

Nuclear Facility Licensing and Authorization by Nuclear Regulatory Commission and the Department of Energy

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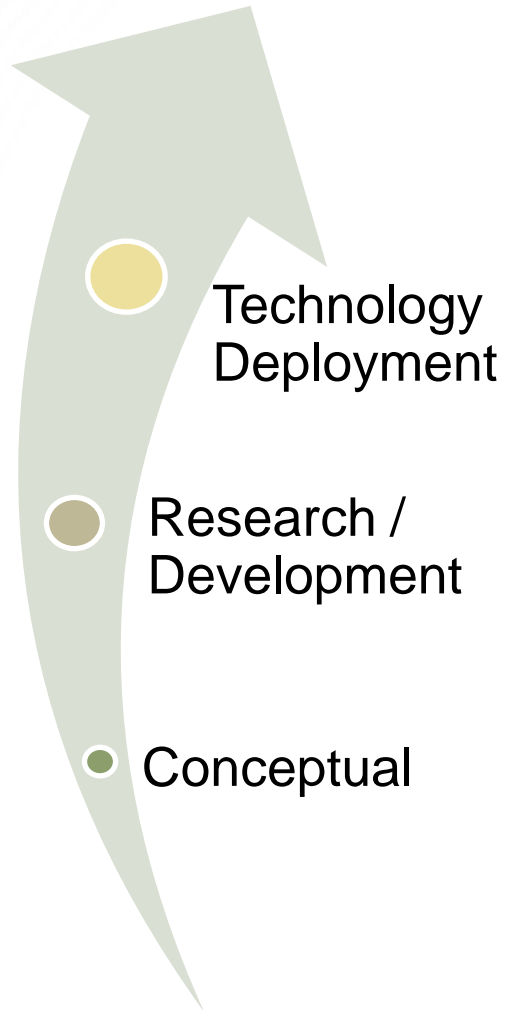
Department of Energy and Nuclear Regulatory Commission Disclaimer

- All content provided herein was developed through the Department of Energy's (DOE) Gateway for Accelerated Innovation in Nuclear (GAIN) initiative in response to industry stakeholder questions
- This presentation does not and is not intended to state any official position of the DOE nor the Nuclear Regulatory Commission (NRC)
- This presentation should not be relied upon in preparing an NRC application
- Rather, this presentation is intended to promote general awareness of DOE authorizations and NRC licensing processes as governed by applicable statutes and their general regulatory purview
- All developers of new nuclear technologies should discuss any approach to licensing or authorization of a nuclear technology in pre-application interactions with the appropriate government agency before proceeding with development of an approach to technology regulatory deployment

Objective and Scope

- **Objective** – To provide a general overview of statutes, regulations, and processes governing licensing and authorization of reactor and fuel facility development
- **Scope**
 - **Statutory Authority**
 - The Atomic Energy Act of 1954, as amended (AEA), Energy Reorganization Act of 1974 (ERA), and Department of Energy Organization Act of 1977
 - **Reactor Licensing and Authorization Regulatory Constructs**
 - NRC and DOE reactor facility regulatory process overview and application
 - **Fuel Fabrication Licensing and Authorization Regulatory Constructs**
 - NRC and DOE fuel fabrication facility regulatory process overview and application
 - **Cooperative Opportunities**
 - Discuss Idaho National Laboratory (INL) and DOE opportunities to collaboratively innovate and develop technologies supporting reactor and fuels development

Considerations for Advanced Reactor and Fuel Developers in Support of Today's Accelerated Nuclear Technology Arena



- Advanced reactor and fuel fabrication technologies are being developed to help battle climate change. Developers strive to find the most efficient and cost-effective regulatory path to technology deployment which can capitalize on:
 - Modern technologies that have increased safety through passive designed safety and security.
 - Government and private sector fiscal and cooperative assistance with demonstrations of partial or whole technologies.
- This GAIN sponsored presentation responds to industry questions and is intended to help stakeholders understand the available avenues for technology deployment.
 - When must a reactor or fuel fabrication facility be specifically licensed by the NRC?

History of the Government's Role in Research and Development & Commercial Operations



- Under the AEA of 1954, the Atomic Energy Commission (AEC) supported both research and development (R&D) and licensing activities under its statutory authorities



- These roles were split with the enactment of the ERA of 1974
- The ERA delegated the role of government supporting research, development, and demonstration of nuclear technologies to the Energy Research and Development Administration (whose functions were transferred to the DOE by the Department of Energy Organization Act of 1977)
- The ERA delegated the role of regulating commercial nuclear activities (including non-government research reactors) and licensing and regulatory authority over the DOE facilities listed in section 202 of the ERA to the NRC

