Developing a Regulatory Framework for Fusion Energy Systems

March 30, 2021

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Agenda

Time	Topic	Speaker(s)
12:30-12:40pm	Introduction/Opening Remarks	NRC
12:40-1:10pm	Discussion on NAS Report "Key Goals and Innovations Needed for a U.S. Fusion Pilot Plant"	Jennifer Uhle (NEI) Rich Hawryluk (PPPL)
1:10-1:40pm	Social License and Ethical Review of Fusion: Methods to Achieve Social Acceptance	Seth Hoedl (PRF)
1:40-2:40pm	Developers Perspectives on Potential Hazards, Consequences, and Regulatory Frameworks for Commercial Deployment: • Fusion Industry Association - *Industry Remarks* • TAE – *Regulatory Insights* • Commonwealth Fusion Systems – *Fusion Technology and Radiological Hazards*	Andrew Holland (FIA) Michl Binderbauer (TAE) Bob Mumgaard (CFS)
2:40-2:50pm	**Break**	
2:50-3:10pm	Licensing and Regulating Byproduct Materials by the NRC and Agreement States	NRC
3:10-4:10pm	Discussions of Possible Frameworks for Licensing/Regulating Commercial Fusion • NRC Perspectives – Byproduct approach • NRC Perspectives – Hybrid Approach • Hogan Lovells	NRC/OAS NRC Sachin Desai (Hogan Lovells)
4:10-4:30pm	Next Steps/Questions	All

Public Meeting Format

The new categories map to the old Category 1, 2, and 3 as shown below.

Old Category	Purpose of Meeting	Level of Public Participation	New Category
1	For the NRC to staff meet with representatives of a single external entity in a public forum	Other attendees observe the business portion of the meeting and can ask questions of the NRC staff at designated points	Observation Public Meeting
2	For the NRC staff to meet with representatives of multiple external entities in a public forum		
3	For the NRC staff to meet with individuals to inform them and discuss regulatory topics	Public discussion is actively sought	Information Public Meeting
	For the NRC staff to meet with individuals to inform them and take their feedback/comments	Public discussion and feedback/comments are actively sought	Comment- Gathering Public Meeting

The Commission recently revised its policy statement on how the agency conducts public meetings (ADAMS No.: ML21050A046).

NRC Public Website - Fusion

NUCLEAR REACTORS | NUCLEAR MATERIALS | RADIOACTIVE WASTE | NUCLEAR SECURITY | PUBLIC MEETINGS & INVOLVEMENT | NRC LIBRARY | ABOUT NRC

Home ▸ Nuclear Reactors ▸ New Reactors ▸ Advanced Reactors (non-LWR designs)

Fusion Energy Reactors

In SRM-SECY-09-0064, "Staff Requirements—SECY-09-0064—Regulation of Fusion-Based Power Generation Devices," the Commission asserted, as a general matter, that the NRC has regulatory jurisdiction over commercial fusion energy devices whenever such devices are of significance to the common defense and security, or could affect the health and safety of the public.

In SRM-SECY-20-0032, "Staff Requirements—SECY-20-0032—Rulemaking Plan on 'Risk--Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," the Commission directed the staff to "consider appropriate treatment of fusion reactor designs in our regulatory structure by developing options for Commission consideration on licensing and regulating fusion energy systems."

In meetings such as the joint DOE, NRC, and Fusion Industry Association public forum in October 2019, the staff characterized possible regulatory approaches as being ones similar to (1) utilization facilities, (2) materials licenses such as those related to accelerator-produced radionuclides, and (3) some hybrid or new approach developed as part of the current activities. The staff's development of options for the Commission to consider will include assessing the potential risks posed by various fusion technologies and possible regulatory approaches for fusion facilities. The staff's activities also include coordination with the Organization of Agreement States, holding a series of public meetings, and interacting with the Advisory Committee on Reactor Safeguards.

Key Public Meetings	
Upcoming Public Meetings	**Date**
Virtual Public Meeting on Developing Options for a Regulatory Framework for Fusion Energy Systems	March 30, 2021
Meeting with Advisory Committee for Reactor Safeguards Future Plants Subcommittee Tentatively Planned for May 2021	TBD
Recent Public Meetings	**Date**
Virtual Public Meeting on Developing Options for a Regulatory Framework for Fusion Energy Systems • Presentations	January 26, 2021
DOE, NRC, and Fusion Industry Association public forum	October 6, 2020 EXIT

https://www.nrc.gov/reactors/new-reactors/advanced/fusion-energy.html

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Protecting People and the Environment

NAS Report “Key Goals and Innovations Needed for a U.S. Fusion Pilot Plant”

The National Academies of SCIENCES ENGINEERING MEDICINE

Bringing Fusion to the U.S. Grid

R. J. Hawryluk
J. Uhle
D. Roop
D. Whyte

March 30, 2021

Committee Composition

Richard J. Hawryluk (Chair)
Princeton Plasma Physics Laboratory

Brenda L. Garcia-Diaz
Savannah River National Laboratory

Gerald L. Kulcinski (NAE)
University of Wisconsin-Madison

Kathryn A. McCarthy (NAE)
Oak Ridge National Laboratory

Per F. Peterson (NAE)
University of California, Berkeley/ Kairos Power

Jeffrey P. Quintenz
TechSource, Inc.

Wanda K. Reder (NAE)
Grid-X Partners

David W. Roop (NAE)
DWR Associates, LLC

Philip Snyder
General Atomics

Jennifer L. Uhle
Nuclear Energy Institute

Dennis G. Whyte
Massachusetts Institute of Technology

Brian D. Wirth
University of Tennessee, Knoxville

Statement of Task

The National Academies of Sciences, Engineering, and Medicine (NASEM) shall assemble a committee to provide guidance to the U.S. Department of Energy, and others, that are aligned with the objective of constructing a pilot plant in the United States that produces electricity from fusion at the lowest possible capital cost ("Pilot Plant").
The committee shall provide a concise report that addresses the following points:

- Establish key goals for all critical aspects of the Pilot Plant, independent of confinement concept and during each of the plant's anticipated phases of operation.
- Identify the principal innovations needed from both the private sector and government to meet those key goals.
- Seek input from potential "future owners" of power plants and potential manufacturers of fusion power plant components.
- Characterize the energy market for fusion and provide input on how a fusion pilot plant could contribute to national energy needs.

NOTE: TASK STATEMENT PARAPHRASED TO FIT ON SLIDE

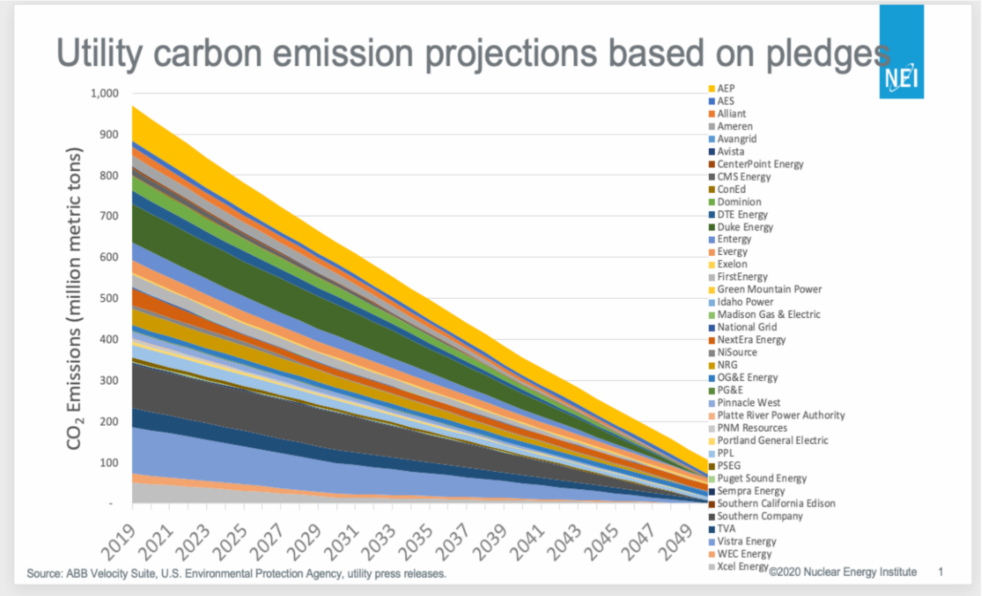
Key Takeaways

Recommendation: For the United States to be a leader in fusion and to make an impact on the transition to a low-carbon emission electrical system by 2050, the Department of Energy and the private sector should produce net electricity in a fusion pilot plant in the United States in the 2035—2040 timeframe.

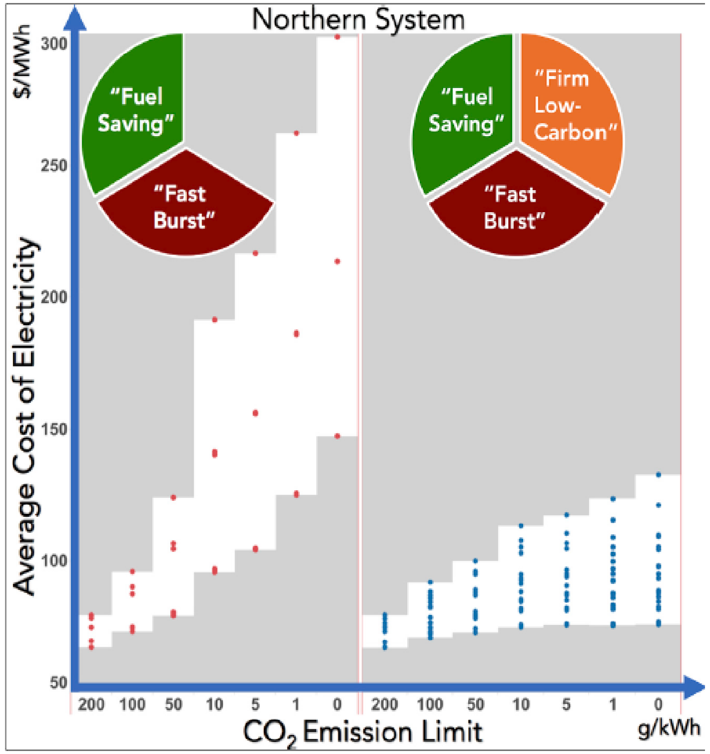
Recommendation: DOE should move forward now to foster the creation of national teams, including public-private partnerships, that will develop conceptual pilot plant designs and technology roadmaps that will lead to an engineering design of a pilot plant that will bring fusion to commercial viability.

Conclusion*:* Successful operation of a pilot plant in the 2035—2040 timeframe requires urgent investments by DOE and private industry — both to resolve the remaining technical and scientific issues, and to design, construct, and commission a pilot plant.

