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The Regulation of Fusion – A Practical and Innovation-Friendly Approach

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Amy C. Roma and Sachin S. Desai

AUTHORS

Amy C. Roma
Partner, Washington, D.C.
T +1 202 637 6831
amy.roma@hoganlovells.com

Sachin S. Desai
Senior Associate, Washington, D.C.
T +1 202 637 3671
sachin.desai@hoganlovells.com

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TABLE OF CONTENTS

I. EXECUTIVE SUMMARY 1

II. THE STATE OF FUSION INNOVATION 3

A) An Introduction to Fusion Energy 3
B) A Rapid Growth in Private-Sector Fusion Innovation 4

III. U.S. REGULATION OF ATOMIC ENERGY - NOT ONE SIZE FITS ALL 7

A) The Foundation of U.S. Nuclear Regulation - The Atomic Energy Act and the NRC 7
B) The Atomic Energy Act Embraces Different Regulations for Different Situations 7
1. NRC Frameworks for Different Safety Cases 8
2. Delegation of Regulatory Authority to States 9

IV. THE REGULATION OF FUSION - A PRACTICAL AND INNOVATION-FRIENDLY APPROACH 10

A) Fusion Regulation Comes to the Fore, Raising Key Questions 10
B) A Regulatory Proposal That Recognizes the Safety Case of Fusion and the Needs of Fusion Innovators 11
1. Near-Term: Regulation of Fusion Under the Part 30 Framework is Appropriate Through Development and Demonstration 11
2. Long-Term: The NRC Should Develop an Independent Regulatory Framework for Fusion at Commercial Scale, Not Adopt a Fission Framework 12

V. CONCLUSION 14

I. EXECUTIVE SUMMARY

Fusion, the process that powers the Sun, has long been seen as the "holy grail" of energy production. In contrast with fission, which splits apart atoms in a nuclear reactor, fusion literally fuses hydrogen atoms together, releasing immense amounts of carbon-free energy in the process, with no spent nuclear fuel or risk of a runaway chain reaction.

The long-running popular belief has been that fusion power on a commercial scale, while promising to be just around the corner, has always been decades away. Yet this ignores that the U.S. is now in a nuclear innovation renaissance, building upon substantial R&D investments and technology advancements over the last seventy years. Now, more than at any point in history, break-even fusion energy production seems achievable within a decade, with commercial-scale fusion generation available sometime within the next decade or two. Multiple fusion ventures have emerged in the U.S. that strive to actualize the elusive promises of the energy of the future by bringing to market cost-competitive, carbon-free power that will raise the global standard of living and halt climate change. Companies are now looking to develop ever-more advanced testing and demonstration facilities, laying the groundwork for eventual commercial deployment.

We have therefore reached a critical juncture in the commercial fusion creation story, as we now must ask: *how is it—and how should it be—regulated*?

Fusion innovation is still marked by extreme diversity in approach, as numerous technologies and methods are being explored. This document provides an initial introduction to fusion energy and the nuclear regulatory considerations that could affect the development, demonstration, and eventual commercial deployment of fusion facilities. It also proposes a high-level approach the U.S. Nuclear Regulatory Commission (NRC) should take to regulating fusion.

Most fusion technologies are already regulated by the NRC under the Atomic Energy Act (AEA), based solely on the fact that they consume or generate tritium, a radioactive material known as "byproduct material" that is regulated by the NRC. However, being "regulated" under the AEA does not mean that any future fusion facility must be regulated like a nuclear power plant, nor should it. While fission and fusion both produce energy, they actually involve quite different processes and technologies.

The NRC manages many frameworks under which a wide variety of radioactive materials are regulated, with a fission-based nuclear reactor framework being the most stringent. But for every one reactor license managed by the agency, the NRC, or states acting under authority delegated by the NRC (known as Agreement States), manage thousands of radioactive materials licenses (also known as byproduct materials licenses) that are subject to significantly less onerous regulatory requirements than are nuclear power plants. The regulatory category that fusion facilities ultimately find themselves in will greatly affect their overall regulatory burden, including time to market and regulatory fees—that is, the cost the industry needs to pay the NRC to be regulated.

What framework the NRC elects to apply should depend on the safety case for the system. Given the role fusion energy can play in transforming the world—and the ways an unnecessarily burdensome regulatory framework can set back a ground-breaking but nascent industry—the NRC should take a risk-informed and thoughtful approach both to *near* and *long*-term regulation of the industry at this critical inflection point, and it should not presume to regulate fusion like it has regulated fission.

Recommendations

- **Near-Term Regulation:** Current efforts to develop and demonstrate fusion energy are regulated under the "Part 30" radioactive materials framework. This framework has allowed innovation to proceed while still promoting the public health and safety. This stage of fusion development is marked by rapid advancement and very limited radiological concern—inventories of tritium are low to nonexistent (depending on fuel type and stage), and tests are of brief duration and extremely low duty cycles. The radiological risks at this stage are minor and do not present any unique concerns that the NRC or states operating under delegated NRC authority are unfamiliar with.

  As a result, the current radioactive materials regulatory framework in 10 CFR Part 30, or as implemented by an Agreement State where applicable, is appropriate for the development and demonstration of fusion energy.

- **Long-Term Regulation:** The safety concerns associated with fission (e.g., avoiding supercriticality, core cooling) are fundamentally different from those of fusion (e.g., magnetic quenching, tritium management), making it very unlikely that a fission-based framework could be effectively ported over to fusion without most of the framework having to be rewritten—a long and arduous process that could hurt fusion commercialization. Moreover, whereas fission reactors always need to use a fissile fuel, a regulatory framework for fusion must consider that fusion technologies may make use of different fuel types, requiring a regulatory framework that can scale its requirements accordingly with the very different safety cases associated with the different fuels.

  As a result, it should not be presumed that higher levels of regulation, akin to that of fission reactors, are needed for commercial-scale fusion. The NRC should first evaluate whether additional regulation beyond the Part 30 framework is necessary for commercial-scale fusion energy. If the analysis thereafter calls for closer regulation, the NRC should develop an independent regulatory framework for fusion in collaboration with industry and the public—not apply a fission-based framework to fusion energy.

