



**NEW REACTOR LICENSING PROCESS
LESSONS LEARNED REVIEW:
10 CFR PART 52**

April 2013

Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) fully implemented the licensing portion of its new reactor licensing process¹ with the issuance of combined licenses (COLs) for Vogtle, Units 3 and 4, and V.C. Summer, Units 2 and 3. Following the issuance of these licenses, the NRC initiated a lessons learned review to identify potential enhancements to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” licensing process and contribute to more effective and efficient reviews of future applications. This lessons learned review is limited to the licensing portion of Part 52 and does not include experiences from post-COL issuance activities. To facilitate this lessons learned review, the NRC conducted an extensive outreach effort to solicit feedback from external and internal stakeholders on their experiences using the new reactor licensing process. Specifically, the NRC staff drew on previous assessments of portions of the new reactor licensing process, lessons shared at the NRC’s 2012 Regulatory Information Conference, feedback received at a public meeting on lessons learned, and the results of internal and external surveys on the new reactor licensing process.

Although design certification and combined license reviews have taken longer and have been more technically challenging than anticipated, the results of this lessons learned review revealed no significant problems or impediments associated with the Part 52 licensing process. Its implementation achieved the intended result of resolving safety and environmental issues before authorizing plant construction. Overall, the NRC received positive feedback on the licensing process and best practices that made the successful execution of the Part 52 licensing process possible. The design-centered review approach, as supported by design-centered working groups, standard designs, and standard format and content of licensing applications, was frequently cited as a licensing process success. Several other best practices were identified, such as frequent meetings between the applicants and the NRC to resolve complex technical issues.

As expected with any new process, the first-time implementation of the Part 52 licensing process has resulted in challenges. An evaluation of these challenges identified the following lessons:

1. High-quality applications, with sufficient level of design detail and environmental information, are a significant contributor to overall project performance.

¹ 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants”

2. Timely development and maintenance of regulatory guidance are important to support the development of a high-quality application as well as contribute to an efficient regulatory review.
3. Strong design standardization contributes to an efficient regulatory review while on-going design changes have the opposite effect.
4. Early identification and timely resolution of complex technical issues minimize impacts on the review schedules.
5. Improvements to NRC's management system for requests for additional information (RAIs) can further enhance project knowledge management and contribute to a more efficient review.
6. Concurrent reviews of design certifications and combined license applications contribute to maximizing standardization. Design certification rulemakings should not commence until all design issues are resolved.
7. Updates to the regulations incorporating lessons learned will contribute to an enhanced licensing process.

Stakeholders also identified communications as a critical cross-cutting area. A commitment by all parties to engage in an open, transparent, and timely manner, more than any other action, has led to, and will continue to result in, the successful implementation of the Part 52 licensing process.

This lessons learned review identified several planned and potential actions that can be used to enhance the licensing process and improve the efficiency of future licensing reviews. Planned actions for each of the lessons learned are listed below:

1. Quality of Applications

- The NRC staff plans to review its acceptance review guidance to identify areas in need of enhancement.
- The NRC staff plans to adhere more strictly to acceptance review criteria for future applications.
- The NRC staff plans to engage future applicants with regards to the best timing for pre-application audits. The audits will evaluate level of detail of the application to ensure consistency with lessons-learned in reviews since 2006.

2. New Reactor Review Guidance

- The NRC staff plans to update Regulatory Guide 1.206, “Combined License Applications for Nuclear Power Plants (LWR Edition),” consistent with budgeted resources.
- The NRC staff will consider establishing a process for synchronizing updates to Regulatory Guide 1.206 with updates to the Standard Review Plan. The NRC staff will consider reorganizing Regulatory Guide 1.206 to be more consistent with the organization of the Standard Review Plan. The NRC staff will also incorporate review experience by considering the results of commonly asked RAIs and their respective responses when Regulatory Guide 1.206 is updated.
- The NRC staff plans to continue its systematic Standard Review Plan update, consistent with budgeted resources, in a timely manner to support combined license, design certification, early site permit, and limited work authorization application reviews.
- The NRC staff plans to proceed with environmental review guidance updates, consistent with budgeted resources.

3. Standardization

- The NRC staff plans to review ISG-11, “Finalizing Licensing-Basis Information,” to identify areas in need of enhancement.
- The NRC staff plans to work with industry to expand the design-centered working group role to address common technical issues to ensure consistency across different design centers.

4. Identification and Resolution of Technical Issues

- The NRC staff plans to update its staff guidance to ensure consistent use of best practices that facilitate timely resolution of complex technical issues and to more quickly engage higher levels of NRC and applicant management, when necessary, to resolve complex technical issues.
- The NRC staff plans to continue to engage stakeholders, including vendors, standards organizations, and other regulatory bodies on complex and evolving technologies to enhance safety while streamlining the review process.

5. Knowledge Management

- The NRC staff plans to enhance its RAI management system to improve search capability, consistent with budgeted resources.
- The NRC staff plans to continue to examine its RAI process to ensure that RAIs are tracked consistently across design centers and information is communicated to applicants and management in a timely fashion.

6. Application Timing and Sequencing

- The NRC staff plans to apply the rulemaking process for future design certifications consistent with the 2009 streamlined approach, in which all design issues have been resolved before rulemaking begins.

7. Updates to Regulations

- Although this lessons learned effort did not identify any significant problems or impediments with the Part 52 licensing process, it has identified areas that could be enhanced. In fact, the staff has been identifying and collecting ideas for improvements since the 2007 Part 52 update. The NRC staff plans to communicate potential regulatory enhancements to the Commission along with a proposed rulemaking plan to obtain Commission approval to move forward with an update to Part 52 and associated regulations.

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I. BACKGROUND

The U.S. Nuclear Regulatory Commission (NRC) revised its regulations in 1989 to establish Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” (Part 52) as an alternative to the existing process for reactor licensing under 10 CFR Part 50 (Reference 1). The NRC updated Part 52 in 2007 ([72 FR 49517](#) and [72 FR 57446](#)) to increase regulatory certainty and stability and to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and regulatory approval processes. This new licensing and regulatory approval process encouraged design standardization and provided a more predictable licensing process by resolving safety and environmental issues before authorizing plant construction. Under Part 52, an applicant may seek a combined license (COL) that provides authorization to construct and operate— subject to specific conditions—a nuclear power plant. Part 52 also includes the design certification (DC) process to approve a standard reactor design, and the early site permit (ESP) process to approve the suitability of a site for a nuclear power facility. The process also includes provisions for approval to perform limited construction activities before a COL is issued under a limited work authorization (LWA). A brief description of these licensing processes is provided in Appendix A, “New Reactor Licensing Process,” to this report, and additional details are available in NUREG/BR-0468, “Frequently Asked Questions About License Applications for New Nuclear Power Reactors” (Reference 2).