Role of the Pilot Plant:
Future Electricity Generation Market

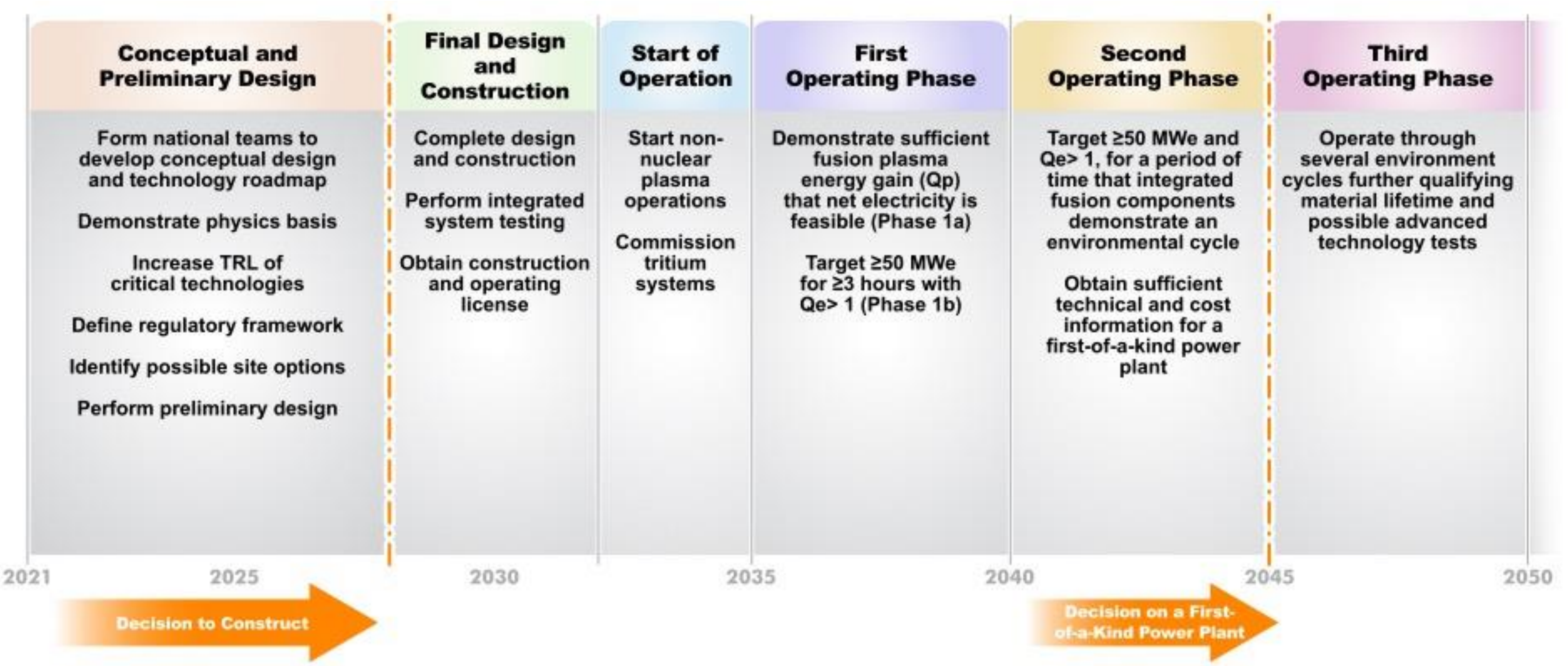


Utilities foresee a transition to low-carbon electrical generation by 2050.



Firm low-carbon/non-carbon electrical energy generation will be needed to decrease the cost.

Strategy and Roadmap



Pilot Plant Design

Considerations for Phase 1

First Operating Phase

Demonstrate sufficient fusion plasma energy gain (Qp) that net electricity is feasible (Phase 1a)

Target ≥50 MWe for ≥3 hours with Qe> 1 (Phase 1b)

Phase 1a

-target 100-500 MW time-averaged thermal power for ≥100 s

-for pulsed concepts, operate at the design repetition rate for Phase 2

Phase 1b

-for D-T fusion, demonstrate production, extraction, and refueling of tritium on a timescale sufficient to maintain reasonable operations

-for pulsed concepts, these should be for a comparable time scale of ≥3 hours at the design repetition rate for Phase 2

Finding*:* The need for sufficient tritium self-production in a pilot is because the available world's supply of tritium is of the same order as a D-T pilot plant's annual tritium consumption. A D-T pilot plant operator will need to procure sufficient tritium to startup the facility.

Goals for a Fusion Pilot Plant:

Considerations for Phases 2 and 3

Second Operating Phase

Target ≥50 MWe and Qe> 1, for a period of time that integrated fusion components demonstrate an environmental cycle

Obtain sufficient technical and cost information for a first-of-a-kind power plant

Phase 2

- demonstrate operation for an environmental cycle including maintenance
- require operation on the order of one full power year

Phase 3

- demonstrate and improve average availability for commercial fusion
- provide additional data on the mean time to failure and replacement time for materials/components
- use for testing advanced materials and technology and novel deployment of fusion to the grid

Third Operating Phase

Operate through several environment cycles further qualifying material lifetime and possible advanced technology tests

Demonstration of safe operation of the fusion pilot plant is one of its most important goals.

- Tritium dominates the source term and mitigation of tritium release is key
  - Experience with JET and TFTR operations and ITER design exists
  - Goal of pilot program to have < 1 kg of tritium on site
  - Full scale plant would have more tritium
- Neutron activation of structural materials can be mitigated by material choice
  - Desire to avoid greater than Class C waste in the pilot plant
    - Demonstrate that FOAK can use low activation materials in blanket and structures
  - Minimize volume of waste in near-surface disposal facility
  - Obviate the need for reliance on repository, if possible

Finding: A fusion pilot's integrated tritium processing rate will be 10 - 100x faster per day than present experience in heavy-water moderated fission.

Recommendation: DOE should establish and demonstrate efficient tritium processing technologies at relevant rates and processing conditions before operation of a pilot plant.

NRC is required to develop a regulatory process for fusion by Dec. 31, 2027

- Meetings are underway and exploring three regulatory framework approaches:
  - Utilization facility with Part 50 – reliance on exemptions
  - Byproduct material – assumes fusion can be considered an accelerator
  - Hybrid approach –- uses parts of both through rulemaking
- ***Recommendation:*** NRC should establish the regulatory framework, including the decommissioning stage, of fusion power plants as well as the pilot plant.
- ***Finding:*** A regulatory process that minimizes unnecessary regulatory burden is a critical element of the nation’s development of the most cost-effective fusion pilot plant.
- A flexible regulatory framework is necessary to accommodate different designs and to keep pace with innovation

Key Regulatory Issues

- Radiological protection – presence of tritium and activation products
- Tritium management – existing practices and pilot recommendation to keep levels < 1 kg
- Siting and EP – design specific issue, depends on release likelihood and source term
- Decommissioning – don't believe any unique issues are presented with fusion
- Waste steam – greater than Class C disposal depends on Part 51 rulemaking
- Agreement state authority - if byproduct material framework used
- Licensed operators – not handled in Part 30, design specific issue

Finding: Existing nuclear regulatory requirements for utilization facilities (10 CFR Part 50) are tailored to fission and not well suited for fusion

Finding: Regulatory framework for radiation protection and byproduct material provided under 10 CFR Parts 20 and 30 is well suited to fusion

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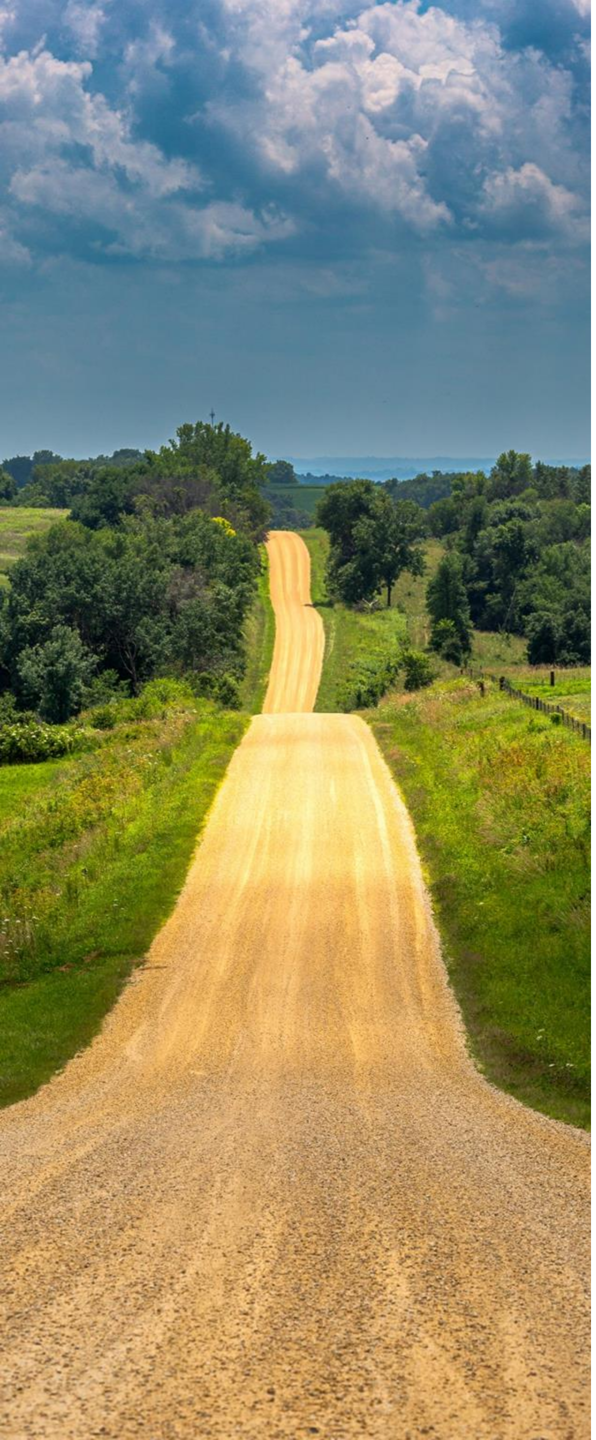
Any Questions?

For more information, please visit the study website at

http://nas.edu/fusion

Social License and Ethical Review of Fusion: Methods to Achieve Social Acceptance



Social Acceptance for Nuclear Technologies

NRC Public Meeting on Regulatory Framework for Fusion
March 30, 2021

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Hoedl, Seth A. "A Social License for Nuclear Technologies." *Nuclear Non-Proliferation in International Law-Volume IV*. TMC Asser Press, The Hague, 2019. 19-44. https://arxiv.org/pdf/2009.09844

Hoedl, Seth A. "Ethical Review for Nuclear Power: Inspiration from Bioethics." *Nuclear Non-Proliferation in International Law-Volume VI.* (Springer/Asser Press, forthcoming in 2021)

Motivation: A Lack of Social Acceptance is a Risk to Fusion

- Examples of technologies that face this risk:
  1. Genetically modified food[1]
  2. Facial recognition
  3. Fission[2]
- A lack of acceptance increases capitals costs, litigation costs and risks, and regulatory burdens[3]

Risk-reducing technical solutions, regulatory compliance, and better "communication" or "education" are unlikely, on their own, to alleviate a lack of social acceptance[4]

1. Devos Y, Maeseele P, Reheul D, et al. "Ethics in the Societal Debate on Genetically Modified Organisms: A (Re)Quest for Sense and Sensibility." Agricultural and Environmental Ethics 21:29–61 (2008). https://doi.org/10.1007/s10806-007-9057-6
2. Bickerstaffe, J., Pearce, D., "Can there be a consensus on nuclear power?" *Social Studies of Science* 10:309:344 (1980); Slovic, P., "Perceived Risk, Trust, and the Politics of Nuclear Waste" *Science* 254:1603-1607 (1991).
3. Gunningham N, Kagan RA, Thornton D, "Social license and environmental protection: why businesses go beyond compliance," *Law & Social Inquiry* 29:307–341 (2004).
4. Otway HJ, Maurer D, Thomas K, "Nuclear power: The question of public acceptance," *Futures* 10:109–118 (1978). doi: 10.1016/0016-3287(78)90065-4

A Cautionary Fission Example: The Muria Nuclear Power Plant

- In July 2006, Indonesian government proposed four 1 GW reactors near the village of Balog, on the Muria peninsula[1]
- In September 2007, the Nahdlatul Ulama, the largest ‘traditionalist’ Islamic organization in Indonesia, determined that the reactors were forbidden under Islamic jurisprudence:
  1. Radioactive waste & local impacts, particular from thermal load to fish
  2. Business model
     - Transferred profits abroad, while Indonesia bore the risk and expense of decommissioning
     - Ongoing dependence on foreign expertise and materials

Neither fusion nor “outreach”/education would have likely been persuasive

1. Tanter R., “Nuclear fatwa: Islamic jurisprudence and the Muria nuclear power station proposal.” Nautilus Institute for Security and Sustainability, https://nautilus.org/apsnet/nuclear-fatwa-islamic-jurisprudence-and-the-muria-nuclear-power-station-proposal/ (2007).