II. THE STATE OF FUSION INNOVATION

A. An Introduction to Fusion Energy

Fusion has long been seen as a key technology to transforming our energy industry, and human civilization as a whole. It has the potential to significantly address climate change, provide clean power to the approximately one billion people with limited or no access to power, and enhance human progress on Earth and in space. At its simplest, fusion is the process of combining two low-mass elements together (commonly two hydrogen atoms), to produce a heavier element (commonly helium), and releasing energy in the process. This is different from fission, a process which breaks apart a very heavy element—in particular Uranium 235—and also releases energy in the process. Although fusion is similar to fission in that both involve physics at the atomic level, the technology and considerations involved could not be more different, as this paper explores below.[1] Fusion energy is a potential game-changer for energy production because it is capable of providing an effectively unlimited supply of zero-carbon, clean energy using common elements—without producing any of the long-lived radioactive waste associated with generating energy from Uranium—or any risk of a runaway chain reaction. The ability to use hydrogen and other common elements as a fuel makes fusion energy theoretically available anywhere, even as a form of propulsion in outer space.[2]

The Sun drives fusion through gravity, as the sheer mass of the Sun applies immense pressure on the hydrogen atoms at the center, so that they fuse naturally into helium. Gravity-based fusion is not possible on Earth, and thus researchers funded by various governments have been studying for decades how to replicate a similar set of conditions using separate approaches, in particular: (1) using magnets to confine the hydrogen, which is heated to its plasma state where its constituent charged nuclei and electrons are subject to magnetic forces (magnetic confinement fusion); and (2) driving charged particles together using momentum to compress and heat the hydrogen fuel to fusion-relevant conditions (inertial confinement fusion).

The quintessential example of magnetic confinement fusion is the "tokamak," a torus (i.e., doughnut)-shaped object that keeps the hydrogen (in the form of a plasma) confined to a loop defined by magnetic field lines, while various methods, including radio-frequency heating and neutral beam injection, are used to heat the fuel to high temperatures.[3] The quintessential example of inertial confinement fusion is the National Ignition Facility, which uses 192 lasers to heat and compress a hydrogen-bearing pellet from all directions to fusion conditions.[4] All these approaches seek to optimize three parameters: plasma temperature (T), plasma density (n), and energy confinement time (τ_E), to reach net energy gain via controlled fusion.[5]

Fusion energy has always been considered to be just around the corner since it was first identified as a source of power production in the 1950s, nearly 70 years ago. The concept of fusion has even been leveraged as a mainstream metaphor for delays. A recent Economist article on Texas trending Democratic, for example, stated that "[t]urning Texas blue is rather like nuclear fusion: a transformative idea in theory that in practice is always just a few years away."[6] However, that basic approach belies a more complex history. For a long time, advancements in fusion energy were being made at a reasonable pace. But fusion faces a scaling problem in that larger devices, particular the tokamak design that was becoming widely accepted, were needed to get closer to "break-even" conditions—where the energy released meets or exceeds the energy required for the confinement system.

The epitome of this is ITER, a goliath, tokamak-based fusion experiment under construction in France, supported by a coalition of 35 governments. Many believe ITER will reach break-even fusion conditions once operational, even returning more than ten times the energy out over heating energy in (represented by the term "Q=10"). However, it does so at a cost—the ITER fusion vacuum vessel is intended to measure 19.4 meters in diameter and weigh

1 For those that are interested, there are many public resources that discuss fusion energy. *See, e.g.*, Burning Plasma Assessment Committee, et al., Burning Plasma: Bringing a Star to Earth, The National Academies Press (2004), at 170, https://www.nap.edu/download/10816.

2 *See* John Slough, The Fusion Driven Rocket: Nuclear Propulsion through Direct Conversion of Fusion Energy, NASA (Mar. 25, 2019), https://www.nasa.gov/directorates/spacetech/niac/2012_Phase_II_fusion_driven_rocket.

3 Kirsten Haupt, Fusion Machines: Searching for the Perfect Shape (June 11, 2019), https://www.iter.org/newsline/-/3037.

4 How NIF Works, Lawrence Livermore National Laboratory (last visited Feb. 10, 2020), https://lasers.llnl.gov/about/how-nif-works.

5 Phil Dooley, Lawson's Magic Formula (Mar. 18, 2013), https://www.iter.org/newsline/261/1527.

6 Building a Multiracial Coalition is More Difficult than it Seems, The Economist (July 12, 2018), https://www.economist.com/special-report/2018/07/12/building-a-multiracial-coalition-is-more-difficult-than-it-seems.

52,000 metric tons[7], and will be no smaller than many large nuclear power plants. More so than being able to demonstrate commercial fusion power production, the ITER project is a large, government run, international science experiment using technology frozen in time in the 1990s—or about 30 years old. As a result, its costs are measured in the tens of billions of dollars for producing 500MW of thermal power, and it is 15 years away from reaching break-even conditions. This approach may generate fusion energy and provide useful information for the advancement of science but fails to create a commercializable product.

B. A Rapid Growth in Private-Sector Fusion Innovation

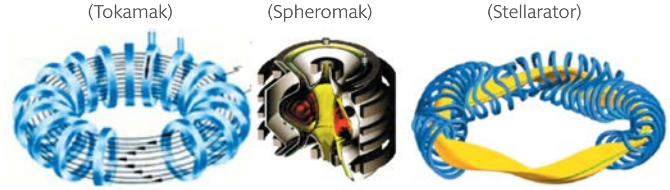
Waiting in the wings, however, entrepreneurs and researchers in the private sector are leveraging other approaches for harnessing fusion energy. While most governments focus on the ITER experiment, in which they are heavily financially invested, these private-sector ventures[8]—mostly out of the United States—believe that fusion innovation is no longer the sole province of large governments. This group of innovators has raised collectively over a billion dollars in investment for a variety of different designs. Multiple of these ventures have timelines for reaching "break-even" or even "pre-commercial demonstration" of fusion in this decade.[9] As an example of progress in the private sector, over 20 private-sector fusion ventures have recently formed their own trade group—the Fusion Industry Association.[10]

