March 25, 2021

Helion Energy

William Reckley
Senior Project Manager
Division of Advanced Reactors &
Non-Power Production and Utilization Facilities
Office of Nuclear Reactor Regulation

SUBJECT: Developing a Graded Approach to Fusion Regulation

Mr. Reckley,

Helion Energy, Inc. ("Helion") sincerely appreciates the work undertaken by the U.S. Nuclear Regulatory Commission ("NRC") staff to engage with the fusion community as it seeks to develop a regulatory framework for fusion power devices. Recent advancements in fusion energy research bring its promise of abundant, clean, and safe energy finally within reach. It is critical that fusion power is regulated in a manner that promotes the public health and safety, while recognizing the significant safety benefits fusion has to offer and the needs of the fusion community for flexibility as it continues to iterate and develop. We respectfully offer the following comments to build off the productive discussion at the January 26, 2021 virtual workshop (January Fusion Workshop), and to help lay the groundwork for future engagement.

In particular, we understand that the NRC staff is seeking feedback on the fundamental approach to regulating fusion, given that it is a new technology not explicitly addressed in the NRC's current regulatory framework. We agree with the NRC staff's suggestion that a hybrid, graded approach to fusion regulation ("graded approach") complements the diversity of technologies and directions that define this emerging industry, and enables the NRC to right size its regulatory requirements to fit the technology and safety case of the facility. To promote discussion in the upcoming public meetings, this letter touches on the following topics:

- The vast diversity of fusion technologies under development, and applications in industry and power generation, requires a graded approach as a practical matter.
- A graded approach aligns with NRC best practices. It is risk-informed and performance based, includes state partners, and is built for the long-term.
- The NRC staff could leverage the illustrative tiered approach Helion presented in January in evaluating a potential graded regulatory framework. It should start off recognizing that fusion devices are similar to accelerators rather than fission reactors. It can also leverage performance-based concepts to divide between the different tiers, with different licensing processes within each tiers.

If the NRC staff agrees that a graded approach is the best path forward, future discussions should build out this concept further, sufficient to enable the staff to present a path forward to the Commission by year-end, for a rulemaking concluding by 2027.

I. THE DIVERSITY OF FUSION CONCEPTS REQUIRES A GRADED APPROACH TO REGULATION

Imagine trying to develop a single regulatory framework for all uses of radioactive materials—from small moisture density gauges, to fuel fabrication and enrichment facilities, to small research reactors at universities, to large light-water reactors and non-light water advanced reactors for power generation. The challenge there would not be unlike regulating fusion. "Fusion" is not a single power generation concept, it is a field of physics with countless and yet-to-be-discovered possibilities. And just like how Congress and the NRC rightfully decided to regulate the various uses of radioactive materials under different frameworks—with graded increases in regulatory burdens commensurate with the risks—the same approach only makes sense here.

To illustrate this scope, fusion technologies can range from small neutron generators for industrial use, such as those manufactured by Phoenix, LLC today; to the research and test devices currently under development by the fusion community; to small power devices using aneutronic fuels potentially on the horizon; to large projects like the International Thermonuclear Experimental Reactor ("ITER") 500 MW tokamak fusion device currently under construction or the 2000 MW DEMOnstration Power Station ("DEMO") planned for the future—and everything in between. Even within just the power generation space, fusion approaches vary significantly in terms of the type of plasma confinement (e.g., magnetic, inertial, magneto-inertial), scale, energy extraction methods, and fuel type. The latter variable—fuel type—particularly impacts radiological consequences, although many of the design variants carry with them different regulatory implications. Some of these devices will also fabricate fuel within the same plant or at nearby facility. Dr. Derek Sutherland's diagram of the fusion power technologies under development today, from the January Fusion Workshop, hints at the diversity of technologies being explored at just the dawn of the fusion age (see Appendix A).

