

The background of the slide features a complex, abstract network diagram. It consists of numerous nodes of varying sizes and colors (black, blue, and grey) interconnected by a web of thin, light grey lines. Some nodes are highlighted with larger, solid-colored circles. The overall aesthetic is technical and modern, suggesting a focus on systems, infrastructure, or interconnected networks.

Developing a Regulatory Framework for Fusion Energy Systems

March 30, 2021

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: <ul style="list-style-type: none">• Fusion Industry Association - <i>Industry Remarks</i>• TAE – <i>Regulatory Insights</i>• Commonwealth Fusion Systems – <i>Fusion Technology and Radiological Hazards</i>	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 <ul style="list-style-type: none">• NRC Perspectives – Byproduct Approach• NRC Perspectives – Hybrid Approach• Industry Perspectives - Hybrid Approach	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 [a](#), "Staff Requirements—SECY-09-0064 [a](#)—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 [a](#), "Staff Requirements—SECY-20-0032 [a](#)—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 a
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 <ul style="list-style-type: none">Presentations a	January 26, 2021 a
DOE, NRC, and Fusion Industry Association public forum	October 6, 2020 EXIT

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

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

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**.

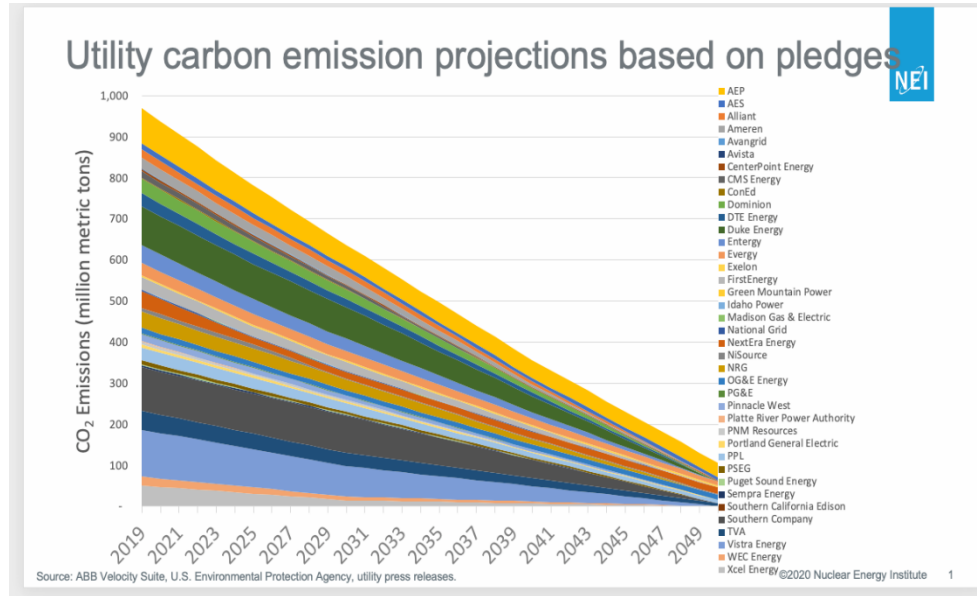
Key Takeaways

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.

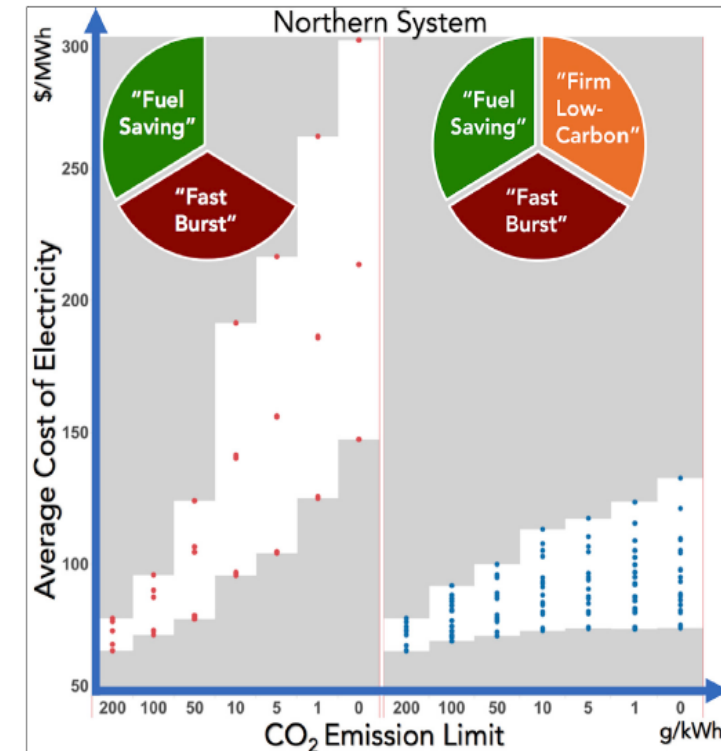
Recommendation: DOE should move forward now to foster the creation of national teams, including public-private partnerships, that will develop conceptual pilot plant designs and technology roadmaps that will lead to an engineering design of a pilot plant that will bring fusion to commercial viability.

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

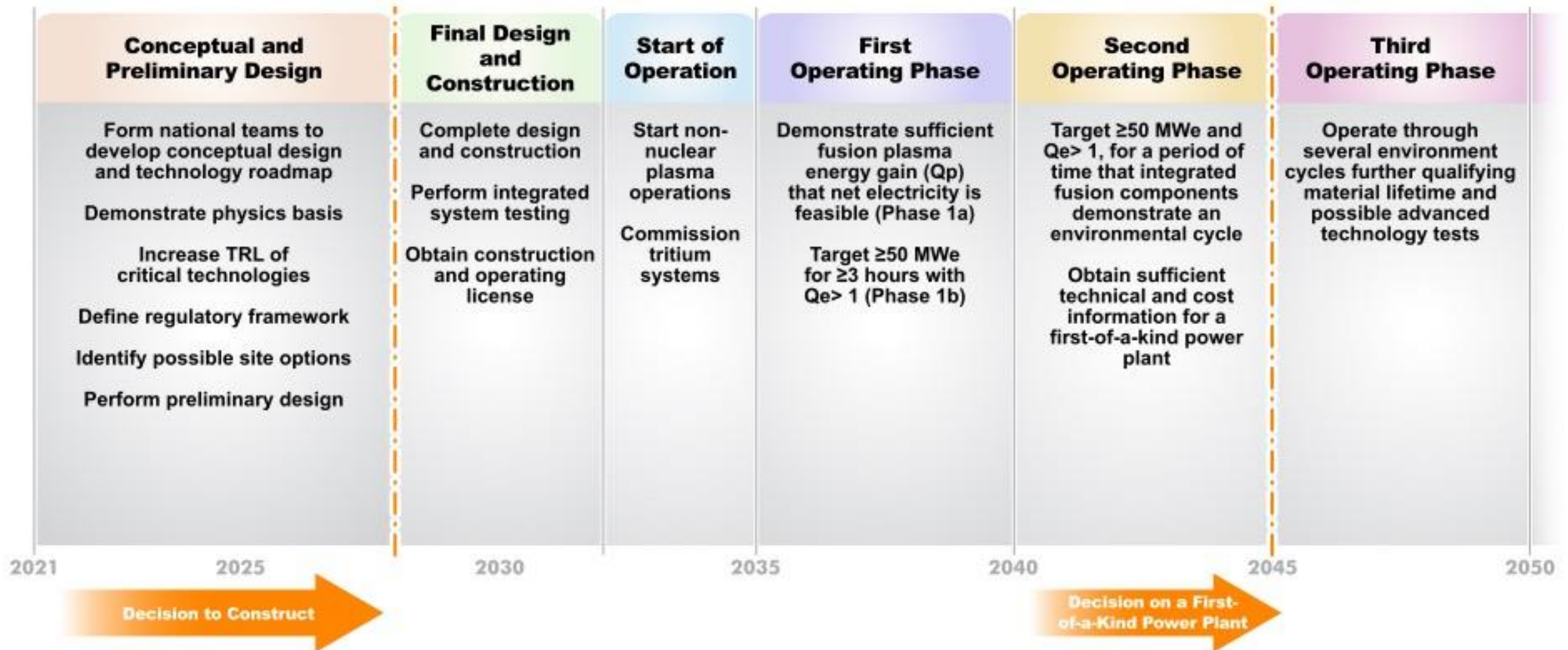


Utilities foresee a transition to low-carbon electrical generation by 2050.



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 (Q_p)
that net electricity is
feasible (Phase 1a)

Target ≥ 50 MWe
for ≥ 3 hours with
 $Q_e > 1$ (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 $Q_e > 1$, 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



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)



The Social Acceptance Challenge

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

- Examples of technologies that face this risk:
 1. Genetically modified food¹
 2. Facial recognition
 3. Vaccines²
 4. Fission³
- A lack of acceptance increases capitals costs, litigation costs and risks, and regulatory burdens⁴

Risk-reducing technical solutions, regulatory compliance, and better “communication” or “education” are unlikely, on their own, to alleviate a lack of social acceptance⁵

1. Devos Y, Maesele 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. Robbins, R., Tavernise, S., Otterman, S., “Cash, Breakfasts and Firings: An All-Out Push to Vaccinate Wary Medical Workers” *NY Times*, Jan 14, 2021, <https://www.nytimes.com/2021/01/14/business/covid-vaccine-health-hospitals.html>
3. 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).
4. Gunningham N, Kagan RA, Thornton D, “Social license and environmental protection: why businesses go beyond compliance,” *Law & Social Inquiry* 29:307–341 (2004).
5. 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 peninsula¹
- 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).

The Social Acceptance Challenge for 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 other energy technologies, not just in how it uses physics, 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 Committees²

- 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 activity³
- Acts as a form of peer review that generally improves outcomes for proponents and society⁴

Far more than a legal license or permit⁵: successful examples see regulatory compliance as only a starting point for social acceptance⁶

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 Trust¹
2. Transparency^{1,2}
3. Meaningful Public Engagement^{1,2,3}
4. Protecting Human Health and Safety⁴

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).
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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 referendums²
 - Disseminated what would otherwise be confidential information to facilitate transparency³

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. Process¹

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

U.S. repository is stalled

Swedish²/Finish³ Process

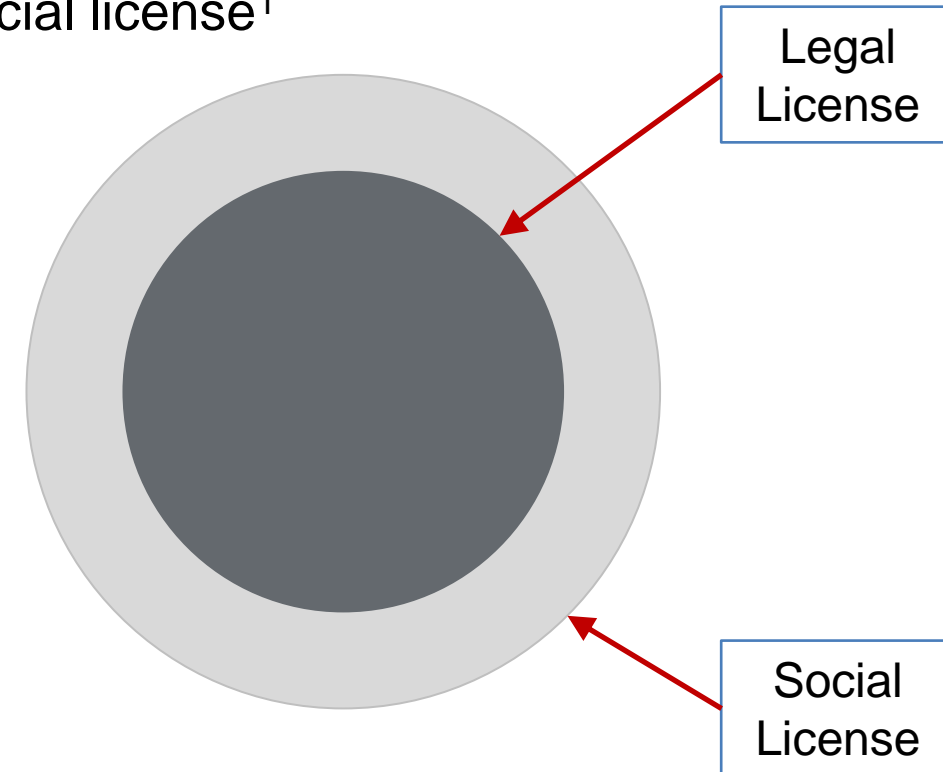
1. Invited communities to participate in a study
2. Evaluated geology in participating communities
3. Undertook a competition between communities
4. Selected a community
5. Build a repository

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/pressreleasesstockexchangerelases/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 license¹
- 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

Review Committee:

- Generally created by governments, funders or non-profits, but not health/safety regulators
- Identifies ethical issues and proposes solutions to regulators, funders and governments
- Is composed of a mixture of experts and non-experts, including lawyers, ethicists, religious scholars, and members of the general public¹
- Seeks compromise between competing ethical perspectives²
- Subjects proposed solutions to multi-stakeholder review and public comment³

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: Mitochondrial Replacement Therapy in the U.K.