The private-sector fusion community is marked by an incredible diversity of thought, with most innovators taking vastly different approaches to fusion system design than the current government-led projects such as ITER. To provide just a sample of the innovation in the field:

- ***Advanced Magnetic Confinement Fusion:*** Many fusion entrepreneurs are pursing "magnetic confinement" fusion, using the same basic concept as the tokamak being built at ITER, but making dramatically different design choices. Some of these ventures plan to build essentially an upgraded tokamak, fielding recent innovations in advanced high-temperature superconducting magnets to allow for a much smaller and cheaper reactor than what is being built at ITER.[11] Others are taking different approaches to the design of the torus itself, instead moving towards stellarators[12] or spheromaks[13]. These latter approaches, while earlier in development, present novel methods to address challenges with magnetic confinement instabilities that have plagued traditional tokamak designs.[14]

Example Magnetic Confinement Fusion Concepts

(Tokamak) (Spheromak) (Stellarator)



[15]

7 Vacuum Vessel, ITER (last visited Feb. 10, 2020), https://www.iter.org/mach/VacuumVessel.

8 2019 Advanced Nuclear Map, Third Way (Oct. 17, 2019), https://www.thirdway.org/graphic/2019-advanced-nuclear-map.

9 For the purposes of this paper, "break-even" fusion refers to the point at which the energy released from a fusion event equals the energy input required to create fusion conditions (colloquially known as "Q=1"). "Pre-commercial demonstration" of fusion refers to demonstration of fusion such that the power produced exceeds the power required by 10 times, enabling commercial application of the technology (colloquially known as "Q=10"). The ITER Project, for example, is designed to achieve a fusion gain of Q=10 to help demonstrate commercial application of fusion energy. *See* What is ITER?, ITER (Jan. 31, 2020), https://www.iter.org/proj/inafewlines.
Prospects for break-even and pre-commercial demonstration of fusion have significantly accelerated over the past decade. *See, e.g.*, Prospects for Low Cost Fusion Development, JASON (Nov. 2018), https://fas.org/irp/agency/dod/jason/fusiondev.pdf; Brian Wang, Helion Energy Got Funding for Possible Breakeven Fusion Device This Year (Oct. 1, 2018), https://www.nextbigfuture.com/2018/10/helion-energy-got-funding-for-possible-breakeven-fusion-device-this-year.html; Commonwealth Fusion Systems Raises $115 Million and Closes Series A Round to Commercialize Fusion Energy (June 27, 2019), https://www.prnewswire.com/news-releases/commonwealth-fusion-systems-raises-115-million-and-closes-series-a-round-to-commercialize-fusion-energy-300875732.html.

10 Fusion Industry Association (last visited Feb. 10, 2020), Fusionindustryassociation.org.

11 *See, e.g.*, SPARC, MIT Plasma Science and Fusion Center (PSFC) (last visited Feb. 10, 2020), http://www.psfc.mit.edu/sparc.

12 *See* The Stellarator as an Alternative Concept, ITER (Apr. 2, 2015)), https://www.iter.org/of-interest/449; *see also* Technology, Renaissance Fusion (last visited Feb. 10, 2020), https://stellarator.energy/technology/; Go-Ahead for International Stellarator Project: German-American Joint Project/Funding by Helmholtz Association (Oct. 28, 2019), https://www.eurekalert.org/pub_releases/2019-10/mfp-gfi102819.php.

13 James Conca, CTFusion -- Bringing The Sun's Power To Earth (Feb. 26, 2019), https://www.forbes.com/sites/jamesconca/2019/02/26/ctfusion-nuclear-bringing-the-suns-power-to-earth/#217803406b82.

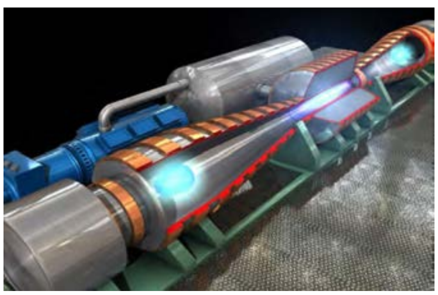
14 *See* Yuhong Xu, A General Comparison between Tokamak and Stellarator Plasmas (July 2016), https://www.sciencedirect.com/science/article/pii/S2468080X16300322.

15 Burning Plasma Assessment Committee, et al., *supra* note 1, at 92, 170.

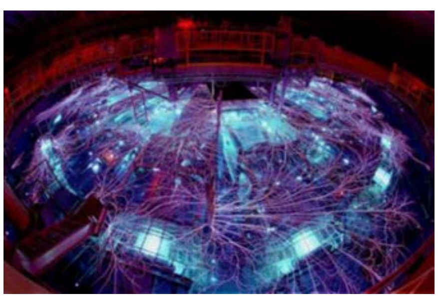
- ***Magneto-Inertial Fusion (MIF):*** This approach, which has seen tremendous growth in the past decade, combines magnetic and inertial confinement to try to get the best of both worlds. There are a number of ventures piloting very different MIF designs. Some are using field-reversed configuration devices to drive two plasmas together while compressing them,[16] while another also uses pistons to create shockwaves through liquid metal to help compress a plasma target.[17] Promising results on the flagship Magnetized Liner Inertial Fusion (MagLIF) fusion project at Sandia National Laboratories (Z Machine) have also highlighted the potential of the MIF approach to fusion.[18]

- ***Z-Pinch Fusion:*** Other fusion ventures and university projects are seeking to create fusion by driving an electric current in a column of plasma, which heats the plasma and creates a magnetic field confining and compressing the plasma to fusion conditions. This "Z-Pinch" approach to fusion, if stabilized as at least one venture seems to have done in laboratory conditions,[21] can result in particularly compact fusion devices.[22] The Z-Pinch approach is being pursued as an independent route to achieving net-energy-positive fusion, and also in configurations that can be described as analogous to MIF.[23]

Example MIF Concepts



19



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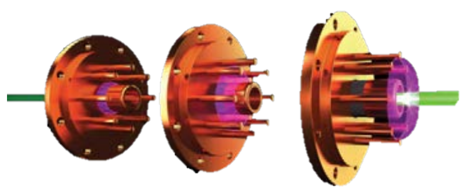
Example Z-Pinch Fusion Concept
(Dense Plasma Focus)



24

16 *See* The Fusion Engine (Graphic), Helion Energy (last visited Feb. 10, 2020), https://www.helionenergy.com.

