So – Just What is the Regulatory "Framework?"

Ryan Lighty

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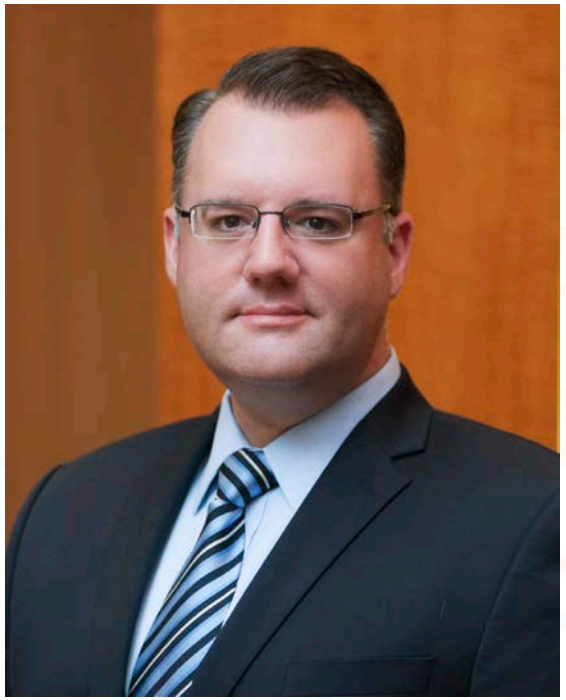
GAIN Gateway for Accelerated Innovation in Nuclear



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Ryan K. Lighty is an attorney with the global law firm of Morgan, Lewis & Bockius LLP. He represents and advises energy industry participants and investors in litigation, transactional, and regulatory matters before the US Nuclear Regulatory Commission (NRC), other state and federal agencies, and in federal court. Ryan regularly counsels businesses on a range of complex issues related to licensing nuclear materials, nuclear reactors (including power and non-power reactors, advanced reactors, and small modular reactors) and medical isotope facilities. Ryan has represented NRC licensees as counsel of record in more contested adjudicatory proceedings before the NRC than any other attorney in the past five years, and has litigated a variety of technical, environmental, and financial matters. He also routinely guides clients on multifaceted regulatory compliance issues and is part of the firm's Classified Information Services practice. Before joining Morgan Lewis, Ryan was an attorney in the NRC's Office of the General Counsel and served as Acting Regional Counsel in the agency's Region III office.

