

# **Best Practices and Lessons Learned from Review of the Clinch River Nuclear Site Early Site Permit Application**

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## **Executive Summary**

The purpose of this report is to provide an overarching retrospective and analysis of the Clinch River Nuclear (CRN) Site Early Site Permit (ESP) application review. This report provides an overview of the lessons learned and best practices that facilitated significant progress in conducting the staff's review, which allowed staff to successfully complete the safety and environmental reviews, as well as the mandatory hearing, ahead of the original schedule. This report provides detailed analyses of processes and procedures that contributed to this successful outcome. In addition, this report identifies and discusses lessons learned that staff can employ to improve the efficiency and effectiveness of pre-application activities for future reviews.

The report is organized by phases, including Pre-Application and Readiness Assessments, Acceptance Review and Requests for Supplemental Information; and Application Reviews – Safety and Environmental (including ACRS review and the Mandatory Hearing). Each phase is presented in terms of a brief overarching narrative, successful best practices, improvements identified as lessons learned and follow-on recommendations that can be applied for all future licensing reviews. A summary of key issues, best practices, and lessons learned from the CRN Site ESPA review is provided at the end of the report. Key drivers for the successful review efforts included:

- A timely open and collaborative approach to issue resolution for the NRC review processes, that helped foster mutual trust and respect between the applicant and the U.S. Nuclear Regulatory Commission (NRC) management and staff.
- Thoroughly planned and executed audits that were focused and well-coordinated with the applicant. These audits provided forums for enhancing mutual understanding of technical and regulatory issues and questions and helped to reduce the number of requests for additional information (RAIs) for both the safety and environmental reviews.

This review resulted in lessons learned in a wide range of areas. The preapplication interactions between NRC and the applicant were not considered highly successful from the standpoint of both the applicant and the NRC. At the start of preapplication engagement, there was a fair amount of uncertainty on the part of the applicant regarding a plant design and regulatory approach (i.e., Part 50 or Part 52), which resulted in a longer period of preapplication engagement and higher costs. On NRC's part, some of the issues that were verbally communicated during preapplication interactions were not captured as acceptance issues in the letter on preapplication observations sent to the applicant. Consequently, the application did not address some of the verbally identified acceptance issues and the application was not initially accepted for docketing. Subsequent acceptance of the application was contingent on supplemental information that the applicant needed to provide to NRC, and that process took about six months. After the supplemental information was provided and the ESP application was accepted for the docketing, the review progressed efficiently and was completed ahead of the established review schedule milestones, even though there were some novel and challenging technical and policy issues to address (most notably, exemption requests on reduced emergency planning zone methodologies). Achieving these successes were the result of the staff

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review team, supported by management, taking innovative approaches in order to optimize review processes and efficiencies.

Most notably, staff were able to help expedite the review schedule by significantly reducing the number of RAIs. Specifically, staff leveraged the audit process and conducted multiple well-planned and well-documented audits, which were especially useful for the timely resolution of complex technical and policy issues. Staff also used public meetings, followed up by detailed meeting summaries, for the discussion and resolution of simple technical issues. While audits and public meetings are useful tools for staff to obtain additional information, the RAI process is also an essential tool for staff to use during licensing reviews and RAIs were issued by technical reviewers for the CRN Site ESPA review, albeit in fewer numbers. Over the course of the different review phases, the staff progressively reduced duration of each phase by both focusing the most risk significant items while also ensuring that other less risk-significant review items stayed on track for timely completion.

## **Purpose, Outcome, Process**

The purpose of this report is to provide an analysis of the CRN Site ESPA review and to identify lessons learned, best practices, and procedures that facilitated significant progress in conducting the staff's reviews including pre-application, acceptance review/docketing, application review activities through safety Phase D (Final Safety Evaluation Report (SER) Issued), and environmental Phase 4 (Final Environmental Impact Statement (EIS) Issued), as well as the mandatory hearing process.

