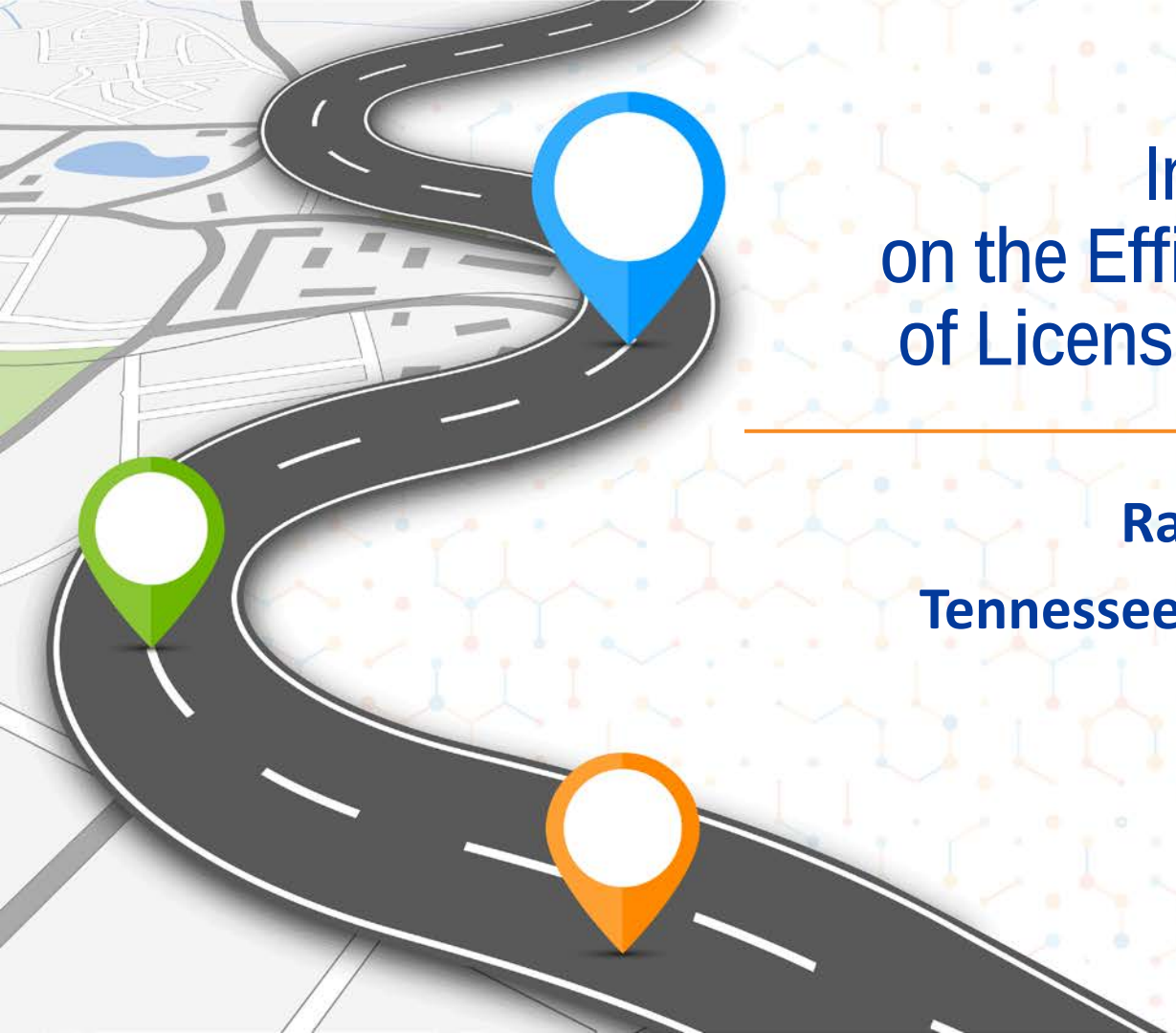

# Insights on the Efficient Exchange of Licensing Information

**Ray Schiele**

**Tennessee Valley Authority**

GAIN Gateway for Accelerated Innovation in Nuclear

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Mr. Schiele is the Licensing Manager for the TVA Nuclear Technology Innovation Team. As the Licensing Manager, Mr. Schiele is currently part of the leadership team that is developing the regulatory and permitting strategy to support a business case for long term deployment of an advanced reactor.