Structure and Function of the NRC's Component Offices

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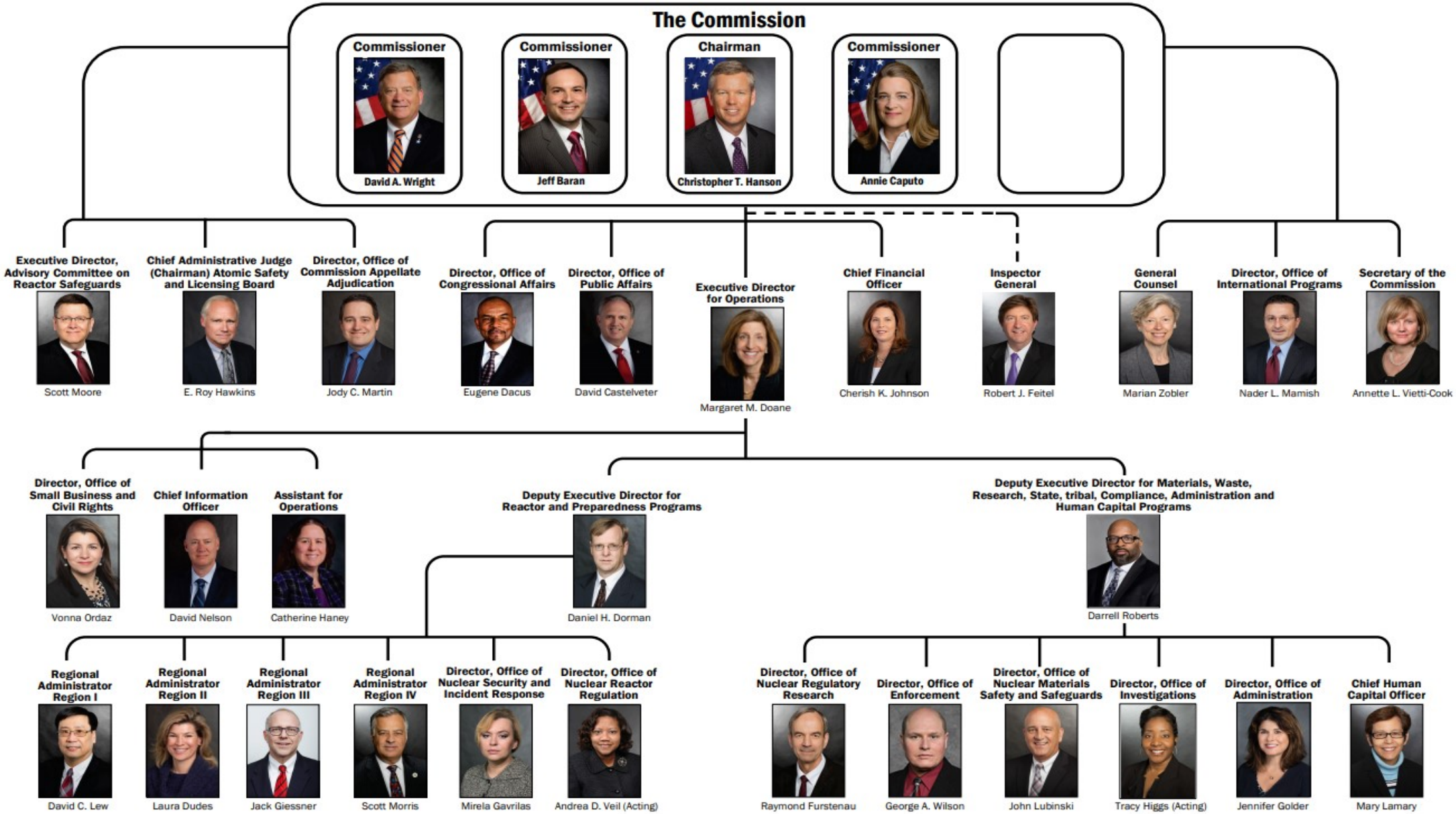
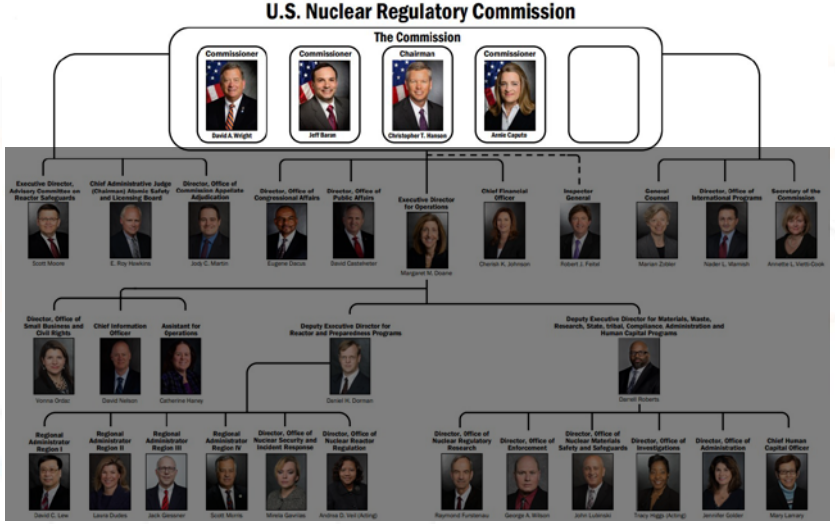
U.S. Nuclear Regulatory Commission



The "Commission"

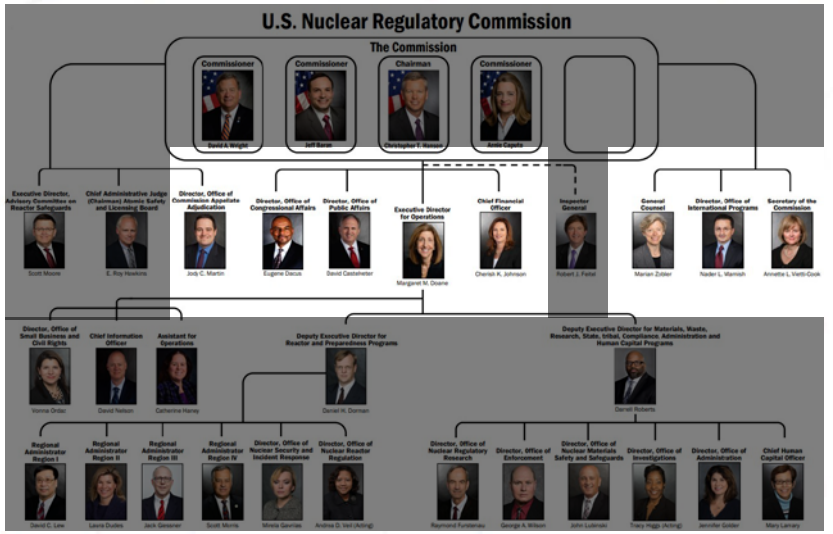


- The agency is headed by a five-member "Commission"
  - As distinguished from the "Staff"
  - Collectively "Commission" and "Staff" are the "NRC"
- Appointment & Term: Commissioners are nominated by the President and confirmed by the Senate for staggered five-year terms (one expires each year on June 30th).
- Political Party Makeup: No more than three members of the Commission shall be members of the same political party.
- Principal Executive: One member of the Commission is designated by the President (no Senate confirmation required) to serve as Chairman. The Chairman (or his/her designee) presides at all meetings of the Commission, provides day-to-day directions to staff, and serves as the spokesperson for the Commission.