The outcome of this process is identification and documentation of lessons learned and best practices that facilitate effective and efficient safety and environmental review processes for an ESP. In addition, many of the identified best practices and lessons learned may be applicable to other types of licensing reviews (combined licenses, design certification applications, construction permits, license amendment requests, etc.).

The process followed by the authors of this report was to identify and break-out specific phases (pre-application, acceptance review, and safety and environmental review phases) and identify specific activities for these phases in the CRN Site ESPA review. Within each phase of the review evaluated, the authors identified key aspects of the review processes that were either best practices or lessons learned. To ensure that a wide range of perspectives were captured, the authors identified key technical staff, PMs, supervisors, Senior Executive Service (SES) managers, Pacific Northwest National Laboratory (PNNL) contractor staff, and applicants to be involved in the project's lessons learned survey. To collect objective data regarding the review, the authors developed a survey questionnaire for all phases of the review including both safety and environmental reviews. The survey was provided to 28 individuals and responses were received from 20 individuals and two organizations by email. There was a 79% response rate. In addition to collecting feedback via the survey, the authors identified resource expenditures from information in Enterprise Project Management and HRMS for the entire project and identified the resources utilized for all phases of the CRN Site ESPA review.

## **Pre-application and Readiness Assessments (January 2015 to May 2016)**

The NRC has historically encouraged prospective applicants to engage in pre-application activities prior to submittal of significant licensing actions. Pre-application activities are a voluntary activity intended to: (1) identify information gaps between the draft application and the technical content expected to be included in the final application submitted to the NRC, (2) identify major technical or policy issues that may adversely impact the docketing or technical review of the application, and (3)

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become familiar with the application, particularly in areas where prospective applicants are proposing new concepts or novel design features. The results of the pre-application activities and the readiness assessment will help inform prospective applicants in finalizing their application and assist the NRC staff in planning NRC resources in preparation for the review once the application is formally submitted. The pre-application activities with TVA were informed, in part, by Office of New Reactors office instruction NRO-REG-104, "Pre-Application Readiness Assessment", which has been replaced by the Office of Nuclear Reactor Regulation office instruction NRR-LIC-116.

The pre-application activities for the CRN Site ESPA extended over a year and a half and provided NRC staff and contractors with multiple opportunities to interact with the applicant on the draft application and included visits to the site. Site visits allowed staff to become familiar with features and characteristics of the CRN Site and identify potential siting issues. These site visits, along with examination of early drafts of the site safety analysis report (SSAR) and Environmental Report (ER) helped inform NRC staff feedback to the applicant. The staff also discussed with the applicant submittal of specific supporting information that would facilitate an effective and efficient application review. Following these pre-application interactions, NRC sent TVA a letter (ADAMS Accession No. ML15316A509) highlighting several key readiness assessment observations for consideration. This letter, however, should have included clear expectations regarding all gaps in the application that needed to be addressed prior to application submittal to ensure a timely acceptance review. Furthermore, although staff noted in the letter that TVA's proposed exemptions for reduced emergency planning zones (EPZs) could complicate and lengthen the review, the application review would have been better served if a process and path for closure had been formulated by staff as soon as they became aware of the EPZ exemptions during the pre-application phase. Because this was not done, a significant amount of time was spent on determining a path forward on addressing these exemption requests during Phase A and B of the safety review.

### Best Practices Identified:

- Early interactions between the applicant, staff, and their respective contractors should be used to establish a mutual understanding of the review scope and to identify key areas of significance in the draft application.
- Pre-application meetings and interactions need to be well-focused and have the appropriate technical experts (from both sides) participating so that they discuss specific features, topics and issues that are expected to be technically complex, unique or novel, or challenging from a policy perspective.
- Prior to pre-application interactions, the applicant should make the draft SSAR and/or ER, along with supporting information, available well in advance of the pre-application meeting (at least 3 to 4 weeks prior). Electronic reading rooms (eRRs) have been used effectively to support this process, though large images and files are sometimes best viewed in hard copy in a local reading room. Providing this information will facilitate staff being fully prepared for fulsome discussions with the applicant and their contractors during the pre-app interactions.
- Pre-application site visits should include walk-downs and on-site interactions with applicant staff and contractors. These are very important for both NRC/contractors and applicant staff/contractors, as they provide a hands-on common understanding of site characteristics and the representation of those features in the contents of the application. Site visits also can help

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staff and PMs identify areas where focused, expanded technical evaluations, and/or further clarifications are needed.