As a result, the NRC needs to embrace a graded regulatory approach commensurate with the wide range of impacts different fusion devices could have, and that further recognizes that fusion is not fission. Under a graded approach, the NRC could leverage its existing framework for smaller-scale or lower impact facilities, maintaining the existing state oversight of the accelerator and NRC/Agreement State oversight of related radioactive materials, with scaling regulatory requirements for facilities that could have more significant impacts—bookending with something akin to ITER or DEMO on the upper end of the spectrum (although we note that no commercial U.S. fusion company currently intends to build facilities like ITER or DEMO). Part II of this letter further discusses how a graded approach aligns with NRC best practices and is built for the long-term. But beyond those reasons, it may well be the only approach that technically makes sense for fusion.

This begs the question – what is a "graded" approach? Although Part III of this letter discusses this in more detail, to add some color on this topic, in the January Fusion Workshop Helion introduced an illustrative concept for a simple, 3-tiered graded approach to fusion regulation, with performance-based dividing lines between the tiers (see Appendices B and C). Such a multi-tiered concept can prove a workable solution to implementing a graded approach to fusion regulation.

II. A GRADED APPROACH TO FUSION REGULATION ALIGNS WITH NRC BEST PRACTICES

A graded approach to fusion regulation aligns with the NRC's recent activities to move towards a risk-informed and performance-based regulatory approach for licensing innovative technologies. It also enables states to serve as regulatory partners with the NRC where appropriate, and is adaptable and built for the long-term.

- **A Graded Approach Is Risk-Informed:** As part of the NRC's Transformation Initiative, the agency has made great strides in the conversion to a modern, risk-informed regulator. As part of this initiative, the NRC should embrace this unique opportunity to risk-inform the regulation of fusion from the very outset.

  And to that end, a graded approach for fusion is fundamentally the risk-informed choice. A risk-informed regulation is a regulation that balances regulatory burdens to the safety significance of the harm trying to be controlled. However, beyond just risk-informing individual regulations within a single one-size-fits-all framework, a graded approach to fusion regulation takes risk-informed regulation one step further. It would allow the agency to establish different regulatory tiers, each with different expectations, processes and timelines for licensing fusion devices, commensurate with the vastly different risk levels of those devices. A graded approach to fusion thus allows for the NRC to align the level of regulation with the level of risk in a more fundamental manner than would be possible in a one-size-fits-all approach.

- **A Graded Approach Is Performance Based:** Along with being risk-informed, the NRC appropriately prides itself on its move to performance-based regulation. A performance-based regulatory framework sets forth clear objectives to meet, and leaves the applicant freedom as to how to achieve that objective. The NRC has made significant strides in becoming a performance-based regulator, such as through the Reactor Oversight Process, implementation of performance based concepts in 10 CFR 50.65 and in 10 CFR Parts 60 and 61, and now within the new Part 53 rulemaking.

  To this end, a graded approach to fusion regulation aligns with performance-based approaches. Indeed, the diversity of fusion designs alone makes it difficult to apply anything else. The fact that each device under consideration today looks and acts differently, and that there are so many alternatives, makes it challenging to try to regulate to each technology under deterministic approaches. Instead, a graded approach allows the NRC to set forth clear performance requirements within each tier, that if met entail a materially different approach to regulating fusion devices within each tier.

- **A Graded Approach Recognizes the Role State Partners Can Play:** States are the experts today in accelerator regulation. From proton beams in hospitals, to Phoenix's neutron generators, to the large 70 MeV medical cyclotrons that support medical isotope producers, to the current fusion experimental facilities such as DIII-D in California, states have decades of experience in the regulation of accelerators including fusion devices. States regulate accelerators with very significant radiological consequences. Certain state-regulated accelerators require meters of shielding, and have in place very strict safety protocols to handle the device and activated materials produced.

The states are already regulating the use of particle accelerators used in research and industrial applications. For example, Washington State University has a Positron Annihilation Spectrometer used for material research at temperatures from 100K to 1300K. The University of Washington has a cyclotron used for patient irradiation and providing beam lines for research. These higher energy facilities are capable of generating neutrons which increases the need for additional shielding over that required for x-ray production. The UW machine is actually designed for fast neutron therapy resulting in significant neutron shielding. The Van de Graaff accelerator at UW can accelerate hydrogen and helium atoms to energies up to 7.5 MeV. All of these are registered and regulated by the State of Washington Department of Health. State regulators have demonstrated competency in regulating devices that can require over a meter of shielding, automatic machine cutoffs, exclusion areas, access controls, and significant safeguards over fugitive emissions and leaks, among other safety protections. This is all in addition to the variety of large devices using radioactive materials—including nuclear irradiators that can hold millions of curies of radioactive materials,[1] and significant quantities of radioisotopes produced by large cyclotrons—which are regulated by states today.