17 General Fusion, The Most Practical Path to Fusion Energy (last visited Feb. 10, 2020), https://generalfusion.com/technology-magnetized-target-fusion/.

18 About Z, Sandia National Laboratories (last visited Feb. 10, 2020), https://www.sandia.gov/z-machine/about_z/index.html.

19 Helion Energy, Executive Summary for the Fusion Engine (last visited Feb. 10, 2020), http://www.agrion.org/upload/fichier/Helion%20Energy%20Executive%20Summary.pdf.

20 Joel S. Lash, The Sandia Z Machine: an Overview of the World's most Powerful Pulsed Power Facility, Sandia National Laboratories (Jan. 1, 2017), https://www.osti.gov/servlets/purl/1429410.

21 *See* Uri Shumlak, et al., Roadmap to a Compact Fusion Device Based on the Sheared Flow Stabilized Z-Pinch, University of Washington, ARPA-E Fusion Workshop (Aug. 13-14, 2019), https://arpa-e.energy.gov/sites/default/files/Shumlak_arpae2019_compressed.pdf (stabilized using sheared flows).

22 Sustained Nuclear Fusion in the Z Pinch Concept, Lawrence Livermore National Laboratory (May 8, 2019), https://pls.llnl.gov/news/sustained-nuclear-fusion-z-pinch.

23 *See, e.g.*, Technology, Magneto-Inertial Fusion Technologies, Inc. (last visited Feb. 10, 2020), http://miftec.com/TECHNOLOGY.html.

24 Ann Parker, Coming Through in a Pinch—Z-Pinch Plasma Heralds Novel Accelerator Designs, Lawrence Livermore National Laboratory (July 2013), https://str.llnl.gov/july-2013/tang.

- ***Different Fusion Fuels:*** Incredible innovations in different fuel sources are also being explored. Although it is generally understood that the "easiest" fuel for fusion is a mixture of two isotopes of hydrogen—deuterium and tritium (D-T)—due to this combination's higher fusion cross section,[25] other fusion fuels are being actively considered. At least one venture seeking to reach break-even fusion in the near term is proposing to use D-D or D-^{3}He fuel.[26] Other endeavors are trying to use hydrogen-boron (p-^{11}B) fuels.[27]

  This is relevant because the implications of the different fuels, such as the neutron flux, tritium required on site, power and spectrum of emitted photons, and amount of activated metals created from fusion, change dramatically with fuel type. For example, while D-T fuel when fused emits most of its energy in high-energy neutrons, D-D and D-^{3}He fuels when fused emit a smaller fraction of total fusion power as lower-energy neutrons, also potentially lowering the quantity of tritium and activated metals on site. Additionally, less-neutronic fuels may utilize a higher fraction of direct energy conversion, reducing or eliminating the need for coolant loops and their associated radiological challenges.

  It is important to recognize in particular that the choice of fusion fuel is not necessarily tied to the choice of technology. Many of the fundamental concepts used to create fusion conditions described above remain applicable to multiple fuel types.

Therefore, although the fusion system commercialized in the future will certainly rely on the current government-led initiatives for critical insights, its design likely will look very different. Any regulatory framework for fusion must embrace the current diversity of the field and should not inhibit the rapid pace of development. It is particularly critical that any future regulatory framework for fusion not crystalize around or presume a single fusion technology or fuel.

25 *See* Basic Fusion Physics, International Atomic Energy Agency (Sept. 18, 2014), http://www-naweb.iaea.org/napc/physics/fusion-basic.htm.

26 Helion Energy, *supra* note 16.

27 Technology Overview, TAE Technologies (last visited Feb. 10, 2020), https://tae.com/technology-overview/.

III. U.S. REGULATION OF ATOMIC ENERGY - NOT ONE SIZE FITS ALL

Casting a pall over incredible innovation in the fusion sector is the immense and almost overwhelming framework of nuclear regulation in the United States. With the commercial fusion sector fast-advancing, the time has arrived to consider how the field would be regulated. Private ventures have much to worry about if this process is not carefully navigated. The complex and arduous process of licensing traditional fission nuclear reactors can cost up to US$500 million per reactor and take many years—a process that if applied to fusion would hinder most nascent ventures and set the field back a decade, incurring unaffordable costs to the climate and U.S. leadership in energy generation. Fortunately, this outcome can be avoided if the right approach is taken from the start, and that requires understanding the nuclear regulatory framework and where opportunities for flexibility exist.

A. The Foundation of U.S. Nuclear Regulation - The Atomic Energy Act and the NRC

Any analysis of whether or how fusion is and should be regulated has to start with an examination of the statute which establishes the national regulatory framework governing radioactive materials and significant uses of atomic energy—the Atomic Energy Act of 1954, as amended (codified at 42 USC § 2011 et seq., and commonly known as the "AEA"). The AEA sets forth the basic set of rules for all civilian uses of radioactive materials and nuclear energy.

The statute controls the civilian use of radioactive materials, including "byproduct materials" (e.g., naturally radioactive materials; radioactive materials produced by accelerators; and other materials, such as low-level radioactive waste (LLRW) created from nuclear decay, nuclear reactions, or irradiation).[28] Tritium, an isotope of hydrogen commonly used in fusion energy systems, is regulated under the AEA, as implemented by the NRC, as a "byproduct material."[29] The statute's reach also extends to "facilities" that use, produce, or incorporate radioactive materials, as well as facilities that use "atomic energy in such quantity as to be of significance" to the national interest and public health. The classic example of a regulated facility is a nuclear power plant (which is termed a "utilization facility" in the AEA),[30] but there are other examples as well, including certain medical isotope and fuel cycle facilities (discussed more below).