Mr. Schiele has more than 45 years of nuclear engineering and licensing experience which includes service in the United States Navy, 16 years commercial nuclear power plant experience as a Control Room Supervisor/Shift Manager and for the past 20 years as a Senior Project Licensing Manager.

Prior to being a member of the TVA Nuclear Technology Innovation Team, Mr. Schiele was the Licensing Manager supporting the TVA team that successfully obtained an NRC approved Early Site Permit for Clinch River Site. The project was completed ahead of schedule and included the approval for a scalable Emergency Planning Zone methodology.

As a Project Manager, Mr. Schiele led regulatory, engineering, programmatic and implementation activities supporting the license conversion of 22 nuclear utility reactor's current technical specifications to the NRC approved, technology specific NUREG addressing the Improved Standard Technical Specifications.

# Executing A Regulatory Engagement Strategy

## Discussion Topics

### Regulatory Engagement Strategy

- Establish Communication Protocols
- Pre-Application Engagement

### Regulatory Engagement-Lessons Learned

- Clinch River Early Site Permit Application

# 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 robust REP can provide project **stability and predictability** in the full scope of activities supporting the licensing process. A REP provides the framework to:

- Establish and Manage Communication Protocols with NRC Staff
- Establishing Effective Pre-application Engagement
- Provide Framework of Engagement Strategy thru Completion of Regulatory Action

# Communication Protocols

# Communication Protocols


Regular communication with the NRC staff (e.g., project manager) can be essential to successful interaction and progress during all phases of regulatory engagement.

**Communication protocols should be implemented early in pre-application discussions**

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

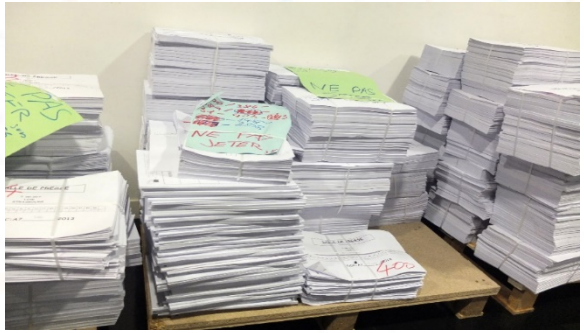
**Project Management "Drop-In Visits"**

- Drop-in visits with the NRC are non-public meetings (as needed basis) between the project and the NRC project management team.

**Routine NRC Project Management Discussions**

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

# Written Communication



*Formal licensing submittals (e.g., application for license, permit, certification, etc., and submittal of associated reports, letters, and other documents) are governed by specific regulations such as 10 CFR 50.4 and 52.3.*

Regulations provide, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. Examples include:

- Applications for permits and licenses, and amendments to applications.
- Security plan and related submissions
- Updated FSAR
- Quality assurance related submissions
- Certification of permanent fuel removal

# Meetings Open to the Public

Most interactions between the Applicant/Licensee and NRC staff are either conducted in public, or documented in publicly-available records. The forum for public participation includes:

- Participation in meetings
- Access to documents
- Participation in NRC-sponsored information sessions and scoping meetings
- Review of draft NRC safety evaluations, environmental impact statements, and design certification rulemaking-related documents
- Participation in hearings

# Meetings Closed to the Public

The determination of whether a meeting should be open to the public is based on subject and not who may attend. In general, meetings will be open to the public, unless the NRC staff determines the meetings contain (for example):

- Proprietary information
- Safeguards information
- Personal nature where such disclosure would constitute a clearly unwarranted invasion of personal privacy
- Planned, ongoing, or completed investigation or contains information for law enforcement purposes
- Potential for inappropriate disclosure and dissemination of preliminary, unverified information

# Completeness and Accuracy of Information

*Information provided to NRC, or required to be maintained by statutes, regulations, orders, or license conditions must be complete and accurate in all material respects. 50.9/52.6*

Omissions relevant to the subject correspondence must be considered for their effect as well as the material provided. Information can be considered incomplete or inaccurate as a result of:

- An affirmative statement which is false or because of a material omission.
- Inadequate review or failure to review.
- Inadvertent clerical or similar error involving information which, had it been available to NRC and accurate at the time the information was submitted, would probably have resulted in regulatory action or the NRC seeking additional information.