Scientific Risk/Benefits Assessment

U.K. Human Fertility and Embryology Authority (2011 - 2014)

Public Consultation

U.K. Human Fertility and Embryology Authority (2012)

Ethics Assessment

Nuffield Council (2012)

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

Proposed Regulation (2014)



Public Consultation (2014)



Legislative Approval (2015)

1. Cohen IG, Savulescu J, Adashi EY, "Transatlantic lessons in regulation of mitochondrial replacement therapy." *Science* (2015) 348:178–180
2. Castro RJ, "Mitochondrial replacement therapy: the UK and US regulatory landscapes." *Journal of Law and the Biosciences* (2016) 3:726–735

Relationship between Ethical Review and Regulatory Agencies

- There is a time gap between the ethical review and adoption of the review's recommendations by regulatory agencies
- Recommendations are often respected prior to formal legal adoption as “guidelines” for companies and researchers
- Neither regulatory agencies nor regulated entities typically undertake ethical review

Summary of Social Acceptance Insights for the Development of a Regulatory Framework for Fusion

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

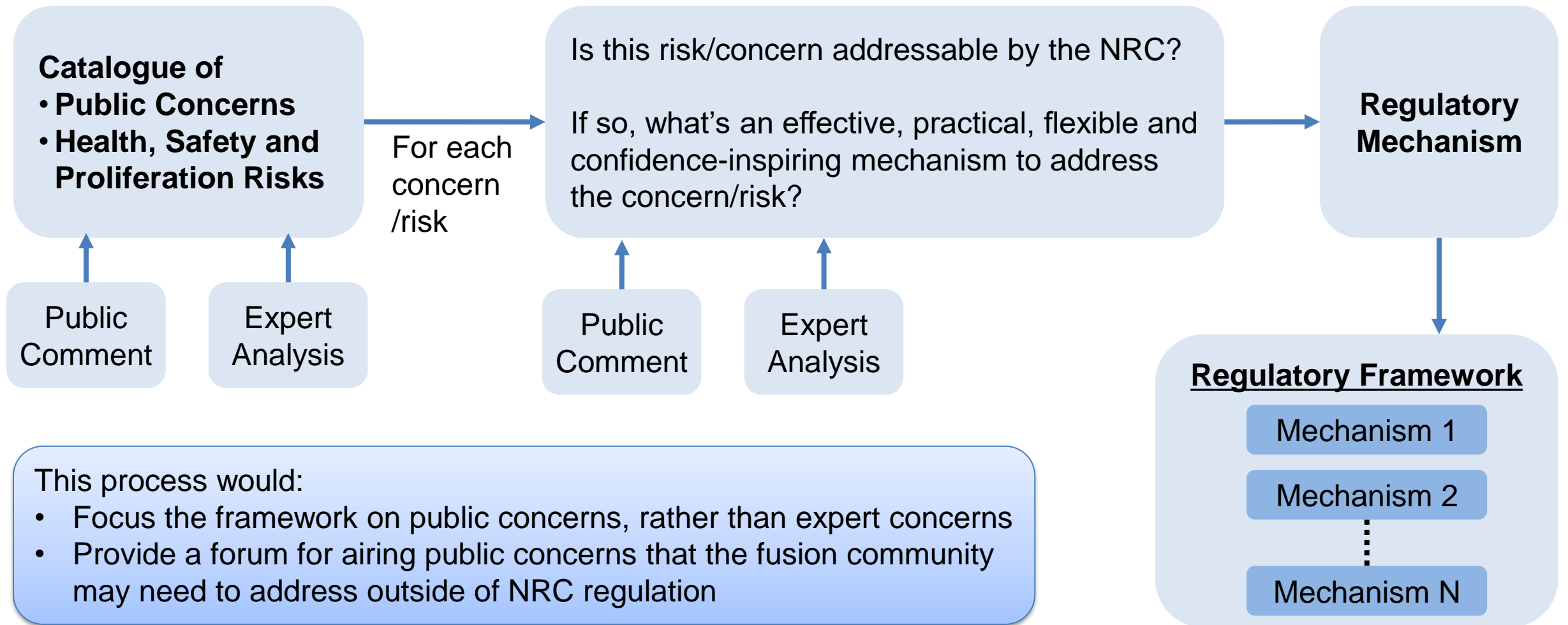
Insights for the Public

- Engage in these meeting and use them as an opportunity to share concerns to both the NRC and the 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
- Participate in ethical review

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



Final Thoughts



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



FUSION INDUSTRY ASSOCIATION

The Voice
of a new
Industry

The Fusion Industry Association is an international coalition of companies working to electrify the world with fusion - the unparalleled power of the stars. Energy from fusion will provide clean power for everyone that's safe, affordable, and limitless.

Building the Fusion Economy

Fusion energy will revolutionize the global energy system. It can solve the climate crisis and build energy abundance.

- The Fusion Industry Association is **accelerating commercially viable fusion energy** by advocating for policies that support our 24 member companies as they develop commercial fusion power.
- The FIA **is building a movement** to tell the world should know how important clean, safe, affordable, and secure fusion will be to the future energy system. The FIA is educating key stakeholders in the private, public, and philanthropic sectors about the importance of tomorrow's fusion power economy.

Fusion must be deployed fast enough to meet the world's challenges.

Mission of the FIA

*The Fusion Industry Association is the voice of the growing fusion industry. It supports efforts to **accelerate commercially viable fusion** research and development. The Association promotes the interests of the fusion industry around the world by advocating for ways to commercialize fusion power on a time-scale that matters.*

Membership

FUSION
INDUSTRY
ASSOCIATION



generalfusion®



TYPE ONE
ENERGY



fuse



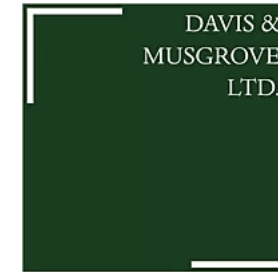
COMPACT
FUSION SYSTEMS

EMC2

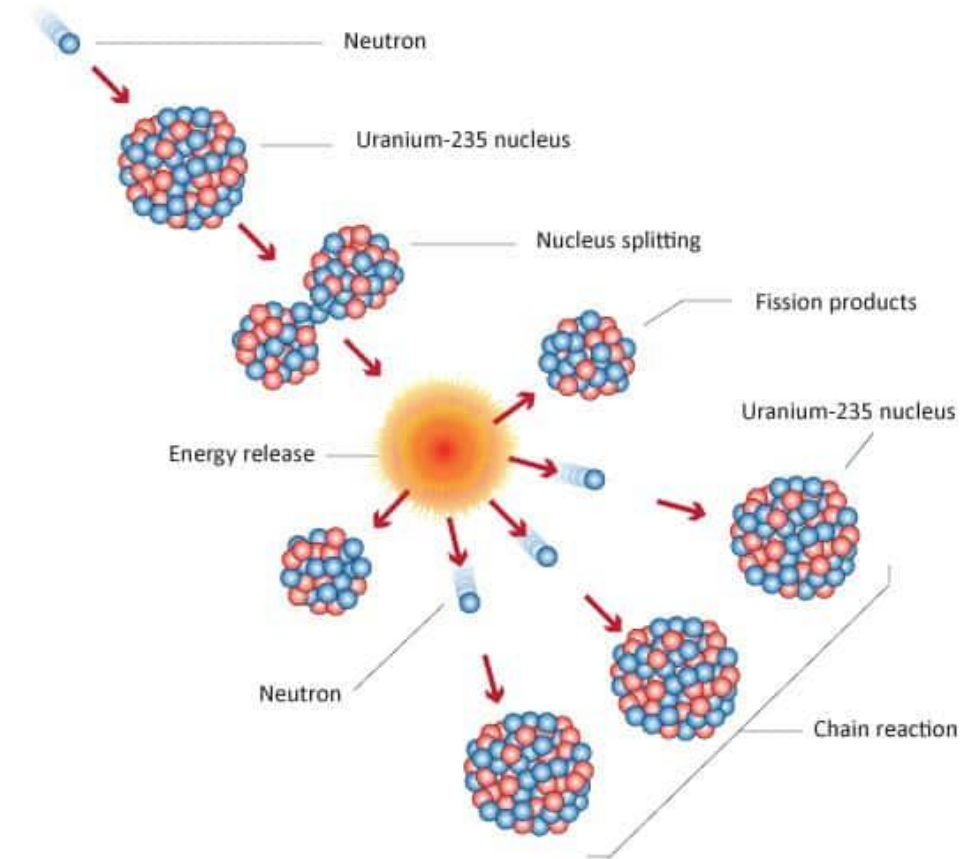
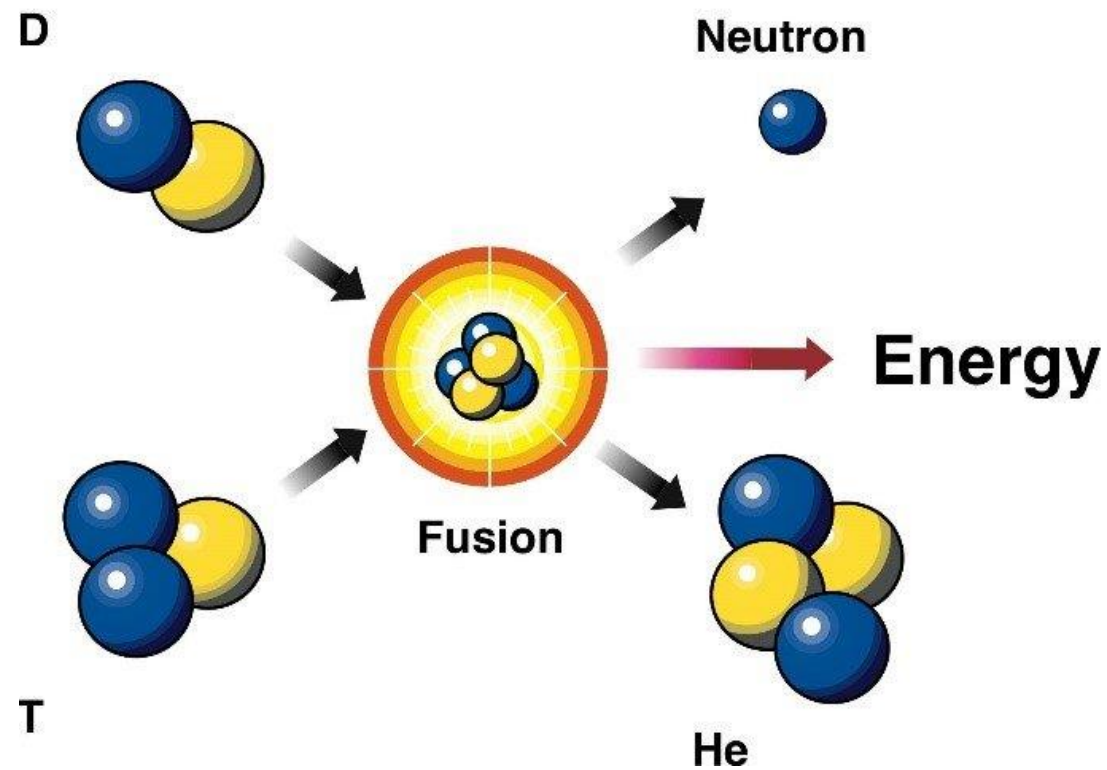


Affiliate Members

FUSION
INDUSTRY
ASSOCIATION



Fusion is different from Fission



Fusion is different from Fission

- **No Chance of Meltdown** Fusion energy devices do **not** use any special nuclear material or source material, creating a much lower risk profile than fission facilities, thus, criticality or meltdown accidents are physically impossible
- **Minimal Safety Risk to the General Public** With reasonable design, construction, and operations procedures, fusion energy generating facilities would not create a credible safety risk to the general public (i.e., that requires an evacuation of members of the public near the fusion energy generating station) that is any greater than hydrocarbon power plants or other comparably sized industrial facilities
- **No long-lived, highly radioactive waste** The waste output from a fusion facility consists of helium plus small amounts of solid, slightly activated device components and other materials that can easily be disposed of as low-level waste.

FIA Regulatory Goal

*U.S. policymakers should establish a broad legislative and regulatory framework that **explicitly and permanently removes fusion energy from the regulatory approaches that the federal government has taken towards fission power plants.***

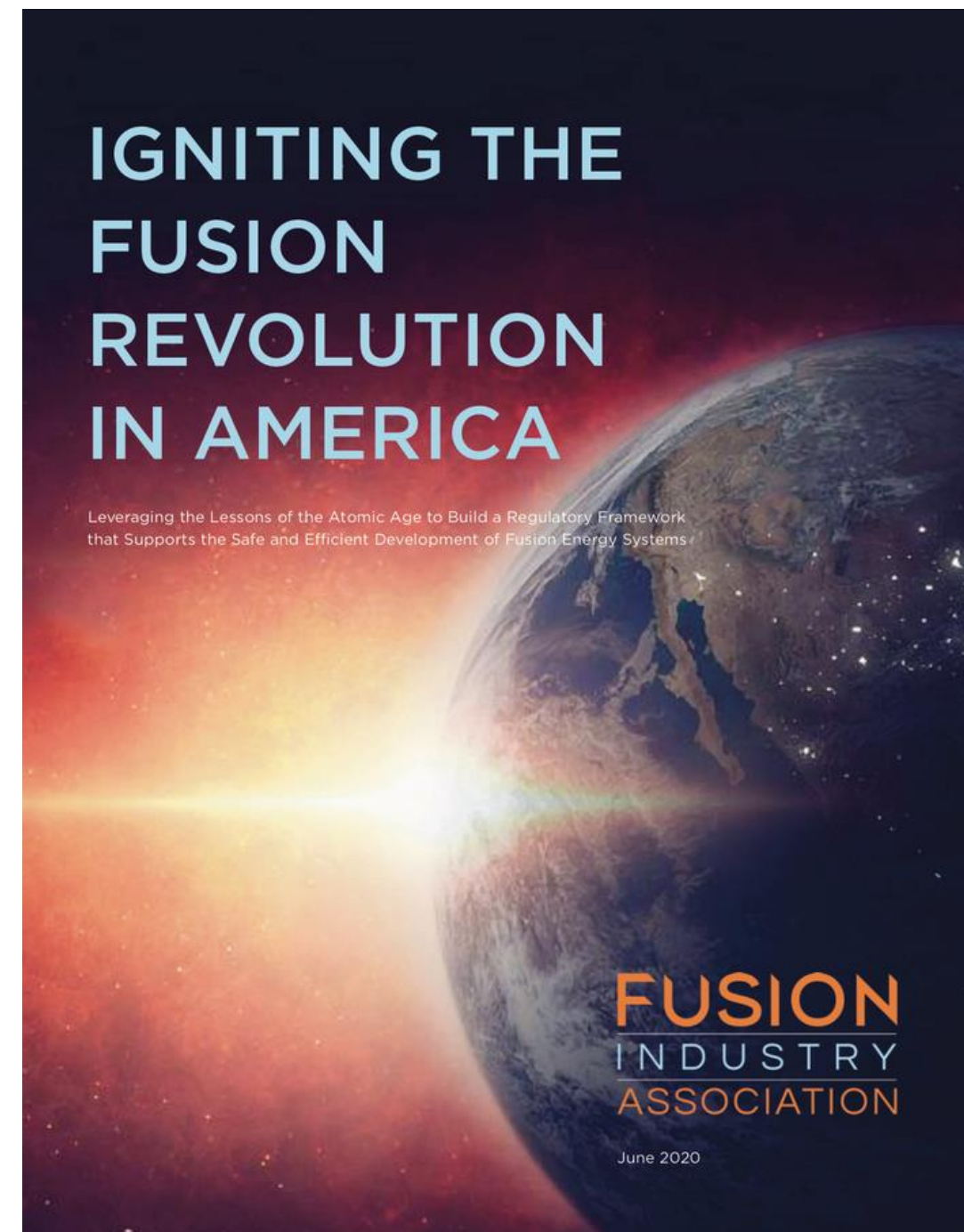


A Different Approach than Fission

- The NRC's Part 50, 52 and proposed 53 regulations for large commercial fission reactors address a **different suite of risks** compared to risks that fusion facilities could create and therefore are not appropriate for fusion systems.

