

NRIC Tech Talk:

Best Practices and Lessons Learned on Application Preparation for NRC Reviews

- Early and regular engagement between future applicants and the U.S. Nuclear Regulatory Commission (NRC) is important to consider when planning to prepare an application for eventual NRC review.
- This webinar will include perspectives from recent and long-term applicants regarding application development and the application review process.

How to Participate

- For the best experience, we recommend turning off VPN connections.
- Submit any questions you might have by typing the question into the Q&A section. We will address them at the end.
- If you have any technical problems, please put them in the Q&A.
- If you have programmatic questions, email us at NRIC@inl.gov.
- This event is being recorded and will be posted on the NRIC website. Your attendance is consent to that recording.

NRIC is a DOE-NE center, launched in FY2020

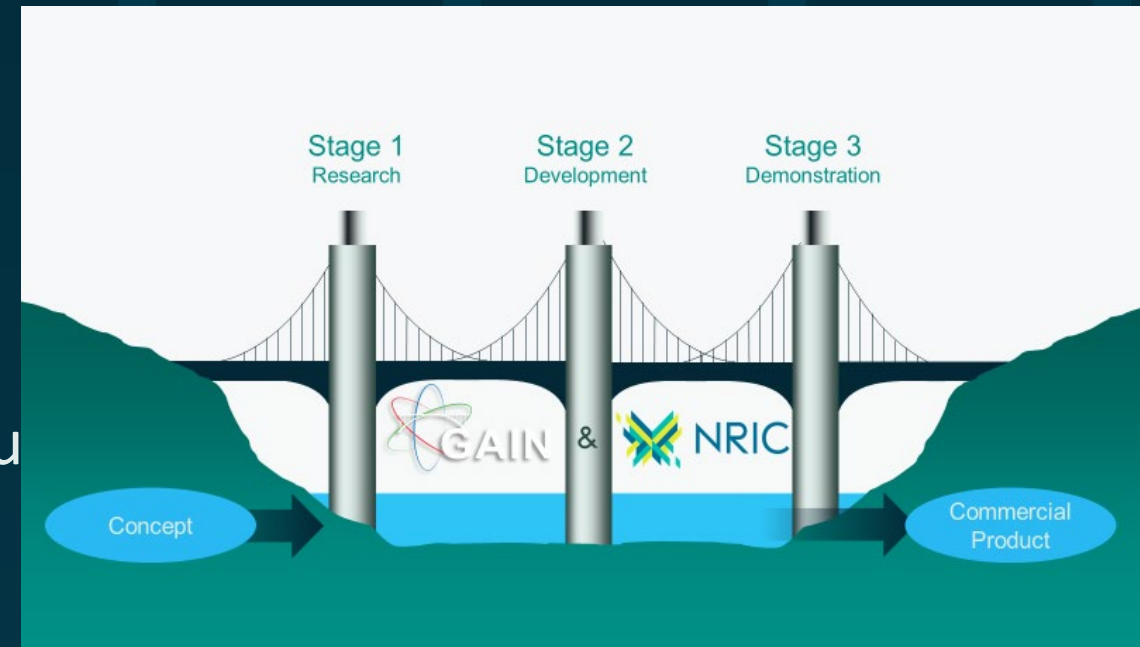


NRIC

National
Reactor
Innovation
Center

NRIC Accelerates Nuclear Reactor Demonstrations

- Authorized by the Nuclear Energy Innovation Capabilities Act (NEICA)
- Partner with industry to bridge the gap between research and commercial deployment
- Leverage national lab expertise and infrastructure
- Manage demonstrations to success



NRIC Vision



Abundant clean
energy

U.S. nuclear
energy leadership

Commercial Advanced Nuclear by 2030

inspire

empower

deliver



mission



NRIC

NRIC is partnering regionally and nationally to support demonstrations



Speakers



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Clinch River Nuclear Site Early Site Permit Licensing Insights



Ray Schiele
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TVA New Nuclear Program

Licensing of TVA Clinch River Early Site Permit

Agenda

ESP Engagement Milestones

TVA Regulatory Engagement Strategy

- Establish Communication Protocol
- Pre-Application Engagement
- NRC Readiness Assessment
- ESPA NRC Licensing Review

TVA CRN ESPA NRC Engagement Milestones

CRN ESPA Key NRC Engagement Milestones (2013-2019)