How the Commission Functions

- The Commission, as a whole, formulates policies and regulations governing nuclear reactor and materials safety, issues orders to licensees, and adjudicates legal matters brought before it
  - Formal procedures governing collegial activities, functions of the Chairman, internal document processes, voting and conduct of mandatory hearings are set out in the "Internal Commission Procedures" (ICP)
  - The Commission acts by a majority of a quorum in the issuance of policy statements, adjudicatory decisions, and promulgation of regulations
  - The Commission provides direction to the NRC Staff through Staff Requirements Memoranda (SRMs)

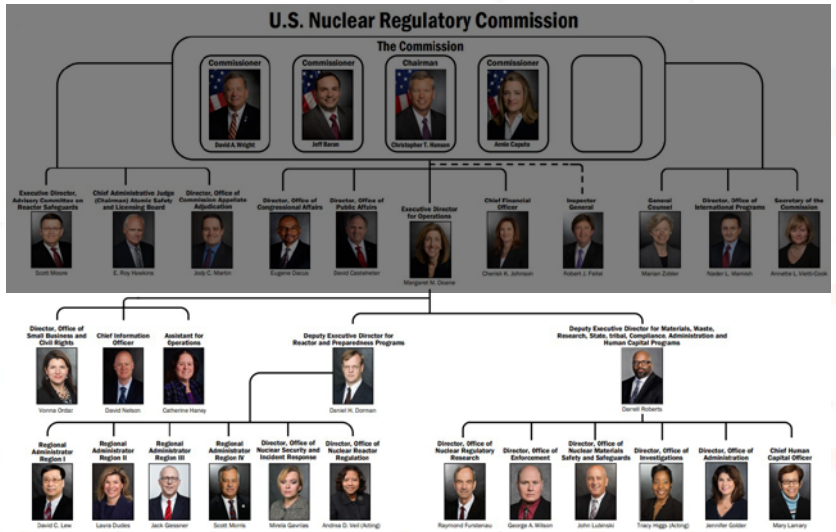
Commission Staff Offices



OEDO	Office of the Executive Director for Operations *Carries out the policies and decisions of the Commission and directs the activities of the EDO offices.*
OGC	Office of the General Counsel
SECY	Office of the Secretary
OCAA	Office of Commission Appellate Adjudication
OCA	Office of Congressional Affairs
OPA	Office of Public Affairs
OIP	Office of International Programs
OCFO	Office of the Chief Financial Officer

EDO Offices

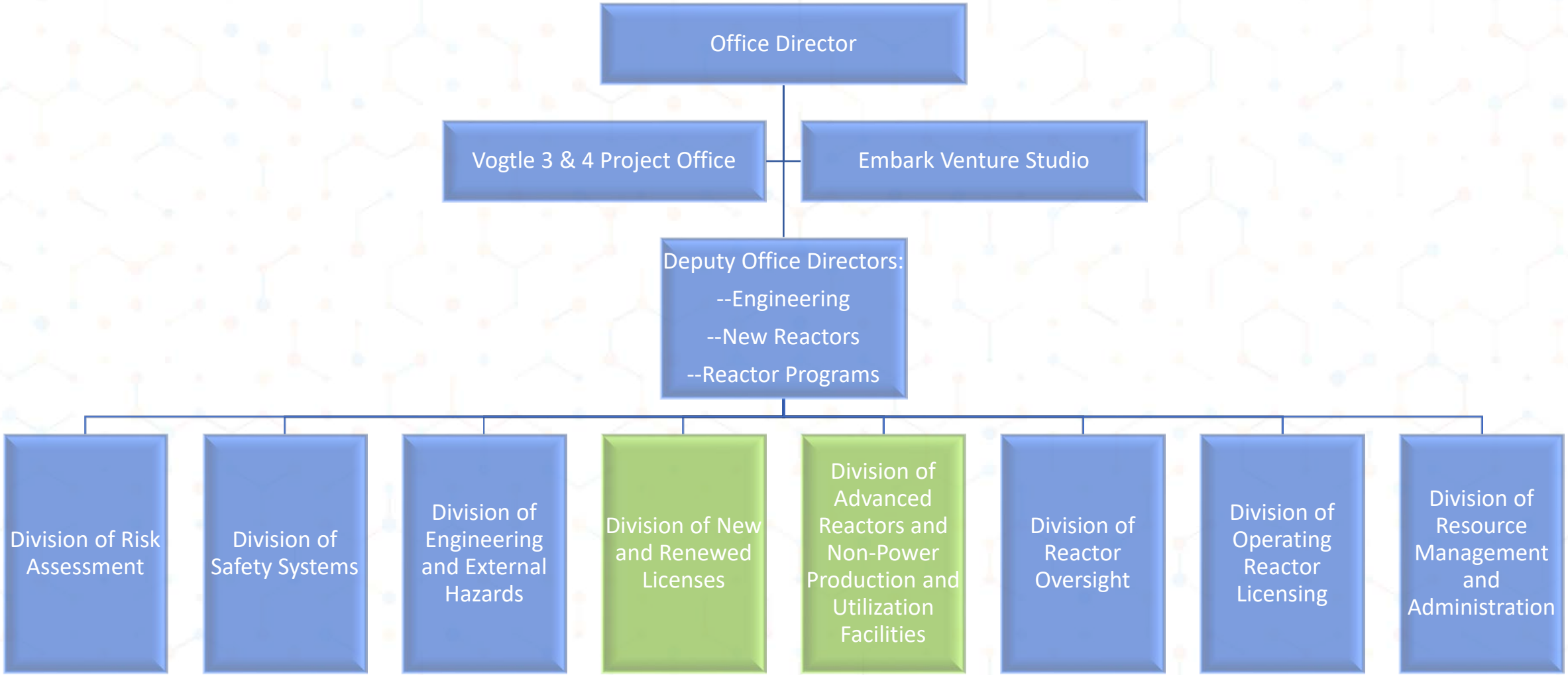
- The offices reporting to the EDO ensure that the commercial use of nuclear materials in the United States is safely conducted. As part of the regulatory process, the four regional offices conduct inspection, enforcement, and emergency response programs for licensees within their borders.
  - Program Offices
  - Regional Offices
  - Administrative Offices (ADM, OCIO, OCHCO, SBCR)