The AEA encourages the use of nuclear materials for scientific and commercial endeavors, but directs that the government regulate all uses of atomic energy or radioactive materials to ensure "the common defense and security and to protect the health and safety of the public."[31] The Congressional mandate in the AEA is clear that the government has a stake in the regulation of nuclear energy. As a result of the clear mandate and technical nature of the industry, the NRC, the government agency that implements the AEA, is given great deference as to all key decisions regarding regulation of the field. As the United States Supreme Court famously said, the NRC operates at "the frontiers of science," and as a result, "a reviewing court must generally be at its most deferential."[32]

B. The Atomic Energy Act Embraces Different Regulations for Different Situations

Due to the scope of the AEA to cover a broad range of uses of radioactive materials, the associated regulation of radioactive materials comes in many shapes and sizes. The drafters of the AEA recognized that the statute would have to be flexible in order to effectively regulate the different types and uses of radioactive material. Regulation of the nuclear field runs the gamut of gigawatt-scale nuclear power plants to hand-held gauges and patient diagnostic procedures. And while large scale nuclear power plants may be one of the most well-known uses of radioactive materials overseen by the NRC, the agency (and state regulators delegated certain regulatory responsibilities by the NRC—i.e., Agreement States) at the same time oversees thousands

28 You can see how these terms are defined in the statute itself by looking to 42 USC § 2014. The NRC Glossary also provides definitions of key terms. Glossary, NRC (last updated July 6, 2018), https://www.nrc.gov/reading-rm/basic-ref/glossary.html. A more complete discussion of examples of byproduct materials can be found on the NRC "Byproduct Material" webpage. Byproduct Material, NRC (last updated July 7, 2017), https://www.nrc.gov/materials/byproduct-mat.html. The AEA also governs the use of other types of radioactive materials, specifically "special nuclear material" (e.g., enriched uranium), which is typically used in fuel for nuclear reactors, as well as "source" material (e.g., natural uranium and thorium).

29 Byproduct Material, NRC, *supra* note 28.

30 *See* 42 USC § 2014 (defining "utilization facility"); *see also* 42 USC § 2133 (mandating a license to operate utilization facilities).

31 *See* 42 USC §§ 2012, 2013 (discussing Congress's views and the purposes of the AEA). Note that "atomic energy" and "nuclear energy" are synonymous; "atomic energy" is a more dated phrase, and "nuclear energy" is more commonly used today.

32 *Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983).

of applications of other radioactive materials, from gauges to cancer treatments. Even within the commercial nuclear power industry, the NRC applies a different—and lighter—regulatory framework for non-reactor technologies, such as fuel fabrication facilities.

As a result, the AEA is flexible and allows for different levels of regulation for different safety cases. Depending on the situation, the NRC (1) can create different frameworks for regulating different types of materials or facilities, and (2) can delegate regulatory authority for certain lower-risk activities to Agreement States.

1. NRC Frameworks for Different Safety Cases

There are many frameworks under which radioactive materials are regulated by the NRC or Agreement States. When thinking about fusion, three current NRC regulatory frameworks are worthy of reference:[33]

- **10 CFR Part 30 (E.g., Medical/Industrial Users of Radioactive Materials):** This regulatory category (which spans from 10 CFR Part 30 through 37, but here for ease is termed "Part 30") covers the use of radioactive materials in all aspects of civilian use, from exit signs and smoke detectors, to industrial gauges, manufacturing, and complex medical procedures. The scope of this regulatory framework extends to a large group of materials known as "byproduct materials," which is essentially all radioactive materials that are not uranium or other fissile/fissionable materials, like plutonium or thorium. There are nearly 20,000 active byproduct materials licenses, a quarter of which have been issued by the NRC alone (and the rest by Agreement States).[34] The delegation of regulatory authority to Agreement States acknowledges the limited nature of the risk from small amounts of radioactive materials, along with the need for local regulatory engagement.[35]

- **10 CFR Part 50 (E.g., Nuclear Reactors and Production Facilities):** This category primarily covers nuclear fission reactors (which are a type of "utilization facility").[36] The AEA defines "utilization facility" to include those facilities that use "special nuclear material" or "atomic energy" "in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public."[37] Nonetheless, traditionally the NRC has limited this regulatory category by definition to nuclear fission reactors and one specific other facility that uses special nuclear material.[38]

  The Part 50 framework is among the NRC's strictest regulatory regimes, given the unique safety concerns with nuclear reactors, such as the risk for a runaway nuclear reaction, and the high amount of nuclear materials stored in irradiated nuclear fuel that could impact the public if released.

- **10 CFR Part 70 (E.g., Fuel Cycle Facilities):** The regulatory category (which spans from 10 CFR Part 70 through Part 76, but here for ease is termed "Part 70") largely concerns the possession of fissile materials (a.k.a. "special nuclear material"), such as enriched uranium, plutonium, and thorium. Larger Part 70 licensees include nuclear fuel fabrication and fuel cycle facilities. The Part 70 framework is a middle ground between Part 30 and Part 50 and focuses on the unique but limited risks associated with managing large quantities of un-irradiated fissile material, including on-site work health and safety, prevention of criticality, and monitoring of the material against diversion.

33 In addition to the three frameworks described, another section of the NRC regulatory framework, 10 CFR Part 20 (Standards for Radiation Protection), applies globally to all types of licenses. A "definitions section" of sorts for nuclear regulation, Part 20 sets forth the basic regulatory requirements for all licensees' radiation protection programs, including general radiation dose limits, and the concept that any radiation protection program strive to achieve radiation dose rates to the public and workers that are "as low as reasonably achievable" (ALARA).

34 Regulation of Radioactive Materials, NRC (last updated Sept. 22, 2017), https://www.nrc.gov/about-nrc/radiation/protects-you/reg-matls.html (noting that there are "more than 20,000 active source, byproduct, and special nuclear materials licenses in place in the United States"—of which, source and special nuclear material licenses are comparatively very rare).

35 The NRC has four regional offices around the United States, which are referred to as "Regions I-IV." Locations, NRC (last updated Sept. 25, 2017), https://www.nrc.gov/about-nrc/locations.html.

36 Production facilities are a limited category of facilities "capable of the production of special nuclear material in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public." 42 USC § 2014(v). In general this category should not apply to fusion facilities unless they are specifically designed for this purpose.

37 42 USC § 2014(cc).

38 10 CFR § 50.2 (limiting the NRC's definition of "utilization facility" to nuclear fission reactors and the facility subject to licensing under NRC docket number 50–608 (the SHINE facility, discussed more below)).