Fusion is already Regulated

- Rules like the NRC's Part 20 regulations for general radiation protection and Part 30 rules for handling byproduct material **properly address fusion** facilities' risk profiles.



Fusion Regulation Proceeds under existing rules

- Under the Energy Reorganization Act of 1974, the Department of Energy governs aspects of nuclear weapons and energy development, while the NRC regulates civilian nuclear safety and public health.
- Agreement States are already providing sufficient regulation to ensure safety in fusion devices around the country.
- Private fusion facilities are already licensed in Agreement States under the NRC's Part 20 regulations for general radiation protection and Part 30 rules for handling byproduct material.

What is the Industry NOT Asking for?

Fusion Fission Hybrids

Tech / Science & Research

How China hopes to solve nuclear waste issue with hybrid fusion-fission reactor at top secret facility



Stephen Chen [+ FOLLOW](#)

Published: 8:00am, 17 Jul, 2015

[Why you can trust SCMP](#)

Russian Scientists Reveal Plans for Fusion-Fission Reactor

It runs almost entirely on thorium, not uranium.



// BY [CAROLINE DELBERT](#) JAN 30, 2020

Regulation of DoE Experiments



TFTR Test Cell, Ready for 1st Plasma - December 1982

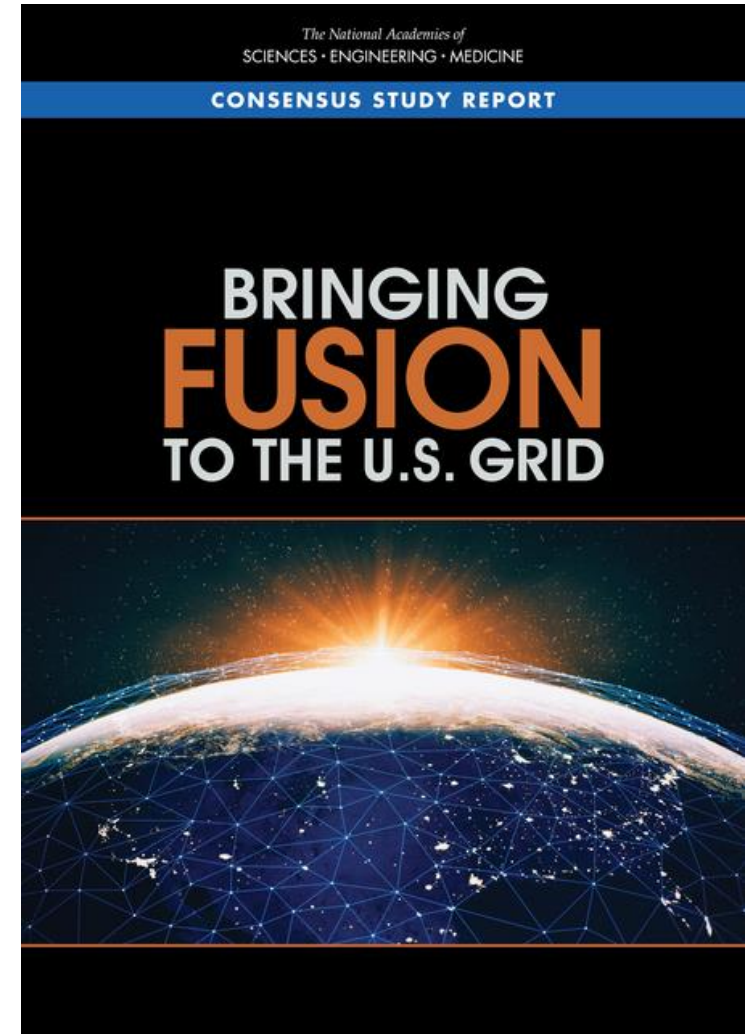
There are No Commercial Plans for ITER-scale Machines

- The large scale of an ITER/DEMO machine would challenge Agreement States
- Significant tritium requirements (e.g. 5-15 kg)
- Large scale will result in large amount of activated materials and low-level waste
- Most of the academic literature and DoE expertise is focused on machines at these scales



National Academies Roadmap to a Pilot Plant

- **Recommendation:** The Department of Energy 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 and lead to an engineering design of a pilot plant that will bring fusion to commercial viability.



FIA Will Work Collaboratively with NRC

- A deliberative process would allow for the NRC to gain a better understanding of the nature of technology and risk.
- The current licensing regime provides comprehensive and appropriate standards for all conceivable private approaches within the current decade.
- 2009 NRC guidance said that an evaluation of technical and legal issues related to regulation of fusion “*would likely span several years*” and would commit the NRC “*to expend significant resources to develop a regulatory framework for fusion energy.*”
- The FIA will work collaboratively over the coming years to help develop any new framework that’s needed.

IGNITING THE FUSION REVOLUTION IN AMERICA

Leveraging the Lessons of the Atomic Age to Build a Regulatory Framework
that Supports the Safe and Efficient Development of Fusion Energy Systems

FUSION
INDUSTRY
ASSOCIATION

June 2020

Thank You

<https://www.fusionindustryassociation.org/post/fusion-regulatory-white-paper>

TAE's Expected Safety Profile of $p\text{-B}^{11}$ Aneutronic Fusion

Michl Binderbauer, CEO | TAE Technologies
Public Meeting on Regulatory Framework for Fusion | 03/30/2021

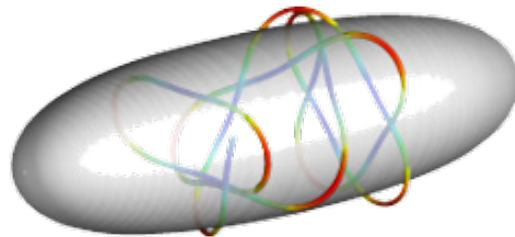
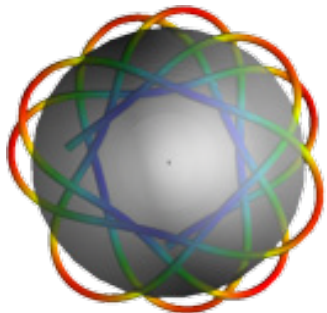
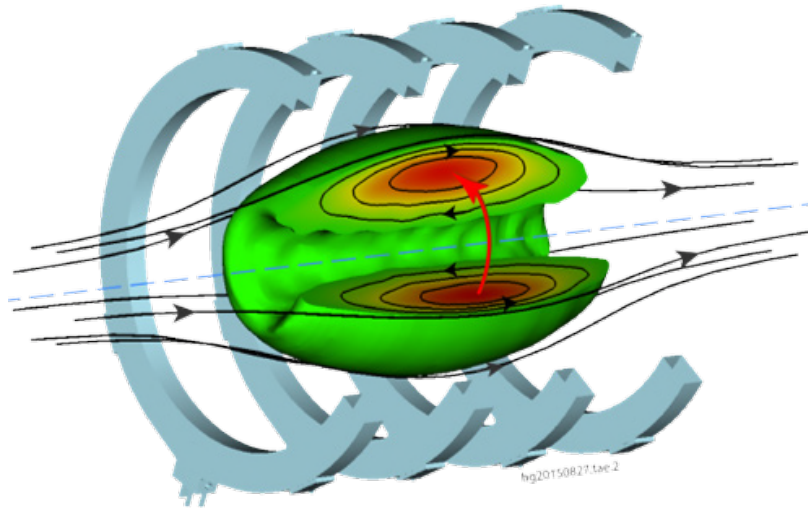
Based on advanced beam-driven
Field Reversed Configuration (FRC)
using $p+B^{11} \rightarrow 3He^4 + 8.7 \text{ MeV}$

$p-B^{11}$ highly abundant and <1% of
total energy carried by neutrons
from secondary reactions

Performed comprehensive safety study
following ITER methodology –
radiation analysis based on detailed
MCNP and Atilla calculations

- ▶ Radioactive inventory and operating characteristics closely emulate particle accelerators
- ▶ Expected neutron yield ~100x less than that of AP1000-PWR
- ▶ Induced component activation minimal – dose rates to general public during normal operation ~100x lower than regulatory limit
- ▶ Expected dose to general public from air-borne radioactivity during hypothesized catastrophic accident ~100x lower than regulatory limit
- ▶ End-of-life radioactive inventory expected to be classified as low-level waste

Advanced beam-driven FRC core



HIGH PLASMA $\beta \sim 1$

- ▶ compact and high power density
- ▶ aneutronic fuel capability indigenous large orbit particles

TANGENTIAL NEUTRAL BEAM INJECTION

- ▶ large orbit ion population decouples from micro-turbulence
- ▶ improved stability and transport

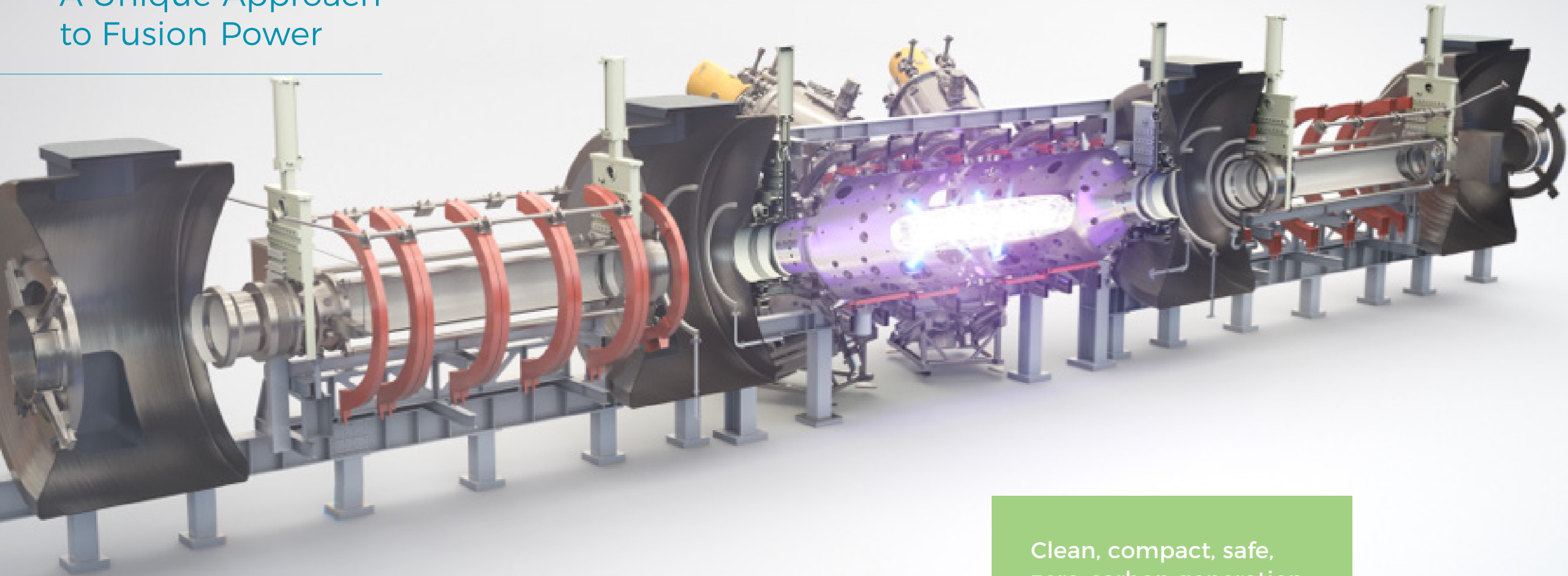
SIMPLE GEOMETRY

- ▶ only diamagnetic currents easier
- ▶ design and maintenance

LINEAR UNRESTRICTED DIVERTOR

- ▶ facilitates impurity, ash and power removal

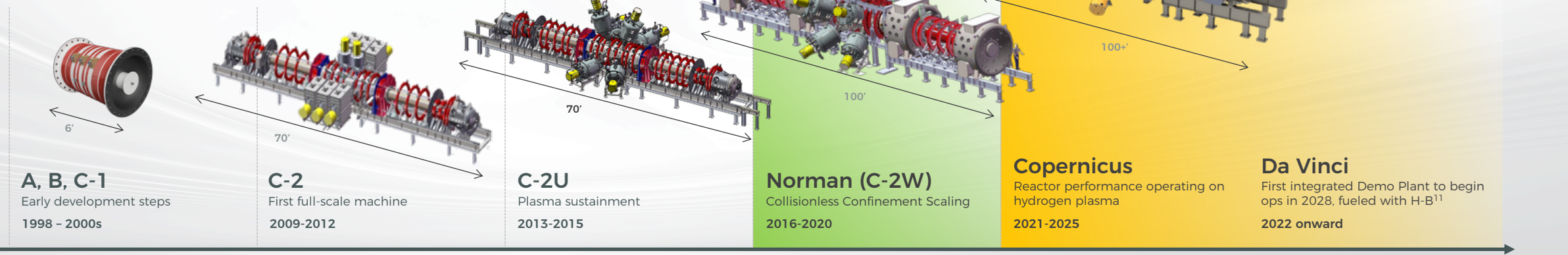
A Unique Approach to Fusion Power



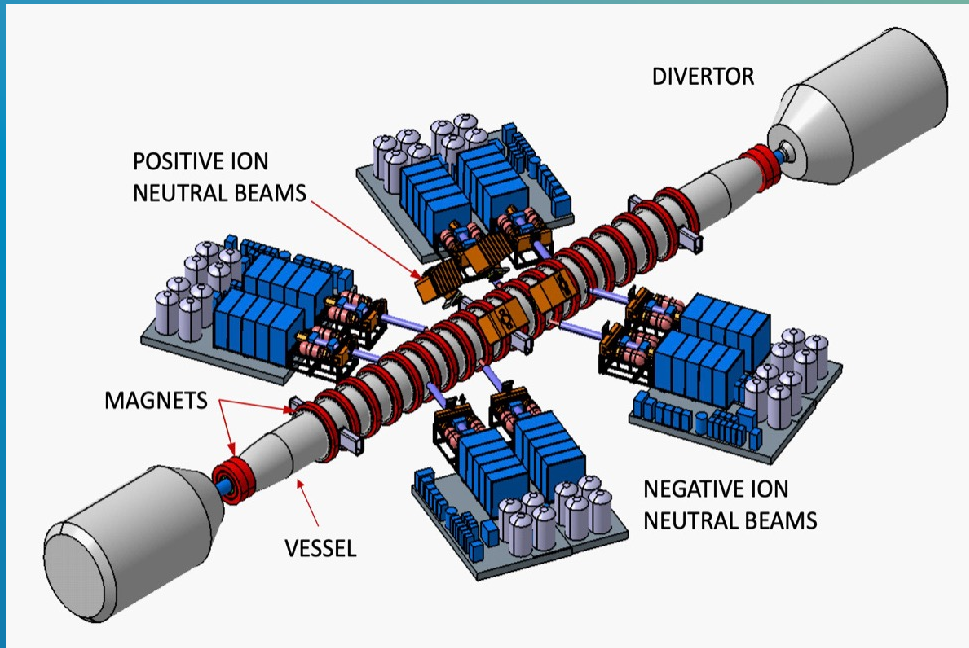
Clean, compact, safe,
zero-carbon generation
of affordable electricity