- Observations/issues identified during pre-application interactions should be clearly documented and summarized, with next steps/actions identified in a manner that are understandable and actionable by the applicant (e.g., similar to audit summary reports that are transmitted to applicants via letter). These practices would help ensure that any key issues are fully addressed in the application, which would support a more timely and predictable licensing review.

### Lessons Learned:

- ❖ Clear timely communications, an agreement upon scope, and aligned expectations prior to a site visit are essential for successful pre-application interactions.
- ❖ Availability of all pertinent draft documents to evaluate and sufficient time to review them thoroughly is essential for having productive and focused interactions.
- ❖ An applicant's SSAR and ER should be sufficiently mature (and supporting documents should be available) in order to enhance the efficiency and effectiveness of pre-application interactions for both NRC and the applicant.
- ❖ Comprehensive site-safety and environmental interactions between staff and applicant and respective subject matter experts (SMEs) consultants/management need to be appropriately focused on key technical reviewers and the safety and environmental issues that the application will need to address.

### Recommendations:

The use of the Office Instruction, NRR-LIC-116, "Pre-Application Readiness Assessment", processes and other practices should be an important expectation of staff in order to reduce gaps in the draft application by implementing the following practices:

- ❖ Clearly identify information gaps between information in the draft application and the technical content necessary to meet regulatory requirements that needs to be included in the application submitted to the NRC.
- ❖ Clearly identify and obtain NRC-applicant alignment on major risk-informed technical and/or policy issues that may adversely impact the docketing or technical review of the application, and enable staff to become familiar with the application, particularly in areas where prospective applicants are proposing new concepts or novel design features.
- ❖ For new and/or novel issues identified during pre-application (e.g., exemption requests on EPZ sizing methodology) staff should, as much as possible, establish and map out the process and path for closure on issues prior to receipt of the application to help ensure timely reviews.
- ❖ NRR-LIC-116 should be used with consideration of reasonable flexibility in the pre-application process. The results of this process will inform prospective applicants by identifying all

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significant gaps before they finalize their application and will assist the NRC staff in planning its resources for the review once the application is formally submitted.

- ❖ Clear timely communication with the applicant regarding what NRC expectations are with respect to pre-application observations is imperative, and the utilization of appropriate interactions should be encouraged as tools to resolve issues in an efficient manner prior to submittal.

### **Acceptance Review and Requests for Supplemental Information (May 2016 – December 2016)**

The Acceptance Review (AR) for the CRN Site ESP spanned from May 2016 – December 2016. This extended review time included additional interactions (public meetings) with the applicant on key issues after the application was submitted. The key issues were documented by staff in draft requests for supplemental information (RSIs) that the applicant needed to address prior to the acceptance and docketing of the application. Clarification of several RSIs was accomplished through public meetings, wherein the applicant and key technical staff from the NRC engaged in productive detailed discussions of technical issues such that the applicant was able to address the RSIs and make appropriate supplements to the initial submittal. TVA submitted supplemental information between mid-July and mid-December 2016, and the staff determined that the application, as supplemented, was acceptable for docketing and detailed technical review on December 30, 2016.