These frameworks demonstrate that the NRC has a range of regulations it can apply to a given type or use of radioactive materials. As a general matter, under Part 30, the NRC regulates byproduct material but not the facilities/equipment that may be associated with it (e.g., accelerators); under Part 70, which is stricter than Part 30 but not as strict as Part 50, the NRC regulates special nuclear material, and in certain circumstances the underlying facilities associated with it (e.g., uranium enrichment and nuclear reactor fuel fabrication facilities); and under Part 50 the NRC sets forth its strictest regulations for nuclear reactors.

2. Delegation of Regulatory Authority to States

When looking at the U.S. nuclear regulatory framework, a key question is not just *what* the regulatory framework is (e.g., Part 30 or Part 50), but also *who* is the regulator. The AEA delegates all regulatory authority pertaining to civilian use of radioactive materials and nuclear facilities first to the NRC.[39] However, the AEA then empowers the NRC to *delegate* certain regulatory authority to interested states—the "Agreement States" identified above. This authority can include all regulatory activities involving byproduct materials (i.e., those materials regulated under Part 30), as well as source materials and special nuclear materials up to a small amount.[40]

Most U.S. states have established such agreements with the NRC.[41] These Agreement States then become the primary nuclear regulator-in-practice for the covered activities. That is why although the NRC regulates all fission power reactors under Part 50 (the NRC cannot delegate regulation of nuclear reactors to states), most users of byproduct materials, from tritium exit sign manufacturers to radiopharmaceutical distributors, are regulated by Agreement States under NRC oversight.

However, this Agreement State delegation is subject to certain restrictions. First and foremost, the state's regulations must be "equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the [NRC] for the same purpose."[42] The NRC may also pass along certain environmental regulatory requirements to states.[43] This also means that if the NRC were to tighten its regulatory standards, it would require the states to do so as well. Second, the NRC at any time can revoke its delegation of authority "upon its own initiative after reasonable notice and opportunity for hearing."[44] This gives the NRC significant leeway to retain regulatory jurisdiction for novel applications of nuclear energy that raise significant policy concerns.

39 *See, e.g.*, 42 USC §§ 2131 through 2134 (delegating authority to license nuclear power plants to the "Commission"—i.e., the NRC); 42 USC §§ 2111 through 2114 (delegating authority to license and set safety standards for byproduct materials to the NRC).

40 42 USC § 2021(b).

41 NMSS - State Regulations and Legislation, NRC (last updated Jan. 29, 2020), https://scp.nrc.gov/rulemaking.html (listing NRC Agreement States and the requisite agreements).

42 42 USC § 2021(o)(2); *see also* NRC Agreement State Program Policy Statement, 82 Fed. Reg. 48,535, 48,538 (Oct. 18, 2017) ("[T]he overall level of protection of public health and safety provided by a State program should be equivalent to, or in some cases can be greater than, the level provided by the NRC program.").

43 For example, the AEA requires that state agencies conduct an environmental review for certain byproduct materials applications that can have a "significant impact on the human environment." 42 USC § 2021(o)(3)(C), (D).

44 42 USC § 2021(j).

IV. THE REGULATION OF FUSION - A PRACTICAL AND INNOVATION-FRIENDLY APPROACH

A. Fusion Regulation Comes to the Fore, Raising Key Questions

Serious discussion of civilian fusion regulation has remained on the back burner while the technology has been in development.[45] The result is that although it is clear the NRC asserts some form of regulatory jurisdiction over fusion, it is unclear *how* the NRC should regulate fusion. The time to answer that question, however, is fast approaching.

In 2009, the NRC staff first raised the question of fusion regulation to the Commission. In its paper, *Regulation of Fusion-Based Power Generation Devices*, the NRC staff sought the Commission's feedback because certain export licensing questions had arisen, which required answers to the basic question of the NRC's jurisdiction over fusion.[46] The NRC staff in their analysis focused on the definition of "utilization facility" in the AEA (42 USC § 2014). As previously noted, the AEA defines "utilization facility" to include those facilities that use "special nuclear material" or "atomic energy" "in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public."[47] The NRC further narrows the definition of "utilization facility" in its definitions to include primarily nuclear fission reactors.[48]

Because of the broader scope of the definition of "utilization facility" in the AEA, the door is open for the NRC to amend its regulations to expand the scope of a "utilization facility" to include any system "adapted for making use of atomic energy in such quantity as to be of significance to the common defense and security, or in such manner as to affect the health and safety of the public." The NRC staff believed in its 2009 paper that this could incorporate fusion devices. Although the NRC staff did not reach a final determination as to whether fusion activities would have significant security or public health impacts, based on this reading and an evaluation of the legislative history of the AEA, the NRC staff determined that the statute meant to incorporate fusion energy and recommended that the NRC establish jurisdiction over fusion facilities.[49] The Commission agreed to assert regulatory jurisdiction over fusion, but punted on the issue of how to regulate—instructing the staff to leave the question alone until the technology developed further.[50]

In some ways, the conversation was redundant on the jurisdictional question. The use (and in some cases production) of tritium at these facilities already put most fusion facilities within the scope of NRC jurisdiction, as tritium is an NRC-regulated byproduct material. Indeed, the NRC staff paper noted that in the radiopharmaceutical context, the NRC asserts jurisdiction of the byproduct materials produced by particle accelerators, but not the accelerators themselves (a potential analog for fusion facilities, as discussed more below).[51]

But this exchange previewed a larger and more important discussion as to *how* fusion would be regulated. By focusing on the "utilization facility" framework for its analysis, the NRC staff appeared to favor adding fusion facilities directly *into the utilization facility* regulatory regime—i.e., regulating fusion facilities like fission reactors in its Part 50 regulatory framework. This was partially reinforced by the NRC's most recent engagement with a sizable fusion system—SHINE Medical Technologies, Inc. (SHINE),[52] which has been seeking to use a D-T fusion system to generate neutrons for a medical isotope production facility to produce Molybdenum-99. During the NRC review of the construction permit application for this facility, the NRC determined that the SHINE facility fusion systems were more appropriately regulated as utilization facilities, although a key factor was that the fusion systems were generating neutrons aimed at a uranium target.[53] Up until

45 The DOE in the early 1990s explored the regulation of fusion in the scope of the ITER project. *See, e.g.*, DOE-STD-6002-96, DOE Standard – Safety of Magnetic Fusion Facilities: Requirements (May 1996), https://www.standards.doe.gov/standards-documents/6000/6002-astd-1996/@@images/file. However, these efforts from more than two decades ago were preliminary analyses geared towards a single government project, and they do not consider current evolution of the field.

