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STAFF REPORT:
10 CFR PART 52 APPLICATION REVIEWS—EFFICIENCY OPPORTUNITIES AND REVIEW TIMELINES

EXECUTIVE SUMMARY

In a staff requirements memorandum dated September 16, 2014,[1] the U.S. Nuclear Regulatory Commission (NRC) staff was directed by the Commission to continue the practice of conducting lessons learned reviews of the experience implementing Title 10 of the *Code of Federal Regulations* Part 52 (Part 52), "Licenses, Certifications, and Approvals for Nuclear Power Plants." In particular, the staff was directed to address whether the NRC could capture greater efficiencies in the Part 52 review process and whether the NRC should update the estimates for the length of time it will take to perform new reactor reviews under Part 52, based on experience.

Recognizing that there are several types of applications in Part 52, the staff chose to focus its studies on its experiences in reviewing standard design certifications (DCs) because DC applications may often include first-of-a-kind approaches that may introduce technical and policy challenges to the review process. Therefore, DC reviews are likely to result in more lessons learned and afford more opportunities to capture additional efficiency gains in a variety of supporting processes. The staff also considered recommendations and implementation impacts from the April 2013 Part 52 Lessons Learned Review.[2]

The staff has determined that the Part 52 DC review process is sound and allows for an efficient review, as long as an applicant submits a high-quality, technically sufficient application, commits to providing the resources necessary to support the staff's review, and addresses key policy and technical issues during preapplication discussions with the staff. Additionally, the staff has made considerable efforts to implement the lessons learned from previous reviews and to implement other new changes to improve review efficiency. The staff will continue to monitor DC review efficiencies gained by implementation of the actions identified in this report, and will continue to look for opportunities to gain additional DC review efficiency.

In summary, the staff believes that the goal for the length of time it should take to perform new DC safety reviews for large light-water reactors (LWRs) under Part 52 has been set appropriately at 42 months. The staff will undertake efforts to communicate the review assumptions and expectations to stakeholders in a comprehensive manner.

Recognizing that some project delays are not attributable to the NRC staff, the staff intends to change the manner in which the project total project durations are calculated and communicated, to provide clearer information on the cause of schedule changes.

The staff concludes that the findings and actions discussed in this report provide a sound basis for high quality safety, security and environmental reviews which are consistent with the NRC's mission and responsive to applicant and stakeholder needs and expectations.

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[1] Staff Requirements – Briefing on Strategic Programmatic Overview of the New Reactor Business Line, September 16, 2014 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML14259A359)

[2] New Reactor Licensing Process Lessons Learned Review: 10 CFR Part 52, April 2013 (ADAMS Accession No. ML13059A239)

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INTRODUCTION

In a staff requirements memorandum (SRM) dated September 16, 2014,[3] the U.S. Nuclear Regulatory Commission (NRC) staff was directed by the Commission to continue the practice of conducting lessons learned reviews of the experience implementing Title 10 of the *Code of Federal Regulations* Part 52 (10 CFR Part 52 or "Part 52"), "Licenses, Certifications, and Approvals for Nuclear Power Plants."

In particular, the staff was directed to address: (1) whether the NRC can capture greater efficiencies in the Part 52 review process; and (2) whether the staff should update the estimates for the length of time it will take to perform new reactor reviews under Part 52, based on experience.

The staff most recently conducted lessons learned reviews of Part 52 application reviews, including combined licenses (COLs) and Standard Design Certifications (DCs) in April 2013, and identified actions for improvement. The staff has made significant progress on implementing these improvements. To address the Commission's questions in the SRM, the staff chose to supplement the 2013 information by looking more closely at its experiences in reviewing DCs. This subset of Part 52 applications was selected for review because DC applications may often include first-of-a-kind approaches that may introduce technical and policy challenges to the review process. Therefore, DC reviews are likely to result in more lessons learned and afford more opportunities to capture additional efficiency gains in a variety of supporting processes.

The report includes a brief background on the standard DC process in Part 52 and summaries of the staff's review experiences for the advanced boiling-water reactor (ABWR), System 80+, Advanced Passive (AP) 600, AP1000, AP1000 amendment, Economic Simplified Boiling-Water Reactor (ESBWR), U.S. Evolutionary Power Reactor (EPR), U.S. Advanced Pressurized-Water Reactor (US-APWR), and APR1400 designs. The staff also considered recommendations and implementation impacts from the April 2013 Part 52 Lessons Learned Review [4] in forming its conclusions and responses to the SRM.