### **Best Practices/Historical Information:**

The PMs coordinated and communicated regularly with the technical branches on potential acceptance issues regarding AR evaluations and branch chief (BC) memorandums, and, based on these inputs, the lead PM communicated the staff's recommendation to NRO management regarding application acceptance. In this instance some information necessary for docketing of the application was considered insufficient to conduct a timely and predictable review. As such, the application was not accepted for docketing, but kept in tendered status contingent on the receipt of supplemental information sufficient for application acceptance and docketing within 6 months (by December 30, 2016). As mentioned in the "Pre-Application and Readiness Assessment" section above, some of the information that staff considered to be insufficient had been discussed verbally with the applicant during preapplication interactions but was not included in the readiness assessment observations letter. While in tendered status, staff worked to develop specific and detailed draft RSIs on the sections of the application deemed insufficient. The RSIs and follow-up interactions proved to be effective as the supplemental information needed for the application was provided by TVA, evaluated, and determined to be acceptable for docketing. The AR process continued effectively, and the docketing decision was made on December 26, 2016, approximately two weeks after the last submission of supplemental information by the applicant.

### **Lessons Learned:**

While holding an application in tendered status is not necessarily something to advocate as a best practice, delaying the start of CRNS ESPA review until adequate supplemental information was submitted ultimately led to NRC to a more effective and efficient safety and environmental review. This, in turn, led to the staff finishing its review several months earlier than the original schedule.

For future acceptance reviews, the applicant recommended that more focused communication from NRC during the formal 60-day AR would help facilitate earlier closure on issues. Appropriate and frequent communication at the management level would facilitate the applicant's understanding of

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information gaps identified by technical reviewers and would allow the applicant to propose “cure plans” for addressing shortcomings in the application in a timely manner.

### Recommendations:

- ❖ The AR process should emphasize NRC-applicant interactions in NRR-LIC-117, which has superseded NRO-REG-100, “Acceptance Review Process for Design Certification and Combined License Applications.” A discussion of appropriate interactions and public meetings should be outlined if pre-application gaps identified by NRC were not addressed by the applicant and could result in RSIs.
- ❖ The staff should initiate clear and timely communications with the applicant regarding what NRC needs to see in the application with respect to pre-application observations, and the utilization of public meetings and “mini” audit-like interactions should be encouraged as tools to resolve issues in a timely manner
- ❖ The staff should initiate clear timely communications with the applicant on issues that rise to the level of an RSI (i.e., insufficient information for staff to conduct a review in a predictable or timely manner) and those issues that can be readily addressed using audits and RAIs over the course of a regular application review

### **Application Reviews – Safety and Environmental (January 2017 – June 2019)**

#### Best Practices/Historical Information:

After the acceptance review, NRC staff, management and the applicant resolved to improve the regularity and clarity of communication on the application review status and on any emerging project issues associated with both the environmental and safety reviews. Routine counterpart calls were established at both the PM and management levels; and recurring public meetings were set up to allow the timely discussion and resolution of technical issues.

- The NRC staff and the applicant adopted a cooperative approach to the NRC review process for all areas, which helped foster mutual responsiveness while maintaining NRC independence. This allowed both the applicant and the staff to identify further information needs to support the regulatory decision-making and resulted in enhanced review efficiencies.
- A PM-technical reviewer team approach was established for the review process within the NRC. This enabled the more effective tackling of challenging technical issues, with an emphasis on planning and sequencing review efforts to meet/exceed project milestones.

This cooperative model was established at the beginning of the project and was maintained throughout by team meetings and numerous focused interactions between the PMs, technical branches/BCs and individual technical reviewers. The project management team supported and worked exceptionally well with the technical staff, which created a high degree of trust among the teams. While the PMs did perform due diligence in challenging the technical staff individually, the PMs also kept the technical team apprised of the overall project status and various challenges to the review. For example, the PMs held weekly team meetings during Phase A of the review, which was beneficial because it kept the different disciplines up to date on what other disciplines were doing and outlined upcoming deadlines and the next step of the review. These weekly team meetings also help to inform regular

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briefings to management on technical/logistical issues so that technical challenges and emerging issues could be addressed in a timely manner.

An example of this cooperative model working well during the application review was the extensive efforts exhibited by the NRC staff and the applicant to address the exemption requests related to the EPZ methodology<sup>1</sup>. The success of this effort can be attributed to 4 key factors:

- PM leadership and support;
- Setting expectations and consistently applying them;
- Frequent clear communications; and
- Staff teamwork and collaboration.