A growing interest in new nuclear power generation in the industry gained support from the U.S. Department of Energy in 2002, through its Nuclear Power 2010 program, and the U.S. Congress in 2005, through incentives included in the Energy Policy Act of 2005, which included production tax credits, loan guarantees, and standby support in the event of regulatory delays. In preparation for the submittal of a large number of applications to construct and operate new nuclear reactors, in 2006 the NRC created the Office of New Reactors (Reference 3) to better prepare the agency for the anticipated new reactor licensing and construction inspection activities.

On September 17, 2009—by which time there had been three DC applications, two DC amendment applications, and COL applications for 28 reactors at 18 sites submitted to the NRC for review—U.S. Representatives Joe Barton and Greg Walden sent a letter to former Chairman Jaczko expressing concerns about potential regulatory delays in the licensing process for new reactors (Reference 4). In response, former NRC Chairman Jaczko requested that the Bipartisan Policy Center review the NRC’s licensing process for new reactors to determine whether there were unnecessary delays in that process caused either by the NRC or the nuclear industry.

The Bipartisan Policy Center issued its report on April 6, 2010 (Reference 5), and stated that it did not find any evidence that either the NRC or the nuclear industry had needlessly delayed or extended the licensing process. The Bipartisan Policy Center further concluded the following:

Although the licensing process is new, both the NRC and the industry have done a remarkable job in very trying circumstances assuring the thorough and timely evaluation of license applications. The fact that all parties have experienced some problems in navigating the process was to be expected under the circumstances. But it is apparent that all those involved have been diligent in working through the issues in a forthright manner.

Nonetheless, the Bipartisan Policy Center recommended that the Commission “... ensure that the lessons learned in the first round of applications are rigorously applied to make the processing of subsequent applications more efficient.”

In response, the NRC staff has undertaken a review to identify, assess, and document enhancements to the new reactor licensing review process one year after issuance of the first COL.

II. SCOPE AND METHODOLOGY

The NRC staff reviewed the new reactor licensing process, and assessed the experiences to date to identify enhancements that would increase the effectiveness and efficiency in future application reviews. The results are discussed in Section III of this report. The scope of this effort included the ESP, LWA, DC, and COL licensing processes (see Appendix A). A separate NRC lessons learned effort has addressed the mandatory hearing process. Post-COL activities (e.g., license amendments; inspections, tests, analyses, and acceptance criteria inspectability and closure; construction inspection) are being assessed in a separate activity initiated upon completion of the first year of safety-related construction at Vogtle and Summer.

The NRC staff drew on previous assessments of portions of the new reactor licensing process, lessons shared at the NRC’s 2012 Regulatory Information Conference, feedback received at a public meeting on lessons learned, and the results of internal and external surveys on the new reactor licensing process (References 6 - 18). In addition, lead project managers, first line supervisors, and team leaders of NRC technical and licensing staff were interviewed to gather additional insights and lessons learned from experiences performing the ESP, LWA, DC, and COL reviews.

An NRC working group conducted this lessons learned effort. From the sources described above, the working group identified seven lessons and associated planned actions that have the potential for positive gains in licensing review effectiveness and efficiency.

III. ANALYSIS OF FEEDBACK AND SUGGESTED ENHANCEMENTS

Overall, respondents commended the Part 52 process as an improvement over the two-step 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” licensing process because of reduced regulatory uncertainty through early resolution of safety and environmental issues before authorizing plant construction. Respondents also generally found implementation of the licensing process to be effective. They cited several items as key factors in the success of the process, including standardization; development of the design-centered review approach (Reference 19), based on a concept of industry standardization of COL applications referencing a standard design; and the formation of design-centered working groups comprised of DC applicants and one or more COL applicants referencing the same design. From 2007 to the present, both the NRC and industry have developed and adopted numerous best practices and improvements, some of which are described in this report. Further licensing process enhancements were identified from feedback received, and those are presented under the areas discussed below.

Lesson 1: Quality of Applications

One of the most important factors in the success of the licensing process is the submittal of a complete and high-quality application. Many of the schedule challenges in past and ongoing reviews can be linked to application quality as a root cause. Stakeholders indicated three areas that would enhance the quality of applications: (1) pre-application engagement, (2) an enhanced acceptance review process, and (3) the availability of guidance on level of detail.

Pre-application Engagement

The NRC highly encourages pre-application interactions, particularly in areas where applicants are proposing new concepts or novel design features. Feedback indicated that these interactions are most helpful when they are focused on specific topics and detailed enough to enable a thorough understanding of the concept or design feature. This enhances the staff’s ability to identify any related technical or policy issue and develop a timely course of action.

Additionally, pre-application interactions are most effective when initiated well in advance of the expected application date. This allows the NRC adequate time to address any significant technical or policy issues and develop new regulatory tools that may be needed in advance of the application. It also allows an applicant to address staff concerns before submittal, and to prepare a complete and high-quality application.

Another component to pre-application interaction are pre-application audits. These interactions are intended to assess the applicant's readiness to submit a complete and high-quality application. Experience has shown that such audits could be more effective if the audits evaluated level of detail and if they are completed well in advance of the planned application date so that the applicant has time to incorporate any needed changes.

The NRC is incorporating these lessons learned in its current pre-application interactions. The NRC is currently engaged in comprehensive and detailed pre-application interactions in preparation for DC applications for small modular reactors. These efforts are primarily to support the development of design specific review guidance for small modular reactors that will inform content of the applications and enhance review efficiency. The staff is also engaged in detailed pre-application interactions with the Korea Hydro and Nuclear Power, in preparation for an anticipated application for certification of the APR1400 large light water reactor design in calendar year 2013.