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3 Staff Requirements Memorandum M140910 – Briefing on Strategic Programmatic Overview of the New Reactor Business Line, September 16, 2014 (Agencywide Documents Access and Management System (ADAMS Accession No. ML14259A359)

4 New Reactor Licensing Process Lessons Learned Review: 10 CFR Part 52, April 2013 (ADAMS Accession No. ML13059A239)

1.0 BACKGROUND—THE STANDARD DESIGN CERTIFICATION PROCESS

The U.S. Nuclear Regulatory Commission (NRC) issued Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," on April 18, 1989. The rule principally provides for issuance of early site permits (ESPs), DCs, and combined construction permits and operating licenses (combined licenses, or COLs) for nuclear power reactors. Other licensing actions described in Part 52 include standard design approvals (SDAs) and manufacturing licenses (MLs). The rule codified the NRC's policy statement on nuclear power plant standardization, which was intended to achieve the early resolution of licensing issues and to enhance the safety and reliability of nuclear power plants.[5, 6]

Subpart B of Part 52 describes the standard DC process. Under this process, the applicant submits a DC application, including a final safety analysis report (FSAR) that is sufficiently detailed to allow the staff to reach a final conclusion on all safety questions associated with the design before the certification is granted. By certifying a design, the NRC approves a nuclear power plant design, independent of an application to construct or operate a plant. Upon completion of its review of the DC application and through the NRC's rulemaking process, the NRC certifies a design for 15 years. The certification can be renewed[7] for an additional 10 to 15 years, with no restriction on the number of times a design can be renewed. When a COL applicant references a DC, design issues resolved during the DC review process will not require further review or hearing opportunities (the DC has "design finality").

In the 1990s, the NRC certified three designs in accordance with Subpart B, and codified each in an appendix to Part 52:

(1) Appendix A to Part 52—Design Certification Rule for the U.S. Advanced Boiling Water Reactor (ABWR), certified in May 1997 (first implementation of the licensing process requirements under 10 CFR Part 52, Subpart B)

(2) Appendix B to Part 52—Design Certification Rule for the System 80+ Design, certified in May 1997

(3) Appendix C to Part 52—Design Certification Rule for the AP600 Design, certified in December 1999

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5 Final Rule, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors" (54 FR 15372), April 18, 1989 (ADAMS Accession No. ML003711593)

6 "Nuclear Power Plant Standardization" (52 FR 34884), September 15, 1987

7 Provision added to Subpart B when Part 52 was amended (72 FR 49559), August 28, 2007

The ABWR and the System 80+ designs were considered to be "evolutionary" designs.[8] These designs featured new developments in technology and system designs as well as safety enhancements. The DC review of these first two evolutionary designs created technical and administrative challenges for both the staff and applicants with respect to the level of detail to be provided for the design, the implementation of the NRC's severe accident policy statement,[9] and in determining the appropriate format and content for inspections, tests, analyses, and acceptance criteria (ITAAC).

The AP600 was considered to be the first "advanced"[10] light-water reactor (LWR) reviewed by the NRC. The DC review included policy and technical challenges associated with passive features of the design (e.g., the regulatory treatment of non-safety systems (RTNSS), ITAAC, the initial test program, analysis code documentation, and qualification).

During the 1990s, the staff made considerable efforts to resolve technical and policy issues related to the DC reviews for both evolutionary and advanced designs under Part 52. A summary of the regulatory history of DCs is available at Agencywide Documents Access and Management System (ADAMS) Accession No. ML003761550.

In late 2000, the Commission directed the staff to assess its readiness to review applications for licenses and to inspect new nuclear power plants.[11]

In late 2001, the staff documented its assessment in the Secretary of the Commission (SECY) paper SECY-01-0188, the "Future Licensing and Inspection Readiness Assessment" [12] (also called the "FLIRA" assessment). The staff concluded that the NRC and its licensing processes in Part 52 were ready to complete the new reactor licensing activities, such as the preapplication reviews for the AP1000 and the pebble bed modular reactor (PBMR), a high temperature gas-cooled reactor. Additionally, the report provided an extensive list of recommended actions to further support and enhance the staff's readiness, with the intent that specific actions would be prioritized for implementation, as future licensing support needs were identified with additional certainty.