Summary of Risks to Fusion

- Fusion that is not social accepted may face the same challenges as fission
- Technical distinctions between fusion and fission may not be enough, on their own, to secure fusion’s social acceptance
- Social acceptance may be just as important as key technical and economic milestones, such as net energy production, for climate change mitigation

Fusion has an opportunity to distinguish itself from fission, not just in how it uses nuclei, but also in how it approaches social acceptance

Two Established Methods to Achieve Social Acceptance

1. A “Social License”[1]
   - A process of acquiring “society’s consent” to a particular project or endeavor
   - Long history of successful analysis and application
   - Applied to project siting, extractive projects, ecological research, genetic engineering research, etc.
2. Ethical Review Committees[2]
   - 40-year application to controversial biomedical technologies
   - Global adoption and global literature pertaining to diverse ethical perspectives
   - Focus on non-technical perspectives

Neither approach is exclusive – both approaches complement each other

1. Gunningham N, Kagan RA, Thornton D, “Social license and environmental protection: why businesses go beyond compliance,” *Law & Social Inquiry* 29:307–341 (2004).
2. UNESCO, *National bioethics committees in action.* (2010); Watts G, “Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review.” Nuffield Council on Bioethics.(2012); Warnock M, “Report of the Committee of Inquiry into Human Fertilisation and Embryology.” U.K. Department of Health & Social Security, London. (1984) https://www.hfea.gov.uk/media/2608/warnock-report-of-the-committee-of-inquiry-into-human-fertilisation-and-embryology-1984.pdf.

Social License Approach

Features of the Social License Method

A two-way ***process*** that opens expertise to new questions and perspectives:[1]

- More than "education," public relations, or "letting the public see the experts at work"[2]
- Project proponents have to learn from and meaningfully consider input from non-experts
- Addresses what people actually worry about, rather than what they "should" worry about
- Creates a sense of "procedural justice," even for opponents of a particular activity[3]
- Acts as a form of peer review that generally improves outcomes for proponents and society[4]

Far more than a legal license or permit[5]: successful examples see regulatory compliance as only a starting point for social acceptance[6]

1. Stilgoe, J, *The received wisdom: opening up expert advice*. Demos, London, 2006. https://www.demos.co.uk/files/receivedwisdom.pdf
2. Raman, S, Mohr, A, "A social license for science: capturing the public or co-constructing research?," *Social Epistemology* 28:258-276 (2014).
3. Ottinger, G. "Changing Knowledge, Local Knowledge, and Knowledge Gaps: STS Insights into Procedural Justice." *Science, Technology, & Human Values* 38:250 (2013).
4. Reed, MS, "Stakeholder participation for environmental management: A literature review." *Biological Conservation* 141:2417-2431 (2008).
5. Rooney, D., Leach, J., Ashworth, P., "Doing the Social in Social License." *Social Epistemology* 28:209-218 (2014).
6. Gunningham N, Kagan RA, Thornton D, "Social license and environmental protection: why businesses go beyond compliance," *Law & Social Inquiry* 29:307–341 (2004).

Four Key Elements of a Social License

1. Engendering Trust[1]
2. Transparency[1,2]
3. Meaningful Public Engagement[1,2,3]
4. Protecting Human Health and Safety[4]

1. Rooney, D., Leach, J., Ashworth, P., "Doing the Social in Social License." *Social Epistemology* 28:209-218 (2014); Hall, N., Lacey, J., Carr-Cornish, S., Dowd, A-M., "Social licence to operate: understanding how a concept has been translated into practice in energy industries." Journal of Cleaner Production 86:301–310 (2015); National Academies of Sciences, Engineering, and Medicine, "Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values," National Academies Press (2016).
2. Coglianese C, Kilmartin H, Mendelson E "Transparency and public participation in the federal rulemaking process: Recommendations for the new administration." Geo Wash L Rev 77:924 (2008); Long JC, Scott D "Vested Interests and Geoengineering Research" *Issues in Science and Technology* 29:45–52 (2013).
3. Institute of Medicine "Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee." National Academies Press (2014).
4. Gunningham N, Kagan RA, Thornton D, "Social license and environmental protection: why businesses go beyond compliance," *Law & Social Inquiry* 29:307–341 (2004).

Social License Example 1: Pulp Mill Expansion Case Study

Traditional Process

1. Design a new plant
2. Seek legal approval
3. Inform the public regarding plans
4. Build new plant

Social License Process

1. Seek public input
2. Design new plant in light of public concerns
3. Seek legal approval
4. Build new plant

Reduced civil litigation, accelerated build, and improved result for community

1. Gunningham N, Kagan RA, Thornton D, “Social license and environmental protection: why businesses go beyond compliance,” *Law & Social Inquiry* 29:307–341 (2004).

Social License Example 2: Release of Sterile *Aedes Aegypti* Mosquitoes

Oxitec and the Florida Keys Mosquito Control District are jointly studying the use of genetically engineered *Aedes Aegypti*[1] mosquitoes for population control

Oxitec has undertaken deliberate and purposeful steps to acquire and keep a social license:

- Decades-long public engagement
- Exceeded U.S. and Florida regulatory compliance:
  - Experimental use conditional on non-binding local referendums[2]
  - Disseminated what would otherwise be confidential information to facilitate transparency[3]

1. https://www.keysmosquitoproject.com
2. Servick, K. "Update: Florida voters split on releasing GM mosquitoes," *Science*, Nov 10, 2016, https://www.sciencemag.org/news/2016/11/update-florida-voters-split-releasing-gm-mosquitoes
3. "Letter from Oxitec Ltd. To FDA DDM re: Draft Environmental Assessment for Investigational Use of Aedes aegypti OX513A, available at https://www.regulations.gov/document?D=FDA-2014-N-2235-1294

Social License Example 3: Nuclear Waste Siting in the U.S., Sweden and Finland

U.S. Process[1]

1. Yucca Mountain designated by Congress
2. DOE evaluated safety
3. NRC/EPA confirms evaluation
4. DOE builds repository

U.S. repository is stalled

Swedish[2]/Finish[3] Process

1. Invited communities to participate in a study
2. Evaluated geology in participating communities
3. Undertook a competition between communities
4. Selected a community
5. Build a repository

Finish repository is under construction
Swedish repository is pending approval

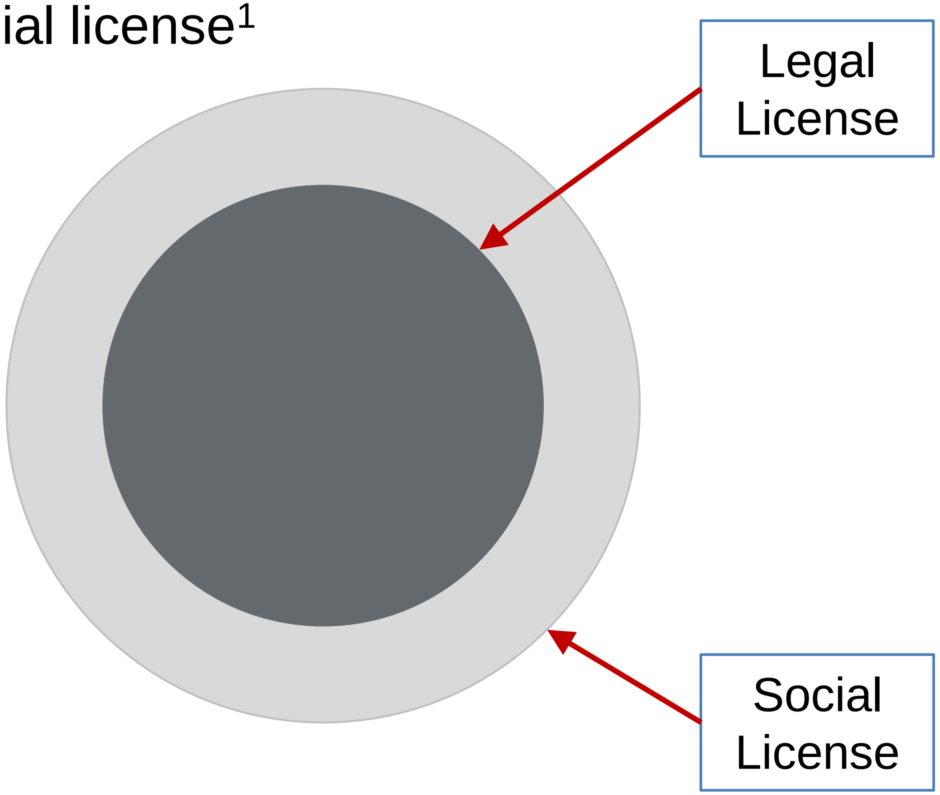
1. Cotton T "Nuclear Waste Story: Setting the Stage." In: Macfarlane A, Ewing RC (eds) Uncertainty Underground: Yucca Mountain and the Nation's High-level Nuclear Waste. MIT Press (2006); Stover, D., "The "scientization" of Yucca Mountain," Bulletin of the Atomic Scientists. https://thebulletin.org/scientization-yucca-mountain (2011).
2. Lidskog R, Sundqvist G, "On the right track? Technology, geology and society in Swedish nuclear waste management." Journal of Risk Research 7:251–268 (2004); Swedish Nuclear Fuel and Waste Management Company, Application for license under the nuclear activities act, http://www.skb.com/future-projects/the-spent-fuel-repository/our-applications/ (2011); SKB, "How Forsmark was selected," https://www.skb.com/future-projects/the-spent-fuel-repository/how-forsmark-was-selected/ (2021).
3. Curry, A., "What Lies Beneath," The Atlantic, https://www.theatlantic.com/magazine/archive/2017/10/what-lies-beneath/537894/ (2017); McEven, T., Aikas, T., "The Site Selection Process for a Spent Fuel Repository in Finland – Summary Report," Posiva Reports 2000-15 (2012); "Posiva is granted construction licence for final disposal facility of spent nuclear fuel," https://www.posiva.fi/en/index/news/pressreleasesstockexchangereleases/2015/ posiva_is_granted_construction_licence_for_final_disposal_facility_of_spent_nuclear_fuel.3225.html (2015).

Relationship between Social License and Legal License

- Regulatory compliance is necessary, but not sufficient, for a social license[1]

- Legal license can help by:
  - Addressing health and safety concerns
  - Facilitating meaningful engagement and transparency

- Regulatory frameworks can hinder social acceptance:
  - Foreclose meaningful engagement and/or transparency
  - Undercut confidence in health and safety
  - Undercut trust by giving the impression of a hidden agenda



Regulatory agencies generally do not have responsibility for a social license

1. Gunningham N, Kagan RA, Thornton D, "Social license and environmental protection: why businesses go beyond compliance," *Law & Social Inquiry* 29:307–341 (2004).