46 *See* SECY-09-0064, Regulation of Fusion-Based Power Generation Devices (Apr. 20, 2009) (SECY-09-0064), https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2009/secy2009-0064/2009-0064scy.pdf.

47 42 USC § 2014(cc).

48 10 CFR § 50.2.

49 SECY-09-0064 at 2-4, 7-8.

50 SRM-SECY-09-0064, Staff Requirements Memorandum -- Regulation of Fusion-Based Power Generation Devices (July 16, 2009), https://www.nrc.gov/docs/ML0922/ML092230198.pdf (The Commission asserted "as a general matter" jurisdiction over fusion devices, but largely punted on any analysis thereafter until fusion technologies further matured).

51 Section 651 of the Energy Policy Act of 2005 added accelerator-produced radioactive materials to the definition of "byproduct material." 42 USC § 16041. Since that time, the NRC has not asserted jurisdiction over particle accelerators themselves.

52 SHINE Medical Technologies Inc., NRC (last updated Feb. 20, 2018), https://www.nrc.gov/info-finder/nonpower/shine-medical-tech.html (with links to application and other documents about the project).

53 Definition of Utilization Facility, Direct Final Rule, 79 Fed. Reg. 62,329 (Oct. 17, 2014).

the SHINE application, the Part 50 definition of "utilization facility" had been specifically defined to include *only* fission reactors). The NRC underwent a targeted rulemaking to amend the Part 50 definition to include the SHINE facility. The NRC's 2009 paper and the targeted SHINE rulemaking appears to have established a presumption that fusion should be regulated under a fission reactor framework—*a presumption that is incorrect* based on the actual technical merits of fusion energy.

This question is now coming to the fore. On January 14, 2019, the Nuclear Energy Innovation and Modernization Act (NEIMA) became law.[54] Section 103 of NEIMA required the NRC to engage in a rulemaking for the licensing of "advanced reactors," a term which the statute defined to include fusion systems. As a result, the NRC has started holding periodic meetings with the Department of Energy and other stakeholders on the regulation of fusion, and plans to hold a major public meeting on the topic, potentially in March 2020. As a result, the question of *how* to regulate fusion must be addressed in the near future.

B. A Regulatory Proposal That Recognizes the Safety Case of Fusion and the Needs of Fusion Innovators

The U.S. nuclear regulatory framework rivals the complexity of the modern electric grid. Its multiple frameworks and tools can be used to craft a tailored and risk-informed approach to address the limited safety concerns associated with fusion energy, or it can be used to smother this nascent industry at a developmental stage.

For fusion energy to reach its full potential for the benefit of the climate and nation, the NRC should only regulate when necessary and not try to lump fusion in with fundamentally different fission-based technologies. A thoughtful approach to a regulatory regime for fusion is warranted given the unique considerations and potential benefits of fusion energy. Armed with both an understanding of the underpinnings of fusion innovation, and knowledge of the tools available under the AEA, the authors propose two recommendations to allow for the safe deployment of fusion in a manner that promotes innovation and deployment of this game-changing technology.

1. Near-Term: Regulation of Fusion Under the Part 30 Framework is Appropriate Through Development and Demonstration

Getting to break-even and pre-commercial demonstration of fusion will be watershed moments for the industry, and will signal the start of a new age of energy generation. For the sake of combating climate change and strengthening national security, the current group of fusion innovators should be given a chance to reach these milestones in as expedient a manner as possible.

Fortunately, the NRC regulatory framework for byproduct materials—the framework that currently applies to fusion experiments—already provides for reasonable assurance of public health and safety during these critical years. Multiple radiopharmaceutical generators that use cyclotrons to produce radioactive materials are licensed under Part 30 (including Part 35) to hold up to tens of thousands of curies of radioactive material in different forms. Hospitals and other facilities regulated under Part 30 routinely handle significant amounts of radioactive material, such that shielding of over a meter may sometimes be required, along with significant worker safety measures.[55] The Part 30 regime also regulates irradiators, which can hold millions of curies of radioactive materials.[56] Moreover, the Part 30 framework is already used to regulate D-T fusion systems that do not involve irradiation of fissile material.[57]

In contrast, fusion devices at the development and demonstration stage are anticipated to have far fewer curies of radioactive material than even these examples, with likely similar or lower shielding requirements. Although fusion development projects will produce neutrons from their experiments, this only occurs during intermittent test "pulses." Low-duty-cycle demonstration activities even up to Q=10 will only require a modest use of a fusion demonstration system compared to an actual power-producing unit—also requiring far less tritium fuel on site. Neutron activation of metals is not expected

54 Public Law No: 115-439.

55 Bhaskar Mukherjee, Principle of Radiological Shielding of Medical Cyclotrons (Apr. 2002), https://www.researchgate.net/publication/324151699_Principle_of_Radiological_Shielding_of_Medical_Cyclotrons.

56 Fact Sheet on Commercial Irradiators, NRC (last updated Apr. 2004), https://www.nrc.gov/docs/ML0605/ML060520648.pdf (noting that commercial irradiators can hold up to 10 million curies of radioactive material).

57 DT110-14 MeV Neutron Generator, Adelphi Technology, Inc. (last visited Feb. 10, 2020), https://www.adelphitech.com/products/dt109-dt110.html; Phoenix, Alectryon: High Flux Neutron Generator (last visited Feb. 10, 2020), https://phoenixwi.com/neutron-generators/high-flux-neutron-generator/dt-high-yield-neutron-generator/.

to be a significant issue given the limited nature of the tests involved. Compared to the vastness of the ITER project, privately funded fusion ventures are working with technologies that are orders of magnitude smaller in size, especially at the technology demonstration stage.[58] These much smaller ventures are expected to carry with them correspondingly smaller safety impacts.