The FLIRA assessment also discussed the initial resource estimates for specific licensing scenarios (including preapplication reviews of four designs, the review of two ESP applications, two DC applications, and two COL applications) and the licensing of plants under Part 50 that

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8 SECY-96-077, "Certification of Two Evolutionary Designs," April 16, 1996 (ADAMS Accession No. ML003708129)

9 "Policy Statement on Severe Reactor Accidents regarding Future Designs and Existing Plants" (50 FR 32138), August 8, 1985

10 "Advanced reactors" is the term previously used for reactor designs that differed significantly from the evolutionary light-water designs, or which incorporated, to a greater extent than evolutionary light-water designs do, simplified, inherent, passive, or other innovative means to accomplish their safety functions. Today, the passive large-light reactor designs are generally grouped with other evolutionary large light-water reactors and termed simply "new reactors." See NUREG/BR-0356, "New Reactors: Striving for Enhanced Safety," November 2011 (ADAMS Accession No. ML11343A026).

11 SRM-COMJSM-00-0003, "Staff Readiness for New Nuclear Plant Construction and the Pebble Bed Reactor," February 13, 2001 (ADAMS Accession No. ML010440409)

12 SECY-01-0188, "Future Licensing and Inspection Readiness Assessment," October 12, 2001 (ADAMS Accession No. ML012350040) and supporting attachment (ADAMS Accession No. ML012140585)

have restarted construction or progress towards operation. These assessment efforts were the first step in establishing detailed schedule and resource estimates for new reactor licensing activities. Through the NRC's planning, budgeting, and performance management process, the staff continued to refine the schedule and resource estimates for each licensing scenario assessed to establish detailed resource-loaded schedules for the applications received. From 2001 through early 2007, the FLIRA assessment schedule bases and assumptions were used for DC reviews for AP1000 and (initially) for the ESBWR reviews. Section 2 of this report contains more information on schedule assumptions.

The FLIRA assessment forecasted that the DC review for the AP1000 would require significantly fewer resources than the review of the AP600 because of design commonalities between the two designs. The total duration of the AP1000 DC review (46 months) was about half the duration of the AP600 DC review (90 months). This result supported the FLIRA resource savings estimate for the review. The DC review duration for the ESBWR (109 months) was greater than the 60 months forecast by the FLIRA for the upper end of the review duration range for reasons described in Section 4 of this report.

The planning model described in the FLIRA assessment was superseded in February 2007, when the Office of New Reactors (NRO, established in late 2006) published its New Reactor Licensing Program Plan (LPP).[13] The plan outlined the use of a comprehensive planning, scheduling, and risk management framework with the associated system platform (Enterprise Project Management or "EPM" hardware and software) required for execution. The LPP included model schedule templates for DCs, ESPs, and COL applications. A set of simplifying assumptions was created and embedded in the templates that differed from the set of assumptions used in the FLIRA assessment. The specific schedule assumptions contained in the LPP are described in Section 2 of the document. The LPP became the basis for project planning within NRO, and was used for DC reviews of the AP1000 Amendment, the U.S. EPR, the US-APWR, and, later, in a modified form, for the APR1400.

NRO's LPP built upon the FLIRA assessment initial schedule assumptions and created an execution framework which defined the work, the schedule and resources required to complete the work, the processes to perform the work, and the necessary infrastructure to support the work (e.g., IT requirements for implementing the process). Part of this framework included a six-phase work sequence used as a template for COL reviews. DC review phases are similar, and the phases are described below.

[13] New Reactor Licensing Program Plan, Version 1.0, January 25, 2007 (ADAMS Accession No. ML070720406 – NONPUBLIC)