Given that the emergency planning (EP) review had no clear precedent and/or guidance, it was identified early that some flexibility from both NRC and the applicant would be needed to complete the review. This resulted in productive discussions on review criteria, level of information and documentation needed by the staff to reach a finding. These discussions also paved the way for everyone to quickly identify that some of the “baggage” from previous review precedents (i.e., “This is how we have always done it.”) needed to be set aside to allow for more creative thinking, as necessary.

This also led to the enhanced use of well-planned, focused, and effectively executed audits for all the safety and environmental review areas, which helped reduce the number of RAIs. The success of these audits was due, in part, to the well-developed audit plans with comprehensive sets of information needs, the applicant, NRC staff, and contractors were all well prepared in advance of audits and inspections. Another factor for audit successes was that the applicant posted audit materials (e.g., calculation packages) in an eRR for staff to view prior to the audits. In addition, the applicant had submitted supporting information (e.g., electronic input/output files for the hydrology, health physics, and meteorology computer codes, and other calculation related files in native format) on the docket. This supplemental information reviewed in conjunction with audit materials facilitated the technical staff’s review, which reduced the application review schedule and minimized RAIs.

Additionally, face-to-face and follow-up clarification discussions between the NRC and the applicant’s technical staff and contractors were highly beneficial in understanding why certain methods were used, what the applicant’s technical bases were for these methods/calculations in the application, and what additional information was needed to support staff’s technical review. By the end of each audit a clear path forward was identified for each information need and an agreed upon alignment on issues and what level of information was needed to resolve the issue. The path forward was identified and categorized into one of three bins for audit information needs as follows: (1) No further information needed; or (2) Applicant actions to address; or (3) NRC actions to address (e.g., RAI will be issued). Both applicant and NRC staff practiced a “No Surprises” approach, which involved prompt communication from either party whenever an issue was identified. This facilitated the timely initiation of actions needed (RAIs, public meetings or supplemental audits) to achieve issue resolution.

Another factor for audit success was that reasonable flexibility was permitted for extending the duration of audits for more complex issues. Specifically, audit plans were set up with estimated durations to

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<sup>1</sup> It is noted in the pre-application section above that, in the future, staff should establish and map out the process and path for closure on potentially complex issues prior to receipt of the application, instead of after acceptance of an application. Adopting such a practice would help avoid potential schedule risks and allow for a more predictable review.

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help ensure schedule discipline but were extended on a case-by-case basis to provide the applicant with sufficient additional time to provide the needed information to support NRC safety and environmental findings. Once staff reviewed the additional information and found it acceptable, it eliminated the need for issuing an RAI. However, if the applicant was unable to fully address the information needs, then the NRC staff action was to issue an RAI. However, providing this flexibility within the audit process provided for a more efficient review which, in turn, aided in the overall reduction of the project schedule.

It was also identified that internal NRC close cooperation, coordination, and frequent communications between the NRC safety and environmental technical staff eliminated redundancy and allowed for the quick resolution of technical and regulatory issues that overlapped in both the safety and environmental areas.

### Lessons Learned:

Use of an eRR to post documents and supporting files was extremely valuable, however, future improvements (greater bandwidths/file breakup) would be useful. Timely submission of supporting information early in the application review (e.g., following a public meeting on a technical issue) allowed the technical staff to perform their reviews in a timelier manner. Supporting information reviewed in conjunction with audit materials reduced the time needed in the application review schedule and minimized potential RAIs. If input output files are needed to make a safety finding, they files should be submitted in native format (sometimes requiring an external hard drive due to size and number of files) so that the staff can more efficiently use the data for confirmatory and, if necessary, independent reviews and analyses.