DOE and NRC Missions

- DOE is a cabinet-level government agency that is chartered with (among other things):
 - Encouraging and conducting R&D related to the development and use of energy from nuclear sources
 - DOE maintains, authorizes, and self-regulates nuclear facilities to protect the public health and safety and common defense and security. DOE makes these facilities available for industry use through a variety of agreement structures both with DOE and through DOE’s contractors
- The NRC is an independent government agency charged with overseeing commercial use of nuclear energy
 - The AEA and ERA authorize the NRC to license “persons,” including companies, to construct and operate nuclear reactors and other facilities and to own, possess, and use nuclear materials



DOE
Authorization



Safe, Secure
Nuclear
Materials
Management



NRC
Licensing

- The NRC licenses persons under 10 CFR Parts 30, 40, 50, 52, 70, & 72 and regulates those licensed persons to ensure the protection of the public health and safety and common defense and security

Licensing and Authorization Authorities

- **NRC's Regulatory Jurisdiction**

- Subject to other provisions, the NRC is given “principal licensing and regulation” authority for all reactors, materials facilities, and materials licensed under the AEA {ERA Sections 203(b)(1) & 204(b)(1), 42 USC 5843(b)(1) & 5844(b)(1)}
- Except as specified in AEA Section 110b or other law, the NRC has licensing and regulatory authority for the following types of DOE facilities: {ERA Section 202, 42 USC 5842}
 - Demonstration reactors when operated to generate power for a commercial electrical utility system
 - Demonstration reactors when operated to demonstrate the suitability of a reactor for commercial application
 - Any fuel facility under contract with DOE that is specifically for the fabrication of mixed plutonium-uranium oxide fuel for use in a commercial licensed reactor
 - Facilities for the receipt and storage of high-level waste resulting from licensed activities
 - Long-term Retrievable Surface Storage Facilities and other facilities for storage of Administration generated high-level waste

Licensing and Authorization Authorities (cont.)

The general rule, therefore, is that the DOE ensures the safety of its own developmental nuclear activities through self-regulation, rather than through NRC licensing. Except as to the extent DOE facilities or activities are subject to licensing pursuant to ERA Section 202 or, for source material, the Uranium Mill Tailings Radiation Control Act of 1978, DOE contractors are exempt from NRC licensing as described below and on the next slide.

- **General DOE Exceptions**

- NRC regulations generally exempt contractors performing work for the DOE from obtaining an NRC license for the use of certain nuclear materials (e.g., 10 CFR 30.12 (byproduct material), 10 CFR 40.11 (source material), 10 CFR 70.11 (Special Nuclear Material (SNM)) and for the construction of reactors (10 CFR 50.11)).
- A helpful analysis of these rules, which includes more detail on the exceptions and preconditions, is located at: [HHRG-114-SY20-20150729-SD009.pdf \(house.gov\)](https://www.house.gov/imo/docinfo/?doc_id=360423).

- **General Department of Defense (DOD) Exceptions**

- Additional exceptions are afforded for defense applications, refining, and reactors in sections 91 & 110b of the AEA, {42 USC 2121, 2140} (e.g., DOD Mobile Microreactor).

Licensing and Authorization Authorities (cont.)

- NRC's regulations {10 CFR 50.11(b)} provide some exceptions from NRC licensing of reactors (unless subject to ERA Section 202, 42 USC 5842, which is discussed in a prior slide).
 - “The construction or operation of a production or utilization facility for the Department [of Energy] at a United States Government-owned or controlled site . . . : *Provided*, That such activities are conducted by a prime contractor of the Department under a prime contract with the Department.”
 - “The construction or operation of a production or utilization facility by a prime contractor or subcontractor of the Commission or the Department under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.”
 - DOE reactor projects may not be operated to generate power for a commercial electric utility system or to demonstrate the suitability of a reactor for commercial application.
 - The Department ensures that such facilities are safe and protect the public and the environment.

Research and Development Authorities

- **Research and Development at NRC-Licensed Facilities**
 - NRC licensees may perform R&D activities under a materials license, including fuels development {10 CFR Part 70}
 - NRC licensees may conduct R&D activities of the types specified in AEA Section 31, 42 USC 2051, including for advanced reactor technologies, at research reactors and testing facilities licensed pursuant to 10 CFR Part 50
 - This includes R&D related to nuclear processes, theory and production of atomic energy, and utilization of SNM and other radioactive material for industrial or commercial uses, generation of usable energy, and the demonstration of advances in the commercial or industrial application of atomic energy
- **DOE Research Activities***
 - Chartered by Congress to carry out management of a coordinated and comprehensive national energy policy and enable the necessary supporting energy R&D programs
 - Disseminate (to private industry and other federal agencies) information resulting from R&D programs performed at its self-regulated facilities to support commercial development of energy from nuclear, geothermal, solar, fossil, and other energy technologies

* Full citations for DOE scope are available in 42 USC 7112(1-19)