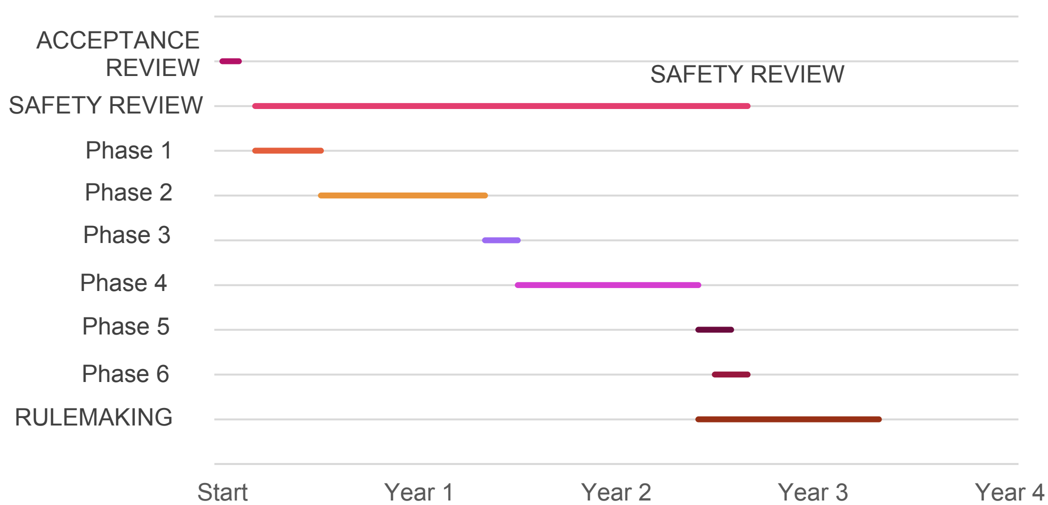
Prior to submitting a DC application for acceptance, prospective applicants typically engage the NRC staff in preapplication activities. While voluntary, this key project phase is very important to align expectations between the staff and prospective applicants. The preapplication phase is also critical to identifying and resolving key policy and technical issues prior to submittal. Resolution of these items prior to application is a key schedule assumption.

For DC reviews, an acceptance review is conducted before docketing, a safety review is performed, and rulemaking is conducted to certify the design after all safety issues have been resolved. The phases of the staff's safety review are as follows:

- Phase 1—Preliminary safety evaluation report (SER) and preparation of requests for additional information (RAIs)
- Phase 2—SER with Open Items (OIs)
- Phase 3—Advisory Committee on Reactor Safeguards (ACRS) review of SER with OIs
- Phase 4—Advance SER with no OIs
- Phase 5—ACRS review of Advance SER
- Phase 6—Final SER with no OIs

This review structure was originally illustrated in LPP Exhibit 3-4: "Gantt Chart of Major Scope Areas of a DC." The following diagram reflects the activities, durations, and phase sequences shown in the LPP, with one modification noted below for rulemaking activities.

LPP Design Certification Review Process *



* Durations and phase overlaps are for illustrative purposes only and are subject to change.

The rulemaking activity sequence shown above has been modified from the original LPP sequencing. In 2009, a business process Lean Six Sigma (LSS) review for rulemaking activities related to DC reviews was conducted.[14] The staff identified the rulemaking duration rule of thumb used by the NRC as 12 months for a proposed rule and 12 months for a final rule (24 months total). As a result of process improvements identified and implemented by the LSS team and NRO, the schedule assumption basis for DC rulemaking was revised from 19.5 months (used in SECY-09-0018 as a best estimate) to 12.5 months. SECY-09-0018 assumed that rulemaking activities could begin before the completion of the last phase of the safety review, after all safety issues have been resolved (at the end of Phase 4). Rulemaking, using the optimized process, would be completed in 7.5 months after completion of Phase 6, as depicted in the graph above.

[14] SECY-09-0018, “Streamlining Design Certification Rulemakings,” January 30, 2009 (ADAMS Accession No. ML082750046)

2.0 EVOLUTION OF SCHEDULING ASSUMPTIONS USED FOR DESIGN CERTIFICATION REVIEWS

In the SRM for this topic, the Commission asked whether the staff should update the estimates for the length of time it will take to perform new reactor reviews under Part 52, based on experience. For example, schedules may be constructed using ranges of durations and resource levels to account for uncertainties in advance, or an idealized ("best case") model may be constructed as a template, with the intent of being customized later for each project. Regardless of the chosen approach, the key assumptions underpinning the schedule should be realistic and should evolve consistent with review progress and accumulated experience.

Early (pre-2001) DC reviews for the ABWR, System 80+, and AP600 designs prior to 2001 were conducted using schedule assumptions that were custom-developed.[15] These assumptions evolved with each successive DC review and certification and were described in the FLIRA assessment, then later in the LPP and the APR1400 review schedules, as described below.