Additionally, early issuance of both the DEIS and FEIS was possible, in part, owing to a pilot agreement with the Office of ADM regarding the draft and final NUREG documents. The licensing division in NRO advocated for waiving ADM's traditional comprehensive review of NUREG content prior to publication, while still having ADM play a role in reviewing key parts of the front matter. The Office of ADM agreed to this pilot based on the demonstrated quality of 18 NUREG documents previously produced by Pacific Northwest National Laboratory (PNNL) in support of new reactor licensing.

### Recommendations

- ❖ The staff should follow the best practices discussed above and devote attention to early identification and alignment on the approaches to resolve the novel, complex and risk-significant elements of a review.
- ❖ To the extent practicable, the PMs, tech staff and management should continually work in a collective manner to identify and implement innovative and creative ways to accelerate phases of application reviews without relying on heroic efforts.
- ❖ The staff should advocate for eRRs with improved bandwidths to help overcome some of the limitations experienced during the CRNS review.
- ❖ The staff should continue their enhanced use of well-planned and executed audits for future application reviews.

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- ❖ The staff should continue to advocate and adopt the practice of a limited ADM review role prior to the publication of NUREGs (not just the draft EIS, but the final EIS as well).

## **Mandatory Hearing (Preparation and Hearing) April - August 2019**

### **Best Practices/Historical Information:**

More than two months prior to the completion of the FSER on June 14, 2019, the NRC staff began to work to prepare the information needed for the mandatory hearing tentatively scheduled for August 14, 2019. These advanced efforts included preparing staff and management presentations for the hearing, and finalization of documents needed to support the hearing proceeding. Those documents were the draft version of the early site permit ESP-006 (ML19107A159), the draft record of decision (ROD) (ML191070A028), and the requisite SECY paper (ML19107A241). Commission hearing procedures stipulate that the SECY paper supporting the hearing be issued by the EDO 7 days after the public issuance of all staff review documents (both FSER and FEIS) has been completed. The SECY paper titled "Staff's Statement in Support of the Uncontested Hearing for Issuance of an Early Site Permit for the Clinch River Nuclear Site" served as the staff's primary pre-filed testimony for the uncontested (mandatory) hearing on whether to issue the ESP for the CRN Site. Following issuance of the SECY paper, the Commission issued a July 12, 2019, order for an August 14, 2019, hearing proceeding, and included 58 pre-hearing questions for staff and, in some cases, the applicant, to address as part of the testimony. Because staff did this effective resource planning and coordination, they were well-positioned to respond to Commission questions in a timely manner and were able to make adjustments to their presentations well ahead of the mandatory hearing proceeding.

A noteworthy matter that staff prepared for in advance of the hearing pertained to concerns by the Federal Emergency Management Agency (FEMA) about potential changes to the size of emergency planning zones. Discussions and written communications between FEMA and NRC occurred throughout the application review process and up until the Commission's decision on issuance of the ESP. Despite some differing views, NRC communicated and engaged professionally with FEMA over the course of the review. Specifically, the NRC made various presentations to FEMA staff on small modular reactors, the technical basis for EPZ sizing, risk-informed emergency planning, and routinely invited FEMA staff to attend various public meetings related to Clinch River ESP as well as with the parallel SMR rulemaking. The staff also responded to questions by FEMA staff during the routinely scheduled NRC-FEMA meetings. The staff broadened their outreach to include all agency members of the FEMA chaired Federal Radiological Protection Coordination Committee (FRPCC which is a committee composed of 21 federal agencies with interest in radiological protection issues). NRC and FEMA staff met jointly with Tennessee emergency management agency officials to discuss emergency preparedness and planning and the Clinch River Nuclear Site.

### **Best Practices**

- ❖ Early outreach and engagement with SECY on the expected completion dates of the FEIS and FSER helped SECY plan a "reserved time" for the mandatory hearing. This advance coordination with SECY was viewed positively and helped ensure the scheduling of a timely mandatory hearing. In parallel the staff started work on documents several months in advance and implemented a proactive and collaborative planning and scheduling approach with OGC and management. This helped ensure that hearing preparation processes were done in advance and that resources were in place prior to receiving the Commission Order to initiate the hearing process.