Acceptance Review Process

The NRC conducts acceptance reviews to ensure that the application is complete and of high quality before the NRC staff begins its detailed technical review. Acceptance reviews are conducted in accordance with the guidance in Office Instruction NRO-REG-100, "Acceptance Review Process for Design Certification and Combined License Applications," (Reference 20). A robust and detailed acceptance review can identify challenging review areas early in the licensing process. This helps both staff and applicants to identify areas that warrant additional focus and resources, and supports the establishment of a predictable and stable review schedule. At the conclusion of the acceptance review, a determination is made to accept the application for docketing, or not. In some cases, the NRC determined that a new reactor application was acceptable for docketing, notwithstanding numerous deficiencies that were identified in the application that prevented the NRC from establishing a review schedule at the time of docketing. While this approach was deemed the best course of action at the time so the staff could begin to review the initial wave of COL applications, this ultimately led to significant challenges in conducting these reviews in an efficient manner and contributed to prolonged review schedules. The staff plans to adhere more strictly to acceptance review guidance for future applications to avoid these challenges in the future.

Guidance on Level of Detail

Feedback from stakeholders indicated ambiguity about the level of detail needed in order for an application to be docketed. As discussed in NRO-REG-100, the NRC staff uses Regulatory Guide 1.206 (Reference 21), which provides guidance on the standard format and content of COL applications, and the review guidance in NUREG-0800, the Standard Review Plan (Reference 22) and NUREG-1555, the Environmental Standard Review Plan (Reference 23). The information required to docket an application must be sufficient for the staff to conduct its review. Currently, the NRC staff is reviewing its acceptance review guidance in NRO-REG-100 for potential clarifications and enhancements to better differentiate what level of detail is acceptable for docketing. The staff also believes it is beneficial to update Regulatory Guide 1.206, the Standard Review Plan, and the Environmental Standard Review Plan to address ambiguity in the level of detail that the NRC considers sufficient to meet the NRC's regulations. In the interim, applicants can enhance the efficiency of a review by modeling their application to address issues at the level of detail included in previous certified designs and previous authorized ESPs and COLs.

Lesson 2: New Reactor Review Guidance

Stakeholders emphasized the importance of developing and maintaining regulatory guidance as a key factor in successful implementation of the licensing process. Some feedback indicated that the NRC should be more proactive rather than reactive in developing and issuing guidance to address emergent issues to support an effective and efficient licensing process. The staff agrees with this comment.

In fact, to support the anticipated submittal of new reactor license applications, in 2007 the NRC issued a comprehensive update to the Standard Review Plan. This was the first comprehensive update to the Standard Review Plan since 1981. In addition, in 2007 the NRC issued Regulatory Guide 1.206 to provide guidance on information to be submitted in a COL application. NRC development of Regulatory Guide 1.206 and the update to the Standard Review Plan were resource intensive and comprehensive. This interoffice effort included extensive outreach through numerous public workshops. The NRC had previously developed guidance to support the reviews of ESP applications (Reference 24). In addition, a major update to the Part 52 regulations (Reference 25) was processed at the same time. Stakeholders noted the challenges that both the NRC staff and industry faced with the development and issuance of new and revised guidance, at the same time that the first wave of COL applications was being prepared for submittal; but recognized that the communications, public interaction, and outreach during the development of the new

reactor licensing regulatory infrastructure was helpful in facilitating effective implementation of the new licensing process. Both internal and external stakeholders credited the issuance of Regulatory Guide 1.206 and the comprehensive updates to the Standard Review Plan and Part 52 in 2007 as major accomplishments that helped facilitate application submittals that were of sufficient quality and completeness to begin NRC application reviews.

Subsequent to the updates to the Standard Review Plan and Part 52 in 2007, the staff recognized the need to ensure that guidance was developed or revised in a timely manner when new technical issues arose during the reviews. To address this need, NRC issued several interim staff guidance (ISG) documents. The ISGs will be incorporated into the Standard Review Plan or Regulatory Guides, as applicable, as time and resources allow. Examples of ISGs that were issued to provide timely guidance include the following:

- DC/COL-ISG-1, Interim Staff Guidance on Seismic Issues of High Frequency Ground Motion
- DC/COL-ISG-7, Assessment of Normal and Extreme Winter Precipitation Loads on the Roofs of Seismic Category I Structures
- DC/COL-ISG-015, Post-Combined License Commitments

A complete listing of the DC/COL/ISGs may be found on the NRC's public Web page: <http://www.nrc.gov/reading-rm/doc-collections/isg/col-app-design-cert.html>.

For digital instrumentation and control systems, the staff also developed and issued several ISG documents to provide additional guidance on new issues associated with application of digital technology in new reactor design. Examples of ISGs applicable for new reactors include the following:

- DI&C-ISG-02, Diversity and Defense-in-depth Issues
- DI&C-ISG-04, Highly-Integrated Control Rooms – Communications Issues
- DI&C-ISG-05, Highly-Integrated Control Rooms – Human Factors Issues

DI&C-ISG-02 has already been incorporated into Revision 6 of Standard Review Plan Branch Technical Position 7-19, and other ISGs are to be incorporated into the formal staff guidance. These digital instrumentation and control ISGs are listed on the NRC's public

Web page: <http://www.nrc.gov/reading-rm/doc-collections/isg/digital-instrumentation-ctrl.html>.

The staff also recognized that a process was needed to address new regulatory requirements that arose during reviews. The most significant examples encountered during the licensing process were the new requirements put in place following the accident at Fukushima. In SECY-12-0069, "Process for Addressing Late-Breaking Issues during a Combined License Application Review," dated May 4, 2012, the staff proposed a process to address post-Fukushima requirements and other "late-breaking" issues at various stages during the COL review process. In its Staff Requirements Memorandum, the Commission approved the staff's proposed approach and stated that the staff should strive to raise new issues before the completion of the mandatory hearing in order to afford applicants and other potential interested parties the greatest opportunity to provide comment.

It should be noted that applicants are required to meet all applicable regulations in effect at the time of DC, and at the time of issuance of the license or permit for COLs and ESPs. Therefore, it is prudent for the staff and applicants to be forward-thinking and proactive in addressing emerging technical and regulatory issues as they arise during the review process to avoid or mitigate schedule impacts. For example, new regulatory guidance and generic communications should be promptly evaluated by the NRC staff to ensure that when new guidance is being created to address new requirements, the guidance is clear about how it pertains specifically to new reactor applications.