<u>FLIRA Assessment (SECY-01-0188) Schedule Assumptions</u>

After October 2001, the staff derived its schedule assumptions for certifying a design under Part 52 primarily from SECY-01-0188. The levels of effort expended to certify the ABWR, System 80+, and AP600 designs prior to 2001 were used to estimate the duration and resources required for certifying other designs under Part 52. In that paper, the staff estimated that the review of a DC application would nominally take 42–60 months from submittal to the completion of rulemaking and granting of the certification, depending on the uniqueness of the design, whether there was a need for vendor testing and the extent of the testing program, and whether policy matters needed to be addressed.

The relevant DC application schedule assumptions described in SECY-01-0188 are as follows:

- Applications will be complete, high-quality submittals supported by sufficient research and development (where necessary), and any followup submittals will provide sufficient information to address the staff's concerns.

- All required testing and code development will be completed by the applicant in time to support the application.

- Preapplication reviews will have been successfully completed with no remaining open policy or technical issues, or only a limited number of issues remain with a clear path to resolution identified to support future licensing activities. The support of vendors and preapplicants in accomplishing this milestone is implicit in this assumption.

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[15] For an example, see SECY-97-051, "Schedule for Staff's Review of the AP600 Design Certification Application," February 26, 1997 (ADAMS Accession No. ML992920131).

- A fully staffed organizational structure exists at the time of the application to complete the review activities staffed with experienced, trained reviewers. Staff reviewers are not assumed to be dedicated to a single project (for example, a technical reviewer may work on a different project while waiting for an RAI response from an applicant).

- Critical skills gaps identified in the FLIRA assessment are filled, as needed, to support the DC reviews.

The staff expected, given its experience with certifying the three designs in the 1990s, that the subsequent review of an evolutionary LWR design would require less time to complete than the review of an LWR with an advanced design.

<u>LPP Schedule Assumptions</u>

NRO's LPP issued in January 2007 included model schedule templates for DCs, early site permits, and COL applications. The total DC review duration of about 43 months includes a 1-month acceptance review, 30 months for a safety review and 12 months for rulemaking. See the six-phase review diagram in Section 1 of this report for an overview of this model schedule.

A set of simplifying assumptions, some different from those used in the FLIRA model, were incorporated in the LPP. The relevant DC application schedule assumptions are as follows:

- Workplace infrastructure is in place including IT systems, processes, and procedures.
- All activities and resources are represented in the schedules.
- Sufficient staff resources at all skill levels are available.
- Major risks are identified and managed.
- Only high-quality applications accepted, SER process is to be completed within 30 months. Unacceptable applications will be rejected.
- RAI responses are timely.
- Resources used in preparing safety evaluations are not redirected to other activities.
- Interactions with ACRS are performed according to schedule milestones.
- Conduct of tasks are not affected by Congressional, budget, or legal issues, or by changes to NRC policies.

The LPP schedule assumptions indicate a shift towards the use of an idealized ("best case") model as a baseline, to be adjusted later as necessary, based on the acceptance review results and other factors, including identification of technical issues and discussions with the applicant. Hence, a single duration goal is identified for a particular type of review (such as a DC), rather than a duration range. Examples of idealized assumptions include access to and availability of all skill sets for the duration of the project, timely (30-day) RAI responses, 12 months to complete all rulemaking, and no impacts on the schedule due to budget or legal factors.
The LPP timeline for DC reviews is aggressive based on the staff's experience to date and aligns roughly with the best-case review duration given in SECY-01-0188 (43 months total for an LPP DC schedule vs. 42–60 months per the FLIRA assessment).

After the LPP was issued for use, the 30-day acceptance review period assumed in the LPP was extended at the direction of the Commission to a period of 60 days.[16] This change was made to allow time for the staff to determine both the completeness and technical sufficiency of an application. The staff implemented this change in the initial issuance of NRO Office Instruction NRO-REG-100 in September 2007.[17]

APR1400 Schedule Assumptions

The EPM schedule for the APR1400 project was designed based on updated LPP DC templates, but it includes several assumption changes intended to make the schedule more realistic, based on experience. The 30-day acceptance review period was previously changed, as described above. The use of a 30-day RAI response time as the "timely" assumption in the LPP has been determined to be unrealistic for use as an average response time. To meet the requirement for a "high quality" application assumed in the LPP, the technical sufficiency standard for accepting an application has changed from having enough information to "begin" the review to having enough information to "conduct" the review. Actions taken to improve these assumptions include conducting management-level reviews of RAIs for quality and clarity prior to issuance, and collecting RAI response time data to identify realistic response time goals to be incorporated into the project schedule, and revising NRO-REG-100 to implement change to the acceptance review process.