ESPA PRE-APPLICATION ENGAGEMENT

- Pre-Environmental Report Visit March 2013
- PPE Development September 2014
- Pre-application Site Visit October 2014
- Alternative Sites Visit June 2015
- **ESPA Readiness Review August 2015**
- **ESPA Submitted to NRC May 2016**

ESPA AUDITS

- Hydrology and Health Physics Audit April 2017
- Seismic/Geotechnical Audit May 2017
- Environmental and Meteorology Audit May 2017
- EPZ Audit 1 November 2017-February 2018
- EPZ Audit 2 April 2018
- QA Inspection April 2018
- Meteorology and Health Physics Audit April 2018

KEY NRC MILESTONES

- **ESPA Docketed January 2017**
- Notice Of Hearing Opportunity April 2017
- Contentions Admitted June & October 2017
- TVA Appeals Contentions November 2017
- Commission Ruling May 2018
- ASLB Ruling July 2018
- FEIS Issued April 2019
- FSER Issued June 2019
- **ESP Issued December 2019**

TVA's Regulatory Engagement Strategy

- A Regulatory Engagement Plan (REP) establishes “**Rules of Engagement**” between the applicant and NRC. The primary goal of the REP is to **reduce regulatory uncertainty** by establishing such agreements as early in the regulatory process as possible.
- Implementation of a comprehensive REP can provide project **stability and predictability** in the full scope of activities supporting the licensing process.
- REP developed for the TVA Construction Permit Application informed by insights from the ESPA licensing activities.

Pre-Application Engagement Strategy

The strategic goal of pre-application engagement is to establish stability and predictability in the licensing process through a full complement of overlapping engagement opportunities, resulting in an optimized licensing process.



Pre-application engagement includes:

- Establish Routine Communication Protocols
- Alignment on Application Content
- Use of Audits
- Availability of Draft Application Content
- Use of Electronic Reading Room
- Use of Site Visits

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Pre-Application Engagement –Readiness Assessment

Pre-Application Readiness Assessment provides the opportunity to:

- Identify information gaps
- Identify major technical and/or policy issues that would impact docketing
- Provide NRC familiarity with new concepts or novel design features contained in the application,
- Inform/Revise application content with results of assessment, thus making the acceptance review more efficient
- Inform NRC staff in planning its resources for the review once the application is formally submitted.

Safety and Environmental Application Review Communication Protocols

TVA's Regulatory Engagement Strategy established a "No Surprises" approach, which enabled prompt communication from both NRC staff and TVA whenever an issue was identified.



Communication protocols established early in ESPA review discussions

- TVA and NRC staff points of contact were established
- Counterparts established at the appropriate management levels to ensure predictable communications paths for escalation.

Project Management "Drop-In Visits"

- Drop-in visits with the NRC on an as needed basis

Routine NRC Project Management Discussions

Licensing Manager was the single point of contact with the NRC Project Managers and was the point of entry for all routine communications, including administrative and technical matters.



Support of Regulatory Audits

A regulatory audit is an opportunity for the NRC staff to examine and evaluate licensee or applicant's information with the intent to:

- Gain Understanding,
- Verify Information, or
- Identify Information That Will Require Docketing To Support The Basis Of A Licensing Or Regulatory Decision

A regulatory audit may be conducted at one facility, all affected facilities, or a sampling, as necessary to support the regulatory action. Audits typically facilitate review of:

- Analyses,
- Procedures,
- Calculations,
- Design Basis Information, or
- Computer Code Information.



CRN ESPA Site Audits-Preparation

Team Preparations for Audit Support

- Use Pre-job briefs and Challenge Boards
- Single Point accountability for each information need
 - Information needs were aligned to “Best Athlete”
 - Created specific SME and Licensing ownership of each information need
 - Goal was to identify resolution, validate, team challenge and post in Reading Room for NRC review (potential to close information need) prior to On-Site Audit meetings.
- Tour Information Packages Created for Each Audit
 - Audit Agenda, Area Maps, Audit Team Contact Information,
 - Recent Copy of All Information Needs in Posted Reading Room
 - Copy of NRC Audit Plan
 - Goal was to create an atmosphere of efficient and transparent information sharing to facilitate issue resolution and the closure of each information need.



