

Regulatory Framework for Fusion Machines Proposed Rule

Options Considered for Implementation of the ADVANCE Act Treatment of Particle Accelerators and Fusion Machines

This enclosure discusses the options, the staff considered, for the narrow purpose of implementing the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024, or ADVANCE Act's, treatment of particle accelerators and fusion machines. Specifically, the staff considered several options to address the distinction in the ADVANCE Act amendments to the Atomic Energy Act of 1954 (AEA) between fusion machines and other particle accelerators. Consistent with this aim, the staff's proposed option would distinguish fusion machines from other particle accelerators for separate regulatory treatment. This approach would establish the foundation for a fusion machine regulatory program and establish the guidance that should be followed for fusion machines.

Background on 10 CFR Part 30 Framework

The 10 CFR Part 30 regulatory framework provides requirements for the possession and use of byproduct material; however, it does not structure those requirements in the same terms as the AEA definitions of byproduct material, which are based on the origins, rather than the nature, of the material. For example, tritium is subject to requirements based on its use rather than whether it is 11e.(1) (fission-produced) or 11e.(3) (accelerator-produced) byproduct material. Fusion machines and other particle accelerator licensees are unusual byproduct material licensees because their activities/technology are both the AEA-cognizable origin of a byproduct material as well as a licensed activity (production and possession). Virtually all other 10 CFR Part 30 licensees take possession of byproduct material produced elsewhere; for those other licensees there is no overlap between the origin of byproduct material and the licensed activity.

The regulations in 10 CFR Part 30 categorize requirements based on how the material will be used, informed by assumptions about the types and quantities of material those uses entail. This approach provides regulatory clarity for applicants based on safety issues common to their particular uses. For the most part, applicants are expected to develop and justify the methods they will use to ensure safety (e.g., by meeting 10 CFR Part 20, "Standards for Protection Against Radiation"), and specific guidance for acceptable approaches is provided in the 21 volumes of NUREG-1556, "Consolidated Guidance About Materials Licenses."

The ADVANCE Act clarifies the definition of byproduct material produced through use of particle accelerators, recognizing two categories of particle accelerators as producers of byproduct material: (1) fusion machines and (2) other particle accelerators. The ADVANCE Act did not change the NRC's substantive authority to regulate the use and production of byproduct material. Further, the ADVANCE Act does not dictate what substantive safety requirements the NRC is authorized to establish for the material.¹ While the ADVANCE Act does not constrain the NRC's fundamental flexibility in this regard, it does establish certain definitions that the NRC must effectuate. Therefore, the draft proposed rule incorporates the definition of fusion machine and of byproduct material (as amended by the ADVANCE Act) and addresses the technical and practical considerations for safety.

¹ AEA sections 81–84 establish the NRC's authority to regulate the possession and use of byproduct material. The ADVANCE Act did not revise these sections.

Consistent with the overall approach of the 10 CFR Part 30 framework, the technology to be employed in a fusion machine or other particle accelerator's production, possession, and use of byproduct material provides the basis for determining which substantive requirements apply to those proposed activities. These substantive requirements are, in turn, informed by certain assumptions about the nature of the licensed activity and the associated radiological hazards (e.g., that many commercial fusion machines will possess and generate quantities of tritium significantly greater than other particle accelerators).

Under the pre-ADVANCE Act regulatory framework, particle accelerators were distinguished from other general 10 CFR Part 30 licensees only for two purposes: (1) to establish application requirements specifically for some production of Positron Emission Tomography radioactive drugs under 10 CFR 30.32(j), and (2) to provide guidance for particle accelerators in NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator." No substantive requirements in 10 CFR Part 30 use the term "particle accelerator." The proposed substantive safety guidance for fusion machines in draft NUREG-1556, Volume 22, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Fusion Machines," would instead reflect differences in how the general byproduct material safety requirements apply to the specific ways fusion machines are expected to operate. Thus, the staff's proposed rule would distinguish fusion machines from other particle accelerators, with specific fusion machine application requirements and specific fusion machine guidance.

The staff considered the following options for integrating fusion machines, as defined by the ADVANCE Act, into the draft proposed rule for the 10 CFR Part 30 regulatory framework. The staff recommends Option 1b, which is reflected in the draft proposed rule, as the most efficient and effective means of delivering viable proposed rule language to the Commission and to stakeholders for public comment with focused, limited changes to effectuate the Commission's direction and the ADVANCE Act. The staff expects there will be opportunities to consider other alternatives and make adjustments, as appropriate, when developing the final rule.

Option 1: Distinguish Fusion Machines from Other Particle Accelerators in Regulatory Definitions

Under this option, the proposed rule would distinguish fusion machines from other types of particle accelerators in the regulatory definitions of "particle accelerator" or "fusion machine" (in 10 CFR Parts 20, 30 and 110) to denote differing regulatory treatment. There are multiple ways to achieve this which are described in sub-options 1a, 1b, and 1c.