In contrast to the LPP model, the baseline DC application review schedule for the APR1400 project includes 2 months for the application acceptance review, 42 months for the staff's safety reviews, and completion of rulemaking 8 months after completion of the safety review (after Phase 6, approximately aligned with the SECY-09-0018 goal). The APR1400 is potentially a best-case example for a DC review execution—it is familiar technology; a high-quality application was submitted and accepted; there is sufficient staff availability; and the project has a high level of applicant support. The staff has also adopted a set of review process strategies to support safe and timely completion of the review (see Attachment).

[16] Staff Requirements – COMDEK-07-001/COMJSM-07-001 – "Report of the Combined License Review Task Force," June 22, 2007 (ADAMS Accession No. ML071760109)

[17] NRO Office Instruction NRO-REG-100, "Acceptance Review Process for Design Certification and Combined License Applications," initial issuance, September 26, 2007 (ADAMS Accession No. ML071980027)

3.0 FACTORS AFFECTING THE NRC'S DC REVIEW SCHEDULING ASSUMPTIONS

The staff's DC review experience to date provides a rich source of information about internal and external factors that support or inhibit review efficiency.

Examples of these internal factors include staff resource management, work prioritization, support for hearings, review phase discipline, critical skills availability, budgetary limitations, computational tool availability for unique reactor designs, the overall staff workload and capacity, and resolution of policy issues that may require rulemaking, as identified summarily in the FLIRA assessment. Examples of the policy issues identified in the FLIRA assessment include: petitions for rulemaking regarding Part 52; financial qualifications and decommissioning funding; nuclear insurance requirements for modular reactors (Price-Anderson Act); annual fees for modular reactors; the continued waste storage rule; and alternative operator staffing approaches.

Examples of external factors include application quality, applicant experience, the degree of design finality, whether or not the technology presented is familiar to the staff, and the availability of contracted subject matter expertise. Some external factors are out of the NRC's control, such as regulatory and programmatic changes by other agencies (for example, the Department of Energy decision to de-prioritize development of the next-generation nuclear plant). Other external factors include public policy changes, such as the Energy Policy Act of 2005, and external events. Some external factors can be foreseen and incorporated as risks in a project risk management program, but some are unforeseeable. Some of the factors are within the NRC's span of control, and experience has provided lessons learned to be incorporated in future plans and schedules. The most significant of these experiential factors have been captured in the 2013 lessons learned report previously referenced. These factors are discussed further in Section 5.

The staff continues to recognize and assess the impacts of these factors, continues to make improvements to the review process to minimize their impacts when possible, and continues to resolve policy issues that impact project plans and schedules.

4.0 STANDARD DESIGN CERTIFICATION REVIEWS CONDUCTED TO DATE

This section provides an overview of reactor designs and DC reviews conducted by the staff to date.[18] The purpose of the overview is to present a discussion of some of the factors that affected DC review timelines so that a context is available when reviewing the summary table of DC review dates and review durations at the end of the section.

4.1 Reactor Designs Certified prior to 2001

Reactor designs certified during this period used individualized schedules, schedule assumptions, and review workflows.

4.1.1 U.S. Advanced Boiling-Water Reactor (ABWR)

The ABWR is a single-cycle, force-circulation, boiling-water reactor (BWR) with a rated power of 1,350 megawatts electric (MWe), designed by General Electric Co. (GE) Nuclear Energy. The design incorporates features of the BWR designs in Europe, Japan, and the United States, and uses digital instrumentation and controls and improved computer, turbine, and fuel technology. The design's safety enhancements include protection against overpressurizing the containment, passive methods to cool accident debris, an independent water resupply system, three emergency diesels, and a combustion turbine as an alternate emergency power source. The NRC certified the U.S. ABWR design in May 1997.

This design was the first to be reviewed and certified by the NRC under the 10 CFR Part 52, Subpart B (DC) process. Refer to Table 1 on page 22 of this report for the associated safety review and rulemaking durations and milestones.

4.1.2 System 80+

The System 80+ reactor design is a 1,300-MWe pressurized-water reactor (PWR) with an updated Combustion Engineering (now Westinghouse Electric Company, LLC) System 80 nuclear steam supply system and a balance-of-plant design developed by Duke Power Co. The design has a reactor depressurization system, a gas-turbine generator as an alternate alternating current (ac) power source beyond the required emergency diesel generators, and an in-containment refueling water storage tank to enhance the reactor's safety and reliability. The NRC certified the System 80+ design in May 1997.