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- ❖ The PMs engaged in exceptional coordination and planning with OGC, technical staff and management to address and finalize the pre-hearing and post-hearing questions in a timely manner.
- ❖ In contrast to previous Part 52 mandatory hearings that were attended by almost all involved with application reviews, the staff's participation during the evidentiary hearing was limited to those who were needed to address technical and policy questions that were likely to be raised by the Commission. This was done in an effort to be more deliberate about the use of staff resources and the overall cost of application reviews. This involved some risk, but nonetheless worked out well and saved project resources.

### Lessons Learned:

- ❖ Limiting staff participation in mandatory hearings to those likely needed to address technical and policy questions by the Commission was an effective and risk-smart approach to helping control application review costs and is recommended for future mandatory hearings.

### **Summary of Key Issues, Best Practices, and Lessons Learned from CRN Site ESPA review Processes**

Applicant, staff, and NRC management processes that facilitated successful outcomes included:

- 1) The applicant and the NRC adopted an open and cooperative approach to issue resolution in the NRC review processes, which helped foster mutual trust and respect, and resource expenditure were focused on technical and policy issues deemed risk-significant to the review schedule (e.g., Exemption requests related to Emergency Planning).
  - a) Substantial coordination and collaboration between the safety and environmental project managers (PMs) and technical reviewers enhanced communications with the applicant and contributed very significantly to an efficient and effective review process.
  - b) NRC management provided needed support to the PMs when assistance was requested and allowed the staff to be innovative in their review processes (e.g., enhanced use of audits).
- 2) Thoroughly planned and executed audits that were well-coordinated with the applicant provided forums for enhancing mutual understanding of technical and regulatory issues and questions and helped to minimize the number of requests for additional information (RAIs). For context, staff issued 13 RAIs comprising 51 questions for the Clinch River ESP review, whereas for the previous ESP review (PSEG Site ESP) staff issued 88 RAIs comprising 240 questions.
  - a) The applicant's responsiveness resulted in time efficiencies with respect to addressing NRC information needs in support of both the safety and audit reviews.
  - b) The identified intent and resulting expectations for each information need was clearly articulated and understood by both staff and applicant at each audit closeout.
  - c) The early alignment achieved when the unprecedented and novel issues arose from the request to approve a methodology for determining the Emergency Planning Zone (EPZ) size and related exemptions benefited greatly from the innovative audit approach.

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- 3) Clear and concise communications by the PMs and managers with the applicant regarding NRC requirements and the link to the information needs during the audits was crucial to successfully establishing the regulatory requirements for the safety and environmental reviews.
  - a) Routine counterpart calls with the applicant were established at both the NRC management and PM/staff levels to improve the regularity and clarity of communication on the application review status and on emerging project issues.
  - b) Supporting information submitted on the docket in conjunction with audit materials posted in the Electronic Reading Room (eRR) helped reduce the staff's review time and minimize potential RAIs.

### Key Lessons Learned (What could NRC do better?):

- 1) A well-structured pre-application process that focuses on advance preparation, coordination and documenting observations in a complete and clear manner. Timely review of draft SSAR and ER, appropriate coordination with the applicant to ensure that pre-application interactions/audits are focused on key safety and environmental issues and that the appropriate SMEs from staff, applicant, and contractors are prepared to address key issues and resolve misunderstandings.
- 2) The pre-application readiness assessment process should be improved by providing for better documentation of staff observations of information gaps in a draft application and relevant supporting information that would preclude acceptance of the application for docketing. Documentation of issues should be captured in concise and understandable publicly available Readiness Assessment Reports/summaries.
- 3) Enhanced use of audits as an important review tool as outlined in Office Instruction NRR-LIC-111, "Regulatory Audits". An emphasis on well-developed audit plans containing detailed audit items/information needs, and the importance of comprehensive audit summary reports detailing interactions, activities and outcomes regarding audit items (audits activities should be transparent and "auditable") coupled with appropriate public meetings to ensure transparency.
- 4) For safety reviews, focus on the risk-significant elements of the review will help reduce review costs and improve the timeliness of application reviews. For environmental reviews, initiatives driven by FAST-41, EO 13807 and other CEQ updates will help streamline and expedite future environmental reviews, which will also help reduce review costs.
- 5) The use of an eRR to post documents and supporting files was useful, but some large files and files with embedded files were cumbersome or difficult to read and sometimes did not load or timed out. It is recommended that improvements be made to the eRR systems (e.g., greater bandwidths and file breakouts from large packages; a very clear table of contents with appropriate descriptions of the documents contained therein, i.e., a roadmap) be implemented.