As the representative from the Wisconsin Department of Health Services stated in the January Fusion Workshop, states already have a role in the regulation of fusion, and they expect that they will continue to have one. Indeed, as the Wisconsin nuclear regulator noted, they are regulating fusion devices now. There is no need for them to cease to continue this work moving forward, especially for less impactful facilities. Instead, a graded approach leaves room for states to regulate devices that meet certain radiological significance thresholds, in line with their experience and expertise, and gives a chance for the NRC to smoothly transition at the right time. It also allows for better knowledge transfer between states and the NRC, given that states have had the lead role in accelerator regulation to date. This process best provides for adequate protection of the public health and safety.

- **A Graded Approach Is Adaptable and Built for the Long Term:** There are two things most everyone can agree on when it comes to the topic of fusion regulation. The first is that we do not know the future, especially for something as complex as fusion. The second is that while the NRC needs to plan for a regulatory framework for the technologies that appear the most imminent, we nonetheless do not want to be developing new regulatory frameworks every time a new technology emerges.

  The challenge for the NRC in developing a bounding framework around fusion, before it has even seen a fusion application, is immense. The challenge extends not only to the variety of technologies being explored, but also to the scale of deployment. The NRC has the unenvious task of developing a framework for regulating fusion that has in place sufficient safeguards for operation of an ITER-type facility, while also being flexible enough to enable the efficient and risk-informed licensing of more widespread low-impact fusion devices. A graded approach is perhaps the only way to cover such a broad spectrum of scenarios. It is also a framework

[1] NRC Fact Sheet, Commercial Irradiators (Apr. 2004).

that allows for more adjustability between tiers as circumstances change and fusion technologies evolve.

III. CONSIDERATIONS FOR DEVELOPING A GRADED APPROACH TO FUSION REGULATION

A key challenge for the NRC going forward will be how to develop a graded approach to fusion regulation, and there are no illusions that this will be an easy task—even if it is easier than the alternatives. To help foster discussion, in the January Fusion Workshop Helion introduced an illustrative concept for a multi-tiered, graded approach to fusion regulation (see Appendix B). Each tier would essentially entail a different sub-framework for regulating devices within the tier (e.g., state licensing of low-impact devices, and NRC licensing of high-impact devices), but with guidance or requirements that could apply on an overarching basis (e.g., practices for managing airborne tritium releases).

This framework was meant to simply assist in discussion, but it and the surrounding January discussion touched on important elements to consider. We discuss these briefly below to help provide some color on how a graded approach to fusion regulation may work.

- **A Graded Approach Should Recognize that Fusion Devices are Accelerators and Work Up—Not that Fusion Devices are Fission Reactors and Work Down:** In our January Fusion Workshop, in response to earlier inquiries by the NRC staff, we posited that fusion devices are more like particle accelerators than fission reactors.

  This is evident from a reading of how the NRC defines the term accelerator. Per the NRC's rulemaking implementing aspects of the Energy Policy Act of 2005, the agency defined an accelerator to be a "device that imparts <u>kinetic energy</u> to <u>subatomic particles</u> by increasing their speed through <u>electromagnetic interactions</u>."[2] Fusion devices easily fall within those terms.

  - First, all fusion devices impart kinetic energy into subatomic particles, as they raise the temperature of the particles to fusion conditions (e.g., 100 to 200 million Kelvin, or 10-20 keV, for a deuterium-tritium process).[3] This increase in temperature/kinetic energy is accomplished fundamentally by increasing the speed of the particles.

  - Second, all fusion devices work with subatomic particles, specifically the nucleus of the atoms that are fusing within the plasma.

  - Third, all fusion devices accomplish this increase in kinetic energy through electromagnetic interactions. Even inertial fusion devices use electromagnetic radiation or electromagnetic fields to compress the ions to fusion temperatures,[4] even if physical forces are used to help drive the magnetic force.