Bioethical Review

Features of the Bioethical Review Committee Method

Instructed to identify ethical issues and propose solutions to regulators, funders and governments

- Composed of a mixture of experts and non-experts, including biologists, physicians, lawyers, ethicists, religious scholars, and members of the general public[1]
- Committees seek compromise between competing ethical perspectives[2]
- Proposed solutions are subject to further multi-stakeholder review and public comment[3]
- Successful compromises are implemented through clear technical limits that are easy to explain, easy to understand and easy to defend[4]

Brings to light and addresses non-technical concerns

1. UNESCO, Universal Declaration on Bioethics and Human Rights. Article 18. (2005) https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights
2. Warnock M, "Moral Thinking and Government Policy: The Warnock Committee on Human Embryology." *The Milbank Quarterly* (1985) 63:504
3. Bioethics Advisory Committee Singapore, "Ethical, legal and social issues in human stem cell research, reproductive and therapeutic cloning." (2002) https://www.bioethics-singapore.gov.sg/publications/reports/ethical-legal-and-social-issues-in-human-stem-cell-research-reproductive-and-therapeutic-cloning
4. Hyun I, Wilkerson A, Johnston J, "Embryology policy: Revisit the 14-day rule." *Nature News* (2016) 533:169; Cavaliere G "A 14-day limit for bioethics: the debate over human embryo research." *BMC Medical Ethics* (2017) 18:38

Bioethical Review Example: Human Embryonic Stem Cell in Singapore

Bioethics Advisory Committee

Expert Analysis

"Consultation Paper"

Public Comment

In-person Focus Groups

Written comment and in-person dialogue

39 Local Organizations

- Medical
- Scientific
- Legal
- Religious

Three Press Conferences

Different states strike different balance between expert/religious and direct public input

Recommendations

Ministry of Health

1. Lim S, Ho C. The Ethical Position of Singapore on Embryonic Stem Cell Research. *SMA News* 35:14 (2003)
2. Bioethics Advisory Committee Singapore. Ethical, legal and social issues in human stem cell research, reproductive and therapeutic cloning. https://www.bioethics-singapore.gov.sg/publications/reports/ethical-legal-and-social-issues-in-human-stem-cell-research-reproductive-and-therapeutic-cloning. (2002)

Relationship between Ethical Review and Regulatory Agencies

- Regulatory agencies generally do not undertake ethical review themselves
- Typically, there is a time gap between ethical review recommendations and adoption by regulatory agencies
- Recommendations are often respected prior to formal legal adoption

Summary of Social Acceptance Insights

Insights for the NRC

- NRC should likely not see itself as responsible for either a social license or ethical review
  - Social acceptance is more likely to be facilitated if NRC does not advocate for fusion
- With social acceptance in mind, the regulatory framework should:
  - Give the NRC the authority and capacity to manage the full set of likely public concerns
  - Put public engagement front and center in the development and implementation of the framework
  - Maximize transparency and presume disclosure rather than non-disclosure
  - Be flexible so that it can respond to changes in both public concerns and the underlying fusion technology
- Framework should be easy to implement, for both NRC and regulated entities

Insights for the Public

- Engage in these meeting and use them as an opportunity to share concerns to both the NRC and/or fusion companies
- Ask colleagues to participate
- If you have concerns, think of ways that the NRC or companies could productively address them

Insights for the Fusion Community

- View the development and implementation of the regulatory framework as a ***process*** of convincing the public that fusion is safe
- Help the NRC identify the public's concerns
- Help the NRC develop flexible, practical and confidence-inspiring mechanisms for addressing these concerns
- Follow the Oxitec, Finnish and Swedish examples and avoid the Yucca Mountain experience:
  - View regulatory compliance as critically necessary, but not sufficient for social acceptance
  - Avoid an exclusive focus on health and safety for social acceptance
  - Encourage public engagement and maximize transparency

Proposal for a ***Process*** of Developing the Regulatory Framework Focused on Public Concerns

Catalogue of
- **Public Concerns**
- **Health, Safety and Proliferation Risks**

Expert Analysis

Public Comment

For each concern /risk

Is this risk/concern addressable by the NRC?

If so, what's an effective, practical, flexible and public-confidence inspiring mechanism to address the concern/risk?

Expert Analysis

Public Comment

Regulatory Mechanism

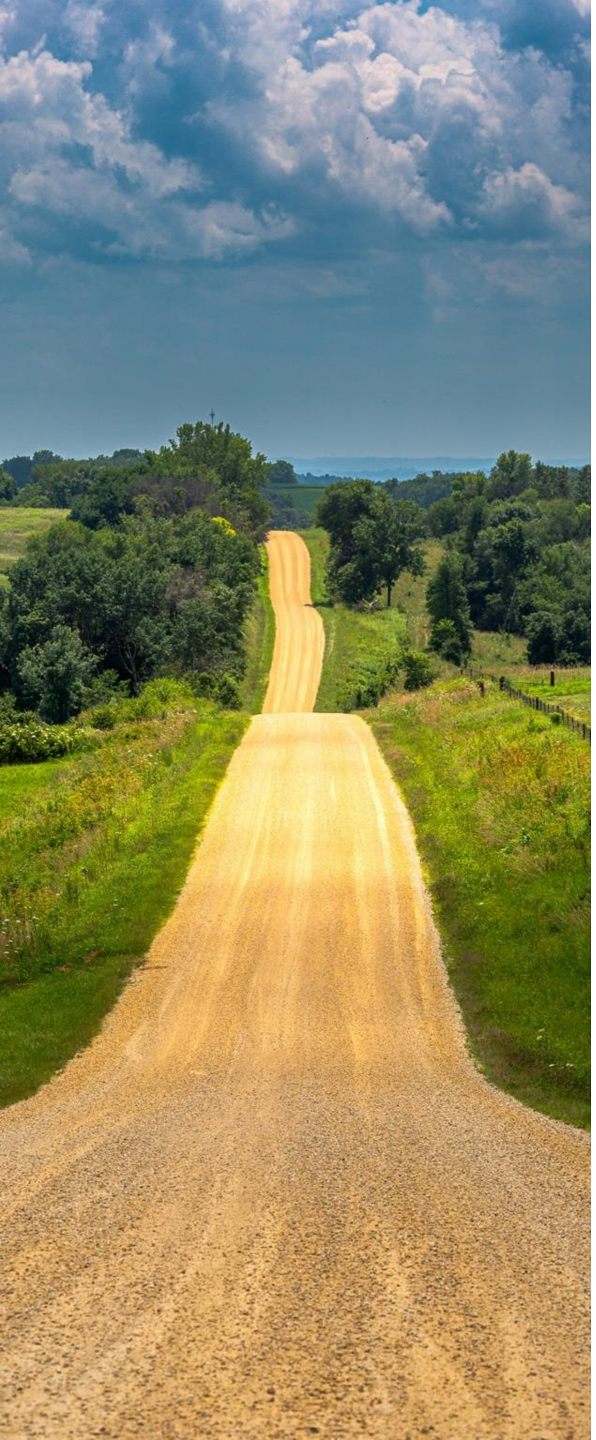
Regulatory Framework

Mechanism 1

Mechanism 2

Mechanism N

This process would:
- Focus the framework on public concerns, rather than expert concerns
- Provide a forum for airing public concerns that the fusion community may need to address outside of NRC regulation



Social Acceptance for Nuclear Technologies

NRC Public Meeting on Regulatory Framework for Fusion

March 30, 2021

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Hoedl, Seth A. "A Social License for Nuclear Technologies." *Nuclear Non-Proliferation in International Law-Volume IV*. TMC Asser Press, The Hague, 2019. 19-44. https://arxiv.org/pdf/2009.09844

Hoedl, Seth A. "Ethical Review for Nuclear Power: Inspiration from Bioethics." *Nuclear Non-Proliferation in International Law-Volume VI.* (Springer/Asser Press, forthcoming in 2021)

Developers Perspectives on Potential Hazards, Consequences, and Regulatory Frameworks for Commercial Deployment

BREAK

2:40pm-2:50pm EST

Licensing and Regulating Byproduct Materials by the NRC and Agreement States

Overview of the State - NRC Regulatory Partnership

NRC – State Interactions

- Agreement State program
- State Liaison Program
- Section 274i of Atomic Energy Act
- Memorandum of Understanding for NPPs
- Emergency Preparedness
- Transportation of Spent Fuel, Waste, and Risk-Significant Sources

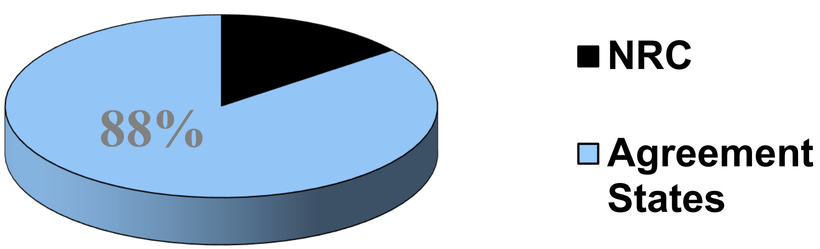
Agreement State Program

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

- Section 274 of Atomic Energy Act
  - Established federal/state roles
  - Recognized States' experience
  - Promotes cooperative relationship
  - Promotes orderly regulatory pattern
- Established in 1959
- First Agreement State in 1962

NRC and Agreement State Licenses

- 39 Agreement States regulate approximately 16,000 specific radioactive material licenses
- NRC regulates approximately 2,200 specific licenses



What is an Agreement State?

- NRC discontinues and the State assumes regulatory authority over certain categories of radioactive materials (i.e., agreement material) through a cooperative Agreement with the NRC
- State becomes responsible for:
  - licensing, inspection, and enforcement of medical, academic, and industrial uses of certain radioactive materials
  - responding to certain types of incidents and allegations within their borders

National Materials Program (NMP)

- The NMP provides a coherent national system for the regulation of agreement material with the goal of protecting public health, safety, security and the environment through compatible regulatory programs. **Through the NMP, the NRC and Agreement States function as regulatory partners.**
- NRC and Agreement State work together on:
  - Development of regulatory guides and procedures
  - Development of regulations
  - Integrated Material Performance Evaluation Program (IMPEP)

    Adequate and Compatible

Adequacy and Compatibility

- Adequate to protect public health safety and security
- Compatible with NRC requirements
  - State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of **agreement material (source, byproduct, and small quantities of special nuclear material)** on a nationwide basis.

Steps to Development Part 30 Requirements

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

If the Commission decides on a Part 30 framework…..

- Regulatory basis
- Prepare draft rule language and compatibility designations
- Prepare licensing and inspection guidance – public comment
- Commission approval to publish for comment
- Public comment
- Address comments – prepare proposed final rule
- Commission approves final rule
- Agreement States adopts and implements compatible rules and guidance

Discussions of Possible Frameworks for Licensing/Regulating Commercial Fusion

Considerations for Part 30 Licensing of Fusion Energy

Basis for the License

- Design and hazard analysis will determine the scope of requirements needed for a license for the safe use of radioactive materials

- Regardless of the regulatory approach, similar information will be needed to evaluate the design and radiological hazards associated with a commercial fusion facility

- The NRC Commission will make the final decision on the regulatory framework prior to the start of any rulemaking for fusion energy systems

Basis for the License

Design Requirements

1. What is the overall design for the fusion facility?
2. How will the facility be constructed?
3. What codes and standards will be used for critical systems, structures, and components?
4. How will critical systems, structures, and components be environmentally qualified?
5. What acceptance testing will be performed for systems, structures, and components prior to initial operation?