REACTOR FACILITIES

NRC LICENSING



AND



DOE AUTHORIZATION

Reactor Licensing – Two NRC Processes

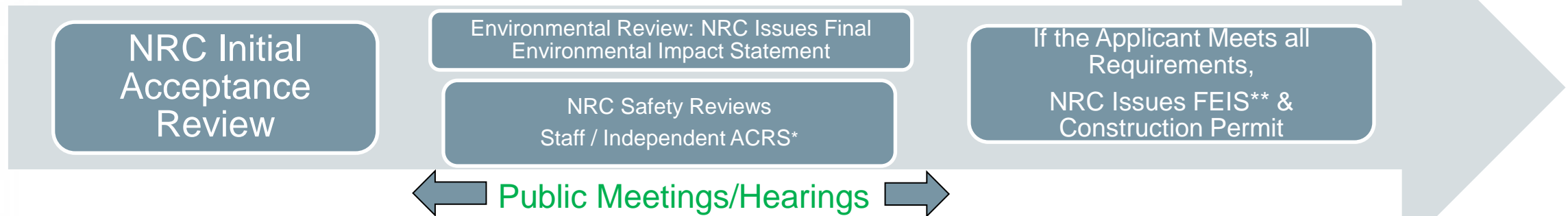
- Currently, two NRC reactor (i.e., “utilization facility”) license processes exist:
 - 10 CFR Part 50
 - Two step licensing process (construction permit / operating license)
 - 10 CFR Part 52
 - Single step combined licensing approach (combined license (COL))
 - Note: Part 52 also includes processes for Early Site Permits (ESP), Design Certifications (DC), and Manufacturing Licenses (ML)
- Note: The NRC is also developing an optional technology-inclusive regulatory framework, which would be designated as 10 CFR Part 53, for use by applicants for new commercial advanced nuclear reactors
 - The new framework would use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of advanced reactor technologies



Power Reactor Licensing – NRC Processes

10 CFR Part 50

- 10 CFR Part 50, Two Step Licensing of Power Reactors Overview - Step 1
 - CONSTRUCTION PERMIT APPLICATION – Applicant initially submits the Preliminary Safety Analysis Report (PSAR), including information regarding preliminary design, site suitability, and technical qualifications, an environmental report and need for power generation basis, and financial information



- The AEA requires a hearing on the construction permit application; members of the public may also contest the application provided they meet specified requirements
- The granting of a construction permit (CP) allows the holder to begin activities that are for construction of systems, structures, or components (SSCs) of the reactor that perform the safety functions specified in 10 CFR 50.10(a). The CP holder updates the PSAR and design through the construction phase with NRC oversight
- The NRC may choose to issue a “Limited Work Authorization” (LWA) prior to the CP but after all environmental and other findings have been established; the LWA authorizes activities that are for SSCs as specified in 10 CFR 50.10(a) (e.g., engineered backfill)

* Advisory Committee on Reactor Safeguards (ACRS) / ** Final Environmental Impact Statement (FEIS)

Power Reactor Licensing – NRC Processes 10

CFR Part 50 (cont.)



- 10 CFR Part 50, Two Step Licensing of Power Reactors Overview - Step 2
 - OPERATING LICENSE APPLICATION – Updated environmental report; Final Safety Analysis Report (FSAR) including final design information, technical specifications, physical security plan, and emergency plans
 - NRC staff reviews and evaluates FSAR for completeness and compliance with NRC safety requirements in areas including:
 - Site information; design of structures, components, equipment, and systems
 - Fuel, thermal, control rod drives/materials, engineered safety features, instrumentation and control, electric power, aux systems, and human factors
 - Reactor coolant and attached systems, steam and power conversion, and radioactive waste
 - Radiation protection, conduct of operations, and transient and accident analysis
 - Initial test program and inspections and quality assurance (QA)
 - NRC staff corresponds formally (requests for additional information) to obtain information to form the basis for the safety determination, as necessary and other interactions may include noticed meetings and audits
 - ACRS independent review of staff recommendations and safety determination
- Upon satisfactory determination that the application meets all NRC safety requirements and completion of the environmental review for the application, including hearings if necessary, the NRC issues the safety evaluation report and the operating license