Going forward, the staff continues its commitment to a continuous, on-going effort to update guidance. For example, several Standard Review Plan sections have been updated since 2007, including the following:

- Standard Review Plan 2.5.4, Stability of Subsurface Materials and Foundations, Revision 4, May 2010
- Branch Technical Position 7-19, Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems, Revision 6, July 2012
- Standard Review Plan 13.6.6, Cyber Security Plan, Revision 0, November 2010 (Initial issuance)
- Standard Review Plan 13.6.1, Physical Security – Combined License and Operating Reactors, Revision 1, October 2010

- Standard Review Plan 13.6.2, Physical Security – Design Certification, Revision 1, October 2010

The current version of all Standard Review Plan Sections may be found on the NRC’s public Web page: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/>.

The NRC staff is in the process of revising a significant number of Standard Review Plan sections to incorporate lessons learned from completed licensing reviews and to reflect guidance for the new regulatory requirements. The staff is focusing its guidance development efforts on review areas in which a significant number of complex requests for additional information (RAIs) have been needed, review areas that are typically a critical path on the review schedule, and areas that have needed more staff resources than anticipated.

As one example, the areas of seismic analysis and structural (addressed in Standard Review Plan Sections 3.7 and 3.8) have proven to be challenging reviews. During the reviews of recent DC and COL applications, the NRC staff identified a number of significant issues related to seismic analysis and structural design that required the applicants to submit additional information. These reviews also tended to be resource intensive and a critical path on the review schedule. The lessons learned from these reviews were used to identify 11 key technical areas related to seismic analysis and structural designs in which the NRC staff guidance in Standard Review Plan Sections 3.7 and 3.8 could be improved to facilitate a more effective and efficient review process for future applications. The enhanced review guidance is intended to clarify the technical issues and staff expectations, and ensure a more uniform review process. The draft revision to seismic and structural review guidance was published for use and comment in February 2013 (Reference 26).

In addition, Standard Review Plan sections in several other technical areas also have been revised to incorporate lessons learned and were recently issued for public comment, including Standard Review Plan Chapter 12, “Radiation Protection” and Standard Review Plan Section 19.0, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors.” New Standard Review Plan Section 19.3, “Regulatory Treatment of Non-Safety Systems for Passive Advanced Light Water Reactors,” was issued to incorporate lessons learned from the review of the Economic Simplified Boiling-Water Reactor and AP 1000 advanced passive reactor designs to support future reviews of small modular reactor designs incorporating passive features. New Standard Review Plan Section 19.5, “Adequacy of Design Features and Functional Capabilities Identified and Described for Withstanding Aircraft Impacts,” was issued to provide review guidance to address the requirements of 10 CFR 50.150, “Aircraft Impact Assessment,” and to reflect staff

experience with completed reviews. Further, a significant number of additional Standard Review Plan sections are scheduled to be issued this calendar year, including Standard Review Plan Sections 2.5.1 through 2.5.5, regarding site seismology and geology; Standard Review Plan Chapter 11, “Radioactive Waste Management;” Standard Review Plan Section 14.3, “Inspections, Tests, Analyses, and Acceptance Criteria;” Standard Review Plan Chapter 18, “Human Factors Engineering;” and new Standard Review Plan Section 19.4, “Loss of Large Area due to Explosions and Fire;” addressing the requirements of 10 CFR 50.54 (h)(h)(2). The NRC plans to continue to develop Standard Review Plan updates to support future applications reviews, including the APR1400 and small modular reactor designs, consistent with budgeted resources.

As a significant new initiative, the NRC has embarked on an effort to incorporate design-specific risk insights and lessons learned from the reviews of large light water reactors and apply these to future reviews of small modular reactors to make them more effective and efficient. To implement these insights and lessons learned, the NRC is developing design specific review standards for staff review of two anticipated small modular reactor DC applications². These review standards will incorporate the lessons learned from staff reviews of both active and passive plant designs and provide greater focus on structures, systems, and components that perform significant functions important to minimizing the accident risk and ensuring plant safety.

For example, in Chapter 7 of the mPower design specific review standard (Reference 27), the NRC incorporated key lessons learned with completed and ongoing reviews of digital instrumentation and control systems. All of the new reactor designs, such as AP1000, U.S. Evolutionary Power Reactor, Economic Simplified Boiling-Water Reactor, and the U.S. Advanced Pressurized-Water Reactor, contain highly-integrated and complex digital instrumentation and control systems and present issues that are not relevant to analog systems. The staff’s licensing reviews to determine the safety of these digital instrumentation and control systems have been resource-intensive and challenging. These reviews have often been on or near a critical path for each of the projects. To address the significant lessons learned from these reviews, the staff undertook an innovative, integrated approach to develop design specific review standards that will allow future review to be more effective and efficient. This integrated approach contributes to the

² The NRC is currently in pre-application discussions with Generation mPower, LLC on their mPower™ small modular reactor design and NuScale Power on their small modular reactor design. The NRC plans to issue design specific review standards for each these small modular reactor designs prior to expected submittal date of the DC applications.

efficiency of the staff reviews by facilitating the timely identification and resolution of the key safety issues involving digital instrumentation and control systems, and enhances the safety focus of the reviews by emphasizing the safety-significant aspects of the design. As one example, in the challenging area of communication independence, the guidance provides greater clarity with respect to the review steps and acceptance criteria. These modifications are intended to discourage unnecessary complexity by encouraging simpler designs with less interdivisional communications. Another example is that the guidance is restructured so that fundamental design principles for instrumentation and control design (e.g., redundancy, independence, and diversity and defense-in-depth), are explicitly discussed to focus the staff's review. As experience is gained with using this new guidance, the NRC staff plans to apply the guidance more broadly to other new reactor application reviews.

As discussed above, the NRC staff has made good progress on updating the Standard Review Plan. Feedback from stakeholders indicates that the NRC should also update Regulatory Guide 1.206 to be consistent with the updated Standard Review Plan information and to incorporate the review experience. The staff agrees this would be beneficial and will also consider the insights from RAIs issued and RAI responses to inform the update. Such an update could help reduce the number of future RAIs. The staff plans to proceed with an update to Regulatory Guide 1.206, consistent with budgeted resources.