EDO Program Offices

NRR	NRO
Office of Nuclear Reactor Regulation Statutory	**Office of New Reactors** Established by the Commission (2006); Merged back into NRR (2019)
Responsible for NRC's nuclear reactor safety mission with respect to all operating reactors through rulemaking, licensing, oversight, and incident response for commercial nuclear power reactors, and research and test reactors; also conducts any new licensing activities under 10 CFR Part 50	Responsible for accomplishing key components of the Commission's nuclear reactor safety mission for new reactor facilities that have applied for a license in accordance with 10 CFR Part 52.

NRR Divisions



EDO Program Offices (cont'd)

NMSS	
Office of Nuclear Material Safety and Safeguards Statutory [merged with the former "Office of Federal and State Materials and Environmental Management Programs" (FSME) in 2014]	
Responsible for regulating the nuclear fuel cycle (uranium recovery, conversion, and enrichment; fuel fabrication; storage, transportation and disposal of high-level waste and spent nuclear fuel); transportation of radioactive materials; domestic and international safeguards policy, including material control and accounting (MC&A); and recycling technologies.	Also responsible for regulation of byproduct, source, and special nuclear materials; coordination with other Federal agencies, Agreement and Non-Agreement States, Native American Tribal governments; the Integrated Materials Performance Evaluation Program; and issues under the Uranium Mill Tailings Radiation Control Act (UMTRCA).

EDO Program Offices (cont'd)

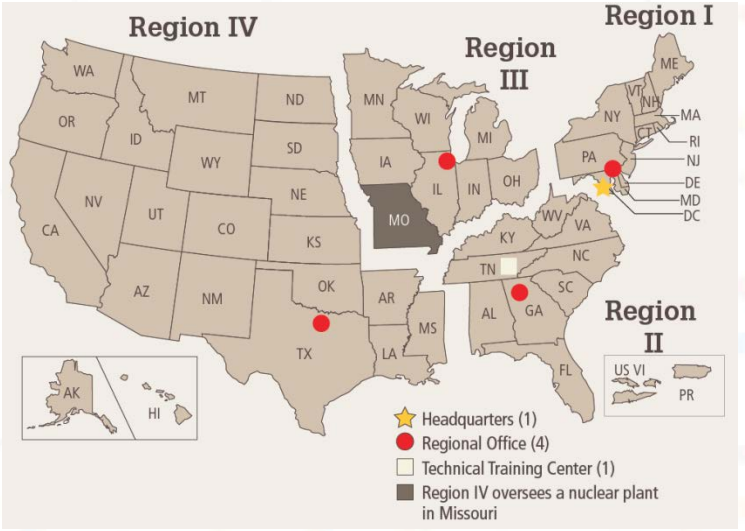
RES	NSIR
Office of Nuclear Regulatory Research Statutory	**Office of Nuclear Security & Incident Response** established by the Commission (2002)
Implements research programs; coordinates development of consensus and voluntary standards; advises on resolution of safety issues, including Generic Safety Issues (GSI); develops technical basis for regulatory actions; provides independent analysis of operational data.	Responsible for coordinating security and safeguards issues (e.g., with Dep't of Homeland Security); threat assessment and advisory programs; incident response; emergency preparedness; performance evaluation for licensed facilities, including the "force on force" program.