# 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

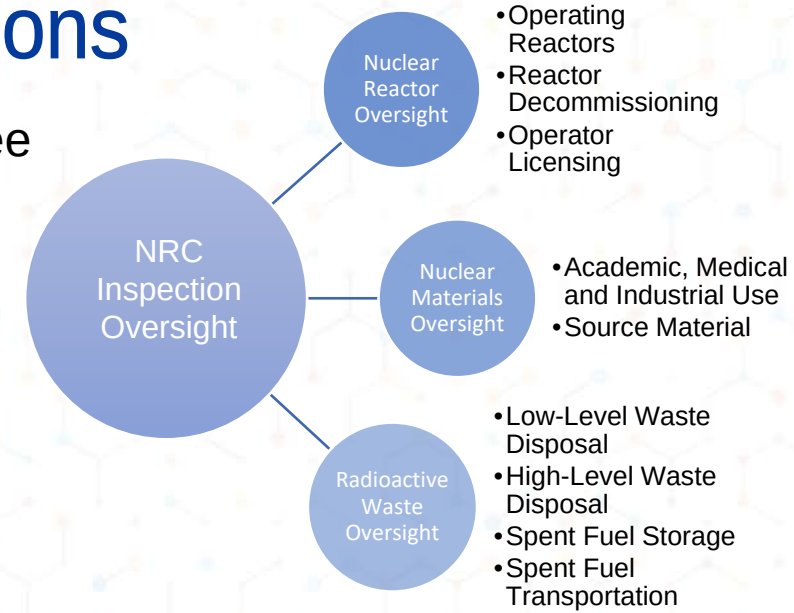
A regulatory audit may be conducted at one facility, all affected facilities, or a sampling, as necessary to support the regulatory action. Audits typically facilitate review of:

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

# Support of NRC Inspections

NRC conducts inspections to ensure that licensee activities comply with NRC safety requirements, such as:

- Organizational Structure,
- Operator Qualifications,
- Design,
- Maintenance,
- Fuel Handling, and
- Environmental And Radiation Protection Programs.




Inspectors follow guidance in the NRC Inspection Manual, which contains objectives and procedures to use for each type of inspection. If an inspection shows that a licensee is not safely conducting an activity or safely operating a facility, corrective measures are identified and follow up inspections performed as needed.

# Pre-Application Engagement Strategy

# Pre-Application Engagement Activities

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:

- Routine communication protocols
- Managing Staged License Submittals
- Audits
- Inspections
- Site Visits

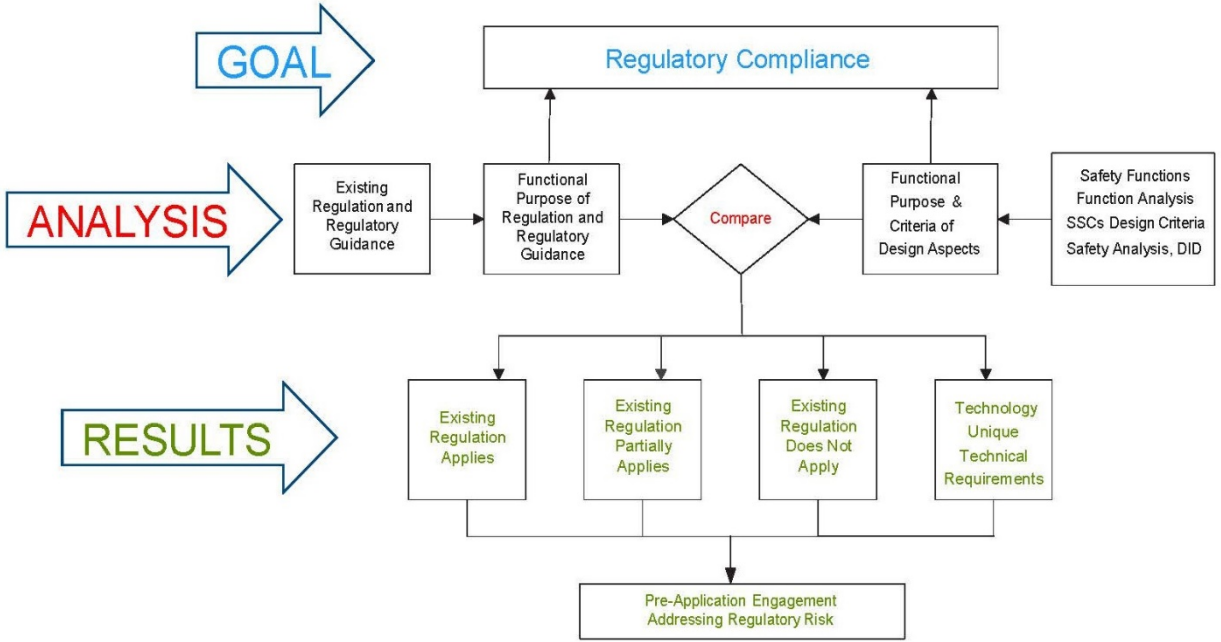
# Pre-Application Engagement - Advantages