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### Applicability to other License Review Processes:

- 1) For combined license applications (COLAs) and design certifications (DCs) consideration of best practices, lessons-learned and recommendations when following the office instructions for pre-application and readiness assessments, the acceptance-review process, and audit process and other suitable review guidance documents will facilitate a risk-significant focus. This could be of particular importance for advanced reactors with potentially greater safety margins and potentially lower environmental impacts.
- 2) In addition, it is essential to develop and implement an audit-like approach within the pre-application process and for interactions with potential applicants for advanced and small modular reactors to ensure that the application submittal has addressed any gaps, issues, and/or concerns identified in pre-application interactions. Such an approach could go a long way to ensuring the completeness of the application.
- 3) Within the application review, the appropriate use of audits and audit processes has proven to be vital in facilitating reviews of complex and difficult technical and regulatory issues.

# Best Practices and Lessons Learned from CRN Site ESPA Review

## Appendix A – Application Review Timeline

### Public Milestones, Completion Dates and Schedule Gains

Safety Review	Public Milestone	Completion Date	Schedule Gain
Phase A – PSER w/open items	08/04/2017	08/04/2017	0 days
Phase B – PSER with no open items	10/20/2018	10/17/2018	3 days
Phase C – ACRS meetings on ASEs	03/26/2019	12/06/2018	111 days
Phase D – FSER issuance	08/17/2019	06/14/2019	66 days
Environmental Review			
Phase 1 – Environmental Scoping	11/02/2017	10/30/2017	3 days
Phase 2 – Draft EIS issuance	06/01/2018	04/27/2018	36 days
Phase 3 – Comment responses (DEIS)	01/20/2019	12/14/2018	38 days
Phase 4 – Final EIS issuance	06/21/2019	04/03/2019	80 days
Mandatory Hearing	N/A	08/04/2019	N/A
Issuance of ESP-006	N/A	12/19/2019	N/A

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## Appendix B – Resource Expenditures

### Summary of Staff and Contractor Hours for ESPA Review and Mandatory Hearing

	Staff Hours	Contract Dollars
Safety Review	26,316	\$69,256
Environmental Review	12,657	~\$3.4M
Totals	38,973	~\$3,469,256

### Breakdown of Overall Resource Expenditures (Pre-application through Mandatory Hearing)

#### a) Identification of Resource Expenditures (January 1, 2015 - December 31, 2019)

##### i) Pre-Application and Readiness Review (January 2015 – May 2016) **Total Staff Hours = 5611**

- (1) Safety ~50 percent
- (2) Environmental ~50 percent
- (3) Contractor expenditures: approximately \$762 thousand

##### ii) Acceptance Review (May 2016 – December 2017) **Total Staff Hours = 3639**

- (1) Safety ~45 percent
- (2) Environmental ~55 percent

##### iii) Application Review and Mandatory Hearing (January 2017 – December 2019) **Total Staff Hours = 38,973**

- (1) Safety = 24,517 (63%) \*\*
- (2) Environmental = 12,657 (32%) \*\*
- (3) EPZ/Exemptions = 1,799 (5%) \*\*
- (4) Contractor expenditures: Environmental (EIS) - \$3.4 million; Safety (FSER) - \$69,256

##### iv) Total staff hours January 2017 through December 31, 2019 = 38,973

\*\* Includes PM/Licensing Assistant/Information Technology