpose.

(v) The presiding officer may, on motion by the staff or any other party to the proceeding, where good cause exists, delay the hearing on the immediately effective order at any time for such periods as are consistent with the due process rights of the licensee or other person and other affected parties.

(vi) The licensee or other person challenging the immediate effectiveness of an order bears the burden of going forward with evidence that the immediately effective order is not based on adequate evidence, but on mere suspicion, unfounded allegations, or error. The NRC staff bears the burden of persuading the presiding officer that adequate evidence supports the grounds for the immediately effective order and immediate effectiveness is warranted.

(vii) The presiding officer shall issue a decision on the motion to set aside the immediate effectiveness of the order expeditiously. During the pendency of the motion to set aside the immediate effectiveness of the order or at any other time, the presiding officer may not stay the immediate effectiveness of the order, either on its own motion, or upon motion of the licensee or other person.

(viii) The presiding officer shall uphold the immediate effectiveness of the order if it finds that there is adequate evidence to support immediate effectiveness. An order upholding immediate effectiveness will constitute the final agency action on immediate effectiveness. The presiding officer will promptly refer an order setting aside immediate effectiveness to the Commission and such order setting aside immediate effectiveness will not be effective pending further order of the Commission.

(d) An answer may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the licensee or other person to whom the order has been issued to the entry of an order shall constitute a waiver by the licensee or other person of a hearing, findings of fact and conclusions of law, and of all right to seek Commission and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the Commission, and shall be effective as provided in the order.

(e)(1) If the order involves the modification of a part 50 license and is a backfit, the requirements of § 50.109 of this chapter shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52 of this chapter, the requirements of § 52.98 of this chapter shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 of this chapter, the requirements of § 52.39 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63 of this chapter must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145 of this chapter must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52, the requirements of § 52.171 of this chapter must be followed, unless the applicant or licensee has consented to the action required.

10 C.F.R. § 2.205

Civil penalties.

(a) Before instituting any proceeding to impose a civil penalty under section 234 of the Act, the Executive Director for Operations or the Executive Director's designee, as appropriate, shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to § 2.201 or § 76.70(d) of this chapter. The notice of violation

shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged, and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, part 76 certificate of compliance or compliance plan, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the Commission, if any, unless compromised, remitted, or mitigated, be collected by civil action, pursuant to Section 234c of the Act.

(b) Within twenty (20) days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments, denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

(c) If the person charged with violation fails to answer within the time specified in paragraph (b) of this section, an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in paragraph (a) of this section.

(d) If the person charged with violation files an answer to the notice of violation, the Executive Director for Operations or the Executive Director's designee, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within twenty (20) days of the date of the order or other time specified in the order, request a hearing.

(e) If the person charged with violation requests a hearing, the Commission will issue an order designating the time and place of hearing.

(f) If a hearing is held, an order will be issued after the hearing by the presiding officer or the Commission dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

(g) The Executive Director for Operations or the Executive Director's designee, as appropriate may compromise any civil penalty, subject to the provisions of § 2.203.

(h) If the civil penalty is not compromised, or is not remitted by the Executive Director for Operations or the Executive Director's designee, as appropriate, the presiding officer, or the Commission, and if payment is not made within ten (10) days following either the service of the order described in paragraph (c) or (f) of this section, or the expiration of the time for requesting a hearing described in paragraph (d) of this section, the Executive Director for Operations or the Executive Director's designee, as appropriate, may refer the matter to the Attorney General for collection.

(i) Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the United States, following reference of the matter to the Attorney General for collection, payment of civil penalties imposed under Section 234 of the Act are to be made payable to the U.S. Nuclear Regulatory Commission, in U.S. funds, by check, draft, money order, credit card, or electronic funds transfer such as Automated Clearing House (ACH) using Electronic Data Interchange (EDI). Federal agencies may also make payment by the On-Line Payment and Collections System (OPAC's). All payments are to be made in accordance with the specific payment instructions provided with Notices of Violation that propose civil penalties and Orders Imposing Civil Monetary Penalties.

(j) Amount. A civil monetary penalty imposed under Section 234 of the Atomic Energy Act of 1954, as amended, or any other statute within the jurisdiction of the Commission that provides for the imposition of a civil penalty in an amount equal to the amount set forth in Section 234, may not exceed $303,471 for each violation. If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purposes of computing the applicable civil penalty.