With regard to environmental reviews, there are a number of initiatives that are being considered or underway to update and enhance guidance. For example, the NRC plans to issue two environmental ISGs in calendar year 2013, one to clarify the guidance in the Environmental Standard Review Plan to incorporate lessons learned from completed reviews, and another to clarify the guidance as applied to environmental reviews for licensing applications for small modular reactors. While portions of the Environmental Standard Review Plan were updated in 2007, many sections have not been updated since 2000. Consequently, a full update is needed to incorporate changes in review methods and numerous lessons learned over the past several years. Progress in updating the Environmental Standard Review Plan has been limited due to competing priorities and resource availability.

The NRC also plans to update regulatory guides associated with the environmental reviews to incorporate lessons learned, specifically Regulatory Guide 4.2, "Preparation of Environmental Reports for Nuclear Power Stations," which provides format and content guidance for environmental reports, and Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations," which provides specific technical guidance for determining the suitability of sites for the construction and operation of nuclear power

stations. The NRC plans to proceed with environmental review guidance updates, consistent with budgeted resources.

In addition to NRC's review guidance, the interactions between NRC and the other agencies with a role in the overall regulatory process could be enhanced. There are numerous other Federal and State regulatory agencies from which a COL or ESP applicant must receive regulatory approval, in addition to the requested NRC license or permit. Experience with the environmental review process has shown that applicants should resolve issues with other Federal and State permitting agencies early in the project development process, so that an issue with another regulatory agency does not cause a delay in the NRC's review. For example, for sites where building the facility may involve impacts to wetlands that require a permit from the U.S. Army Corps of Engineers (USACE), the USACE may require an applicant to demonstrate that its proposal is the Least Environmentally Damaging Practicable Alternative (LEDPA). Applicants should ideally consider the USACE's LEDPA requirements concurrent with preparing their environmental report as part of a COL or ESP application. Doing so will help ensure that an applicant's assessment of potential environmental impacts will meet both NRC and USACE requirements. In light of these concerns, the NRC has worked with industry and other Federal and State agencies to develop guidance for potential applicants. As a result of these interactions, the industry has developed NEI 10-07, Revision 1 (Reference 28) to provide guidance to industry. The staff held two public meetings with other Federal and State agencies to help inform the guidance. The agencies involved included the U.S. Environmental Protection Agency, USACE, U.S. Fish and Wildlife Services, Bureau of Land Reclamation, Advisory Council on Historic Preservation, and the Commonwealth of Virginia.

Lesson 3: Standardization

The DC process is designed to reduce licensing uncertainty by resolving design issues early in the licensing process and to facilitate standardization of future plants. To execute an effective and efficient review of multiple license applications referencing the same certified design, the NRC developed an implementation strategy that leveraged design standardization consistent with Commission policy. This implementation strategy is called the design-centered review approach and is based on a concept of industry standardization of COL applications referencing the same standard design. This approach uses, to the maximum extent practical, a "one issue, one review, one position–multiple applications" strategy. That is, for any given technical, policy, or regulatory issue, the NRC will review that issue one time and develop a single position. That position can then be applied across all COL applications within a design center, as applicable, without requiring further review by the NRC staff.

Standardization of COL information through the implementation of the design-centered review approach was a major factor that made implementation of Part 52 possible when regulations, guidance, and processes were under development. This approach also added efficiency to the licensing process. Stakeholders frequently cited this practice as particularly effective and regarded it as instrumental in the success of COL reviews.

Stakeholders further indicated that the design-centered working groups that were established to support the design-centered review approach were effective in communicating and identifying issues early and resolving them within the established review schedule. Stakeholders mutually agreed on the effectiveness of the design-centered working groups and regarded it as a major factor in the success of the licensing process, so much so that it was suggested that the concept be a mandatory element of the licensing process. Also, because of its efficiency and prominent role in issue resolution, the design-centered working group concept can be expanded to address common technical issues to ensure consistency across different design centers. The staff agrees and continues to encourage the application of the design-centered review approach to certification and licensing reviews.

One difficulty the staff encountered was the number of requests for substantial design changes initiated by DC and COL applicants during the application review process. In these cases, the NRC staff has to re-review portions of the DC application, thus causing schedule delays and reducing review efficiency. Feedback also indicated that changes to the site-specific content in COL and ESP applications during ongoing application reviews can result in schedule delays and inefficiencies.

Stakeholders commonly recognized that a “freeze point” in the design proposed in the DC, COL, or ESP application needs to be established, such that the NRC staff can perform its review efficiently and on a predictable schedule. Ideally, the design would be frozen before submittal to the NRC for review. Recognizing that this is not always achievable, minimizing changes after submittal of an application substantially increases the effectiveness and efficiency of the review. To provide guidance in this area, ISG-11, “Finalizing Licensing-Basis Information,” (Reference 29) outlines a differentiation between the types of changes that must be made before certification or licensing and the types of changes that could be deferred until after certification or licensing. Feedback indicated that ISG-11 guidance could be further clarified. The NRC plans to evaluate the implementation of ISG-11 and determine if additional guidance is warranted.

Lesson 4: Identification and Resolution of Technical Issues

When the staff receives a DC, ESP, or COL application, an acceptance review is conducted to determine if the application is sufficiently complete for the staff to begin its review. If the application is accepted, a baseline review schedule is developed. That schedule is predicated on general expectations for the complexity of the review and on anticipated time for the applicant to respond to RAIs from the staff.

Experience with the reviews that have been conducted shows that the staff identifies issues of varying complexity; some are simple clarifications, while others raise specific and detailed issues. Applicant responses to RAIs on simple to moderately complex issues generally are provided in the 30-day response time the staff anticipated in developing the review schedule. However, some of the complex issues, and resulting complex RAIs, may require detailed analysis or testing to resolve and have led to changes in the design. The time needed for an applicant to address complex issues and RAIs can significantly exceed the anticipated 30-day response time, which adversely affected the overall schedule for some reviews.