An **optimized licensing process** provides review efficiency that translates to lower costs, shorter review schedules and is framed by:

- Early identification and resolution of technical and policy issues that would impact any licensing process
- Early and often public engagement which adds to the transparency of the licensing process
- Performance/Results of both Regulatory and Environmental Gaps analysis are presented to NRC staff for clarification/resolution
- Prompt identification of pending design changes that would result in amendments or supplements to an application and extending completion of the licensing action
- Use of topical reports, standard design approval, and other appropriate mechanisms as tools to introduce stages into the reactor licensing process

# Pre-Application Engagement

## Regulatory Gap Analysis Process




Regulatory Gap Analysis identifies gaps between regulations, or regulatory guidance, and technical aspects of the design.

Gaps are cataloged and managed to mitigate or reduce the regulatory risks

*Environmental Gap Analysis would follow similar identification and engagement process*

# Pre-Application Engagement – Meetings/Audits

Participation in public meetings and audits can be very important to a Pre-Application Engagement Strategy. The following are topic specific meetings that should be considered when developing a engagement strategy:

- Results of Gap Analysis
- Use/scope of staged licensing process by incorporation an ESP, DC, SDA , Topical Reports or other regulatory action.
- Probabilistic Risk Assessment
- Regulatory Exemptions
- Policy Issues
- Novel Design/Siting Features and Approaches
- Codes and Standards
- Planning for Pre-Application Readiness Assessment
- Use Of Engineering Computer Programs

# Pre-Application Engagement – Use of Topical Reports

Topical reports provides an opportunity to address gap analysis results early in the project and mitigate future licensing risks. Topical reports on the following key areas should be considered as an option to mitigate regulatory risk:

- Principle Design Criteria
- Design Basis Events
- Accident Analysis Methodologies
- Classification of Systems Structures and Components
- Source Term Development
- Quality Assurance Program
- Security/Safeguards Program Plan
- Emergency Planning
- Staff Optimization

# Pre-Application Engagement – Readiness Assessment

NRC staff will perform a Pre-Application Readiness Assessment at least 6 months prior to the expected date of submittal. This assessment provides the opportunity to:

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

# Pre-Application Engagement – Environmental Report

The strategy for a predictable environmental review schedule should focus on fundamental pre-application interactions with the NRC staff as early as possible in the planning process. Engagement strategy should be informed by the following (as applicable):

- 10 CFR 51.40, “Consultation with NRC staff,”
- RG 4.2, “Preparation of Environmental Reports for Nuclear Power Stations,”.
- NEI 10-07, “Industry Guideline for Effective Pre-Application Interactions with Agencies Other Than NRC During the Early Site Permit Process,” and
- Interim Staff Guidance (ISG)-29, “Environmental Considerations Associated with Micro-reactors.”

# Pre-Application Engagement – Environmental Report

The use of white papers, public meetings and audits provide diverse opportunities for environmental application interactions with the NRC Staff. Example environmental engagement topics, would be:

- Identify any novel environmental methodology that has not previously been analyzed by the staff
- Site Selection Process/Alternatives to the Proposed Project
- Cooling Water Availability
- Aquatic or terrestrial ecology studies that have been performed
- Federally listed species and critical habitats present, and potential impacts on those species and habitats
- Discussion of the environmental impacts from the transportation of fuels and wastes

# Pre-Application Engagement – Environmental Report

NEI 10-07, “Industry Guideline for Effective Pre-Application Interactions With Agencies Other Than NRC During the Early Site Permit Process,” provides guidance on scheduling meetings with required permitting agencies.