Basis for the License

Hazard considerations

1. What are the hazards associated with this fusion facility?
2. How likely is it that any of these hazardous conditions will occur?
3. What are the consequences if one of these hazardous conditions occurs?
4. What type of defense-in-depth will exist for critical safety systems, structures and components?
5. What mitigating systems, structures, or components will exist for hazardous conditions identified (e.g., interlocks, shielding (primarily neutron), fire protection, worker and public safety protection)?
    - For example, what are the safety systems required to prevent the accidently release of tritium?

Specific License Requirements for Part 30

- Radionuclides (maximum possession limits)
  - Tritium
  - Activation Products
- Emergency plans
- Financial Assurance and Decommissioning
- Training
  - Operator training
  - RSO qualifications
- Facility design requirements – construction, acceptance testing, codes and standards, facility modifications, equipment qualification

Specific License Requirements for Part 30

- Radiation Safety Program
  - Personnel monitoring
  - Radiation monitoring
    - Routine surveys
    - Contamination control
    - Effluent and Environmental Monitoring
  - Operating and Emergency Procedures
    - Procedures for safe use of radionuclides
    - Security of materials
    - Inspection and Maintenance
    - Equipment Testing Requirements
    - Attendance during operation
    - Reporting Requirements
  - Routine Audits

Specific License Requirements for Part 30

- Waste management
- Environmental protection regulations – Part 51
- Other Hazards – e.g., ozone, chemicals, lasers

Questions on Licensing Fusion Systems

- Radionuclides
  - Tritium is soluble, difficult to contain and has a tendency to migrate – are the pathways adequately monitored?
  - Part 30 licensing is based on maximum possession limit - activation products will increase over time. How will this be controlled to ensure that maximum possession limits are not exceeded?
  - What is being activated – is the neutron shielding preventing activation outside the plasma chamber?
- Emergency plans (if required)
  - Regulations require an evaluation of off-site consequences with over 2 grams of tritium and require a plan if greater than 1 rem
    - What are the pathways and potential release scenarios?
    - What do you believe needs to be in the emergency plan?

Questions on Licensing Fusion Systems

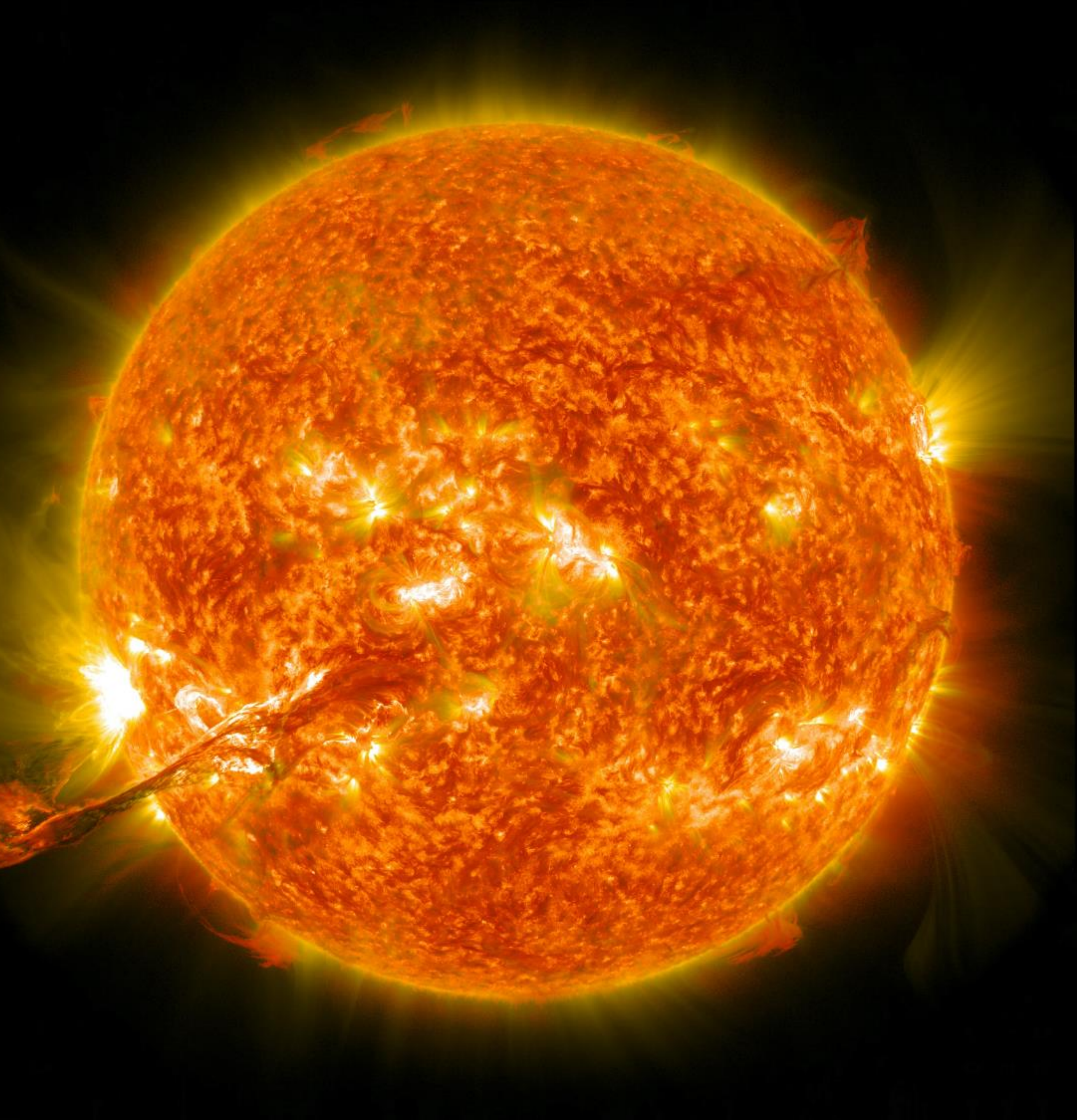
- Financial Assurance and Decommissioning
  - How will you determine the amount of activation products to determine the amount of financial assurance needed?
  - How do you plan to decommission the facility?
- Training
  - What should be the requirements for an individual operating a fusion energy plant?
  - Who will periodically evaluate the performance of the operator?

Questions on Licensing Fusion Systems

- Radiation Safety Program
  - Tritium is challenging to monitor and measure – what equipment and what frequency will be used to routinely measure tritium?
  - What are the energies of the neutrons typically present?
  - How will you ensure that personnel are protected during operations?
  - What radiation hazards will workers at the fusion facility be exposed to during operations and what type of monitoring of these workers is anticipated?

Questions on Licensing Fusion Systems

- Waste management
  - How much radioactive waste will routine operations produce?
  - What is the lifespan of the components at the facility that become activated? Will they need to be replaced periodically? Where will they be securely and safely stored onsite or will be shipped offsite immediately for disposal?
- Environmental protection regulations
  - What considerations are needed to address the requirements in 10 CFR Part 51?
  - Should fusion facilities be considered categorically excluded per 10 CFR Part 51.22?



REGULATING FUSION

UNDER EXISTING BYPRODUCT FRAMEWORK

Agreement State Representative to Fusion Energy Systems Working Group

DIEGO SAENZ
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TODAY'S AGENDA

- Current Definitions
- What Already Applies
- What Doesn't Apply
- Tritium
- Gaps
- Benefits

EXISTING FRAMEWORK-DEFINITIONS

UTILIZATION FACILITY:

OR

SHINE®

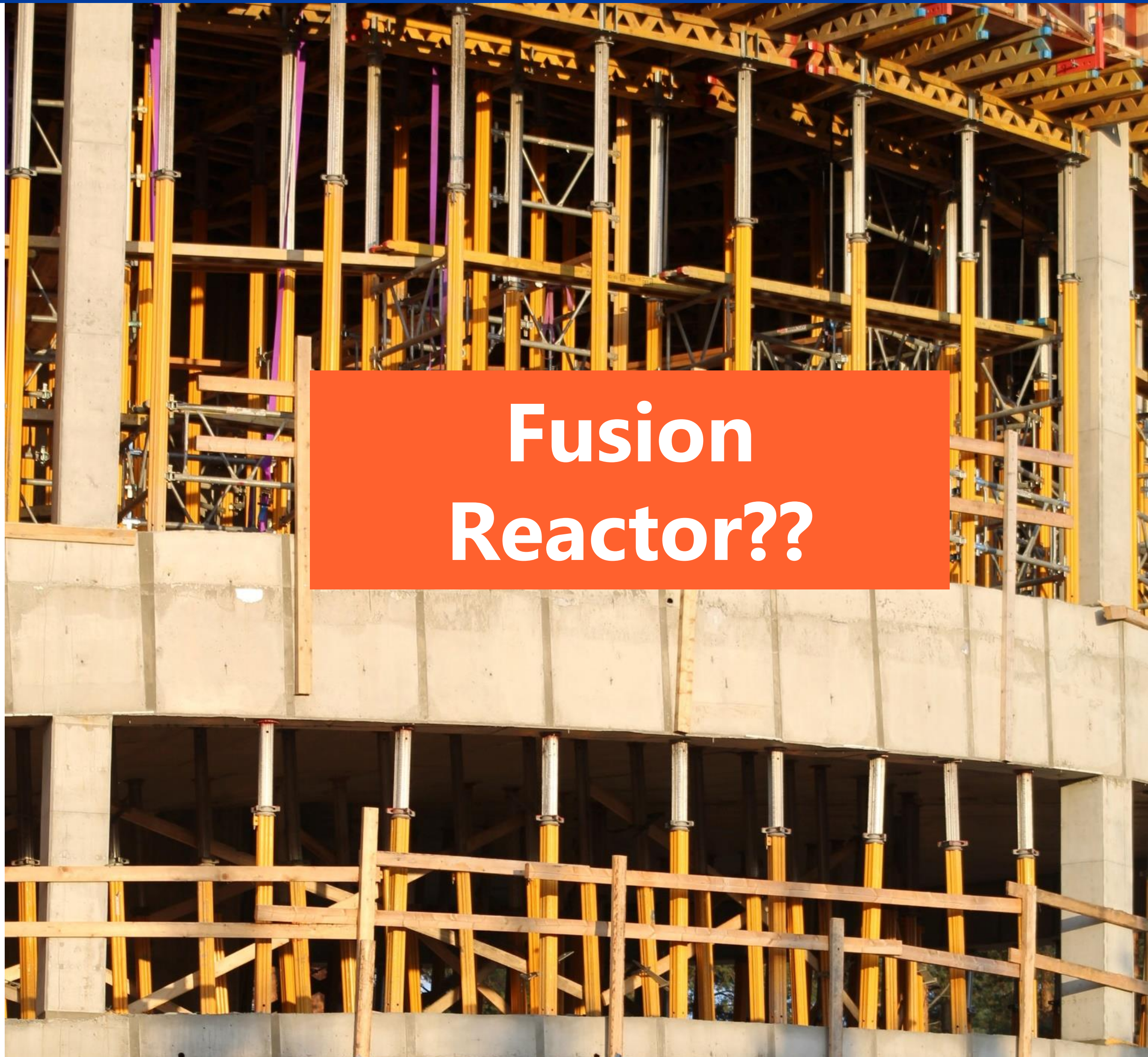
NUCLEAR REACTOR:

EXISTING FRAMEWORK-DEFINITIONS

10 CFR Part 50

WI DHS

NEIMA



Fusion Reactor??