The staff and industry have developed and applied best practices to address complex RAIs, and thereby minimize adverse schedule impacts. For example, the staff may issue draft RAIs before the final RAIs are issued to ensure a common understanding of the additional information being requested and the reason. The NRC staff may also hold public meetings with the applicant to discuss, in depth, difficult technical issues in an effort to resolve them in a timely manner. Stakeholders indicated another best practice the NRC uses to ensure that the staff understands the documentation supporting the application, which can facilitate the staff's review of complex issues, is the conduct of audits. Despite the preceding actions, resolution of complex issues and the associated RAIs still presents significant challenges. These challenges are often exacerbated when multiple rounds of RAIs and responses result in little progress toward resolution. One lesson learned from the RAI and issue resolution experience is that both the staff and applicant need to identify issues as early as possible and elevate them expeditiously, openly, and candidly so that the root cause of the disagreement can be identified and addressed. When applicant response to an RAI does not lead to resolution, NRC division management will hold a meeting with the applicant to help bring closure or mutual agreement to the issue. The NRC staff plans to update its internal guidance to more quickly identify these complex issues, and engage higher levels of NRC and applicant management to resolve these disagreements and to bring about timely resolution.

Another aspect of technical issue resolution identified in industry feedback was the level of detail the NRC staff requested to reach its safety conclusions. The feedback indicated that in some cases, the industry felt that the NRC staff requested applicants to provide more information than was necessary to support the safety finding. Thus, there is the potential for more information to be included in the licensing basis (e.g. in the design control document or final safety analysis report) than is required to support the staff's safety findings. A concern was expressed that the level of detail in the AP1000 design control document may necessitate changes to the licensing basis as the detailed design is completed and construction proceeds for the COLs. According to these industry commenters, determining the appropriate balance between the level of detail required for the NRC to reach safety conclusions (to allow design certification or license issuance and to achieve the finality and standardization contemplated by Part 52) and the flexibility to make changes during construction continues to be a challenge. Recent experience with the construction of the AP1000 reactor at the Vogtle and Summer sites indicate there is some merit to this comment. Such an example is the identification of a specific weld configuration to connect components of the steel-concrete composite modules. The relevant characteristic of the weld in this condition is the capacity, which would be achieved by selecting a weld type. Several weld configurations could be documented in the field. The issue of necessary level of detail will be considered during the NRC staff's guidance development efforts, particularly with respect to updating Regulatory Guide 1.206, discussed above in Lesson 2. In addition, the staff will incorporate post-COL implementation enhancements that are identified as part of the staff's ongoing self-assessment, into a proposed rulemaking activity as appropriate.

The staff believes that the primary issues causing schedule and resource problems have been due to application quality, completeness and level of detail, and technical issue resolution, and are not specifically due to Part 52 license process issues. Complex technical issues and evolving-technology issues (e.g., seismic, structural, and digital instrumentation and control) are being addressed under separate initiatives, such as the Standard Review Plan updates described under Lesson 2.

Lesson 5: Knowledge Management

The NRC established the design-centered review approach to make the reviews of COL applications that reference the same standard design more efficient and effective. One result of design-centered review approach implementation is the standardization of common COL information. This approach leads to efficiency in reviews.

In the past, there were instances where the staff issued RAIs that were duplicative or not relevant to a specific design center, and so proved unnecessary for the particular recipient. This required expenditure of unnecessary resources but did not result in appreciable schedule impacts. A process to ensure consistency across design centers and, more importantly, maintain project knowledge for future applications would be beneficial. In 2007 the staff developed an RAI management system in anticipation of the large number of applications expected. This system is also a database that has searching and reporting capabilities that allow reviewers to see prior questions that have been asked on the same section of the regulation. While the current system has some search capability, it is limited, and the NRC is exploring upgrades to the system to improve this feature.

The NRC's RAI system was recently upgraded to add features to assist with project knowledge management, including enhanced capabilities to monitor and track the status of RAIs. From the initiation of an RAI through its closure, there can be significant interaction between the NRC staff and applicant. It is essential for the staff and the applicant to have accurate and timely information regarding RAI status to facilitate timely resolution. The NRC recognized this as an area in need of improvement and recently formed an internal working group to examine how the NRC staff ensures RAIs are tracked consistently across design centers and that timely information about RAIs is communicated to applicants and management.

Feedback also indicated that the NRC's RAI system was not being used for environmental reviews to capture and track environmental RAIs. Recently, the NRC adopted the RAI process for environmental reviews, including the Levy and Bell Bend COL applications, and plans to follow this practice for future reviews.

The broader subject of knowledge management has been recognized to be a continuing challenge. This is particularly true in highly specialized technical areas where a limited set of experts are available within and outside the agency. For example, the NRC has a limited number of reviewers for seismic margins assessments, as supplemented by contractor support. This can contribute to delays in resolving difficult technical issues. The NRC is evaluating this and other key review areas, where it would be prudent to develop more staff expertise in order to support parallel application reviews. The NRC is also taking actions to transfer knowledge from senior staff before they leave the agency. As an example, the NRC has conducted several knowledge management seminars with senior environmental review staff. It is important that such actions be considered by the industry as well to address limited technical resources.

Lesson 6: Application Timing and Sequencing

Concurrent DC and COL Reviews

To maximize the benefits of standardization and issue finality available under Part 52, a COL application should reference a certified design. However, most COL applicants have submitted applications referencing DC applications or DC amendment applications that are still under NRC review. Feedback indicated both benefits and challenges to this approach. It maximizes the ability to address issues generically in the DC thus enhancing design standardization and minimizing subsequent departures during COL reviews. However, feedback indicated that difficulties can arise if the first application referencing a particular design is submitted too quickly after the DC application is submitted. Subsequent changes to the standard design resulting from the review have required the COL applicant to supplement its COL application to a greater degree than the applicant expected during the review process, resulting in schedule impacts and increased costs. In summary, the Part 52 licensing process allows for concurrent reviews. While this may incur some inefficiencies, there may be situations where the benefits outweigh the challenges.

Commencement of Design Certification Rulemaking

Experience with DC rulemakings, such as the originally certified AP1000, indicated that some schedule efficiencies could be gained in the rulemaking process. To address this, the DC rulemaking process was streamlined in 2009 to reduce the nominal 24-month rulemaking process to 12.5 months and to initiate the rulemaking earlier in the review process (Reference 30). This shorter duration and earlier start were based on a number of assumptions, including that all design issues would be resolved and no design changes would be initiated after the rulemaking process is started.