Pros:

- Option 1 would ensure that the scope of the rulemaking remains limited to fusion machines and does not affect other licensees.
- The distinction between the two definitions provides clarity that the guidance for particle accelerators (NUREG-1556, Volume 21) is not to be used for fusion machines.
- Option 1 would not require changes to the existing regulatory framework for non-fusion machine particle accelerators.
- Distinguishing the definitions minimizes the impact on industry and Agreement States so that no fusion machines or particle accelerators licensed prior to this rule's effective date (or equivalent Agreement State rules' effective dates) are affected.

- Option 1 would present a regulatory structure that would allow for future 10 CFR Parts to be created with minimal disruption for particle accelerators (other than fusion machines) and fusion machines.

Cons:

- There is risk of perception that the NRC did not precisely follow the ADVANCE Act because the treatment of fusion machines is not identical to the text in the ADVANCE Act (although clear explanations in the preamble can help mitigate this con by showing the substantive meaning is the same).

Option 1a.: *Exclusion of fusion machine from the term particle accelerator as discussed at the August 14, 2024, public meeting (“For the purposes of this part, the term particle accelerator does not include fusion machines.”)²*

Pros: This phrasing provides regulatory clarity and uses plain language.

Cons: This phrasing does not parallel the ADVANCE Act’s treatment of fusion machines as a subset of particle accelerators. There is risk of perception that the NRC did not precisely follow the ADVANCE Act.

Option 1b.: *Distinguishing fusion machine from the term particle accelerator as described in the proposed rule (e.g., “For the purposes of this part, the term particle accelerator refers only to particle accelerators that are not fusion machines.”)*

Pros: This phrasing more closely parallels the ADVANCE Act definition. Option 1b delivers viable proposed rule language to the Commission and to stakeholders for public comment with focused, limited changes to effectuate the Commission’s direction and the ADVANCE Act.

Cons: This phrasing does not parallel the ADVANCE Act’s treatment of fusion machines as a subset of particle accelerators. There remains a risk of perception that the NRC did not precisely follow the ADVANCE Act; this risk is lower than for Option 1a because this approach acknowledges that fusion machines would otherwise be included as a subset of particle accelerators.

Option 1c.: *Move exclusion from the particle accelerator definition to the definition of fusion machine (e.g., “In this part, fusion machines are not subject to the requirements for other types of particle accelerators.”)*

Pros: Locating the exclusion under the fusion machine definition avoids potential confusion about how the NRC is addressing the ADVANCE Act’s treatment of fusion machines and particle accelerators.

Cons: This phrasing includes a substantive regulatory effect in a definition. It is also less clear than if the distinction were made under the particle accelerator definition. There remains a risk of perception that the NRC did not precisely follow the ADVANCE Act; this risk is lower than Options 1a or 1b because this approach acknowledges that fusion

² The staff introduced the original proposed revision to the particle accelerator definition at a public meeting on August 14, 2024 (Agencywide Documents Access and Management System Accession No. ML24207A024).

machines are a subset of particle accelerators and does not revise the definition of particle accelerator to exclude fusion machines.

Option 2: Include fusion machines in the existing regulatory definition of particle accelerator (e.g., “Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt, including fusion machines. For purposes of this definition, accelerator is an equivalent term.”)

Pros:

- Adding "including fusion machines" to the existing particle accelerator definition semantically parallels the definitions amended by the ADVANCE Act.

Cons:

- This option would increase the level of effort for Agreement States—States participated in the pre-ADVANCE Act development of the draft rule with the understanding that fusion machines would be subject to wholly new and separate requirements with distinct guidance. Some Agreement States may need to distinguish between accelerators and fusion machines (e.g., for State statute reasons). Thus, this approach may have unintended consequences for the states and would require additional outreach/engagement with States to explore the implications.
- The implications for the Agreement States that do not want to regulate fusion machines are unknown: If fusion machines are subject to requirements for particle accelerators, it may be challenging to parse this authority. Additional time may be needed to determine these potential impacts and whether they can be mitigated.
- This option would require significant effort to revise the discussion in the draft *Federal Register* notice to explain how the regulatory framework for fusion machines is both the same as and different from particle accelerators; it also would require revisions to existing guidance for particle accelerators to exclude fusion machines. Opening an additional NUREG specifically written for licensing accelerators—even if limited in scope to excluding fusion machines—would require additional time and resources to revise, process, and respond to comments.

Option 3: No change to existing particle accelerator definition, regulations, or guidance and make the distinction between fusion machines and other particle accelerators as an interpretation of the existing regulations and guidance

Revise the preamble and SECY to clearly express the NRC’s intent that fusion machines are subject only to regulations specific to fusion machines and that, therefore, only the new specific guidance for fusion machines in NUREG-1556, Volume 22, applies to fusion machines.

Pros

- This option would avoid changes to the existing regulatory framework for particle accelerators.

Cons

- Maintaining the existing definitions without changes would require information outside the regulations and guidance to properly interpret regulatory requirements for fusion machines.

- This approach lacks regulatory clarity and potentially results in uncertainty for applicants and staff.
 - This approach would increase the coordination needed with Agreement State regulators to ensure regulatory consistency across the National Materials Program.
- This option would increase the level of effort for the Agreement States to implement compatible interpretations.
- There is some risk of perception that the NRC did not precisely follow the approach in the ADVANCE Act; this risk could be mitigated by clear explanation in the preamble.