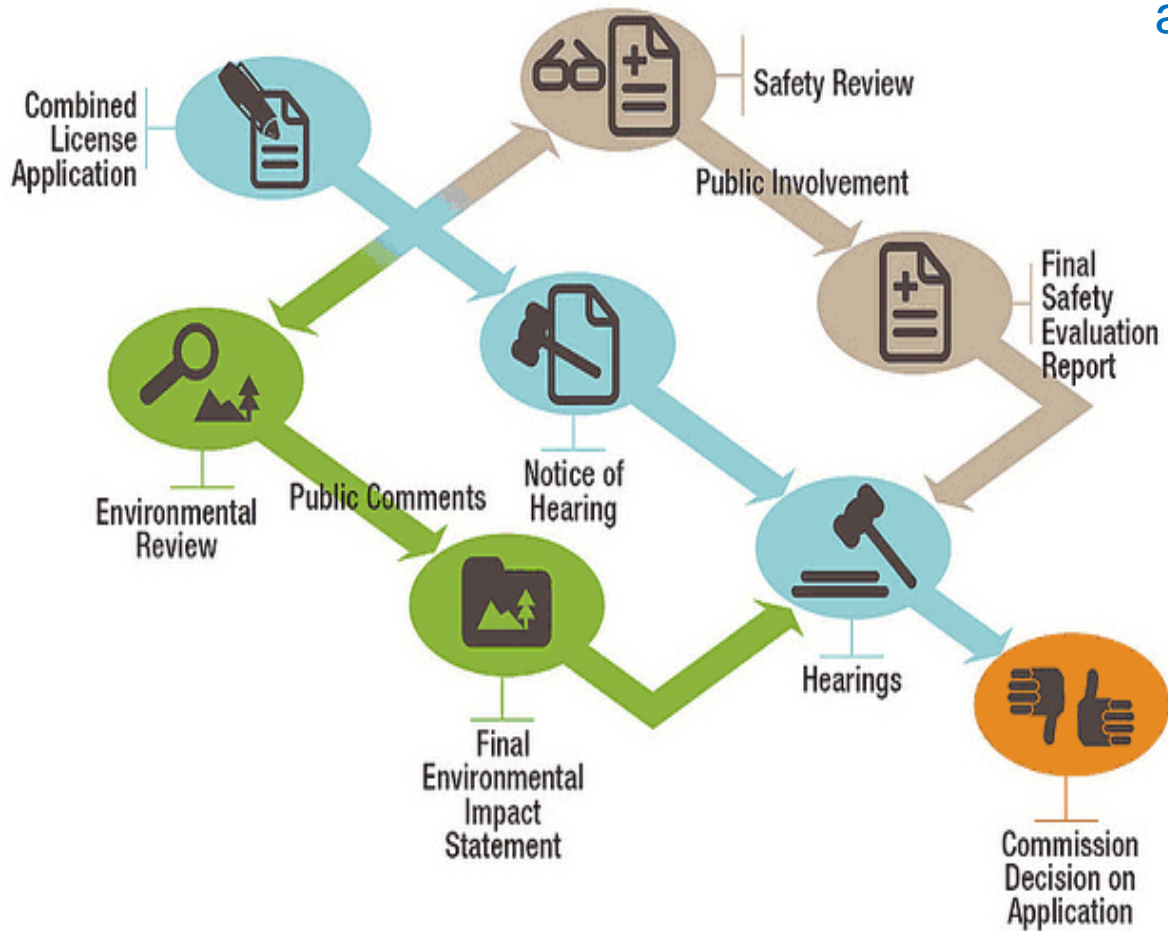
Reactor Licensing – NRC Processes 10 CFR Part 52 Combined License Process – Single Step



GAIN

Gateway for Accelerated
Innovation in Nuclear

- Applicant Applies for Combined Construction Permit and Operating License (COL)

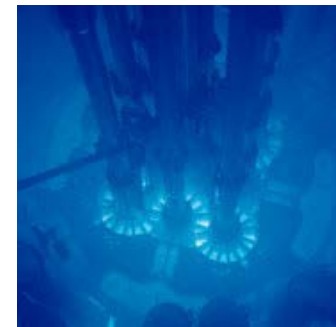


- All siting, safety analysis, design, environmental, financial, emergency planning, safeguards, and security information is required up front
- Can utilize an early site permit for pre-approval of certain environmental and siting issues
- Reviewed and evaluated by NRC staff for completeness and safety in areas as presented for Part 50
- Potential for gained efficiency in parallel reviews for construction, environmental, and design/operation
- Can reference an NRC-approved Design Certification nuclear plant design (resolves safety issues early and achieves regulatory stability)
- Upon NRC issuance of a COL, construction can commence
- Upon completion of construction, operation may commence if the NRC finds that the licensee has successfully performed inspections, tests, and analyses and the acceptance criteria in COL are met