CRN ESPA Site Audits-Field Support

Duration of Audit

- Daily Briefs and De-Briefs (Internal and External)
- Maintain Single Point accountability for each information need. Ownership of information needs continued thru CRN Site Tour and Face to Face discussions
- Dedicated SME during the Audit “1 on 1 coverage” responsible for preparing/maintaining information sharing data packages to support Audit discussions
- Maximized observation of actual field information to support information needs, e.g.:
 - Planned travel to view existing TVA Dams and support features
 - Core bore pictures/videos in addition to actual core bore examinations
 - Planned hiking excursion to view specific aquatic, terrestrial, geologic resource information
 - Provided opportunity for collaboration with other government agencies during information needs discussion (USACE, USFWS, SHPO, EPA, TDEC)



Regulatory Engagement Strategy-Key Take Away

Implementation of a REP provides:

- Project stability and predictability in the full scope of activities supporting the licensing process.
- Regulatory focus from pre-application to completion of the regulatory action.
- Optimization by implementing a full suite of overlapping regulatory engagement techniques.
- Review efficiency which translates to lower costs and shorter review schedules.



Background info
Clinch River Nuclear Site(CRN)
Early Site Permit Application (ESPA)

CRN ESPA Licensing Milestones:

- NRC Commenced Review in FY 17'
- Application contained more than 8000 (SSAR and ER) pages
- Application supported by over 80,000 pages in referenced documents
- Efficient Use of Audits
- Few Requests for Additional Information (RAIs)
- Frequent, Clear, and Candid Communication
- Included major features of Emergency Planning Zone (EPZ) requirements