EDO Program Offices (cont'd)

OI	OE
Office of Investigations established by the Commission	**Office of Enforcement** established by the Commission
Develops policy and conducts investigations of licensees, applicants, their contractors or vendors, including the investigations of all allegations of wrongdoing by other than NRC employees and contractors. Refers potential wrongdoing to DOJ for prosecution determinations.	Develops and implements policies and programs for enforcement of NRC requirements (such as allegations management programs, and safety culture policy matters) and coordinates with the Office of Investigations on issues involving discrimination and wrongdoing associated with allegations from sources external to NRC. Administers new ADR program.

EDO Regional Offices

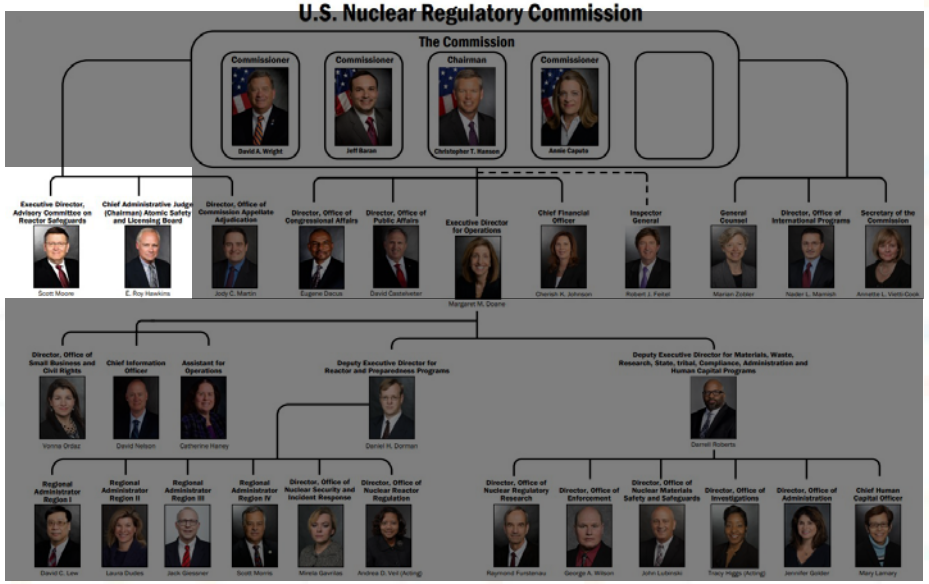
- Region I – King of Prussia, PA
- Region II – Atlanta, GA
- Region III – Lisle, IL
- Region IV – Arlington, TX



- Each Region is headed by a **Regional Administrator** who has considerable authority and flexibility in implementing NRC inspection activities
- The Regional Offices execute established NRC policies and assigned programs relating to inspection, licensing, incident response, and governmental liaison, and play a significant regulatory role in the oversight of nuclear power plants
- Regional Offices administer the region-based inspection program, with inspector expertise in specialized areas, and the Resident Inspector Program, with inspectors stationed at each site

Committees & Boards

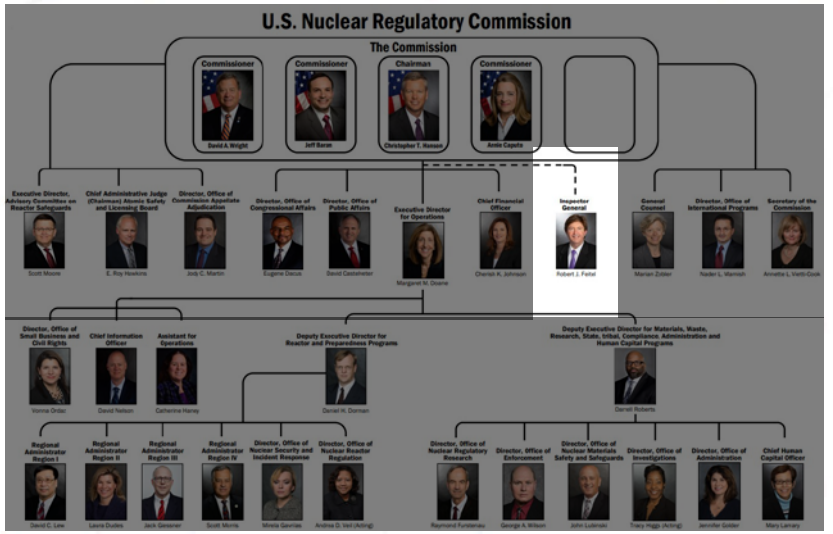
- Principal
  - Advisory Committee on Reactor Safeguards
  - Atomic Safety & Licensing Board
- Other
  - Advisory Committee on the Medical Use of Isotopes
  - Committee to Review Generic Requirements
- Historical
  - Advisory Committee on Nuclear Waste and Materials
  - Atomic Safety & Licensing Appeal Board