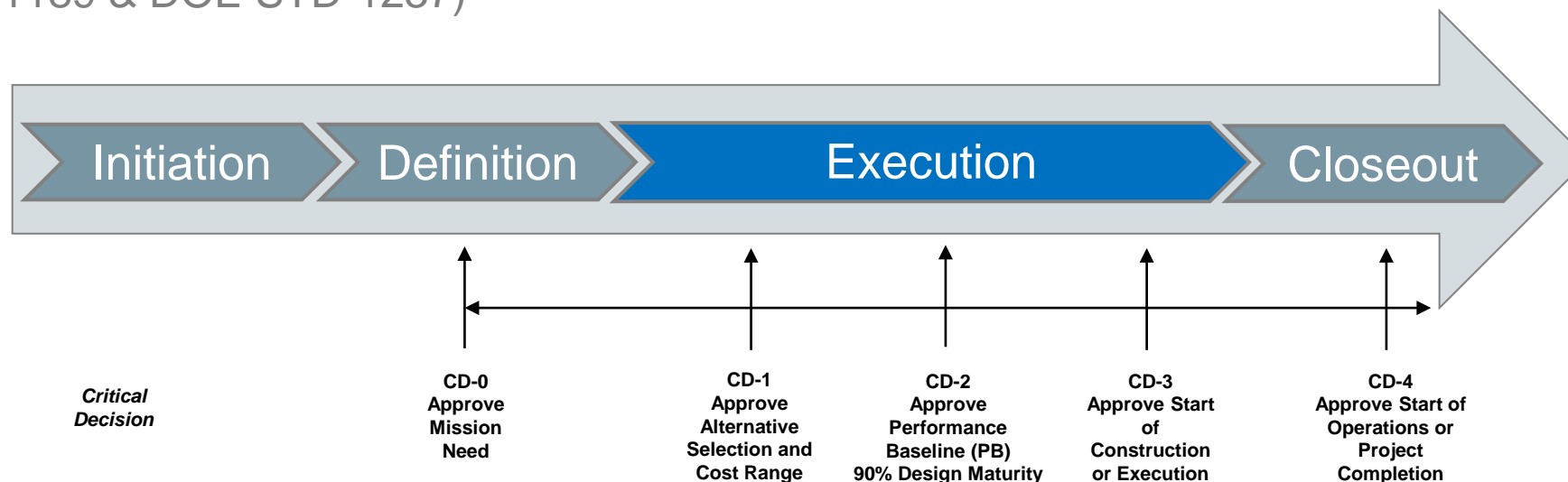
DOE Reactors – Authorization and Oversight 10 CFR Part 830

ERA of 1974 delegated AEC and other agencies' authority to DOE, from its predecessor agency, to operate and self-regulate reactors that it owns and operates (or its contractors operate) at DOE facilities.

- DOE has defined two types of reactors:
 - Category A (Power > 20 MWth) or Category B (Power ≤ 20 MWth)
- DOE process for authorizing new reactor design
 - The DOE capital asset acquisition project management guidelines are applicable
 - These guidelines establish requirements for safety integration into design and project authorization (DOE-STD-1189 & DOE STD-1237)



The DOE Advanced Test Reactor at the Idaho National Laboratory



DOE Reactors – Authorization and Oversight (Cont.)

- **DOE-STD-1189-2016 Establishes a Common Understanding and Agreement at Key Phases for DOE Planning**
 - Conceptual Design
 - Safety Design Strategy – Identification and agreement of Key Regulatory Requirements and Plant Safety Functions (GDC)(CD-1) – May utilize NRC Guidance (e.g., RG 1.70) as part of the safe harbor methodology but still must satisfy DOE requirements or receive exemption
 - Conceptual Safety Design Report – Summarizes hazards and identifies plant safety functions and key systems, structures, and components to meet safety functions and specific design criteria (CD-1)
 - Preliminary and Final Design
 - Preliminary Safety Design Report/Preliminary Documented Safety Analysis/Preliminary SAR (PSAR) – Identification of detailed design parameters necessary to meet plant safety functions and confirmation that design meets general and specific design criteria (Design Complete / Authorization to Construct) (CD-2/3)
 - Construction
 - Final Safety Analysis Report/Documented Safety Analysis – Documentation of as-built configuration and confirmation it meets identified PSAR requirements. Final set of technical specifications developed and approved (CD-4)
 - Obtain Authorization to Operate – Through DOE Order 425.1D, An Operational Readiness Review Assessment evaluates safety prior to operations.

DOE Reactors – Authorization and Oversight (Cont.)



- DOE Reactor Authorization

- Allows for alternative methodologies to demonstrate safety and compliance
 - Can utilize DOE methods, NRC methods, or a combination
- Current DOE efforts are underway to utilize and pilot advanced reactor NRC licensing approaches under development
 - Endeavors to achieve future regulatory stability and pilot new methods with NRC observation
 - Potential to leverage DOE piloting of advanced reactor authorization work to potentially gain efficiencies with future NRC advanced reactor licensing
- Methodology – One option is the Licensing Modernization Project approach, as endorsed by the NRC, and other NRC Advanced Reactor licensing documents as implemented under DOE safety design strategy auspices
 - Regulatory Guide 1.233, Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors
 - Reg Guide 1.232 – Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors
 - NUREG 1537 – Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors

FUEL FABRICATION FACILITIES

NRC LICENSING



AND



DOE AUTHORIZATION

Commercial Fuel Fabrication Facility Licensing Process – NRC

- 10 CFR Part 70 Domestic Licensing of SNM

- Issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material

- General or Specific Licenses (NUREG -1520 Rev 1)

- Specific license requirements vary substantially based on quantities of SNM to be in possession/processed