TAE's Path to Commercial Fusion

- ▶ Major development platforms integrate best design
- ▶ Incremental bases for rapid innovation
- ▶ Copernicus entering phased sequence of reactor performance experiments in 2023
- ▶ DaVinci demo plant by 2028



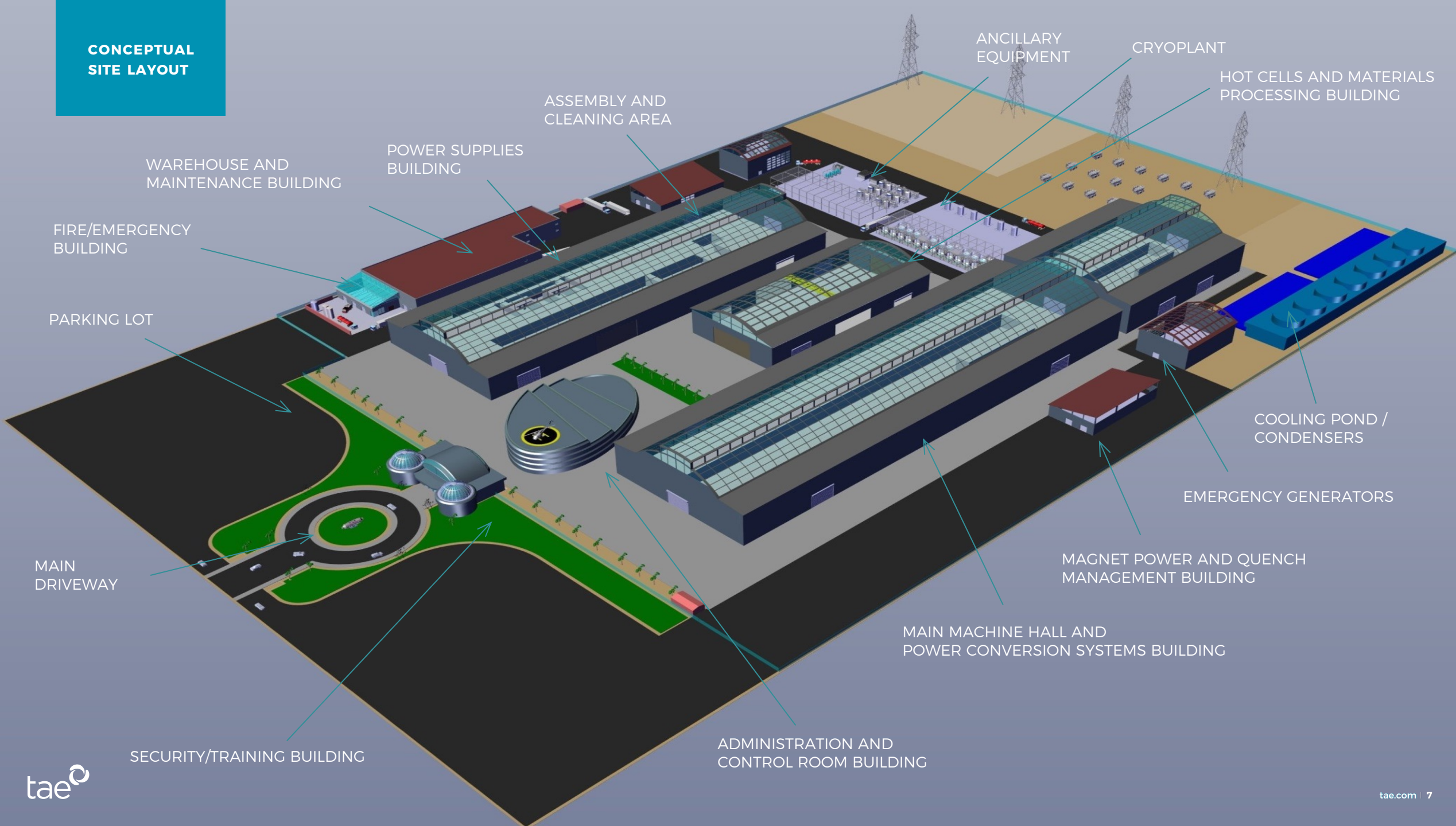
Plasma Electric Generator (PEG) based p-B¹¹ Fusion



Parameter	Value
Fusion reaction	$p + B^{11} \rightarrow 3He^4 + 8.7 \text{ MeV}$
Thermal Power	1,200 MWth
Net Power	350 MWe
Physics Q	5-8
Magnets	Superconducting
Confinement B-field	6.5 T
Vessel Length	80 m

- ▶ p-B¹¹ fuel – stable, non-toxic, no special handling required – dramatically simplifies reactor design and maintenance
- ▶ FRC is a high-power density device suitable for aneutronic fuel cycles

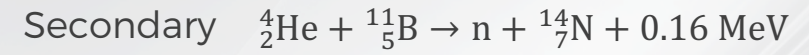
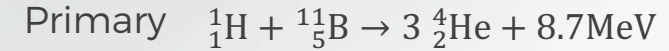
CONCEPTUAL SITE LAYOUT



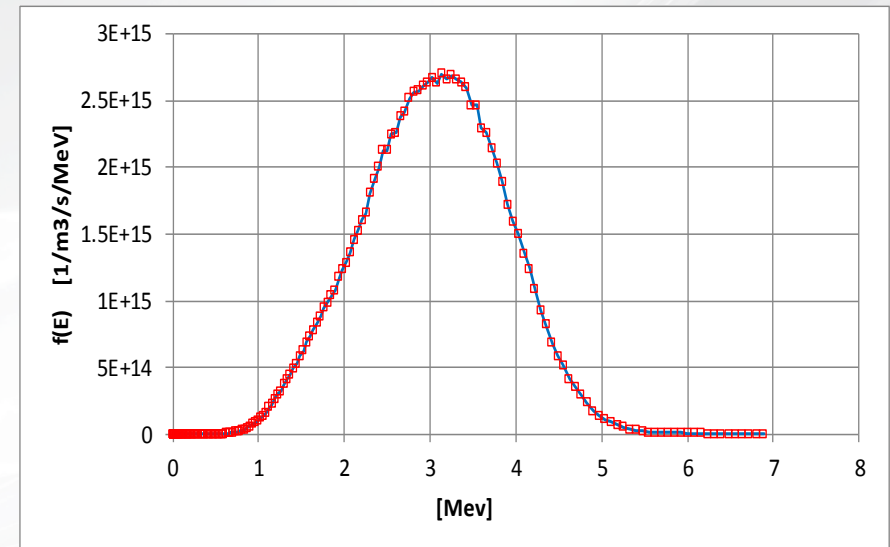
<1% of p-B¹¹ Fusion Power carried by Neutrons

- ▶ Aneutronic¹ — system in which neutrons carry less than 1% of total fusion power
- ▶ Neutron yield in PEG ~100x lower than AP1000-PWR
- ▶ Average neutron energy ~3 MeV
 - ▶ Reduced number of accessible nuclear reactions
 - ▶ Reduced amount of shielding

1) https://www.njleg.state.nj.us/2006/Bills/A3000/2731_11.htm



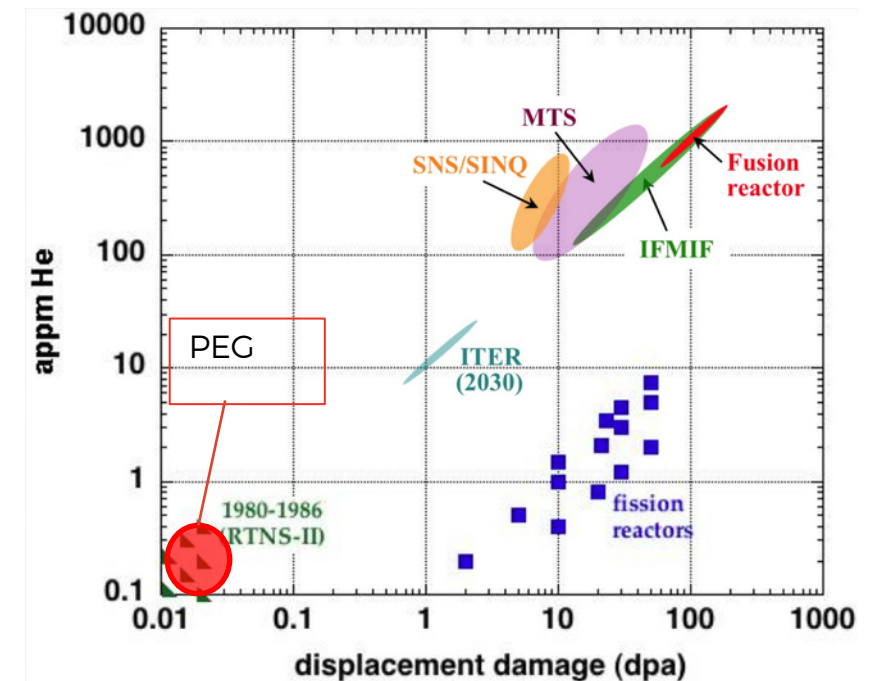
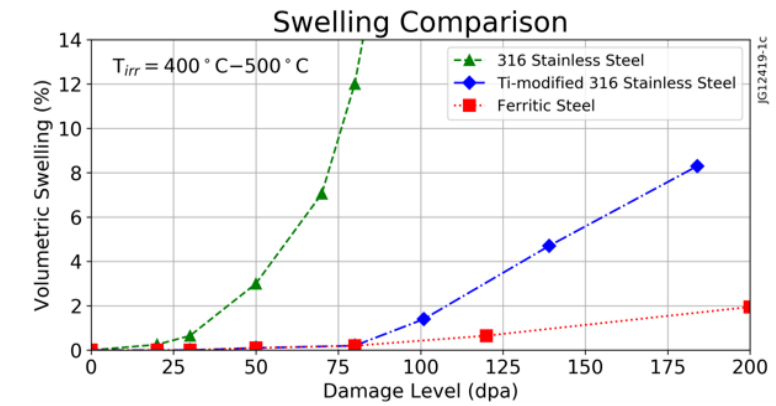
${}^{11}\text{B}(\alpha, \text{n}){}^{14}\text{N}$ neutron energy spectrum inside plasma



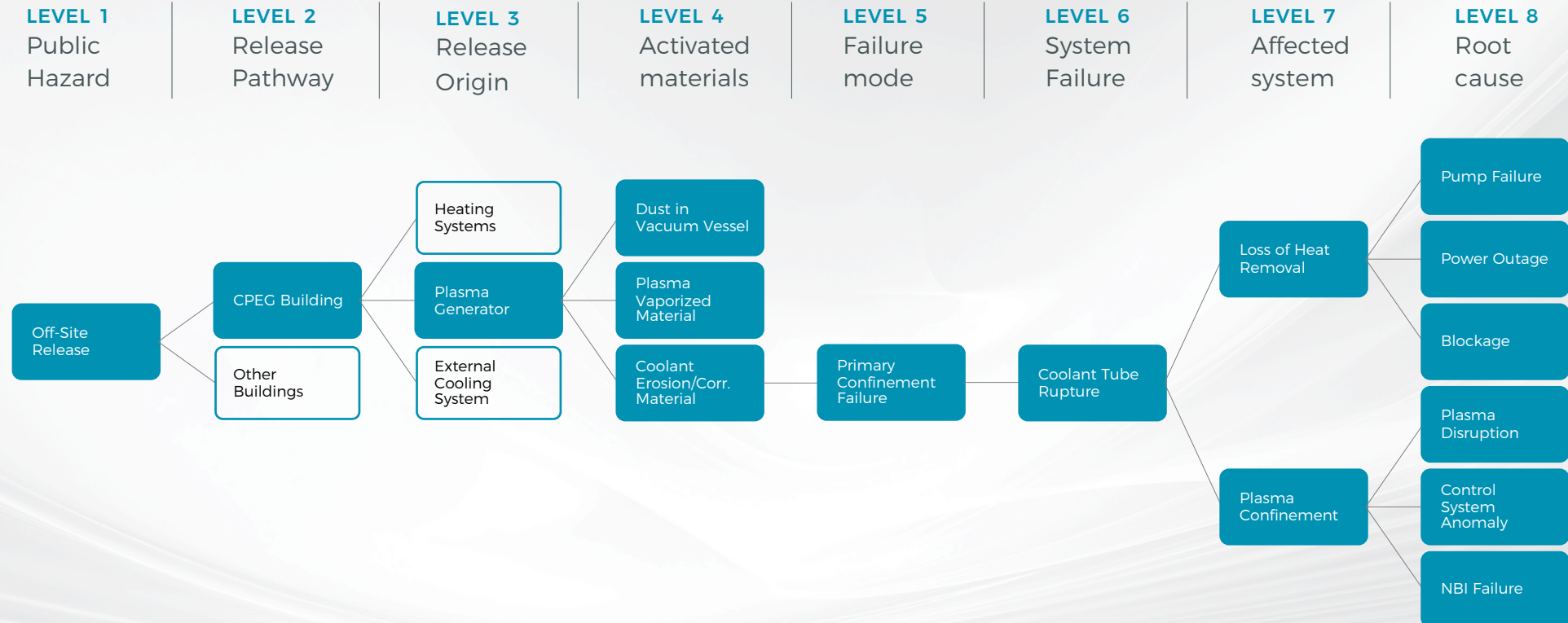
No Lifetime Limitation on Reactor Components

Components can be made from standard materials that can last lifetime of power plant

Fusion Power, GW	1
First Wall Heat Flux [MW/m ²]	1.6 – 2.0
Divertor Heat Flux [MW/m ²]	0.5 – 1.5
Neutron Flux [n/m ² s]	2.3×10^{15}
Neutron Heating Load, >1 MeV range [MW/m ²]	$\sim 1 \times 10^{-3}$
Displacement per atom per full power year (dpa/FPY)	~ 0.02
Transmutation product, helium [appm/FPY]	< 0.1