Principal Committees & Boards

ACRS	ASLBP
Advisory Committee on Reactor Safeguards	**Atomic Safety & Licensing Board Panel**
Reviews and advises the Commission with respect to the licensing and operation of production and utilization facilities and related safety issues; the adequacy of proposed reactor safety standards; technical and policy issues related to the licensing of evolutionary and passive plant designs; and other matters referred to it by the Commission.	Conducts hearings for the Commission and performs such other regulatory functions as the Commission authorizes, primarily through appointment of Atomic Safety and Licensing Boards (ASLB) or single presiding officers. The Panel is composed of administrative judges who are lawyers, engineers, and scientists. ASLBs generally consist of three members: two technical judges, and one legal judge who serves as chair.

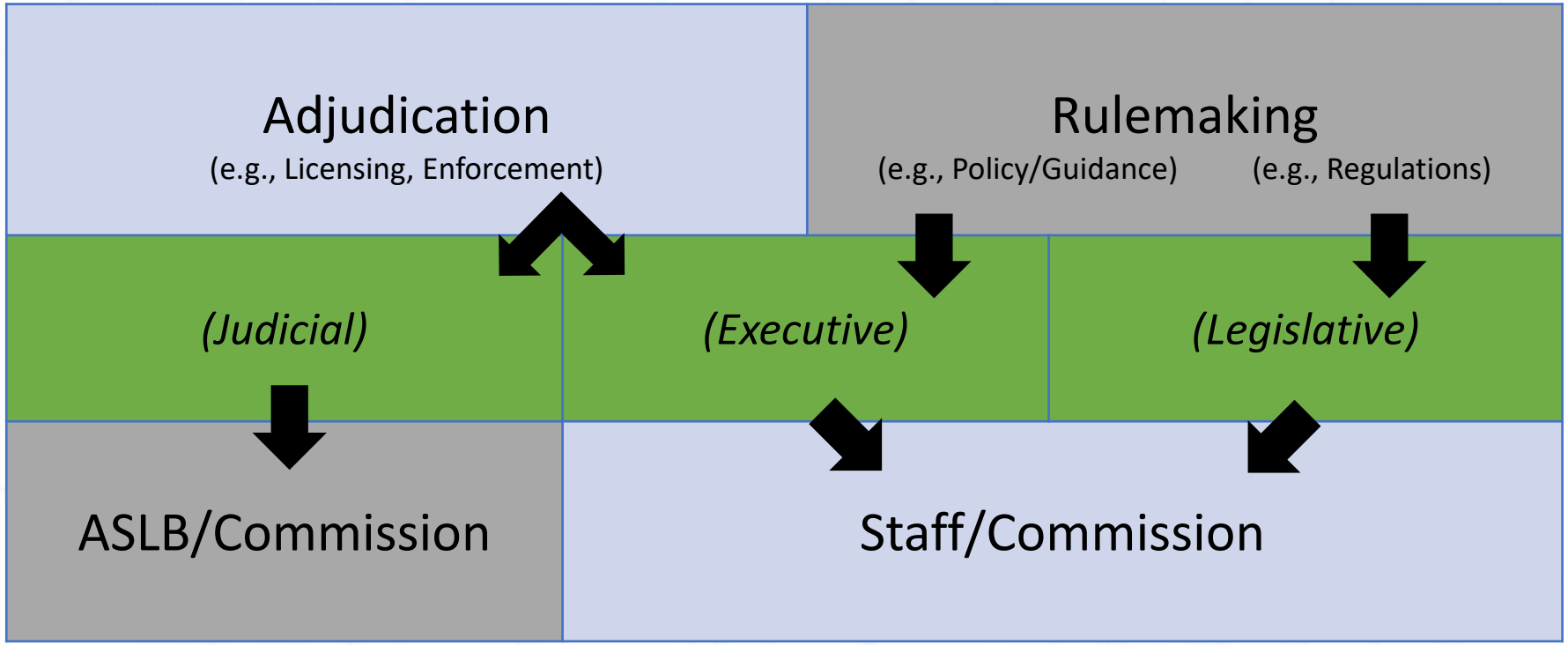
Independent Component



OIG	Office of the Inspector General
An independent office established by the Inspector General Act of 1978. Conducts audits and investigations designed to promote economy, efficiency, and effectiveness within the NRC, and to prevent and detect fraud, waste, abuse, and mismanagement in agency programs and operations.	