---

[2] Requirements for Expanded Definition of Byproduct Material, 72 Fed. Reg. 55,864, 55,868 (Oct. 1, 2007) (emphasis added).

[3] Temperature and kinetic energy are equivalent concepts. Indeed, in the fusion space the temperatures that fusion devices reach are referenced in terms of Kelvin, electron Volts, and meters per second interchangeably.

[4] For example, the National Ignition Facility uses photons to provide the pressure on the fusion target. *See* How NIF Works, Lawrence Livermore National Laboratory.

The NRC's definition of accelerators in 10 CFR 30.4 likewise captures fusion devices. This definition is taken from state definitions of the term, and the states themselves have been capturing fusion devices under this definition for years.

This should be compared with how fusion devices otherwise fit within the definition of a nuclear reactor. The NRC defines a "nuclear reactor" as an "apparatus . . . designed or used to sustain <u>nuclear fission in a self-supporting chain reaction</u>." 10 CFR 50.2 (emphasis added). Given the explicit connection of nuclear reactors to fission processes, fusion devices fall far more readily on first principles within the category of accelerators than reactors. Accordingly, the current definition of nuclear reactor does not cover fusion, and the general definition of "utilization facility" does not cover any fusion devices unless they are tied to a fission process.

From a technical perspective as well, low-impact fusion devices can have similar risk profiles to accelerators and other devices states regulate today. States are well-versed in regulating accelerators and other facilities with significant radiological implications. For example, the Van de Graaff generator at the University of Washington was built in 1966, giving the State of Washington over a half century of experience in regulating a high energy accelerator. The cyclotron was built in the 1980s giving the state extensive experience in regulating an accelerator designed to produce neutrons. With more and more oncology departments switching from traditional therapy using Co-60 and Cs-137 beams to using linear accelerators, the states are developing stronger and more diversified experience in the regulation and control of these devices.

Understanding the similarities between fusion devices and accelerators is helpful from a legal perspective as it justifies state involvement in this area under current statutory authorities. <u>But it is also as helpful for level-setting</u>. We should not start by looking at fusion devices as fission reactors and trying to bring the level of requirements down. This is not risk-informed thinking, and does a disservice to the potential of this industry and decades of state experience in regulation. Given the mismatch between fission and fusion in many areas, it is also probably more work in the end. Instead, the conversation should start with recognizing that fusion devices are types of accelerators or very similar to accelerators, and asking ourselves—when do the safety consequences of fusion rise to a level where direct federal involvement is warranted? This approach is fundamentally risk-informed.

This approach also gives states a role they deserve in licensing of fusion devices, as they are essentially the current regulators. Under a graded approach that recognizes that fusion devices are similar to accelerators, the NRC has the flexibility to let states take the lead in regulating low-impact and demonstration devices to the extent they are comfortable doing so, while only taking control when the safety case warrants it. The NRC can leverage its higher-tier regulatory framework to provide guidance as states request it.

- **A Graded Approach Can Implement Performance-Based Dividing Lines:** An issue with any graded/tiered framework is how to divide between the tiers. To help foster discussion, in our January Fusion Workshop we suggested some performance-based factors to divide between tiers in a graded framework, based on fundamental nuclear safety concepts (see

Appendix C). To illustrate how such factors may be applied and further discussion, below are four sample factors that could form the basis of a comprehensive, performance-based threshold to divide between different framework tiers in a graded system.

Potential Factors To Divide Tiers	Sample Performance-Based Threshold
Accident Risk	• A device may be eligible for a lower tier of regulation if its accident risk falls below the ~1 rem public dose threshold requiring off-site evacuation/sheltering plans, in the case of a total release of non-bound fuel and exhaust inventory and any other easily releasable waste inventory. In addition, any residual heat from the device post-shutoff must be below a threshold that permits passive management with a high margin of safety.
Shielding & Safety During Operations	• A device may be eligible for a lower tier of regulation if it can leverage only low-complexity, passive shielding during operation to meet radiological health and safety requirements.
Waste	• A device may be eligible for a lower tier of regulation if it only generates and stores waste suitable for disposal in a commercial low level radioactive waste facility.
Proliferation Risk	• A device may be eligible for a lower tier of regulation if it does not have a reasonable path for generating significant quantities of special nuclear material if operated as intended and with low-complexity, and/or passive security protections in place.