To support these meetings, the applicant should catalog:

- List of the needed authorizations, permits, licenses, and approvals for the project
- Timeline for obtaining the necessary permits and the current status
- Maintain copies of available correspondence between the applicant and permitting agencies (e.g. State Historic Preservation Office, Tribes, U.S. Fishery and Wildlife Service, U.S. Army Corps of Engineers, National Marine Fisheries Service, state and local officials)

# Clinch River Nuclear Site(CRN)
# Early Site Permit Application (ESPA)
# Regulatory Engagement – Audits Lessons Learned

# CRN ESPA

An Early Site Permit assesses site suitability for potential construction and operation of a nuclear power plant.

**Application includes:**

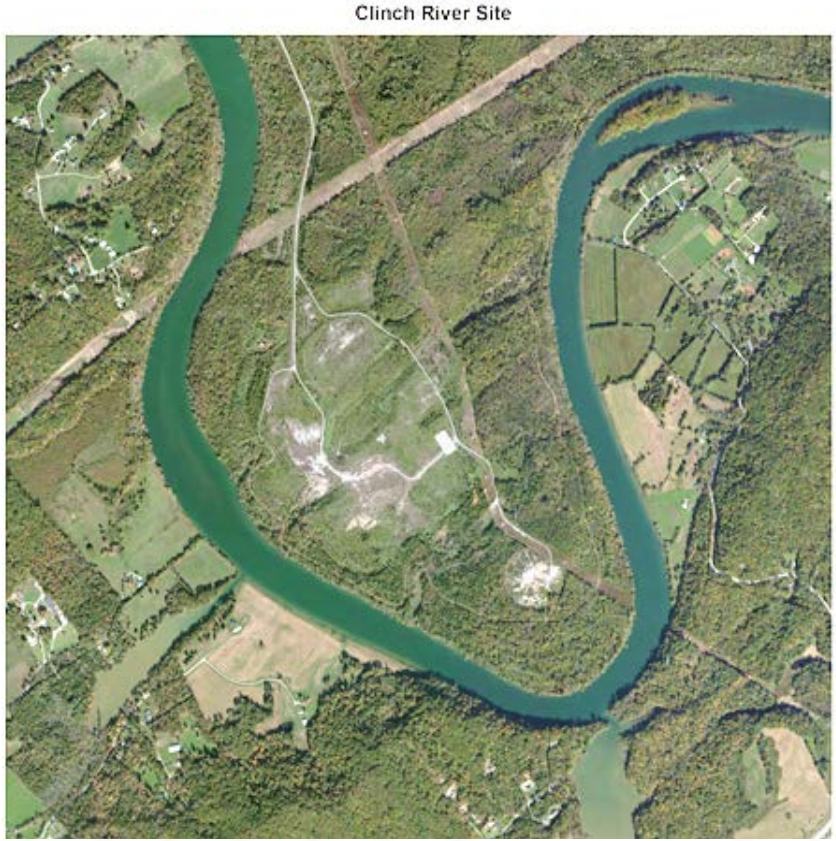
- Site Safety Analysis Report (SSAR) to address impacts of the environment on the plant
- Environmental Report
- Emergency Plans
- Exemptions

**ESPA based on a “plant parameter envelope” (PPE)**

- Composite of reactor and engineered parameters from four U.S. light-water SMR designs with unique design features that bound the safety and environmental impact of plant construction and operation
- Developed based on NEI 10-01 guidance with margin added to specific parameters
- Assumes two or more SMR units of a single design
- Up to 800MWt for a single unit with a combined nuclear generating capacity not exceeding 2420 MWt (800 MWe)

# CRN ESPA Summary

- 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 Informatior (RAIs)
- Frequent, Clear, and Candid Communication
- Included major features of Emergency Planning Zone (EPZ) requirements



# CRN ESP EPZ Major Features

**Plume Exposure Pathway (PEP) EPZ Methodology**

- Approval of the dose-based, consequence oriented methodology for determining the PEP EPZ size.

**EPZ Size**

- Approval to deviate from the current 10-mile PEP EPZ requirements based on the methodology to determine PEP EPZ size.

**Emergency Plan**

- Approval of the major features of the Site Boundary and 2-mile emergency plans.