More recent experience has indicated that initiating the rulemaking process too early in the DC review can result in rework and schedule delays. For example, in an attempt to gain further schedule efficiencies, the rulemaking process for the AP1000 DC amendment began when some significant open items remained. There also were a number of “confirmatory items” for which final resolution had not been completed. Following publication of the proposed rule, the staff concluded that these items required evaluation beyond simple confirmation. In addition, the applicant submitted analysis changes that required additional review. The need for additional staff evaluation of such issues added to the complexity of moving from the proposed to final rules.

While other application-specific factors such as the unusually high volume of public comments also contributed to delays in the schedule, the AP1000 amendment rulemaking took 17 months to complete. This was, in part, due to ongoing review of design changes and associated RAI resolution, some of which were due to errors identified by the applicant after publication of the proposed rule for public comment. The staff continues to believe that completion of a final rule is possible in 12.5 months if all assumptions for the streamlined process are adhered to, including ensuring that all design issues have been resolved before the rulemaking begins. Accordingly, the NRC has scheduled future DC rulemakings in accordance with this approach.

Lesson 7: Updates to Regulations

The NRC updated Part 52 in 2007 to incorporate enhancements that were the result of lessons learned during DC and ESP reviews and stakeholder discussions about the ESP, DC, and COL review processes. For example, one key change included in the 2007 rulemaking was to include a DC amendment process. This process was provided to enhance standardization by further completing or correcting the certification information. This process allows an amendment to the DC notwithstanding otherwise applicable backfitting standards if, for example, the amendment (1) reduces unnecessary regulatory burden and maintains protection to public health and safety and common defense and security; (2) provides the detailed design information necessary to resolve selected design acceptance criteria; (3) corrects material errors in the certification information; (4) substantially increases overall safety, reliability, or security of a facility, and the costs of the change are justified in view of that increase; or (5) contributes to increased standardization of the certification information.

During this same timeframe, the NRC also redefined construction by amending its regulations applicable to limited work authorizations (LWAs) (Reference 31) to clarify that certain activities associated with site development for production and utilization facilities are not defined as “construction” and therefore do not require NRC authorization, so they may commence before a construction permit or COL is issued. As a result of Commission direction that nuclear power plant designers take into account the potential effects of the impact of a large, commercial aircraft, the NRC issued regulations on aircraft impacts in 2009 (Reference 32).

Since the issuance of the 2007 Part 52 rule update, NRC staff has been gathering corrections, clarifications, and other potential enhancements to the regulations in Part 52 and associated requirements. This effort was further informed by stakeholder feedback

obtained as part of this lessons learned effort. Examples of possible enhancements to regulations include:

- Consider adding a process to allow changes in the information contained in an LWA. A process similar to that provided in 10 CFR 50.59, “Changes, Tests, and Experiments,” for changes not requiring prior NRC approval and 10 CFR 50.90, “Application for Amendment of License, Construction Permit, or Early Site Permit,” for license amendments is envisioned.
- Consider a change to the 10 CFR Part 73, “Physical Protection of Plants and Materials,” requirements, particularly as they apply to holders of a COL. The 2009 revision to 10 CFR Part 73 (i.e., 10 CFR 73.55(b)(4)) requires operating reactor security programs be implemented before receiving unirradiated fuel within the protected area. For a COL holder, this may impose an unnecessary burden because the possession and storage of unirradiated fuel is no different in radiological hazards or risks from a license issued under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material.” Therefore, the staff would revise Part 73 (3) to better align Part 52 licensing requirements to those in Part 50 which currently requires a holder of a construction permit to meet the 10 CFR Part 70 requirements for receipt of fuel on site and the Part 73 requirements for protecting a nuclear power reactor are implemented prior to receiving the operating license (i.e., just prior to irradiating fuel).

In addition, the staff will incorporate post-COL implementation enhancements that are identified as part of the staff’s ongoing self-assessment, into a proposed rulemaking activity as appropriate.

Lastly, the staff is preparing a notation-vote paper for Commission consideration of potential policy options relating to the NRC’s requirements and process for evaluating the financial qualifications for merchant plant COL applicants. Industry representatives have asserted that it is difficult, if not impossible, for merchant plant COL applicants to secure project funding to meet the financial qualifications requirements in advance of initial license issuance. The staff will describe various licensing approaches and discuss the benefits and challenges of those approaches for addressing financial qualifications for merchant plant COL applicants.

The staff plans to communicate appropriate regulatory enhancements to the Commission along with a proposed rulemaking plan to obtain Commission approval to move forward with an update to Part 52 and associated regulations. The staff recognizes that the time

required to complete rulemaking would not support having a final rule in place in time to support development of future Part 52 applications including the anticipated small modular reactor and APR1400 applications. However, engaging the public and interested stakeholders in dialogue regarding these potential enhancements and moving forward with potential rulemaking are important steps in making the new reactor licensing process more effective and efficient. Further, through early interactions with stakeholders during the regulatory basis development, future applicants will be fully informed of any potential regulatory changes.

IV. PATH FORWARD AND SUMMARY

Although DC and COL reviews have taken longer and have been more technically challenging than anticipated, the results of this lessons learned review revealed no significant problems or impediments associated with the Part 52 licensing process itself. The first-time implementation of the licensing process has resulted in challenges, as expected with any new process. Feedback indicated that many lessons have already been learned and applied, and best practices implemented. This lessons learned effort identified further enhancements that could be taken to address remaining challenges; these actions are listed below. The staff intends to assess the resource needs of the suggested actions and will address these needs through the Planning, Budgeting and Performance Management process.

1. Quality of Applications

- The NRC staff plans to review its acceptance review guidance to identify areas in need of enhancement.
- The NRC staff plans to adhere more strictly to acceptance review criteria for future applications.
- The NRC staff plans to engage future applicants with regards to the best timing for pre-application audits. The audits will evaluate the level of detail of the application to ensure consistency with lessons-learned in reviews since 2006.