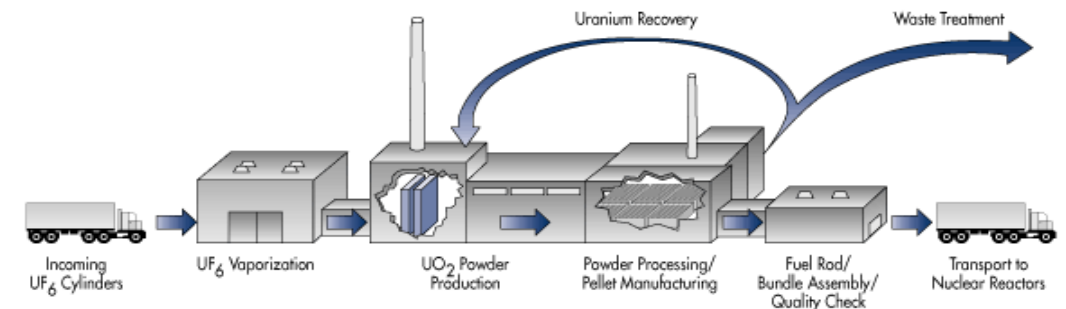
- Integrated Safety Analysis to include:

- Radiation Protection/Criticality Safety
- Chemical Process Safety/Fire Safety
- Emergency Management/Environmental
- Decommissioning/Management

- Examples of fuel fabricated by NRC licensees include:

- BWXT Technologies – Research Reactor Fuels – Advanced Test Reactor/High Flux Isotope Reactor / National Institute of Standards and Technology
- Global Nuclear Fuels (GNF) – Boiling Water Reactor Fuels – GNF2 and GNF3

Typical Light Water Reactor Fuel Fabrication Facility



Fuel Fabrication Facility Exceptions to NRC Licensing Requirements

- The NRC’s regulations {10 CFR 70.11} provide the following exceptions from NRC licensing for use of SNM by DOE prime contractors (unless subject to ERA Section 202, 42 USC 5842):
 - “The performance of work for the Department at a United States Government-owned or controlled site”
 - “any prime contractor or subcontractor of [DOE] is exempt from the requirements for a license set forth in section 53 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor receives title to, owns, acquires, delivers, receives, possesses, uses, or transfers special nuclear material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.”



Fuel Fabrication Facility Authorization Process – DOE ONLY

- DOE’s national laboratories have limitations on competing with the private sector
- In Addition to the project management requirements, DOE-STD-3009-2014 is utilized for safety basis Development and Approvals

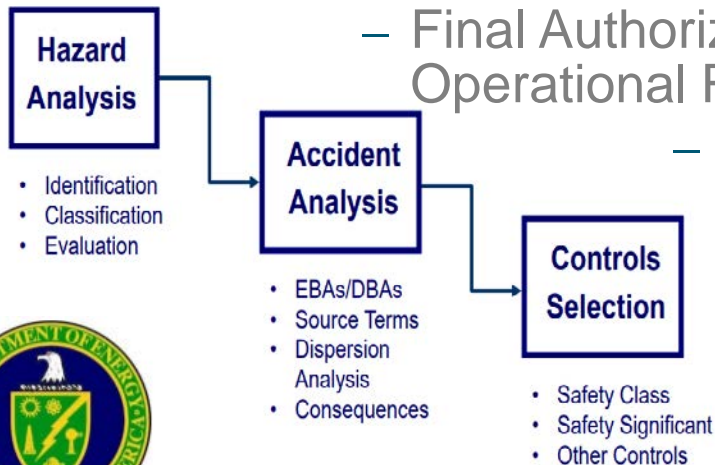
- Demonstrates assurance of public safety and health through DOE approval (Safety Evaluation Report) and DOE regulatory oversight
- Covers all types of DOE Category 1/2/3 Nuclear Facilities, including accelerators, research laboratories, and high hazard nuclear facilities (defense applications under National Nuclear Security Administration)

- A1. Standard Industrial Hazards
- A2. Chemical Hazards
- A3. Initial Conditions
- A4. Hazard Evaluation and Risk Ranking
- A5. Criticality Safety
- A6. Evaluation Basis Accidents
- A7. Dispersion Modeling Protocol
- A8. Hierarchy of Controls
- A9. Defense-in-Depth
- A10. Evaluation Guideline
- A11. Safety Management Programs
- A12. Specific Administrative Controls

– Final Authorization to Operate – Successful DOE Order 425.1D Operational Readiness Review

– Examples of fuel fabricated by DOE include:

- Argonne National Laboratory- Experimental Breeder Reactor (EBR) EBR-I and EBR-II Fuels
- *Most DOE reactor fuels are tested by DOE, then fabricated commercially for scaleup (i.e., Fast Flux Test Facility, Engineering Test Reactor, and Advanced Test Reactor fuels)



Overview of DSA Process



Partnership Opportunities for Industry



Agreement Types for Industry Partnerships



DOE

- **Financial Assistance and Cooperative Agreements**

- Conveys government funds and resources for a public good
- Allows industry to generate protected information and subject inventions using government funding, equipment, material, and expertise in a cost-shared award
- These agreements require DOE Headquarters program direction and congressional appropriations