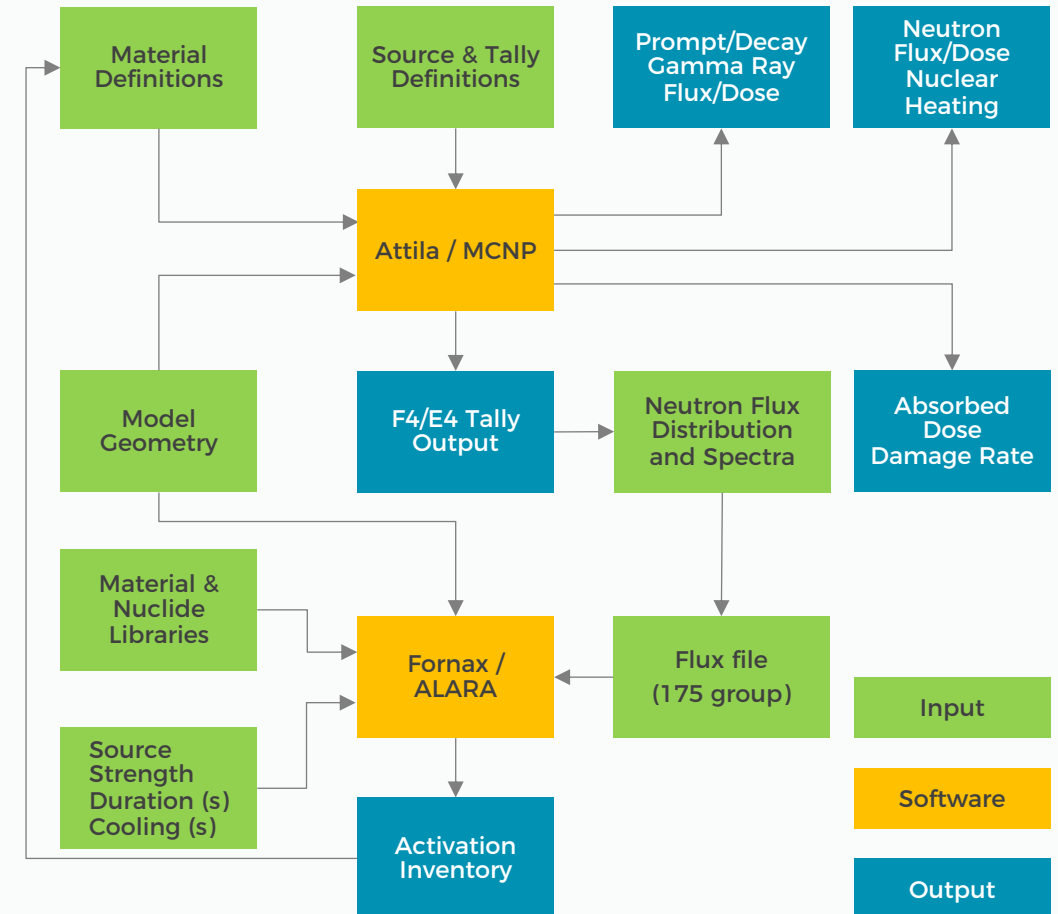


TAE Safety Assessment closely follows that of ITER



MCNP & Attila based Radiation Safety Assessment

- ▶ Two independent codes converged to same solution
- ▶ MCNP – Monte Carlo based transport code, used throughout nuclear industry
- ▶ Attila – deterministic Boltzmann transport solver, used in shielding studies
- ▶ Radially symmetric model of PEG
 - ▶ Time and energy dependent neutron and photon flux
 - ▶ Time-dependent radioisotope inventory through end-of-life (EOL)



Radiation Sources expected during Normal Operations

REACTOR STRUCTURES

- Majority of structural activation in: confinement vessel (CV) and heat exchanger (HX) first wall (FW)

GENERATED “DUST”

- Sputtering of activated material from plasma facing components into CV and divertor vessel (DV)
- Resultant from impurities in p-B¹¹ fuel

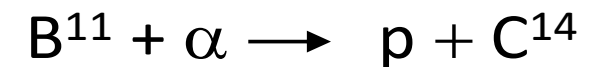
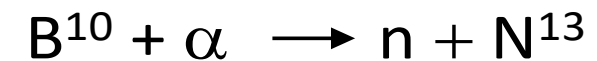
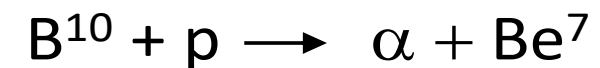
MACHINE COOLANT LOOP

- Erosion of activated first wall HX into high-speed He-gas coolant

Dominant Radioactive Isotopes (1 yr after EOL), mostly from HX components

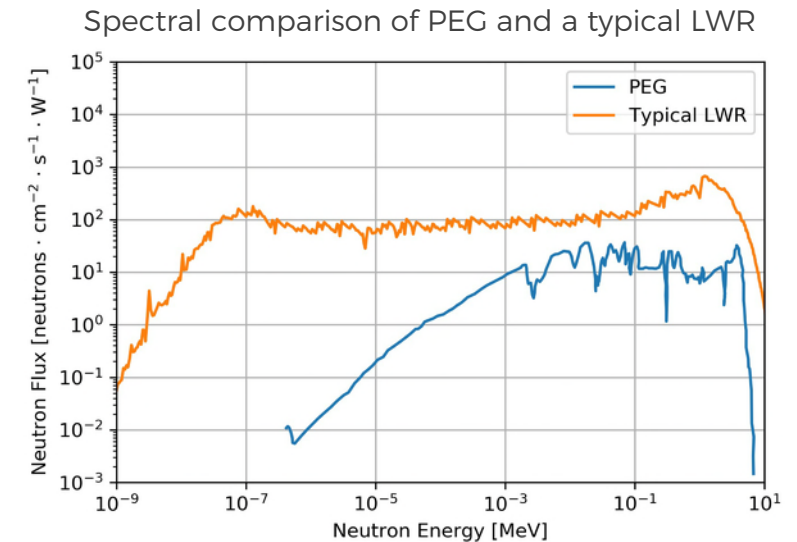
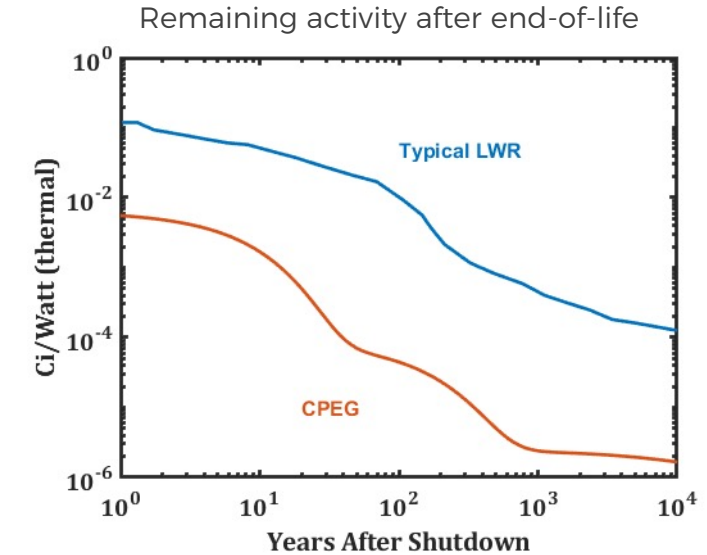
Isotope	t_half (yrs)	Ci/1GW
Co60	5.27E+00	5.16E-03
Fe55	2.73E+00	2.83E-04
Ni63	1.00E+02	8.37E-05
Co58	1.94E-01	1.30E-05
Mn54	8.55E-01	6.36E-06
Ni59	7.60E+04	1.01E-06
Nb94	2.03E+04	8.83E-07
Mo93	3.50E+03	4.21E-07
H3	1.23E+01	1.44E-07
Cr51	7.59E-02	1.19E-07

Plasma Reactions Leading to Activated Dust



Activation in PEG much less than in typical LWR

Neutrons produced in PEG require significant moderation to reach thermal energy, where activation cross-sections are highest



F. Najmabadi et al., Energy & Environment, 13, (2002).

EOL Disposal Rating expected to be Class A Low-level Waste

- ▶ Maximum radioactive inventory (at EOL) used for analysis
- ▶ Total EOL activity sum of fractions rule is >1 mainly due to dust
- ▶ All materials not satisfying 10CFR61.55 to be classified as Class A LLW – will be diluted until sum of fractions rule is met

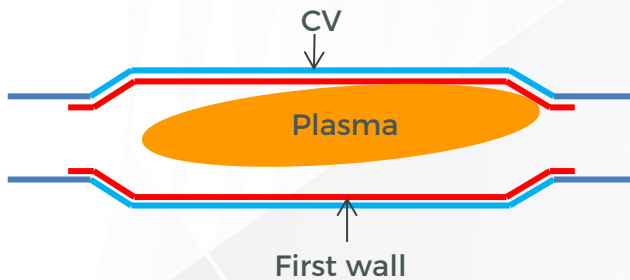
10 CFR 61.55 Table 2 Analysis			
Radionuclide	PEG Concentration ¹ (Ci/m ³)	10 CFR 61.55 Table 2 Concentration (Ci/m ³)	PEG/Table 2 Fractions
Total of all nuclides with less than 5 year half-life ^{2,3}	2.15E+04	700	30.73
H-3 ^{2,3}	1.74E+00	40	0.043
Co-60 ⁴	4.23E+02	700	0.604
Ni-63	0.00E+00	3.5	0
Ni-63 in activated metal	3.92E+01	35	1.120
Sr-90	0	0.04	0
Cs-137	0	1	0
Sum of fractions =			32.5

Ratio > 1

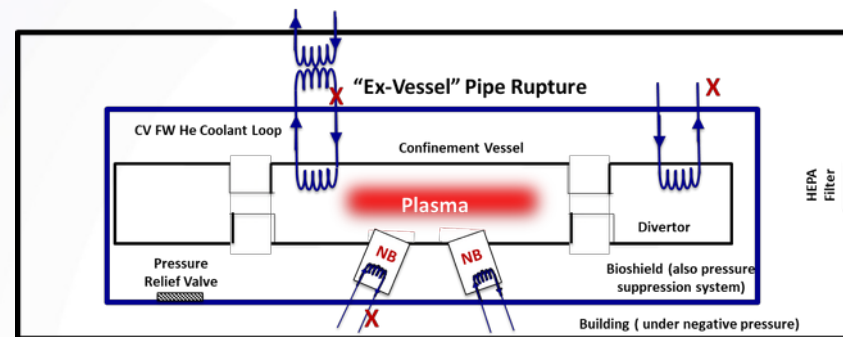
1 Only applicable to those component containing the radionuclide.
 2 Any radionuclide in dust can be diluted to a fraction less than 1.0, prior to shipping offsite.
 3 In activated metal and dust.
 4 Only in activated metal.

Evaluation of 2 worst-case Accident Scenarios

Plasma
Disruption:



Release of activated coolant and/or
dust into machine hall from "ex-vessel"
coolant pipe rupture



Source of Activation	Mass of Activated Material	Total Activity (Ci)
Dust during normal operation in plasma confinement vessel & divertors	801 kg	2×10^5
Activated erosion products in coolant HX piping (w/o filtration)	63 kg	191
Molten FW due to coolant line rupture and plasma disruption	504 kg	135

Occupational & Public Dose well below Regulatory Guidelines

Expected dose from Normal Operations

Occupational Exposure	30 mrem/year
Public Exposure (Worst-Case, for 2 hours)	10^{-3} mrem

Expected dose consistent with dose from
accelerator and medical facilities

- ▶ Annual radiation dose limit to general public is 100 mrem (10CFR 20 Subpart D)
- ▶ Maximum dose to public at normal operations (2 hour uptake) $<10^{-3}$ mrem (at ~800 m)

FOR REFERENCE — annual background
dose rate (NRC) is 310 mrem

Performed comprehensive safety study following ITER methodology – radiation analysis based on detailed MCNP and Atila calculations

Radioactive inventory and operating characteristics closely emulate particle accelerators

- ▶ Expected neutron yield ~100x less than that of AP1000-PWR
- ▶ Induced component activation minimal – dose rates to general public during normal operation ~100x lower than regulatory limit
- ▶ Expected dose to general public from from air-borne radioactivity during hypothesized catastrophic accident ~100x lower than regulatory limit
- ▶ End-of-life radioactive inventory expected to be classified as low-level waste



Fusion Attributes in the Private Industry Context

Commonwealth Fusion Systems



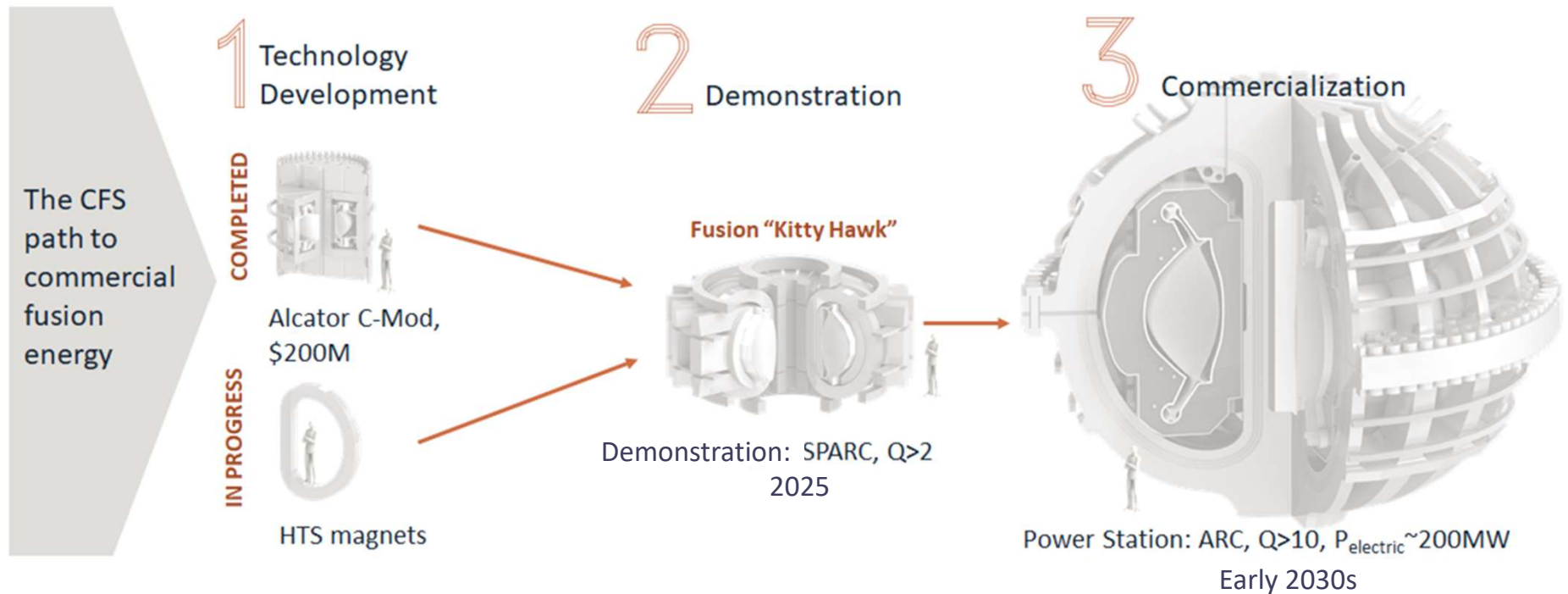
Introduction

- Most of the literature available on describing tritium requirements, low-level waste generation, safety and other topics related to fusion energy generation facilities is exclusively focused on ITER/DEMO sized facilities
- No private companies are pursuing ITER/DEMO sized facilities so this literature can lead to incorrect conclusions based upon the much larger scale of these public facilities compared to private approaches
- Recognizing the importance of social acceptance, private fusion approaches have been selected to require orders of magnitude less tritium, produce much less low-level waste (LLW) and not require emergency off-site evacuation planning
- The scale (tritium inventory, waste generation and safety) of CFS's ARC and other proposed private facilities is similar to accelerators and research/medical facilities which are already effectively regulated under 10 CFR 30/20