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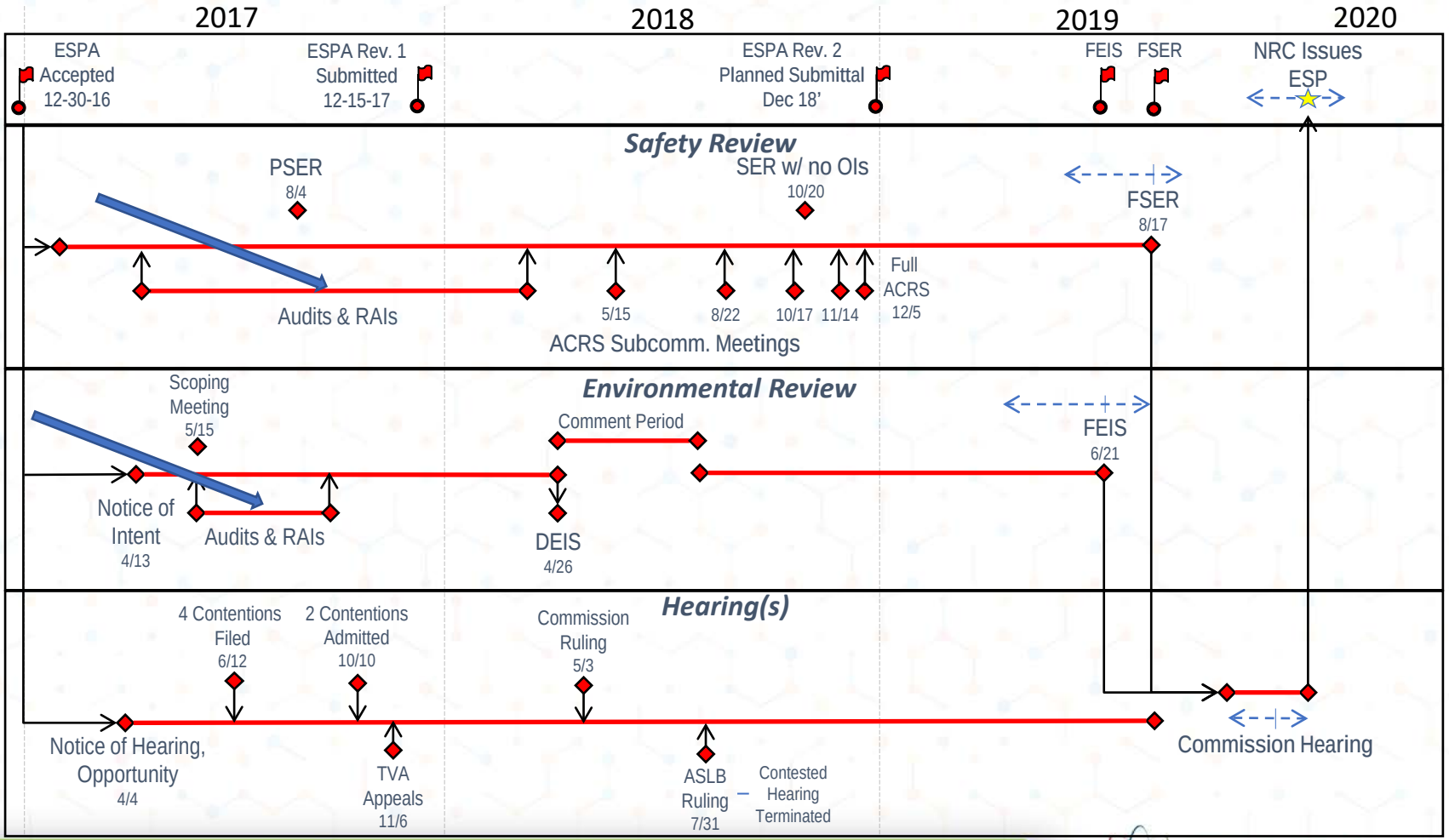




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# ESPA NRC Site Visits/Audits/Inspection

| | |
|---|---|
| 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 |
| 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 | May 2018 |

# 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 - Key Take Away

- Timely REP implementation contributes to project stability and predictability in the full scope of activities supporting the licensing process.
- REP frames the engagement strategy from pre-application to completion of the regulatory action.
- A REP is optimized by implementing a full suite of overlapping regulatory engagement techniques.
- A robust REP enables license review efficiency which translates to lower costs and shorter review schedules.