- Aside from the Commissioners, the "IG" is the only other position subject to Presidential nomination and Senate confirmation.

Functions of the Commission



Regulatory Requirements, Commitments, & Expectations

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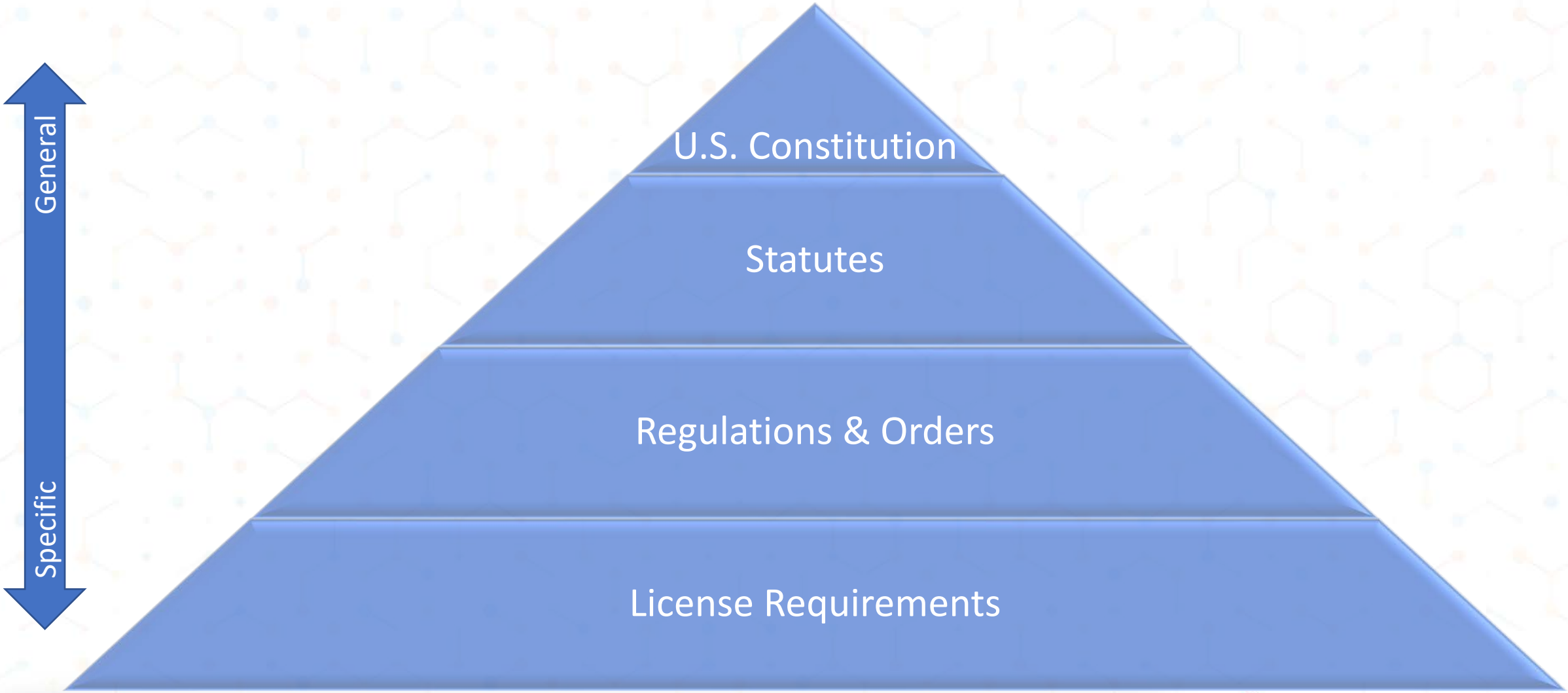
Hierarchy of Law & NRC Requirements



Key Statutes

- Atomic Energy Act (AEA)
  - The NRC's "organic" statute; focus is radiological safety
  - Unusually broad delegation of authority to NRC to implement the statute's purpose
  - But does impose some specific requirements
    - *E.g.*, limiting foreign ownership, imposing criminal penalties, requiring public hearings, etc.
- Administrative Procedure Act (APA)
  - Applicable to federal agencies
  - Requirements guide agency processes
- National Environmental Policy Act (NEPA)
  - Applicable to federal agencies
  - Not "action forcing," but requires a "hard look" at the environmental impacts of major federal actions

Other Examples
Energy Reorganization Act of 1974
Uranium Mill Tailings Radiation Control Act of 1978
Nuclear Non-Proliferation Act of 1978
Low-Level Radioactive Waste Policy Act of 1980
Nuclear Waste Policy Act of 1982
Low-Level Radioactive Waste Policy Amendments Act of 1985
Nuclear Waste Policy Amendments Act of 1987
Energy Policy Act of 1992
Energy Policy Act of 2005