EXISTING FRAMEWORK-WHAT ALREADY APPLIES

- NRC and Agreement States regulate as partners
- Financial Assurance and Decommissioning Funding Plan
- Emergency Plan (or evaluation of less than 1 Rem TEDE)
- Device Specific Safety Evaluation Reviews

- Environmental monitoring
- Quality Assurance and Quality control as well as reporting of defects (Part 21)
- Safety Culture
- Non-NRC requirements

- Existing waste disposal pathways
- Approve user/operator and RSO
- Scaled to quantities of licensed material (e.g., tritium, activation products)
- Environmental Impact Statements reviews as needed

EXISTING FRAMEWORK-DOES NOT APPLY

- Security/Part 37
- Price Anderson Act
- Foreign ownership requirements
- Mandatory Federal Hearings
- Current prescriptive operator staffing requirements
- Import and Export requirements of devices themselves (licensed material currently has import and export requirements)
- Nuclear Waste Fund Fee (42 U.S. Code § 10222)

TRITIUM

- Financial Assurance
- Decommissioning Funding Plan
- Emergency Plan (or evaluation)
- Security (as needed)
- Environmental monitoring

EXISTING FRAMEWORK-PART 30 DEVICES

- Considers useful life of components
- Part 21 requirements
- Safety Evaluation (or SSDR)

GAPS AND POTENTIAL GAPS

- Part 37 Appendix A
- Fusion technology specific licensing guidance
- Detailed/prescriptive training requirements
- Fusion devices without radioactive material
- 10 CFR 50.59 (or like) process

BENEFITS OF REGULATING AS BYPRODUCT MATERIAL

- Current licensees
- Radiological risks consistent with existing byproduct material uses
- Risk informed with scaled requirements
- Framework is flexible
- Devices with little radioactive material


QUESTIONS?

DEFINITIONS – 10 CFR 50

- Utilization facility *[per 10 CFR 50.2]* –
  - (1) Any nuclear reactor other than one designed or used for the formation of plutonium or U-233; *[e.g., Point Beach and UW research Rx]* or
  - (2) An accelerator-driven subcritical operating assembly used for the irradiation of material containing special nuclear material and described in the application assigned docket number 50-608. *[e.g., SHINE]*
- Nuclear reactor *[per 10 CFR 50.2]* –
  - An apparatus, other than an atomic weapon, designed or used to sustain nuclear fission in a self-supporting chain reaction.

DEFINITIONS – 10 CFR 50

- Byproduct material *[per 10 CFR 50.2]*–
  - (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;
  - (2)
    - (i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or
    - (ii) Any material that—
      - (A) Has been made radioactive by use of a particle accelerator; and
      - (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and
  - (3) Any discrete source of naturally occurring radioactive material, other than source material, that—
    - (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and
    - (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.
  - 42 U.S. Code § 2014 (e)(2) - the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content;
- Particle accelerator *[per 10 CFR 50.2]*-
  - 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. For purposes of this definition, accelerator is an equivalent term.

DEFINITIONS - NEIMA

- Advanced Nuclear Reactor *[per Sec. 3 (1) of Nuclear Energy Innovation and Modernization Act]*—
  - The term ''advanced nuclear reactor'' means a nuclear fission or fusion reactor, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10, Code of Federal Regulations (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as— (A) additional inherent safety features; (B) significantly lower levelized cost of electricity; (C) lower waste yields; (D) greater fuel utilization; (E) enhanced reliability; (F) increased proliferation resistance; (G) increased thermal efficiency; or (H) ability to integrate into electric and nonelectric applications.

EXISTING FRAMEWORK - DEFINITIONS

- The State of Wisconsin currently exercises regulatory jurisdiction over all radioactive materials regardless of source
- Radioactive material *[per DHS 157.03(299)]* -
  - Any solid, liquid or gas that emits radiation spontaneously.
- What is a fusion reactor under Part 53?

TRITIUM

- Financial Assurance currently required for greater than 1 Ci (~0.1 mg) of tritium
- Decommissioning Funding Plan currently required for greater than 100 Ci (~10 mg) of tritium
- Emergency Plan (or evaluation) currently required for more than 20 kCi (~2 g)
- 0.54MCi (~54g) is Category 2 quantity and 54MCi (~5.4kg) is Category 1 quantity (IAEA definition – currently not included in NRC definition)
- Environmental monitoring for tritium is something that States currently handle and have experience from existing uses (e.g., operating fission reactors)

EXISTING FRAMEWORK – DOES NOT APPLY

- Security/Part 37 (H-3 not included in Part 37 Appendix A)
- Price Anderson Act
- Foreign ownership requirements
- Mandatory Federal Hearings
- Prescriptive operator staffing requirements
- Import and Export requirements of devices themselves (licensed material currently has import and export requirements)
- 42 U.S. Code § 10222 - Nuclear Waste Fund *[stayed by courts]*
  - (a)(2) For electricity generated by a civilian nuclear power reactor and sold on or after the date 90 days after January 7, 1983, the fee under paragraph (1) shall be equal to 1.0 mil per kilowatt-hour.

Considerations for a New Regulatory Approach for Fusion Energy

U.S Nuclear Regulatory Commission

March 30, 2021

Background

April 2009

SECY-09-0064

- Request for the Commission to establish Regulatory Jurisdiction over commercial Fusion systems. In summary:

  1. Maintain Status Quo, or
  2. Commission asserts (or not) jurisdiction over commercial Fusion systems.

July 2009

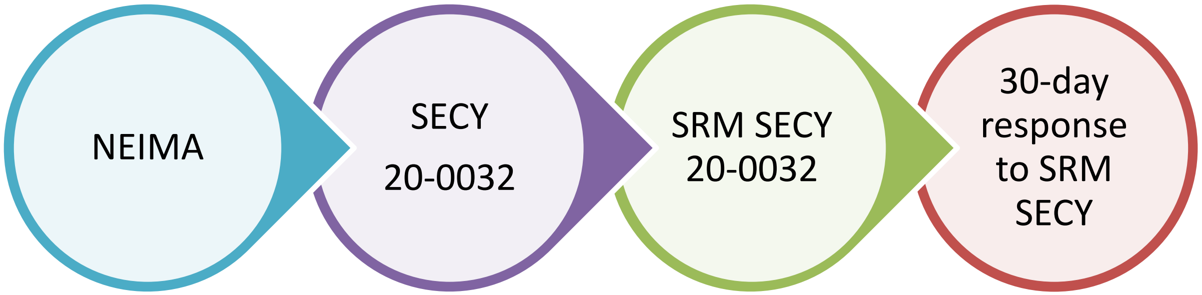
SRM SECY-09-0064

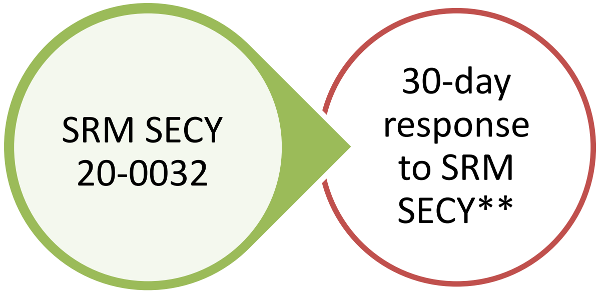
- Commission approved staff's option 2: "…the NRC has regulatory jurisdiction over commercial fusion energy devices whenever such devices are of significance to the common defense and security, or could affect the health and safety of the public."

- "The staff, however *should wait until commercial deployment of fusion technology is more predictable*, by way of successful testing of a fusion technology, before expending significant resources to develop a regulatory framework for fusion technology."

Background

- Nuclear Energy Innovation and Modernization Act (NEIMA) was signed into law in January 2019 and requires the NRC to complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use for commercial advanced nuclear reactors no later than December 2027
    - (1) ADVANCED NUCLEAR REACTOR—The term “advanced nuclear reactor” means a nuclear fission or fusion reactor**,** including a prototype plant… with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, …





Commission Direction on Rulemaking Plan

- In SRM-SECY-20-0032*, the Commission:
  - Approved the staff's proposed approach for the rulemaking
  - Directed the staff to provide:
    - a schedule with milestones and resource requirements to achieve publication of the final Part 53 rule by October 2024
    - key uncertainties impacting publication of the final rule by that date
    - options for Commission consideration on licensing and regulating fusion energy systems
  - Directed the staff to develop and release preliminary proposed rule language intermittently, followed by public outreach and dialogue.

(SRM 10/2/2020- ADAMS ML20276A293) (30-day SRM response 11/2/2020- ADAMS ML20288A240)

U.S.NRC
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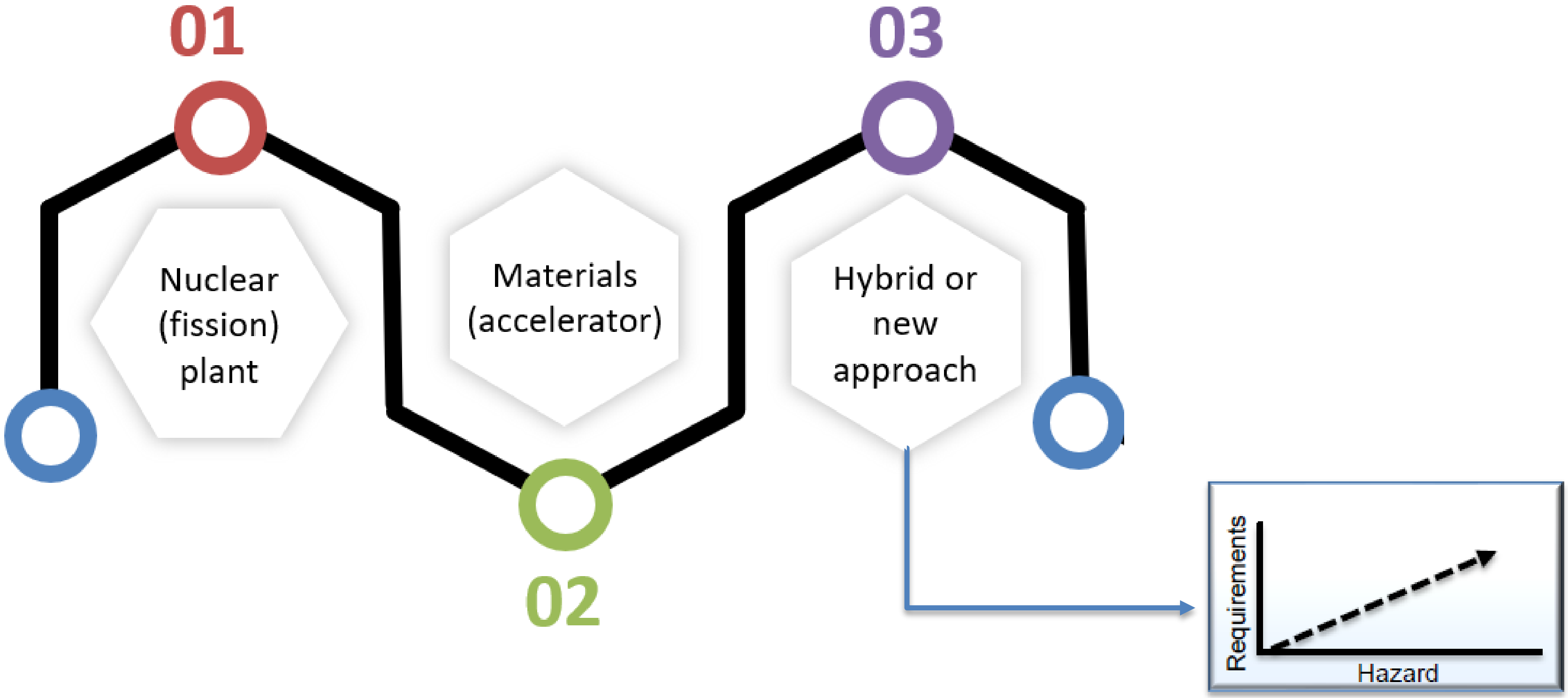
Protecting People and the Environment