10 C.F.R. § 2.804

Notice of proposed rulemaking.

(a) Except as provided by paragraph (d) of this section, when the Commission proposes to adopt, amend, or repeal a regulation, it will cause to be published in the Federal Register a notice of proposed rulemaking, unless all persons subject to the notice are named and either are personally served or otherwise have actual notice in accordance with law.

(b) The notice will include:

(1) Either the terms or substance of the proposed rule, or a specification of the subjects and issues involved;

(2) The manner and time within which interested members of the public may comment, and a statement that copies of comments may be examined will be made available at the NRC Web site, http://www.nrc.gov;

(3) The authority under which the regulation is proposed;

(4) The time, place, and nature of the public hearing, if any;

(5) If a hearing is to be held, designation of the presiding officer and any special directions for the conduct of the hearing; and

(6) Such explanatory statement as the Commission may consider appropriate.

(c) The publication or service of notice will be made not less than fifteen (15) days prior to the time fixed for hearing, if any, unless the Commission for good cause stated in the notice provides otherwise.

(d) The notice and comment provisions contained in paragraphs (a), (b), and (c) of this section will not be required to be applied —

(1) To interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(2) When the Commission for good cause finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest, and are not required by statute. This finding, and the reasons therefor, will

be incorporated into any rule issued without notice and comment for good cause.

(e) The Commission shall provide for a 30-day post-promulgation comment period for —

(1) Any rule adopted without notice and comment under the good cause exception on paragraph (d)(2) of this section where the basis is that notice and comment is "impracticable" or "contrary to the public interest."

(2) Any interpretative rule, or general statement of policy adopted without notice and comment under paragraph (d)(1) of this section, except for those cases for which the Commission finds that such procedures would serve no public interest, or would be so burdensome as to outweigh any foreseeable gain.

(f) For any post-promulgation comments received under paragraph (e) of this section, the Commission shall publish a statement in the Federal Register containing an evaluation of the significant comments and any revisions of the rule or policy statement made as a result of the comments and their evaluation.

10 C.F.R. § 20.1001

Purpose.

(a) The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission. These regulations are issued under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

(b) It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

10 C.F.R. § 20.1002

Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 35.75, or to exposure from voluntary participation in medical research programs.

10 C.F.R. § 20.1003 (excerpted)

Definitions.

…

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

10 C.F.R. § 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

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. § 20.2003

Disposal by release into sanitary sewerage.

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and

(2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction of the limit in table 3 of appendix B to part 20 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in table 3 of appendix B to part 20; and

(ii) The sum of the fractions for each radionuclide required by paragraph (a)(3)(i) of this section does not exceed unity; and

(4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (a) of this section.

10 C.F.R. § 20.2004

Treatment or disposal by incineration.

(a) A licensee may treat or dispose of licensed material by incineration only:

(1) As authorized by paragraph (b) of this section; or

(2) If the material is in a form and concentration specified in § 20.2005; or

(3) As specifically approved by the Commission pursuant to § 20.2002.

(b) (1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under part 50 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50 of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under §§ 50.34 and 50.34a of this chapter associated with this incineration pursuant to § 50.71 of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59 of this chapter with respect to such changes to the facility or procedures.

(2) Solid residues produced in the process of incinerating waste oils must be disposed of as provided by § 20.2001.

(3) The provisions of this section authorize onsite waste oil incineration under the terms of this section and supersede any provision in an individual plant license or technical specification that may be inconsistent.

10 C.F.R. § 20.2006

Transfer for disposal and manifests.

(a) The requirements of this section and appendix G to 10 CFR Part 20 are designed to—

(1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility (as defined in Part 61 of this chapter);

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to 10 CFR Part 20.

(c) Each shipment manifest must include a certification by the waste generator as specified in section II of appendix G to 10 CFR Part 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of appendix G to 10 CFR Part 20.

(e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of Byproduct material set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.

10 C.F.R. § 50.2 (excerpted)

Definitions.

…

Utilization facility means:

(1) Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U–233; or

(2) An accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50–608.

10 C.F.R. § 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.

(5) The Commission shall always require the backfitting of a facility if it determines that such 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.

(6) The documented evaluation required by paragraph (a)(4) of this section shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) Paragraph (a)(3) of this section shall not apply to backfits imposed prior to October 21, 1985.

(c) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) Potential impact on radiological exposure of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(d) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(e) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his designee.

10 C.F.R. § 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.