Clinch River Site

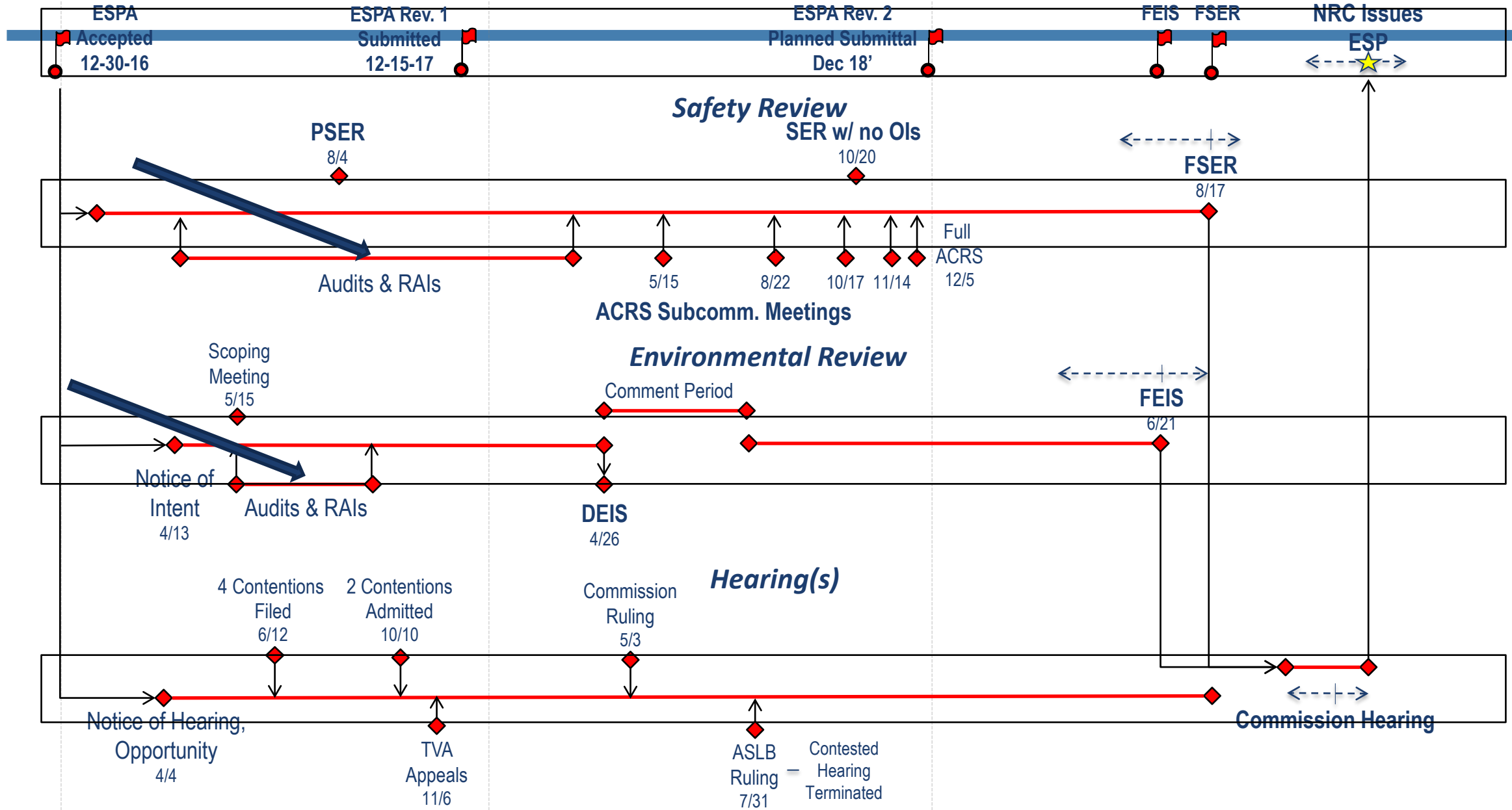


2017

2018

2019

2020



Insights on Adapting Licensing Frameworks to New Non-Power Technologies

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February 2022



Non-Power Technology Responsibilities

- Project management for operating non-power reactors
 - Routine licensing actions
 - License renewal reviews
 - Digital instrumentation and control upgrades
 - Highly enriched uranium to low-enriched uranium fuel conversions
- Licensing infrastructure and policy
 - Guidance development
 - ANS standard committee participation
 - Advanced reactor licensing support
 - Rulemaking development and support
- International activities, including IAEA support and import and export licensing
- Naval reactor reviews
- Initial licensing reviews for medical radioisotope facilities

Non-Power Licensing Process

- Applications contain both general and technical information
- Construction permit application
 - Environmental report
 - Preliminary safety analysis report (PSAR)
- Operating license application
 - Update to environmental report, as necessary
 - Final safety analysis report (FSAR)
- Applications may be submitted separately or together
- Testing facilities and commercial facilities may request limited work authorization to allow certain construction activities prior to the issuance of a construction permit

Pre-Submission

- A shared understanding between the prospective applicant and NRC staff of what to expect, and when to expect it, supports an effective application review
- Coordination may begin years before the submission of a license application
- Goals:
 - Consistent expectations
 - Identification and resolution of technical, policy, and licensing issues prior to application submission
 - Support high-quality application preparation and effective review

Early Engagement

- Frequent and early engagement with NRC staff is the key to success
- May informally discuss project plans with project managers and Branch Chief
- “Drop-in” meetings are a tool for administrative discussions
 - Include NRC management and necessary staff
 - Introduction of licensee/applicant staff, proposed application, high-level discussion of proposed technology, regulations/guidance, and submission schedule
 - Informs budget and resource planning
- Public meetings facilitate technical and licensing discussions
 - Broader NRC staff attendance
 - May be closed, when appropriate to discuss sensitive information

Letters of Intent

- Indicates an initial interest in submitting a license application to inform NRC staff budget and resource planning
- Includes a preliminary idea of the types and number of licensing actions to be requested within a proposed timeframe

Regulatory Engagement Plans

- Includes more detailed plans for pre-application engagement with NRC staff on proposed application(s)
- May include more detailed technical/licensing information, as well as proposed topical reports or other supporting licensing actions

Pre-Submission Activities

- Other pre-application submittals that may be identified in a LOI or REP include:
 - Requests for interpretation of regulations
 - Exemption requests
 - White papers
 - Topical reports
 - Quality Assurance Program Description
 - Safeguards Information Protection Plan
 - Request(s) for approval of reviewing official
- Applicants for initial licenses may also consider engaging the NRC staff in a Pre-Application Readiness Assessment

Pre-Application Readiness Assessments

- NRC LIC-116, “Preapplication Readiness Assessment,” ML20104B698
- Separate from the acceptance review, allows early NRC feedback on draft application
- Should be conducted at least 6 months before the expected application submittal
- Goals of the readiness assessment include:
 - Identify information gaps
 - Identify major technical or policy issues
 - Increase familiarity with content of application
 - Discuss guidance and precedents (if any) used to prepare application

Acceptance Reviews

- Is there is sufficient technical information in scope and depth to allow NRC to begin detailed technical review?
- Does the application have any readily apparent information insufficiencies with respect to regulatory requirements or characterization of licensing basis?
- Acceptance review information requests are **separate** from request for additional information (RAI) process, and are intended to address completeness for docketing (and reduce RAIs)

Application Review Process

Following acceptance review, NRC staff may use a number of tools to effectively resolve information gaps identified during the technical review, including:

- **Regulatory Audits**
 - Help efficiently gain understanding, verify information, and/or identify information that will require docketing
 - May be conducted on-site or virtually
- **Public Meetings**
- **Requests for Additional Information (RAIs)**
 - May provide draft RAIs to ensure understanding
 - NRC/applicant discussions of RAIs before and after transmittal (clarification calls)

Regulatory Guidance and Acceptance Criteria

- NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors”
- Interim Staff Guidance Augmenting NUREG-1537
 - Radioisotope production facilities
 - Incorporates relevant non-reactor guidance from NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility, Rev. 1”
- Other guidance (e.g., regulatory guides and ANSI/ANS standards) and engineering judgement used, as appropriate, to determine what is necessary for construction permit

NRC Review Methodology

- For a construction permit application review, level of detail needed in application different than for an operating license application
- For the purposes of issuing a construction permit, the facility may be adequately described at a functional or conceptual level in the PSAR
- Applicants may defer providing many design and analysis details until the submission of its final safety analysis report (FSAR) with its operating license application
- Staff's review tailored to unique and novel technology described in construction permit application using appropriate regulatory guidance

Resolving Technical Issues of Preliminary Designs

- For technical areas requiring additional information, the staff has several options:
 - The staff may determine that such technical issues must be resolved prior to the issuance of a construction permit
 - The staff may determine that such information may be left until the submission of the FSAR
 - The staff may require that such technical issues be resolved prior to the completion of construction, but after the issuance of the construction permit
- In all cases, staff may issue requests for additional information
- In the second and third options, staff may track regulatory commitments or identify necessary license conditions

Key Takeaways

- For novel technologies, early interactions between NRC staff and applicants support efficient application processing and review
- Pre-application engagement
 - Promotes information exchange between NRC and potential applicant
 - Informs the development of high-quality applications
 - Informs budgeting and resource allocation
 - Informs public of NRC process
- Best practices from initial license application reviews:
 - Emphasis on most safety-significant technical aspects
 - Focused requests for additional information
 - Ongoing communication to address challenges



Best Practices and Lessons Learned on Application Preparation for NRC Reviews

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SHINE TECHNOLOGIES, LLC

SHINE Regulatory Background

- SHINE has requested the issuance of a single operating license under 10 CFR Part 50 for the operation of the eight utilization facilities and one production facility (as defined in 10 CFR § 50.2) which make up the SHINE medical isotope production facility
 - The NRC previously authorized construction of the SHINE medical isotope production facility via the issuance of Construction Permit No. CPMIF-001



SHINE Regulatory Background

- The SHINE PSAR and FSAR were developed following the application guidance of NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors,” and the Interim Staff Guidance (ISG) augmenting NUREG-1537
 - SHINE was the first applicant to utilize the ISG augmenting NUREG-1537 in the development of the PSAR or FSAR



SHINE Regulatory Milestones

Construction Permit (CP) Application

Construction Permit Application (Part 1) Submitted	March 2013
Construction Permit Application (Part 2) Submitted	May 2013
Application (Part 1) Acceptance for Docketing	June 2013
Application (Part 2) Acceptance for Docketing	December 2013
Issuance of Environmental Impact Statement (EIS)	October 2015
Issuance of Safety Evaluation Report	October 2015
Mandatory Hearing	December 2015
Issuance of Construction Permit	February 2016

Operating License (OL) Application

Operating License Application Submitted	July 2019
Application Acceptance for Docketing	October 2019
Issuance of Environmental Impact Statement (EIS) Supplement	January 2023
Issuance of Safety Evaluation Report	February 2023

Best Practices and Lessons Learned

PRE-APPLICATION MEETINGS SUPPORTING A FIRST-OF-ITS-KIND FACILITY

- Ensure pre-application meeting topics are focused, and are the best use of both applicant and NRC Staff resources
 - Recommend a focus on topics which support NRC acceptance of the application for review (i.e., ensuring a complete, high-quality application is tendered by the applicant)
 - Preparing for pre-application meetings are resource-intensive, typically requiring resources otherwise committed to preparing application content
 - Detailed discussions of application content should occur following acceptance (e.g., regulatory audit)



Best Practices and Lessons Learned

PRE-APPLICATION MEETINGS SUPPORTING A FIRST-OF-ITS-KIND FACILITY

- While regulatory decisions are not made during pre-application meetings, regulatory observations and perspectives may be provided by NRC Staff
 - Use the time to ask questions to ensure understanding of the perspectives provided
 - Challenge perspectives provided if it seems inconsistent with published application guidance



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Questions?