Agency Regulations & Orders

REGULATIONS

- Code of Federal Regulations (CFR)
- Legally Binding Requirements
  - Exemptions can be issued by NRC
- Formal Process for Issuance or Change (APA)
  - Agency may initiate rulemaking, or a member of the public may petition
  - Proposed Rule
  - Opportunity for Public Comment
  - Final Rule
  - Process (absent judicial appeal) – typically 2 to 3 Years
- Example: Regulation of Reactors in 10 CFR Part 50
  - Comprehensive, but general; Design Criteria in Part 50, Appendix A
  - More detailed criteria on selected topics

ORDERS

- Types
  - Authorize or direct that certain actions be taken (e.g., Post-9/11 Security Orders, post-Fukushima Orders) (i.e., orders modifying a license)
  - Enforcement (*e.g.*, Prohibiting participation in licensed activities)
  - Impose sanctions (*e.g.*, Order Imposing Civil Penalty)
- May be imposed by NRC unilaterally
  - Subject to hearing opportunity
- "Confirmatory Order"
  - Licensee consents & waives hearing right

Key Regulation: Completeness and Accuracy

- All reactor and materials licensing regulations include a similar provision:
  - (a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be *complete and accurate in all material respects.*
  - (b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a *significant implication for public health and safety or common defense and security*. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. *This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.*
- Covers licensee commitments and other documents submitted in connection with licensing and regulatory matters not otherwise covered

License Requirements

Licensing Basis

Collective NRC requirements applicable to a specific plant, plus the licensee's written commitments for ensuring compliance therewith.

In broad terms, this includes:

- Applicable NRC regulations (and exemptions);
- Applicable NRC orders;
- “The License” (including its conditions and technical specifications);
- Plant-specific design-basis information (defined in 10 CFR 50.2) (documented in the FSAR per 10 CFR 50.71); and
- Licensee commitments remaining in effect that were:
  - made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions; or
  - documented in NRC safety evaluations or licensee event reports.

"The License"

~ 10 pg

~ 300 pages

~ 10 pg

- General vs. Specific Licenses
- Specific License Document
  - High-level (~ 5 to 10 pages)
  - Can authorize multiple activities under different parts of 10 C.F.R.
- Specific License Conditions
  - Technical Specifications *[Primary Source of License Requirements]* (~ 300 pages+)
    - Cover Systems Needed for Safety
    - Identify Operability Requirements and Allowed Outage Times
    - Identify Action Statements for Inoperable Systems
    - NRC and Industry Effort to Standardize
  - Environmental Protection Plan (~ 10 pages)
  - Other Conditions (~1 or 2 pages)
    - E.g., Financial support, Decommissioning Funding, Antitrust (no longer with NRC), Inter-Affiliate Transfers

Final Safety Analysis Report (FSAR) and Commitments

- FSAR: Multiple Binders of Information
  - The Plant Design Procedures and Organization
  - Accident Analysis and Systems to Protect Public Under Accident Condition
- Commitments: Other Promises Made in Writing to NRC
  - Offers in Response to Bulletins and Generic Letters
  - Sometimes Answers to Requests for Additional Information (RAIs)
- Legal Status of FSAR and Commitments
  - FSAR Must Be Controlled and Kept Updated Per 10 CFR §§ 50.59 and 50.71(e)
  - NRC Inspections Check for Conformance with the FSAR
  - Failure to Conform with FSAR May Result in a Notice of Deviation or Notice of Violation Against §§ 50.59 or 50.71(e)

Design and Procedures

- 10 CFR Part 50 Appendix B Requires Design Drawings, Specifications, and Procedures for Safety-Related Activities
- Designs and Procedures are Very Extensive and Detailed
- Legal Status of Design and Procedures
  - Failure to Establish or Implement Design or Procedures as Described in the FSAR Could Be a Violation
  - Therefore, Design and Procedures Needed to Meet Safety Limits Become Requirements
- Design Documents and Procedures May Be Changed by a Licensee Under a Controlled Process Without NRC Approval or Notification

Role of NRC Guidance

- Legal Status of NRC Guidance
  - Identify Acceptable Methods for Complying with NRC Regulations
    - Presumption of compliance
    - May be entitled to "special weight" if challenged in an NRC hearing
  - Not legal requirements, but . . .
    - A Licensee Commitment to Meet Guidance is Binding
    - NRC Often Requires Licensees to Justify Deviations from NRC Guidance

Spectrum of NRC Guidance

Technical / Environmental	Generic Communications	Guidance for Staff
• NUREGs • Regulatory Guides • Interim Staff Guidance (ISG)	• Bulletins • Generic Letters • Information Notices • Regulatory Information Summaries (RIS)	• Standard Review Plan (SRP) • Management Directives • Office Instructions