- **A Graded Approach Should Consider Differences in *Process* As Much As Substance:** While there may well be a need to consider different substantive expectations for devices in different tiers in a graded approach, a key difference between the tiers should be the expected level of process required to demonstrate compliance. This is similar conceptually to how research and non-power reactors need to meet certain similar substantive requirements as power reactors, but go through a different process to get there. In this context, if a fusion device meets the required performance-based threshold to fall within a certain tier, the amount of work the applicant needs to do to demonstrate adequate protection can scale with that performance expectation. For example:

  - Low-impact fusion devices that have safety profiles akin to devices states regulate today may be able to fall within a regulatory tier in which states lead in licensing reviews, simplifying licensing compared to a one-size fits all federal approach.

  - Low-impact fusion devices that fall within a certain tier in a graded approach can potentially be licensed without probabilistic risk analyses, leading to a far less technically complex application.

  - While fusion devices within one tier may have offsite consequences that need to be evaluated in a license application, fusion devices within a lower tier that is pre-determined not to involve offsite consequences can avoid the need for any such analyses, leading to a shorter application.

The challenge with appropriate regulation is not just substance. It is often the licensing process where the rubber meets the road. A graded approach that aligns risks with procedural requirements risk-informs the regulatory process and results in a significantly more efficient process that also enhances public safety.

IV. Suggested Next Steps

Given the opportunities a hybrid, graded approach for fusion regulation offers, we suggest that future meetings explore this topic further, with a goal to identify and resolve any pending issues before the end of the year:

- **Build out the technical framework sufficient for the end-of-year paper to the Commission:** If the NRC staff agrees in the end that a graded approach is the best path forward, it would be helpful to understand what it needs (and doesn't need) from a technical and policy perspective to move forward proposing a graded approach for Commission approval at the end of the year. Future meetings can then focus on resolving these issues.

- **Identify the legal path forward to implement the right policy:** We believe that the Atomic Energy Act as currently drafted gives the NRC significant flexibility to develop a graded approach that meets many or all of the above suggestions. At the same time, we recognize that challenges exist with any complex issue, and there may be opportunities for further legal evaluation and even for Congress to provide clarity. We suggest that as opposed to going to Congress for a blanket ask for a "fusion regulatory framework," it may be easier for the NRC to use upcoming meetings to identify what is the best framework for regulating fusion from a technical and policy perspective, and then see where there are targeted legal or other gaps where Congress can help.

- **Build out a timeline that results in a rulemaking by 2027:** Given the challenges to regulating fusion, using the full time available under NEIMA would enable the NRC to craft the best rule possible. Fitting fusion into the current Part 53 rulemaking also does not appear ideal given the tighter timeline and fundamentally different regulatory strategy that a graded approach may require. There does not appear to be a safety basis for advancing any regulatory determinations before 2027. Nonetheless, it could be useful to spend some time in future meetings understanding the regulatory process and expectations getting from here to 2027.

*   *   *   *   *

We look forward to continuing to work with you on this important topic. Please let us know if you have any questions.