CFS Approach



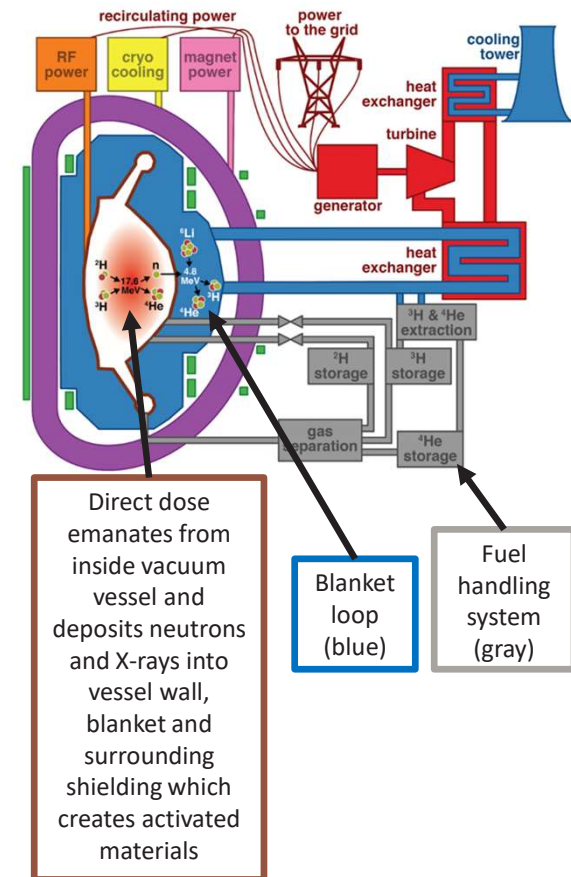
- Extensively studied (since the 1950s), traditional tokamak design which incorporates new magnets utilizing high-temperature superconductors
- If power is cut or vacuum chamber fails, facility simply shuts down, no irradiated fuel decay heat to deal with
- No possibility of a melt-down nor production of long-lived nuclear waste due to the lack of source or special nuclear material
- Solid technical basis described in the Journal of Plasma Physics special issue on [Status of the SPARC Physics Basis](#)



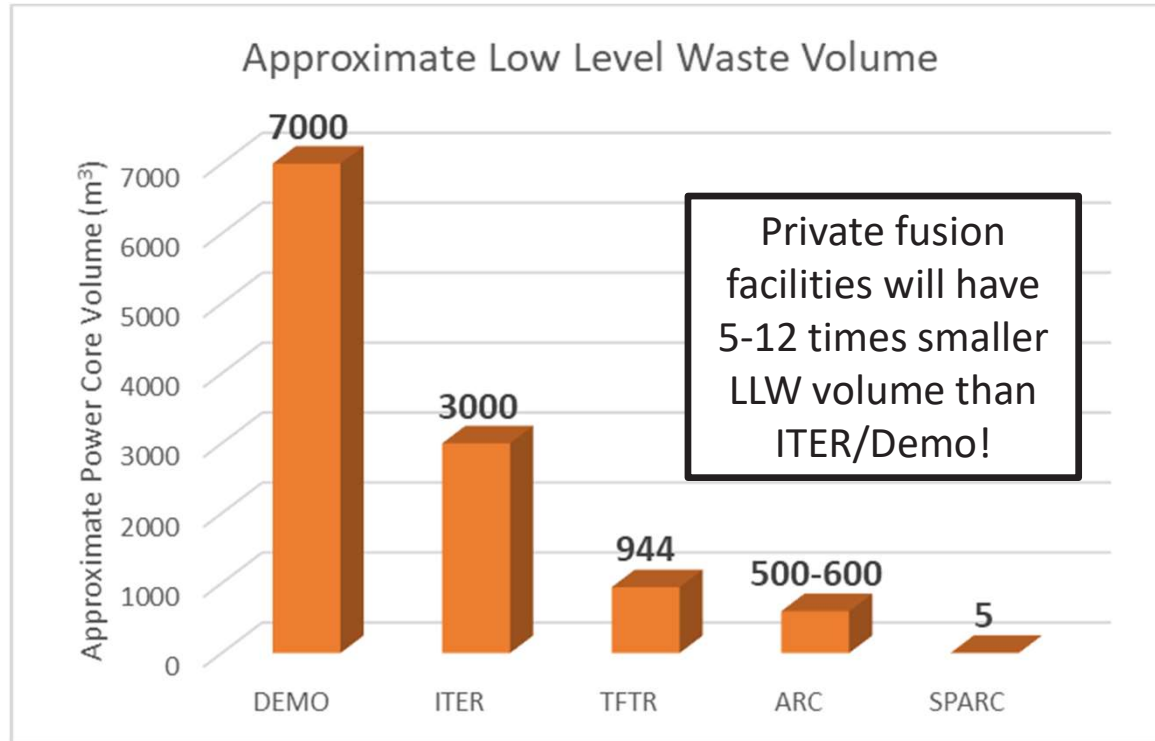
Fusion Hazards



- **Direct Dose:** Operation of the plasma generates neutrons and X-rays – the “direct dose”
 - Carries the energy of the fusion reaction and deposits it in the materials around the vessel and thus providing most of the power that is eventually sold
 - Can be effectively shielded by materials with existing materials
 - Only present when the plasma is operating and fusing
- **Activated Material:** Neutrons create activated materials in the vessel around the machine
 - Materials that provide the shielding of neutrons are transformed by stopping the neutrons – we purposefully select materials for their minimal activation properties and strength
 - Activated materials build up over time as the machine is operated and represent a much lower dose (~10,000 times) than the direct dose
 - Components that become activated can be disposed of as low-level waste at the end of life as given in the decommissioning plan or maintenance scenarios
 - Even aneutronic fuels generate significant neutrons from secondary reactions
- **Tritium:** Tritium is the main radioactive material of concern, and exists predominantly within the vacuum vessel, blanket loop and fuel handling systems
 - All fusion systems have to handle tritium, even the advanced or aneutronic fuels, since tritium is a product of their fuels in lower but still significant amounts
 - Fuel handling systems are put inside a glovebox to provide additional protective barriers
 - Plasma operates at a vacuum, so if the vessel is breached, air rushes in and tritium does not go out
 - Monitoring of the release of the gas is done via monitors on the stack



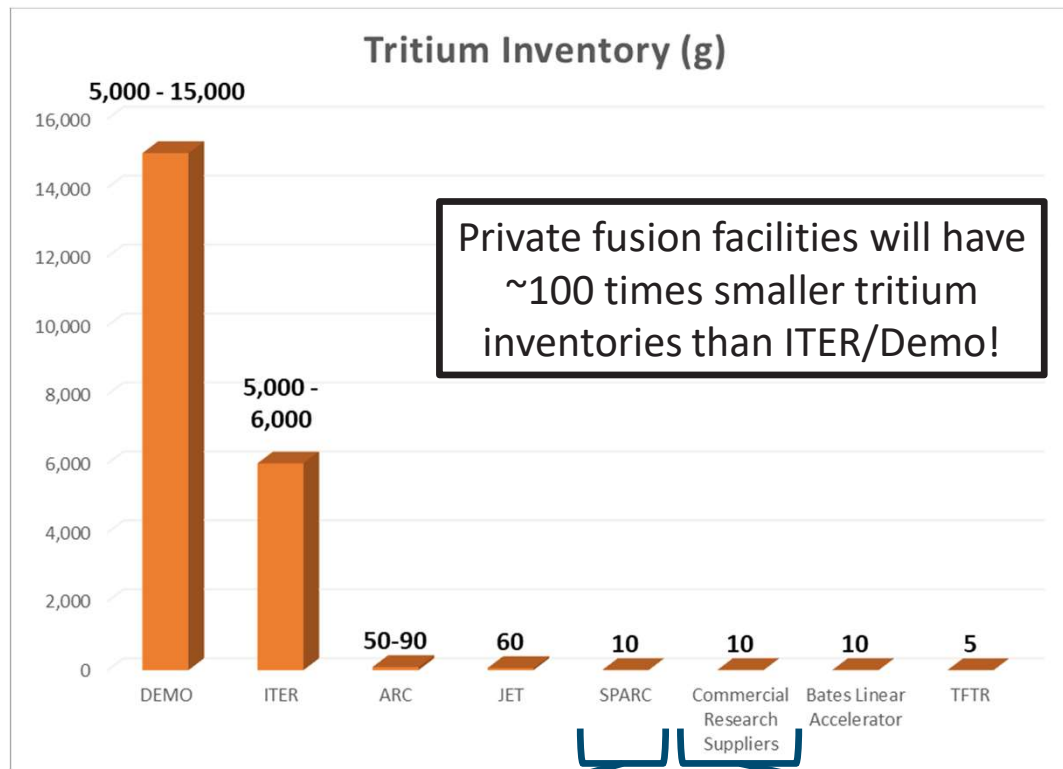
Low Level Waste Generation



Note: Power Core Volume includes blanket, divertor, shield, manifolds, vacuum vessel, magnet, and structure.

- Private fusion facilities and CFS's high-field approach in particular, allows for significantly smaller fusion energy facilities and hence smaller LLW volumes
- For CFS's design, most of this LLW volume is expected to be Class A which allows for shallow land burial and no Class C
- LLW volumes and characteristics are similar to what is already produced at existing accelerators and research/medical facilities

Tritium Inventory Requirements



Applying to be
licensed under
105 CMR 120

Already
licensed under
10 CFR 30/20

- Why is ARC's tritium inventory so much less than ITER and DEMO?
 - Very high temperature interior components preclude bulk retention in vacuum vessel and plasma-facing materials
 - Relative simplicity of tritium recovery in an immersion blanket where the material holding the tritium (e.g. molten salt) is circulated out
 - Lower thermal power compared to DEMO
- There are commercial research suppliers located in the middle of major urban areas who are licensed for maximum tritium inventories up to 10 g under 10 CFR 30 that have safely handled tritium for decades



Radiation Dose Limits

Mode	Dose Pathway to Off-site Public	Regulatory Limit or Guideline (mrem)
Chronic	Annual effluent	10
Chronic	Annual effluent plus direct	100
Chronic	Direct dose in any hour	2
Accident	Accident	1,000

Reference: 10 CFR 20

- The table shows the radiation dose limits to the general public for Agreement States (NRC Part 30 type licensees)
- If a facility can be designed to stay under these limits, then no off-site emergency evacuation planning needs to be conducted to protect public health and safety
- Privately developed fusion energy facilities can be designed to stay under these limits using a combination of these well-established strategies:
 - Set-back of the site boundary
 - Keep tritium systems in negative pressure, helium atmosphere glovebox enclosures
 - Break up the tritium inventory to smaller amounts so that the actual releasable inventory is a small percentage of the total inventory
 - Selection of appropriate materials and barriers
- The fusion industry is working to stay below the dose limits of 10 CFR 30/20



Safety Analysis Example

- Broadly, the fusion community identified Loss of Vacuum as the highest priority radiological safety scenario
 - Vacuum vessels contain small amounts of tritium fuel and a breach creates the potential where some fuel could flow out
- The JET safety analysis case assumed ~10% of the tritium in the vacuum vessel was releasable
- In this scenario, since the vessel is at vacuum, air would enter at a faster rate than the diffusion of tritium out of the vessel and the torus pumps would collect the tritiated inventory for processing and clean-up
- The risk of this scenario can be mitigated by including the following features:
 - Design tritium confinement systems with sufficient redundancy and layers of protection that no single failure can cause a significant tritium release
 - All tritium system components are housed within negative pressure, helium atmosphere gloveboxes which are furnished with an associated clean-up and tritium recovery system in the event of a release to the secondary glovebox confinement
 - Design torus pumps to easily achieve the necessary decontamination factors for any expected torus breach
- Prior experience with component failure and clean-up indicates that these clean-up systems are capable of containing leakage from equipment failure with actual observed decontamination factors greater than 1000

Summary



- Private fusion approaches can be designed to require orders of magnitude less tritium than ITER/DEMO, produce much less low-level waste (LLW) and not require emergency off-site evacuation planning
- The characteristics of CFS's proposed fusion energy approach with regards to tritium inventories, LLW generation, and safety are similar to other privately proposed facilities
- The scale of private fusion energy facility tritium inventories and LLW generation is also similar to current research accelerators and medical facilities which are already effectively regulated under 10 CFR 30/20
- For the foreseeable future, the proposed private fusion energy facilities all have the characteristics that put them under 10 CFR 30/20

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

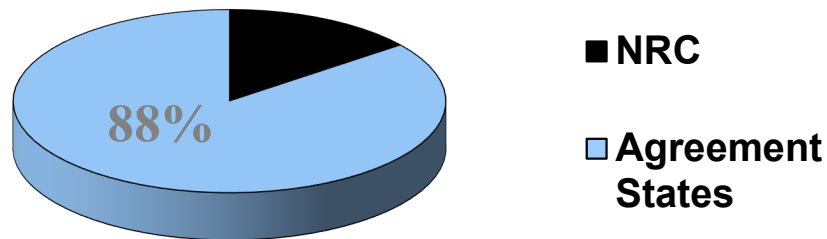
- Agreement State program
- State Liaison Program
- Section 274i of Atomic Energy Act
- Memorandum of Understanding for NPPs
- Emergency Preparedness
- Transportation of Spent Fuel, Waste, and Risk-Significant Sources