This approach—of keeping fusion development and demonstration regulated under a Part 30 framework—aligns with the text of the regulations as they stand now. First, the primary alternative framework, the Part 50 fission reactor framework, is limited by definition to those facilities that use fissile material, and the SHINE facility. A new rulemaking would be needed to extend the reactor framework to fusion development work, which would require a safety justification that is not currently present. Moreover, the NRC has long-adopted a regulatory approach in the medical context to regulate accelerator-produced byproduct materials, without regulating the accelerator itself.[59] This recognizes that in most cases—including in the case of fusion R&D—the byproduct materials represent the greater radiological concern compared to the accelerators. Maintaining its current regulation of the byproduct materials involved in fusion development and demonstration activities gives the NRC the tools it needs to ensure radiological safety without compromising the ability for iteration and experimentation that is crucial for fusion energy to become a reality.

Therefore, continued use of the Part 30 framework to regulate fusion projects up through break-even and pre-commercial scale presents no significant new hazards compared to what the NRC and Agreement States already regulate under the Part 30 framework. Moreover, as further assurance, limitations to the amounts of radioactive materials or the number of pulses involved can likely be worked into a materials license issued under a Part 30 framework (or licensing basis documentation) in a manner that does not impede fusion innovation.

2. Long-Term: The NRC Should Develop an Independent Regulatory Framework for Fusion at Commercial Scale, Not Adopt a Fission Framework

The NRC Part 30 framework may be well-suited to fusion regulation at commercial scale. The determination to apply a new regulatory framework to fusion energy has to be done after careful evaluation as to whether the risk profile warrants it. Nonetheless, if the NRC did determine that fusion facilities should be overseen through a different regulatory lens at commercial scale, a fission-based regulatory paradigm is inappropriate given the differences between fission and fusion.

First and foremost, any fission-based regulatory framework is going to be driven by the safety issues unique to fission—particularly, the important need to prevent super-criticality, ensure core cooling, prevent the release of fission products in the case of an accident, manage proliferation risks associated with the shipment of fissile materials, and safely handle spent nuclear fuel. These issues are foundational principles behind the current Part 50 and Part 52 regulatory frameworks, and will likely carry through every aspect of a new fission-based regulatory framework.

Yet these issues are simply inapplicable to fusion, which physically cannot experience a runaway super-critical event. Moreover, even presuming use of D-T fuel, the radioactive inventory associated with fusion will be comprised of different types of materials—primarily tritium and activated metals—that present a completely different set of concerns than management of spent nuclear fuel.

Instead, there are issues specific to fusion that a regulatory construct designed for fission is unlikely to properly address. These include the potentially higher neutron flux (in D-T fusion, for example, approximately 80% of the energy produced is released in neutrons),[60] failure scenarios associated with superconducting magnets (where magnetic confinement is involved), limited proliferation concerns associated with the trade in tritium and the neutron flux from fusion reactors, and the need to actively manage large quantities of tritium and activated metals during facility operation.

58 *See, e.g.*, Joseph Trevithick, Lockheed Martin Now Has a Patent for Its Potentially World Changing Fusion Reactor (Mar. 26, 2018), https://www.thedrive.com/the-war-zone/19652/lockheed-martin-now-has-a-patent-for-its-potentially-world-changing-fusion-reactor; PSFC, *supra* note 11.

59 42 USC § 16041.

60 Making It Work, ITER (last visited Feb. 10, 2020), https://www.iter.org/sci/MakingitWork.

Moreover, within fission reactors, the need for fissile material is consistent no matter the design, and thus the same concerns will remain even as advanced reactors evolve. The fission regulatory framework therefore can be expected to not require fundamental change over time. However, in the case of fusion, the different fuels under consideration drastically change the associated radiological concerns. For example, D-^{3}He fusion approaches do not require tritium, although the use of this fuel may generate a small amount of tritium. D-D and D-^{3}He fusion also generate fewer high-energy neutrons (and potentially less activated metals). Looking even more into the future, p-^{11}B fusion fuel potentially would generate only a tiny fraction of neutrons and radioactive byproducts. Therefore, a regulatory framework for fusion has to be designed to recognize the drastically different routes available for the field to evolve, which requires specific consideration.

Sample Comparison of Key Regulatory Issues - Fission Versus Fusion

Fission	Fusion (presumes D-T Fuel)
Avoid super-criticality	Managing structure during quenching and disruption events
Core cooling without power	Protecting workers against neutron and high-energy radiation
Containing fission products in case of accident	Containing tritium inventory and tritium deposited within facility/vacuum chamber
Tracking proliferation concerns associated with fissile material	Tracking proliferation concerns associated with tritium and high-flux neutron source
Disposal of spent nuclear fuel	Managing activated materials and LLRW during facility operation
All reactor designs use fissile material, thus the above concerns are consistent	*Facilities can use different fuels, each with vastly different radiological implications*

As a result, if the NRC must explore enhanced regulation of fusion energy at commercial scale, it should consider a rulemaking effort geared towards the specific characteristics of fusion energy, whether as a distinct initiative or as a separate track of the NEIMA-required rulemaking.

V. CONCLUSION

Thanks to an unprecedented renaissance in private-sector fusion innovation, commercial fusion energy is likely to become a reality in the not so distant future. This means that key regulatory questions need to be addressed in the near term. It is easy to simply drop fusion energy into the fission energy regulatory framework, but that would be a mistake with far-reaching consequences for fusion innovation, U.S. technological leadership, and the planet. The NRC should instead further evaluate the safety case associated with fusion, working with the emerging commercial industry to understand their technologies.

As part of this effort, fusion technology development should continue to be regulated under the current Part 30 framework through demonstration, an approach that is consistent with current regulations and facilitates innovation, while providing adequate protection of public health and safety. If, and only if, it determines that fusion cannot be regulated under a Part 30 framework at commercial scale, the agency should initiate efforts to develop a separate regulatory framework distinct to fusion energy, which recognizes the field's unique but more limited safety and security concerns. Additional technical conferences between the NRC staff and the fusion community can help flesh out relevant factors from a regulatory perspective.

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