Labs with DOE Approval

- **Cooperative Research and Development Agreement (CRADA)**

- Allows labs to generate protected information for industry using government resources and in-kind contributions; limited negotiable terms and conditions

- **Strategic Partnership Project (SPP) Agreement**

- Allows labs to generate proprietary information and inventions for industry stemming from partnerships through full cost recovery; negotiable terms and conditions



Industry Agreements to Further Nuclear Technology

A **Cooperative Research and Development Agreement** allows industry partners to work collaboratively with DOE Laboratories to share technical expertise, develop novel technologies/solutions, and access intellectual property emerging from the effort

CRADA Highlights:

- Allows industry partners access to a lab's unique technologies, capabilities, materials, and expertise
- Advances commercialization of federally-developed technologies
- Allows industry partners and labs to collaborate and optimize resources
- Generated data may be protected for up to 30 years for commercialization purposes with DOE authorization
- Protects existing intellectual property and allows industry partners to negotiate exclusive licenses to subject inventions arising from the effort
- Industry partners may provide funds-in to labs and/or in-kind contributions, which may include personnel, services, facilities, equipment, intellectual property, or other resources
- Agreement is between industry partner(s) and lab(s); DOE authorizes these agreements



Cooperative Research and Development Agreement (CRADA)

Strategic Partnership Projects

A Strategic Partnership Project (SPP) is an agreement that enables industry partners to pay a DOE laboratory to perform a defined scope of work with tasks that draw upon the unique facilities, equipment, and personnel of the laboratory.

SPP Highlights:

- Provides assistance to industry partners (or other federal agencies) in accomplishing goals that may otherwise be unattainable
- Provides access to highly specialized or unique DOE facilities, services, or technical expertise
- Increases research and development interactions and transfer of technology originating in DOE laboratories to industry for further development or commercialization
- With certain DOE approvals, the industry partners may obtain ownership of both inventions and data generated
- Industry partners fully pay the cost of work scope and advanced payment is required
- Scope and goals must align with DOE laboratory mission and not compete with private sector



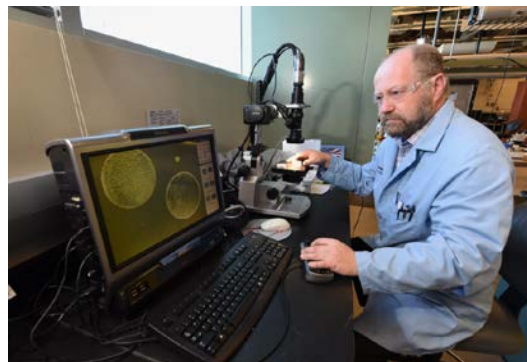
Strategic Partnership Projects

DOE Financial Assistance and Cooperative Agreement Awards

- Subject to Congressional appropriations and the constraints of the Energy Policy Act of 2005 and other controlling legislation, DOE can make awards to support Research Development Demonstration and Commercialization of nuclear technology
- These awards are typically cost-shared between the DOE and private entity and are competitively bid and awarded
 - DOE awards cover many areas including, but not limited to:
 - Encouraging and conducting R&D demonstration of commercial feasibility and practical applications of the extraction, conversion, storage, transmission, and utilization of nuclear energy
 - Participating in and supporting cooperative R&D in conjunction with private and public funding
 - Developing, collecting, distributing, and making available for distribution, scientific and technical information concerning the manufacture or development of energy and its efficient extraction, conversion, transmission, and utilization
 - Making arrangements for R&D with private or public institutions for cooperative research and experimental projects

Potential Resources if Siting on DOE National Laboratories

- Resources may be available regarding geographic siting at a DOE National Laboratory. These possibilities are only permissible with approved agreements from DOE. These may include:
 - Possible government land lease agreements
 - Established public trust and confidence in risk management
 - Established public proximity and maximum credible accident dose consequence
 - Site characterization data (e.g., geological, hydrological, atmospheric, seismic)
 - Transport of materials for research, testing, and analysis at established national laboratory facilities
 - Potential cost-shared resourcing for security and emergency management programs