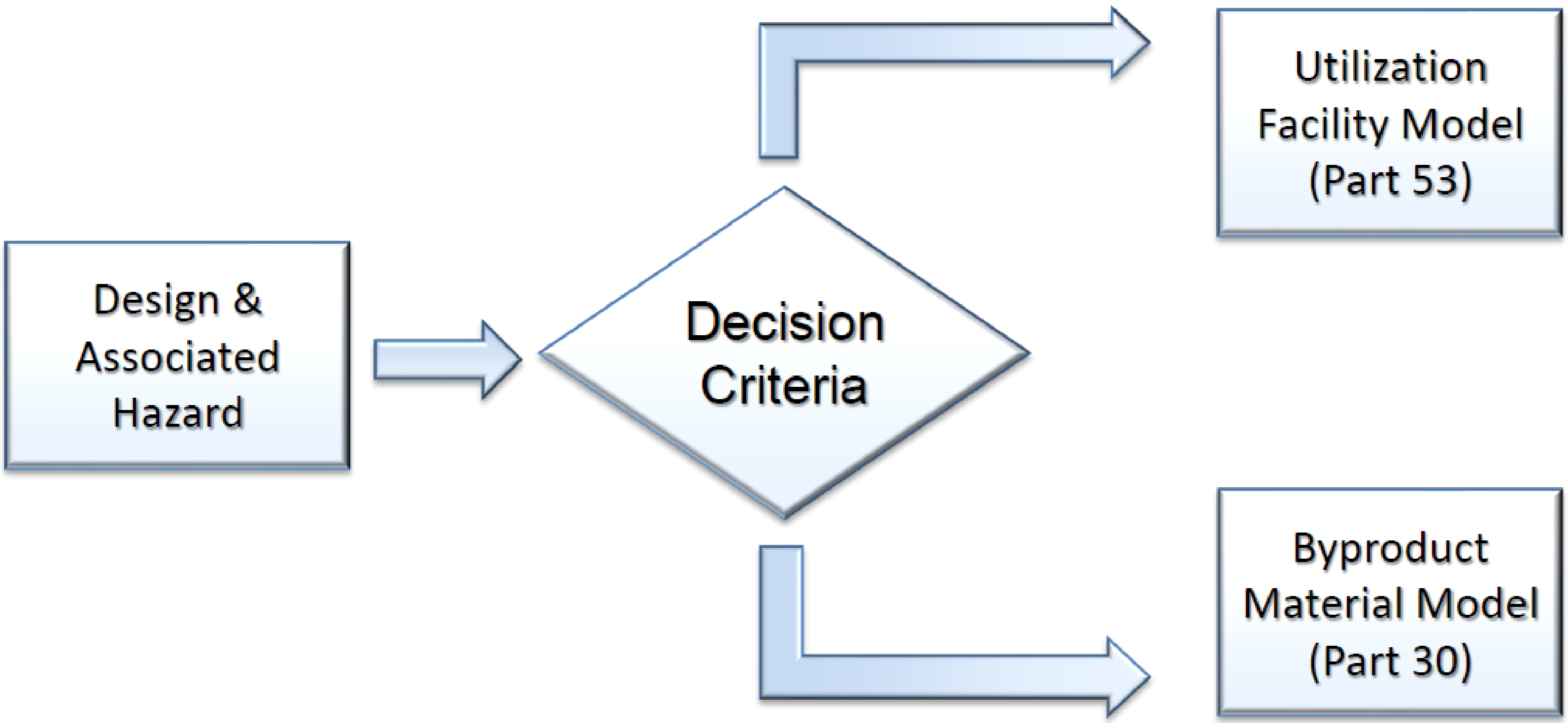
Regulatory Approaches

- Preliminary assessments left open the regulatory approach for commercial fusion reactors
- Possible approaches include treatment similar to:



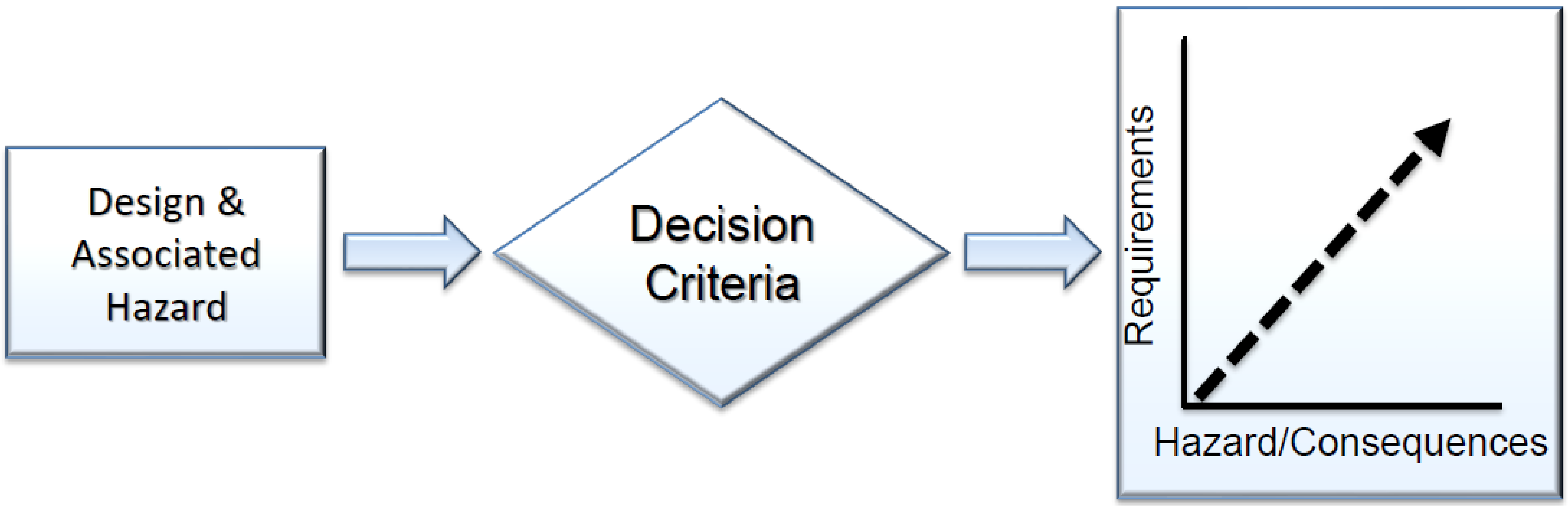
Hybrid Approach

- *3a-Within current framework (fragmented)*:



Hybrid Approach

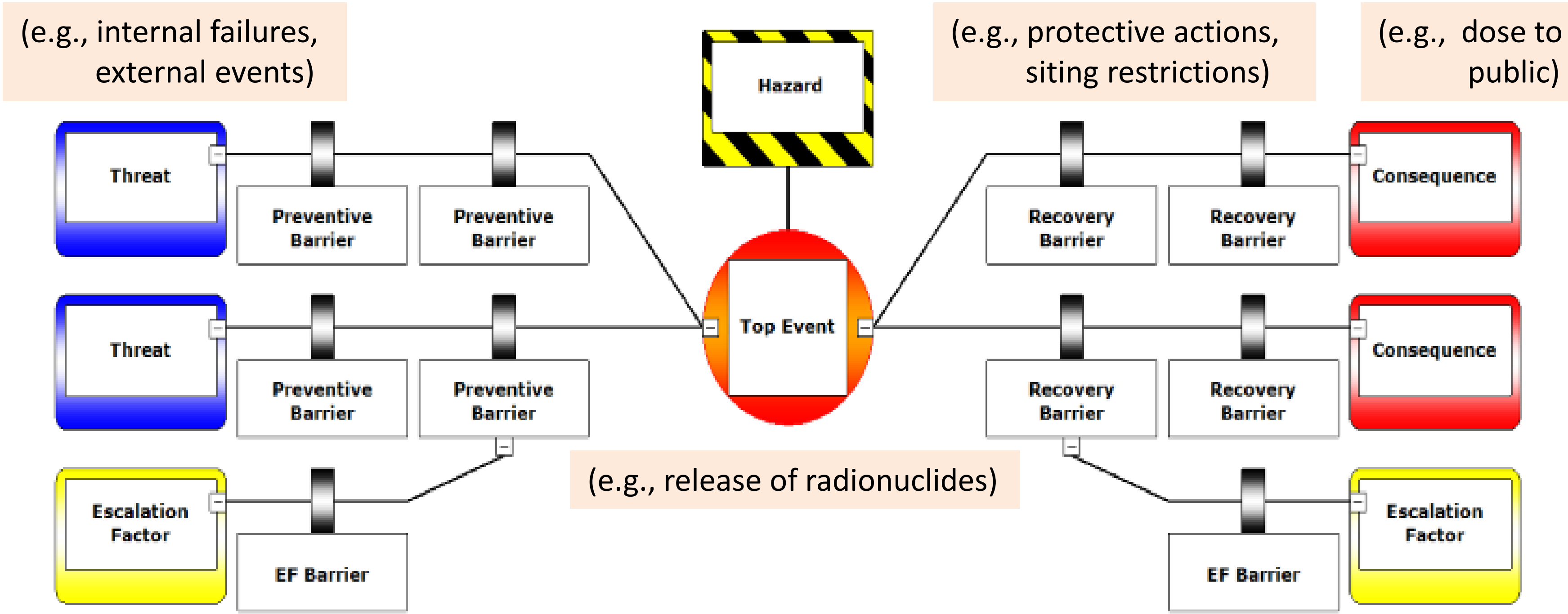
- *3b-Within a dedicated Fusion framework (consolidated):*



Key Elements for Development of Hybrid Approach

- Leverage existing framework (NRC, DOE, OAS, etc) to extent practical,
- Risk-Informed, Performance based approach,
- Technology-Inclusive for various Fusion systems (fuel types and facility designs), and
- Graded and scaled approach that balances requirements against hazard/risk and consequences.