Agreement State Program

- 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

- 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

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

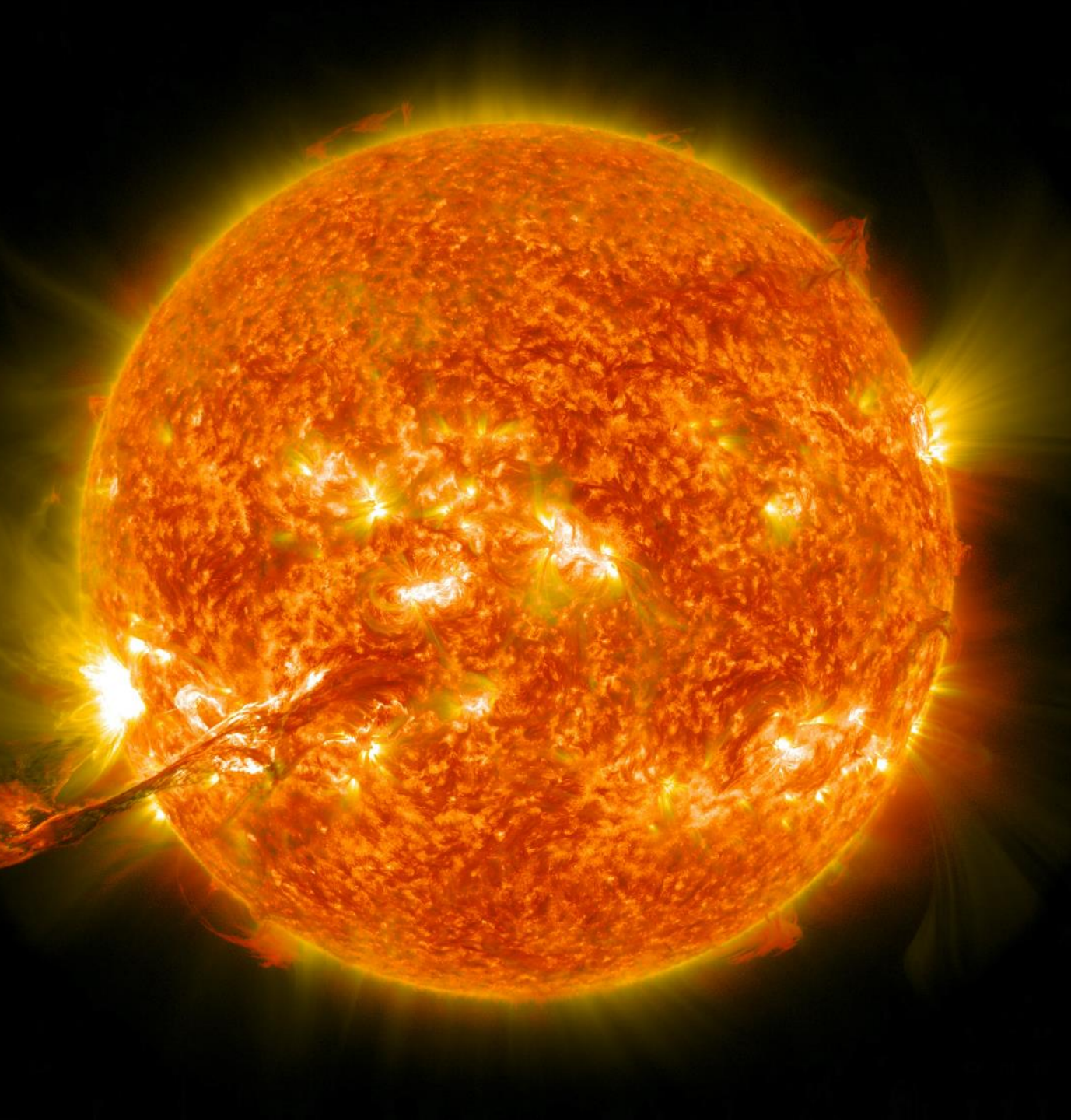
- Financial Assurance and Decommissioning
 - How will you determine the amount of activation products to determine the amount of financial assurance needed?
 - How do you plan to decommission the facility?
- Training
 - What should be the requirements for an individual operating a fusion energy plant?
 - 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
Nuclear Engineer
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TODAY'S AGENDA



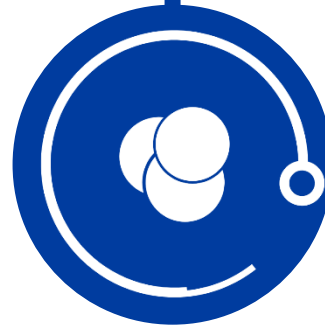
Current
Definitions



What Already
Applies



What Doesn't
Apply



Tritium



Gaps



Benefits

EXISTING FRAMEWORK-DEFINITIONS

UTILIZATION FACILITY:



OR



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 SS DR)



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.

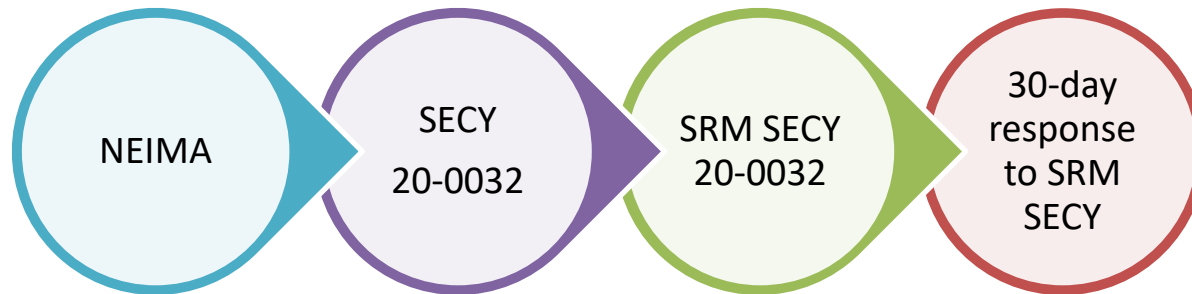
July 2009

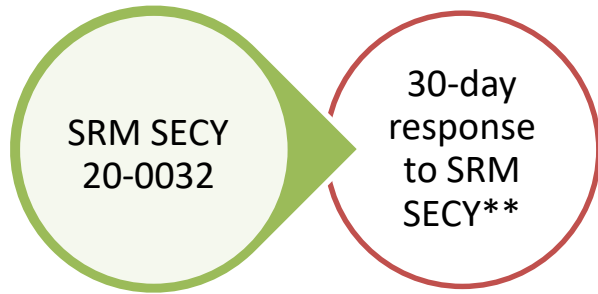
SRM SECY-09-0064

- 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, ...



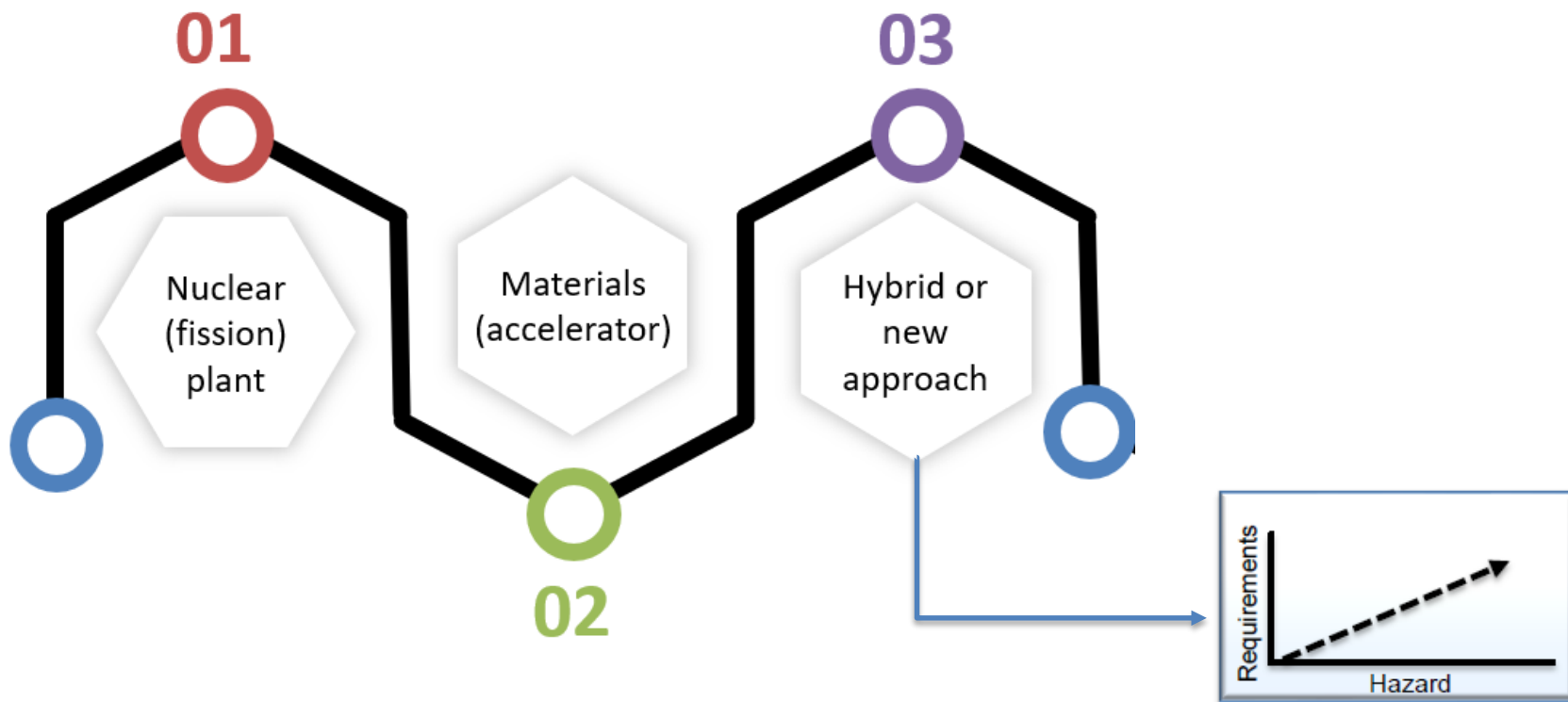


Commission Direction on Rulemaking Plan

- 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.