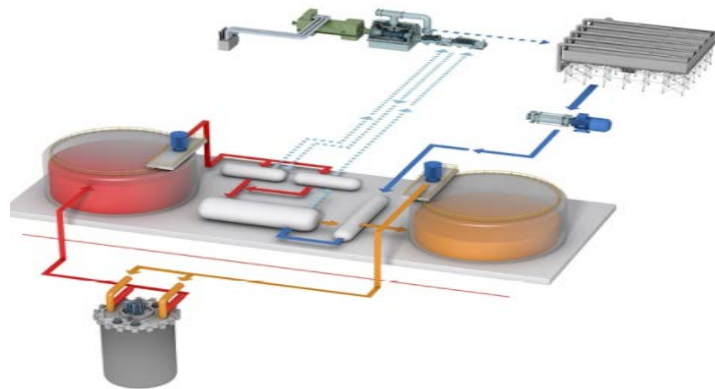


Examples of Large-Scale DOE Cooperative Agreements

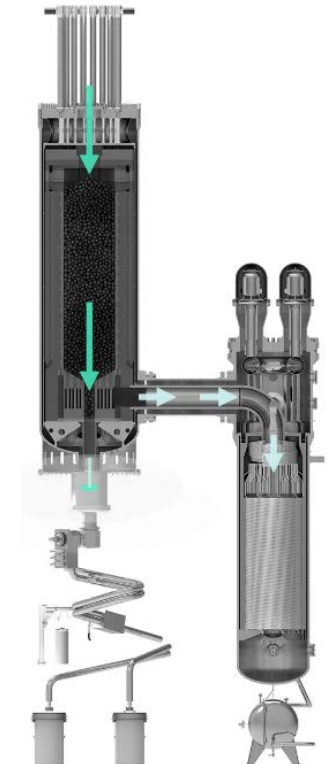
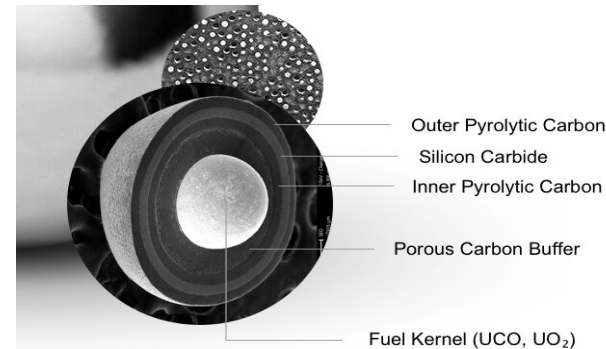
- Examples of DOE Partnerships with Private Industry to Advance Technologies

- Advanced Reactor Demonstration Program (ARDP) – Large scale, cost-shared partnerships with industry, subject to NRC licensing

- TerraPower - Sodium Reactor



- X-energy – XE-100



NRC Response to Large-Scale Cooperative Agreements

- Correspondence between DOE and NRC related to advanced reactor technologies licensing for the ARDP projects: (US NRC Response to DOE RFI DE-FOA RFI-0002271, ADAMS Accession No. ML20140A272)
 - Stated intent of NRC willingness to cooperate with DOE on advanced reactors and engage early with DOE and developers on regulatory issues to minimize complexity and add stability and predictability for Advanced Reactor licensing
 - Summarized and clarified existing NRC and DOE reactor jurisdictions associated with the:
 - Level of affiliation with DOE and level of direct oversight/control by DOE
 - Property the reactor facility is sited on (private or government owned)
 - Transmission of power to the utility grid
 - The demonstration aspects of the reactor for commercial application
 - The letter acknowledges that “Many of these determinations as to whether NRC licensing is required will be fact-specific, and the NRC is ready to discuss jurisdiction and licensing questions with DOE when needed.”
 - Also of interest, the NRC stated:
 - *“Where authorized by law, DOE may enter into an agreement with a private party, with DOE oversight, to construct and operate a research-oriented, non-power reactor without NRC licensing; however, these instances will be fact specific”*

Conclusions

- Both the reactor and fuel fabrication facility authorization or licensing processes provide adequate protection of the public safety and health, however, currently neither agency has an established process that allows for transition through reciprocity from DOE authorization to NRC licensing
- Should a developer establish a facility (reactor or fuel fabrication) under DOE authorization to perform R&D, upon completion of R&D and prior to commencement of commercial application, appropriate NRC permits and/or licenses would be required



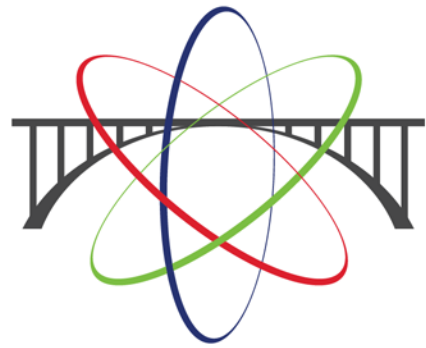
- Intellectual property development and rights during and after the technology development (R&D) phase must be well developed to ensure government work product, proprietary information, technology transfer, and government non-compete aspects are well defined

Summary

Generally, DOE may build and operate a research-oriented non-power reactor, at a United States Government facility without an NRC License. However, each case may be fact specific and necessitate further consultation

- Many DOE activities and facilities may be exempt from NRC licensing by statute
- An NRC license is not required for construction and operation of a DOE reactor operated on Government property for development or testing of new reactor technologies unless the reactor will be used to demonstrate the reactor's suitability for commercial application, e.g., by being operated as part of the power generation facilities of a commercial electrical utility system
- An NRC License is required where a DOE-affiliated reactor is operated by a private party on private property free from DOE oversight and control
- An NRC license is also required, regardless of ownership, for demonstration reactors operated as part of a commercial electrical utility grid

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