2. New Reactor Review Guidance

- The NRC staff plans to update Regulatory Guide 1.206, “Combined License Applications for Nuclear Power Plants (LWR Edition),” consistent with budgeted resources.
- The NRC staff will consider establishing a process for synchronizing updates to Regulatory Guide 1.206 with updates to the Standard Review Plan. The NRC staff will consider reorganizing Regulatory Guide 1.206 to be more consistent with the organization of the Standard Review Plan. The NRC staff will also incorporate review experience by considering the results of commonly asked RAIs and their respective responses when Regulatory Guide 1.206 is updated.
- The NRC staff plans to continue its systematic Standard Review Plan update, consistent with budgeted resources, in a timely manner to support COL, DC, ESP, and limited work authorization application reviews.
- The NRC staff plans to proceed with environmental review guidance updates, consistent with budgeted resources.

3. Standardization

- The NRC staff plans to review ISG-11, “Finalizing Licensing-Basis Information,” to identify areas in need of enhancement.
- The NRC staff plans to work with industry to expand the design-centered working group role to address common technical issues to ensure consistency across different design centers.

4. Identification and Resolution of Technical Issues

- The NRC staff plans to update its staff guidance to ensure consistent use of best practices that facilitate timely resolution of complex technical issues and to more quickly engage higher levels of NRC and applicant management, when necessary, to resolve complex technical issues.
- The NRC staff plans to continue to engage stakeholders, including vendors, standards organizations, and other regulatory bodies on complex and evolving technologies to enhance safety while streamlining the review process.

5. Knowledge Management

- The NRC staff plans to enhance its RAI management system to improve search capability, consistent with budgeted resources.
- The NRC staff plans to continue to examine its RAI process to ensure that RAIs are tracked consistently across design centers and information is communicated to applicants and management in a timely fashion.

6. Application Timing and Sequencing

- The NRC staff plans to apply the rulemaking process for future design certifications consistent with the 2009 streamlined approach, in which all design issues have been resolved before rulemaking begins.

7. Updates to Regulations

- Although this lessons learned effort did not identify any significant problems or impediments with the Part 52 licensing process, it has identified areas that could be enhanced. In fact, the staff has been identifying and collecting ideas for improvements since the 2007 Part 52 update. The NRC staff plans to communicate potential regulatory enhancements to the Commission along with a proposed rulemaking plan to obtain Commission approval to move forward with an update to Part 52 and associated regulations.

In addition to the Part 52 process, the staff has identified technical topics that will be the subject of continuing attention. Issues of high technical complexity (e.g., seismic and structural issues), evolving technologies (e.g., digital I&C applications), and policy matters (e.g., financial qualifications) are among those that warrant the focus of NRC, applicants, and other external organizations to achieve desired improvements in Part 52 implementation.

One area that would require only minimal resources, but have the potential for substantial benefits to the licensing process, is a continued commitment by all parties to communicate more effectively. Even in the most challenging of circumstances, issues were most efficiently resolved when the NRC staff and applicants engaged in open, transparent, and timely communications. Effective communications, more than any other action, has led to successful implementation of the Part 52 licensing process.

Appendix A—New Reactor Licensing Process

Early Site Permit

An early site permit (ESP) approves a site for one or more nuclear power facilities separate from the filing of an application for a construction permit or combined license (COL), providing early resolution and finality for siting issues. ESP requirements are contained in Subpart A, “Early Site Permits,” to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “License, Certifications, and Approvals for Nuclear Power Plants.” In reviewing an ESP application, the staff addresses site-safety issues, environmental issues, and plans for coping with emergencies, independent of the specific nuclear plant design review. ESPs are valid for 10 to 20 years and can be renewed for an additional 10 to 20 years. The NRC staff has issued ESPs for the Clinton, Grand Gulf, Vogtle, and North Anna sites. One ESP application is under NRC review for the Salem/Hope Creek site.

Limited Work Authorization

A limited work authorization (LWA) is a part of the licensing process that provides Commission approval to perform a limited and defined set of construction activities on production and utilization facilities before a COL or construction permit (CP) for the facility is issued. The LWA rule is not specific to 10 CFR Part 52; the applicable definitions and safety provisions are contained in 10 CFR 50.10, “License Required: Limited Work Authorization,” which includes provisions for new reactor license applicants. An LWA application may be submitted in conjunction with an ESP or COL application (or a CP application under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”), or in advance of the CP or COL application under 10 CFR 50.10(d)(2). Those applications address the proposed LWA scope of work. Per 10 CFR Part 51, an LWA is a major Federal action that requires the staff to prepare an environmental impact statement. The interim staff guidance document COL/ESP-ISG-004, “Interim Staff Guidance on the Definition of Construction and on Limited Work Authorizations,” dated February 23, 2009, provides guidance related to LWAs including the definition of construction, preconstruction activities, and those activities that require prior NRC approval. LWAs under the current rule have been granted for Vogtle Units 3 and 4.

Design Certification

The design certification (DC) process allows an applicant to obtain Commission approval of a design through rulemaking. For COL applicants, referencing a certified design reduces licensing uncertainty by resolving design issues generically, outside the scope of the COL review. It also facilitates standardization of future plants. The requirements for DCs are contained in Subpart B, “Standard Design Certifications,” of 10 CFR Part 52. The review of a

standard design is focused on ensuring that the design is safe as a result of compliance with the Commission's regulations. The DC review does not address site-specific design features, operational programs, and environmental impacts of building the design at a particular site. The process for a DC concludes with a rulemaking. Once issued, a DC is valid for 15 years. The Commission recently certified the amended AP1000 and advanced boiling-water reactor designs. The Commission previously certified the System 80+ and AP600 designs. The Economic Simplified Boiling-Water Reactor, U.S. Evolutionary Power Reactor and U.S. Advanced Pressurized-Water Reactor DC applications currently are under NRC review.

Combined License

A combined license (COL) is a combined construction permit and conditional operating license. The requirements for a COL are contained in Subpart C, "Combined Licenses," of 10 CFR Part 52. It authorizes both construction and operation of a new nuclear power facility. A COL application can reference an ESP, a certified design, both, or neither, as long as it addresses all applicable requirements and provides sufficient information for the review. Per 10 CFR Part 51, issuance of a COL is a major Federal action that requires the staff to prepare an environmental impact statement. To date, four COLs have been issued for Vogtle, Units 2 and 3, and V.C. Summer, Units 3 and 4. Several additional COL applications currently are under NRC review.

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