Integrated, Risk-Informed Approach



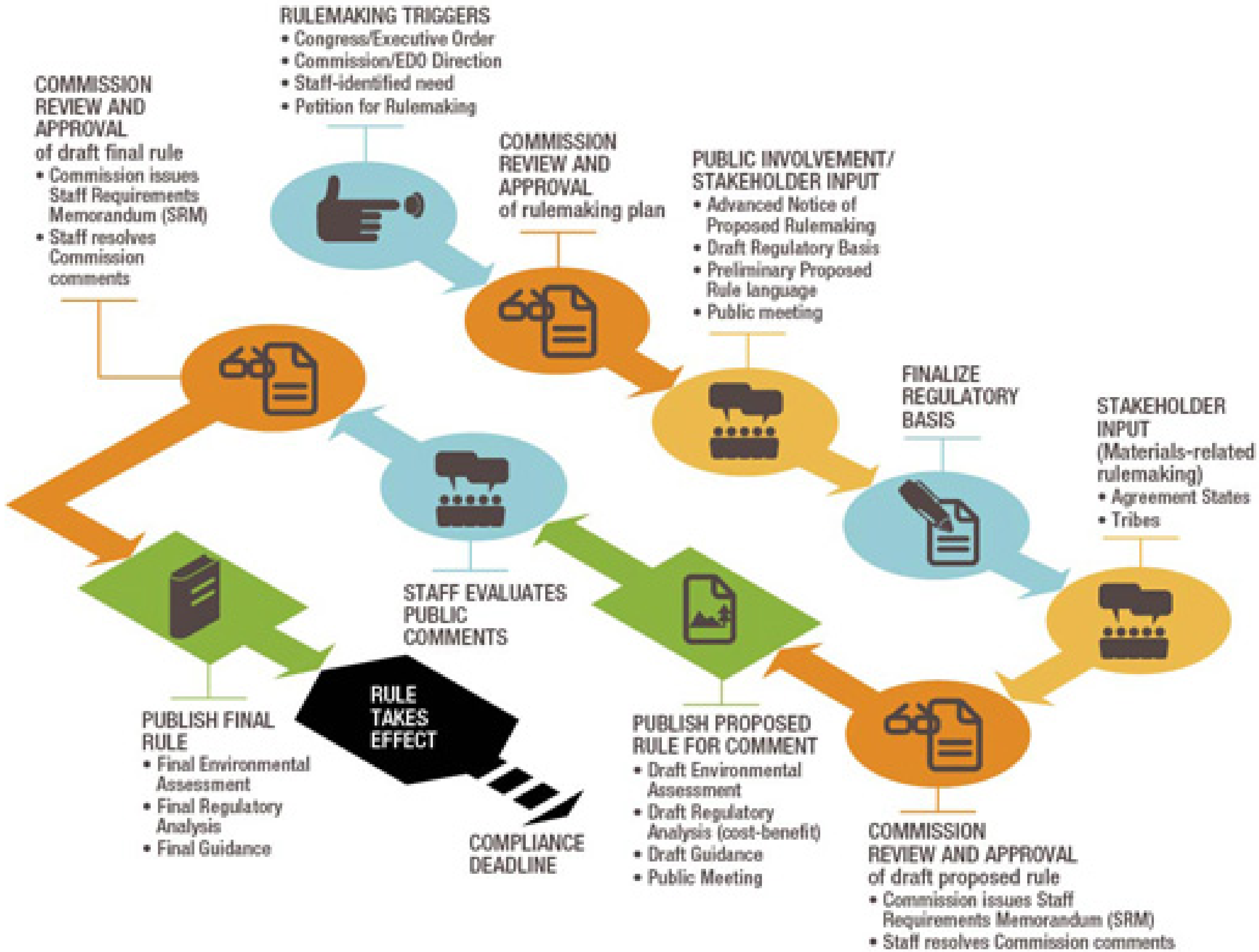
Bow-Tie Risk Management Figure

Hybrid Approach – Performance Based Categorization

- Design criteria in conjunction with safety objectives/requirements would form the basis and allow for a performance-based, graded regulatory approach commensurate with technology.
- Well defined safety objectives/requirements would promote regulatory stability, predictability, and clarity by allowing for a systematic and predictable classification of Fusion systems.
- *For example*:
  - In NPPs (Proposed rulemaking for scalable emergency planning zone)
  - In RTRs (For RTRs licensed to operate at 2 megawatts (2,000,000 watts) or greater, the inspection program is completed annually. For reactors licensed to operate at power levels below 2 megawatts, the inspection program is completed biennially (every two years).
  - In DOE facilities (DOE-STD-1027-2018 provides requirements and guidance for determining if a Department of Energy (DOE) nuclear facility is a Hazard Category (HC) 1, 2, 3, or Below HC-3 nuclear facility based on hazard consequences.)

A DOE nuclear facility categorized as…	Has the potential for…
Hazard Category 1	Significant off-site consequences
Hazard Category 2	Significant on-site consequences beyond localized consequences
Hazard Category 3	Only local significant consequences
Below Hazard Category 3	Only consequences less than those that provide a basis for categorization as a hazard category 1, 2, or 3 nuclear facility.

A TYPICAL RULEMAKING PROCESS



A Graded Approach to Fusion Regulation

NRC Workshop Presentation

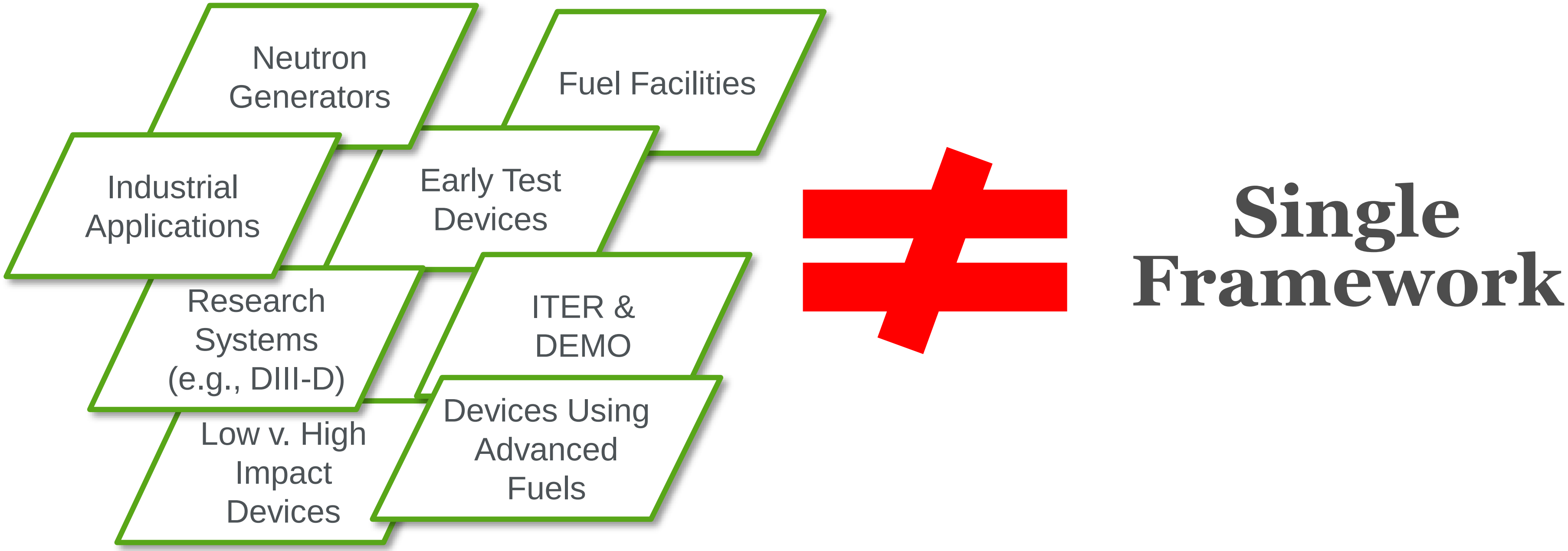
Sachin Desai
March 30, 2021

Agenda

- Fusion Diversity Warrants a Graded Approach
- A Graded Approach & NRC Best Practices
- Preliminary Considerations for a Graded Approach
- Suggested Next Steps

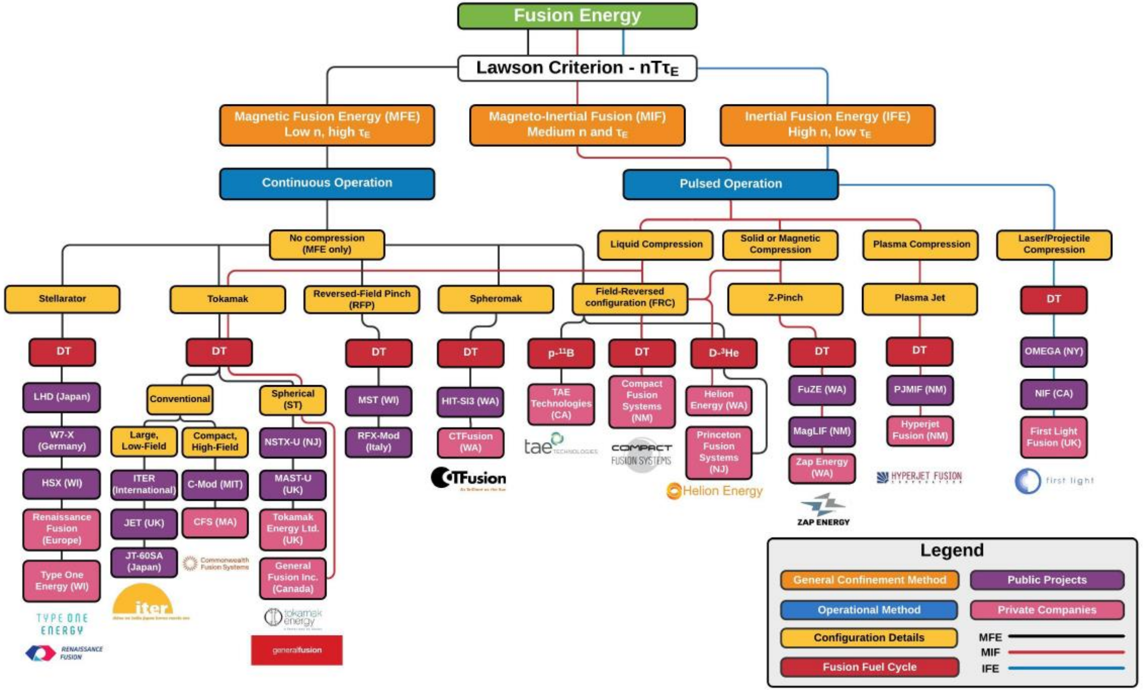
Fusion Diversity Warrants a Graded Approach

Fusion is a field of physics, not just a single power source



Fusion Diversity Warrants a Graded Approach

Incredible diversity at just the dawn of the fusion age . . .



Source: Dr. Sutherland, CTFusion

A Graded Approach & NRC Best Practices

A Graded Approach is . . .

- **Risk-Informed:** Different levels of regulation based on actual risk levels

- **Performance Based:** Performance metrics can inform regulatory tiers

- **Enabling for State Partners:** States are the experts today in regulating accelerators

- **Built for the Long Term:** We don't want to repeat this all in 10 years

Preliminary Considerations

Consideration 1: Work Up, Not Down

- Many planned private-sector fusion devices are more like accelerators than reactors
  - **Legally** (72 Fed. Reg. 55,864 & 10 CFR 30.4)
  - **Technically** (states regulate large accelerators, cyclotrons, and more)
- It is easier to risk-inform when starting fresh
- "Working up" allows states to continue to play an important role

Preliminary Considerations

Consideration 2: Performance Based Dividing Lines

Illustrative Metrics for Discussion

Potential Factors To Divide Tiers	Sample Performance-Based Threshold
Accident Risk	• Accident risk falls below the ~1 rem public dose threshold • Passive management of residual heat with a high margin of safety
Shielding & Safety During Operations	• Leverages only low-complexity, passive shielding during operation
Waste	• Only generates and stores low level radioactive waste
Proliferation Risk	• No reasonable path for generating special nuclear material if operated as intended with low-complexity or passive security protections

Preliminary Considerations

Consideration 3: Implement Differences in Process

- Rubber meets the road with the licensing process
  - Timelines
  - Dollars
  - Certainty

- Sample process improvements based on tier:
  - State licensing for lower-impact devices
  - Depth of analyses (e.g., PRA) differs with tier
  - Number of issues to evaluate drops with tier

Suggested Next Steps

- **Build out the technical framework**
  - What does the community need to provide to get to year-end?
- **Identify the legal path**
  - Identify the right path technically, then solve for legal issues
  - Targeted asks of Congress as needed
- **Build out the timeline to 2027**
  - Take advantage of the full time under NEIMA

QUESTIONS?

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