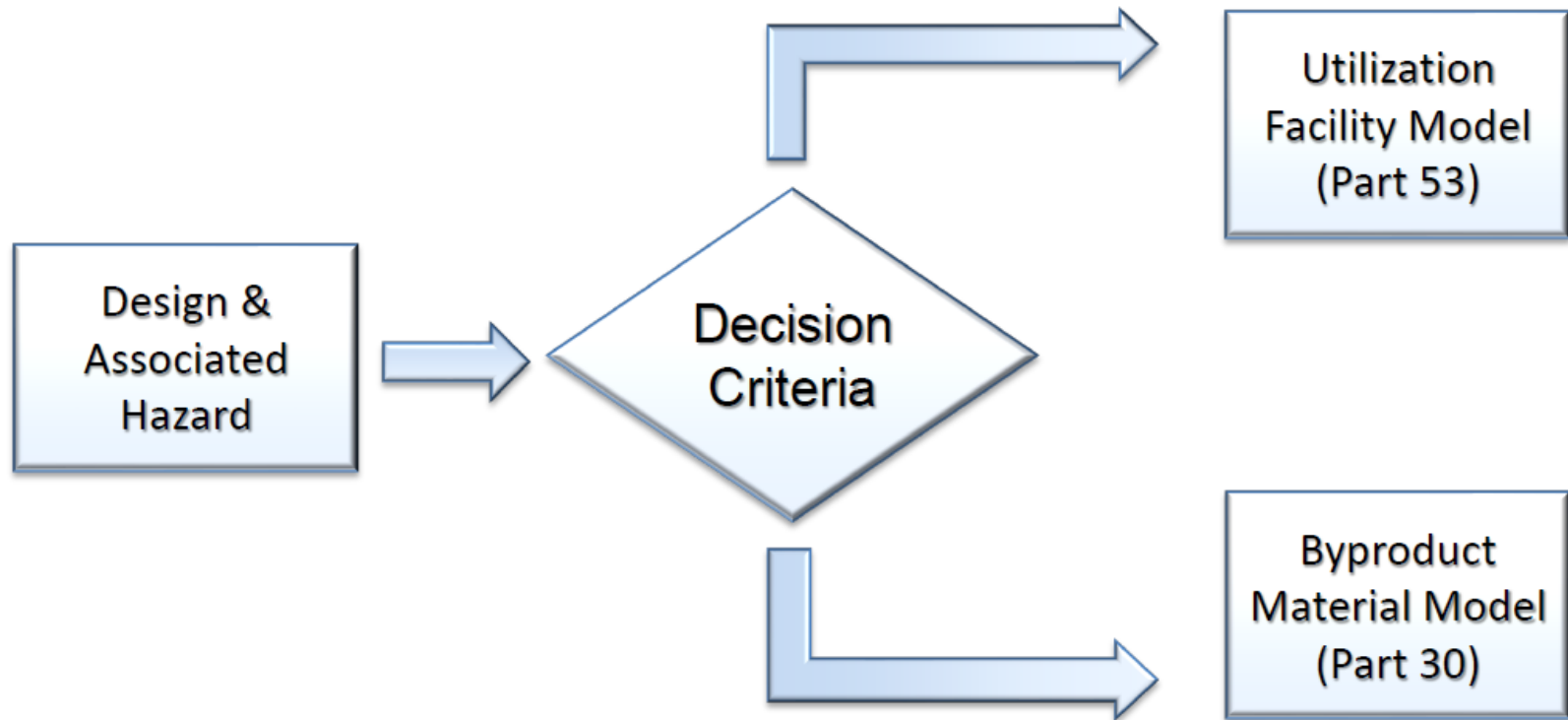
Regulatory Approaches

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



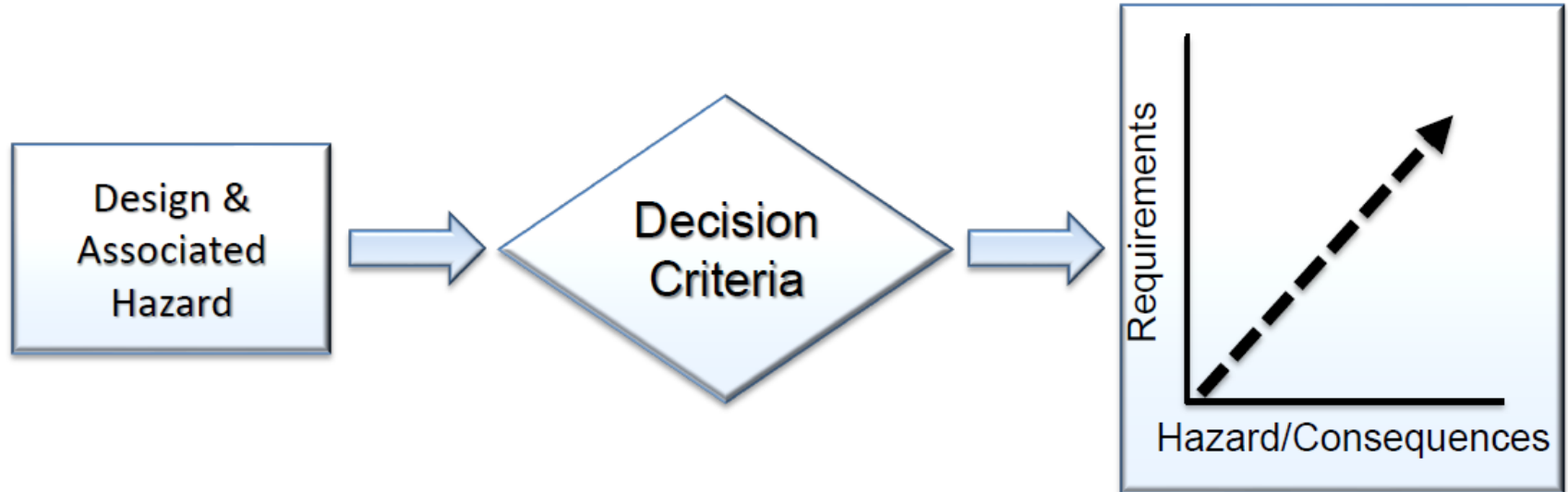
Hybrid Approach

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



Hybrid Approach

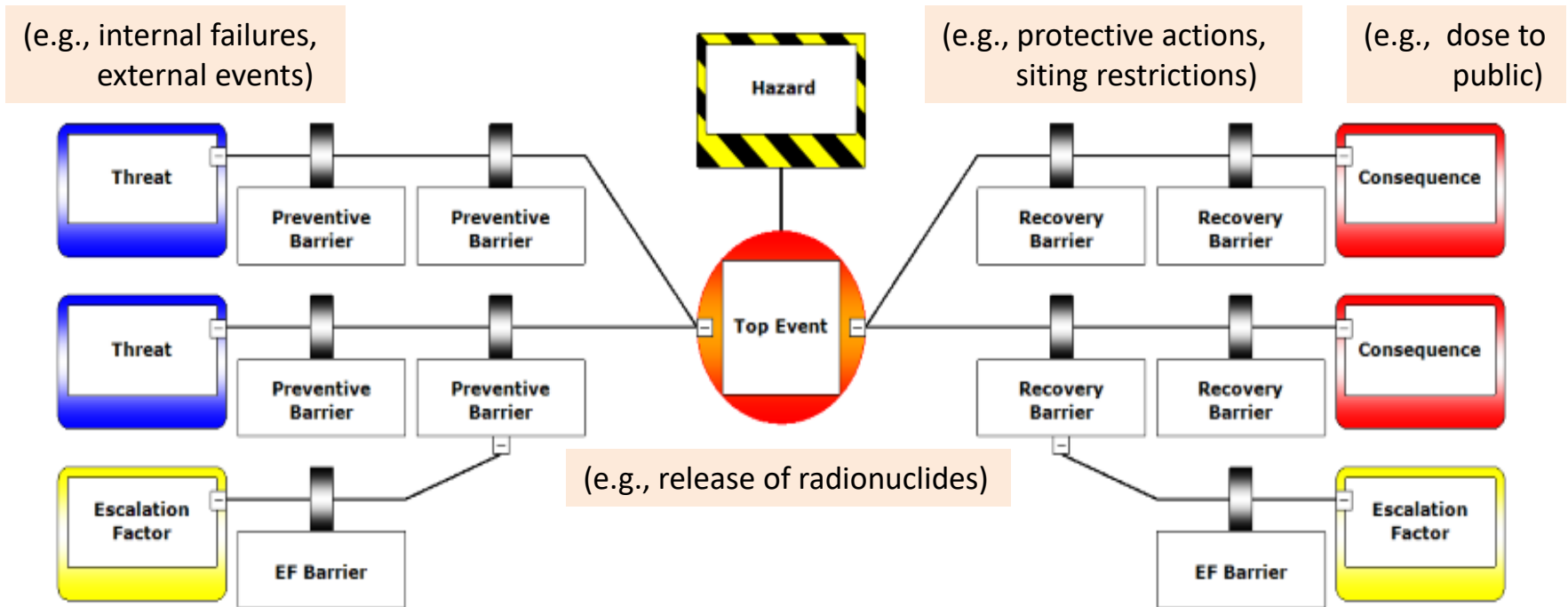
- *3b-Within a dedicated Fusion framework (consolidated):*



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



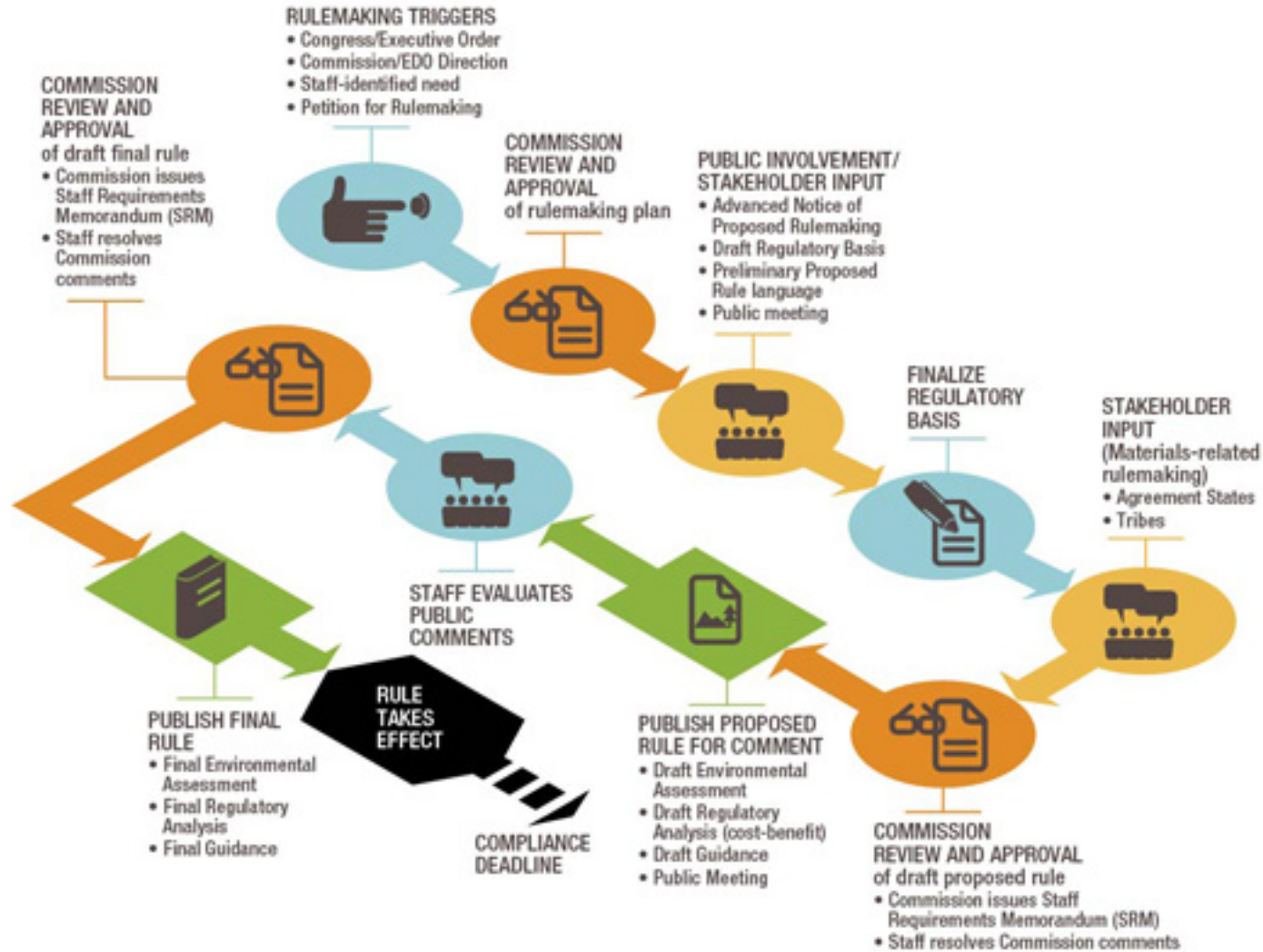
Bow-Tie Risk Management Figure

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

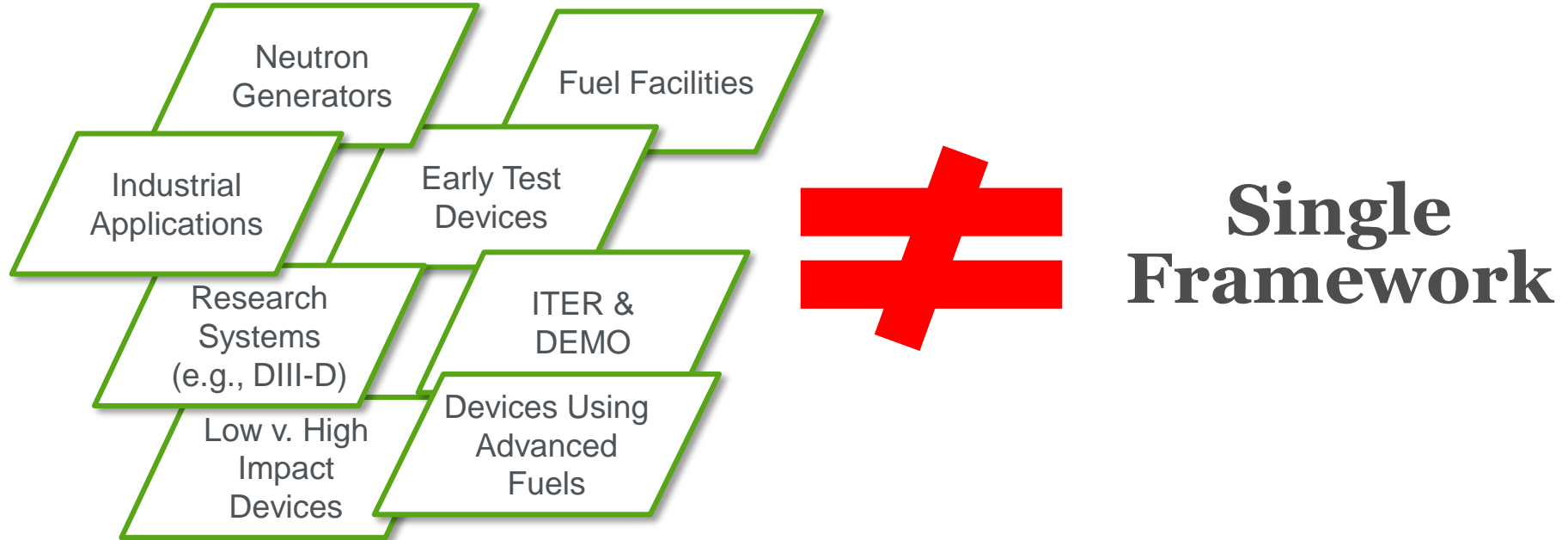
Sachin Desai
March 30, 2021

Agenda

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

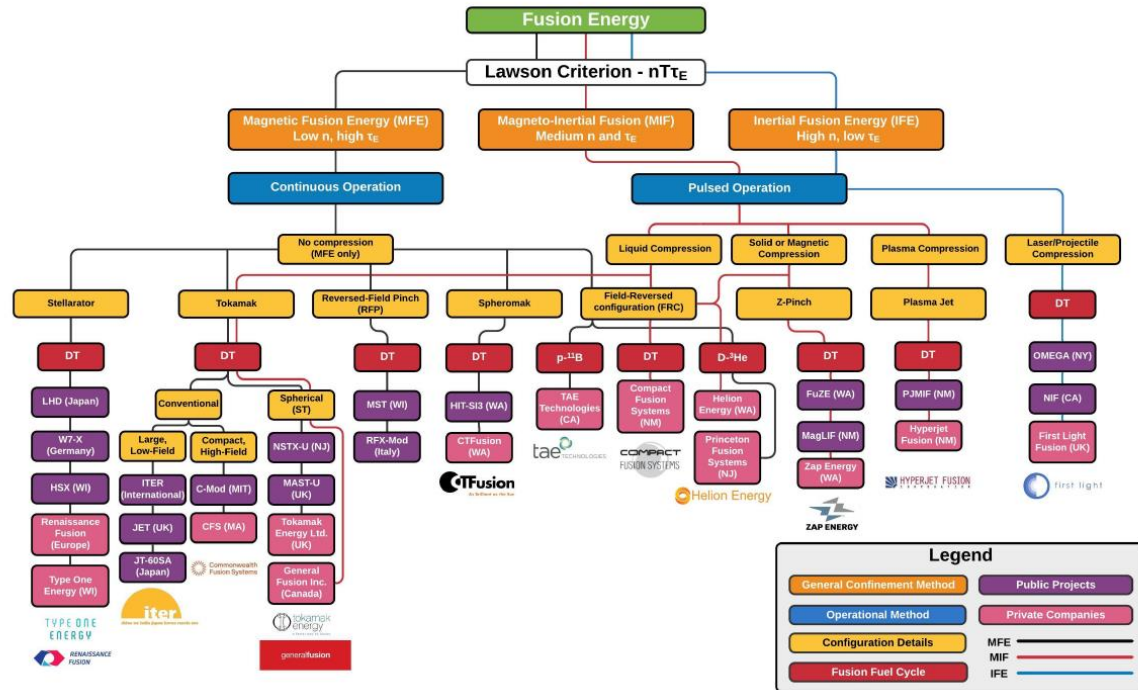
Fusion Diversity Warrants a Graded Approach

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Leverages only low-complexity, passive shielding during operation
Waste	<ul style="list-style-type: none">• Only generates and stores low level radioactive waste
Proliferation Risk	<ul style="list-style-type: none">• 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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