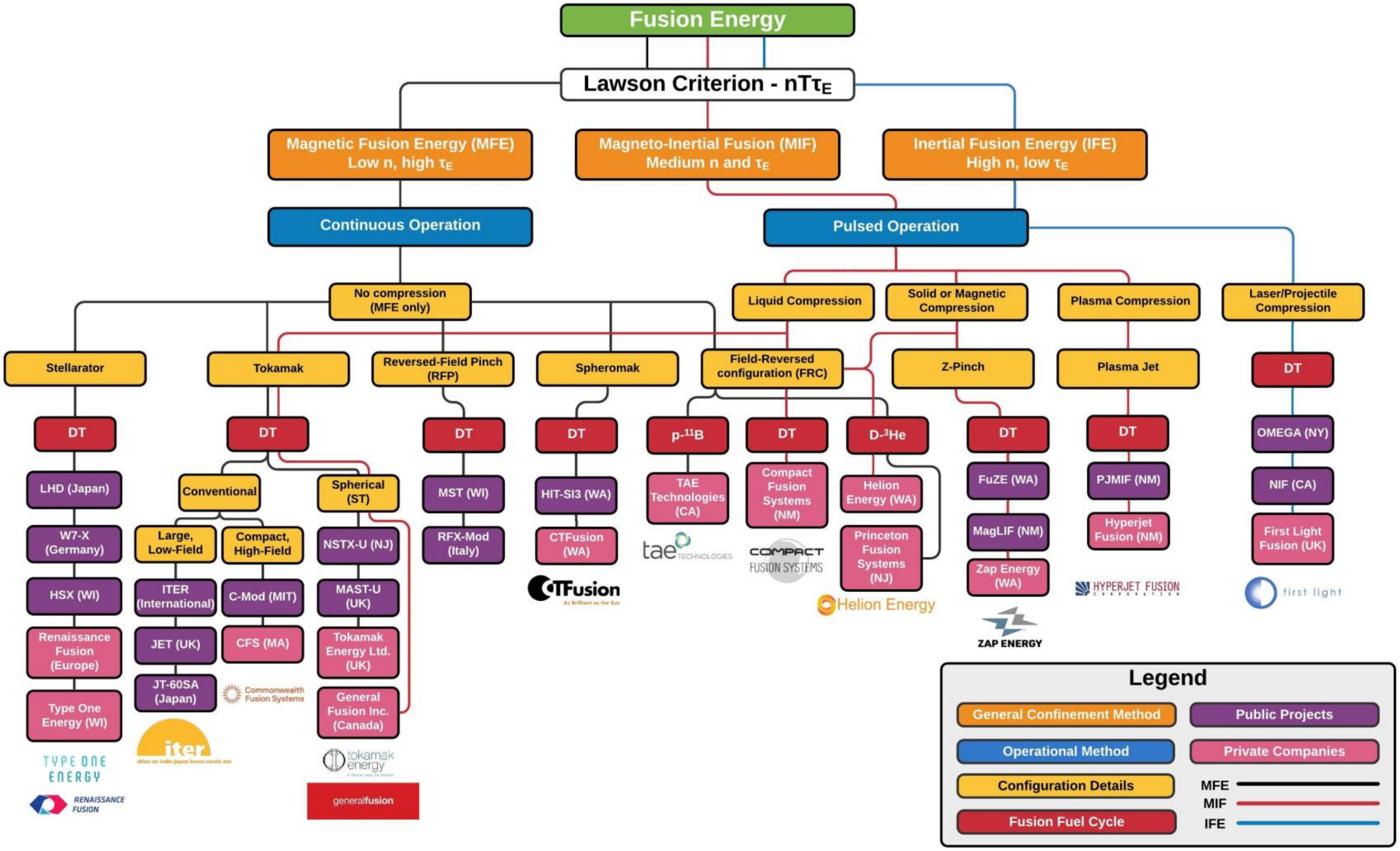
David Kirtley

David Kirtley
Chief Executive Officer
Helion Energy, Inc.

Cc: Scott Krisiloff, Helion Energy, Inc.
      Amy Roma, Hogan Lovells US LLP
      Sachin Desai, Hogan Lovells US LLP

Appendix A

Partial Fusion Energy Landscape



Source: January Workshop Fusion Presentation by Dr. Derek Sutherland, CT Fusion

Appendix B

Illustrative Graded, Tiered Approach to Fusion Regulation

Tier 1 — **No NRC Regulation of R&D**

- Industry is here. No real radiological risk from current R&D work.
- Although no formal NRC regulation of fusion, NRC principles still heavily guide and inform state regulatory frameworks.

Tier 2 — **State-Led Accelerator Framework**

- Industry is heading here, and needs room for innovation.
- Legally fusion devices fall under the "accelerator" definition.
- Technically demo devices and low-impact devices appear to pose no greater risk than current commercial accelerators.
- NRC can assist and guide state regulatory programs.

Tier 3 — **NRC Enhanced Regulation**

- Applicable to large-scale commercial devices if their radiological risk profiles run outside what states are able to regulate.
- Would likely need new regulatory regime.

Appendix C

<u>Illustrative List of Performance-Based Criteria for Determining Regulatory Tiers</u>