Since the System 80+ design was the second evolutionary design to be reviewed under the Part 52 DC process, it required fewer staff resources than the ABWR review and certification. Refer to Table 1 for the associated safety review and rulemaking durations and milestones.

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[18] Note that General Electric initially submitted the simplified boiling-water reactor (SBWR) design for NRC review, but subsequently withdrew the application in order to focus on larger reactor designs. Therefore, the SBWR review is not discussed further in this report. See SECY-96-068, "Status of the Staff's Review of Advanced Reactor Designs," April 1, 1996. (ADAMS Legacy Library Accession No. 9604080059)

4.1.3 AP600

The AP600 is a 600-MWe PWR designed by Westinghouse Electric Company, LLC, that incorporates passive safety systems and simplified system designs. The passive systems respond to transients by relying on gravity and other natural forces rather than electric-powered pumps and other support systems. The system uses redundant, non-safety-related equipment and systems where possible to avoid unnecessary safety-related system activation.

The NRC certified the AP600 design in December 1999. Because the design featured many unique design features, the staff was required to investigate and recommend to the Commission solutions for a variety of policy issues during the review. One such example was the need for policy direction for RTNSS.[19] Additionally, extensive efforts were required to develop thermal-hydraulic codes, and more independent confirmatory testing by the NRC was required for this review than for the other (previously) certified evolutionary designs. Refer to Table 1 for the associated safety review and rulemaking durations and milestones.

4.2 Reactor Designs Reviewed after 2001 (Post-FLIRA Assessment)

Section 2 of this report introduced the FLIRA assessment and the LPP review framework. These documents were used for the staff's reviews of five additional standard DC applications and one amendment to a certified design.[20] The following sections summarize the staff's experiences in reviewing each of these applications, efforts to make reviews more efficient, and cover preapplication review, acceptance review, perspectives on the technical review, and rulemaking activities.

4.2.1 AP1000 and the AP1000 Amendment

The Westinghouse AP1000 is a two-loop PWR, based on the certified AP600 design, with a nominal net electric output of 1,110 MWe. This PWR relies on passive safety systems and simplified system designs, similar to the AP600 design, but generates more power by accommodating more fuel in a longer reactor vessel and using larger steam generators and a larger pressurizer.

Westinghouse initiated preapplication discussions with the NRC and requested the staff to assess the applicability and the acceptability of the certified AP600 design to the AP1000 standard DC review for scaling/testing, safety analysis codes, design acceptance criteria (DAC),

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[19] Early passive cooling reactor designs, such as the AP600, used non-safety grade active systems to provide defense-in-depth capabilities for reactor coolant makeup and decay heat removal. Issues associated with the regulatory treatment of non-safety systems (RTNSS) were identified by the staff and policy recommendations were presented for Commission approval. These recommendations were approved by the Commission in Staff Requirements Memo (SRM)-SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084)," June 28, 1995 (ADAMS Accession No. ML003708019)

[20] The FLIRA schedule assumptions were used for the AP1000 DC review and (initially) for the ESBWR review. The LPP schedule assumptions were used for the AP1000 Amendment, ESBWR, U.S. EPR, and US-APWR. Modified LPP schedule assumptions are being used for the APR1400 DC review.

and regulatory exemptions. Over the course of several months, the staff determined which conclusions from the AP600 review could be used in the AP1000 review and which items would require more review (e.g., thermal hydraulic code analysis).

On March 28, 2002, Westinghouse submitted its application for the AP1000 standard DC. Upon completion of its acceptance review, the staff found that the application fulfilled the completeness requirements of 10 CFR Part 52, considered the application sufficiently complete, and docketed the application on June 25, 2002.[21]

The AP1000 review gained efficiencies from the assignment of staff reviewers, where possible, from the AP600 project. In addition, the development of the AP1000 SER benefited from the readily available and applicable portions of the AP600 conclusions. As a result, the NRC certified the AP1000 design on January 27, 2006. Refer to Table 1 below for the associated safety review and rulemaking durations and milestones.

At about the same time the DC approval for the AP1000 was issued by the NRC, Westinghouse informed the staff of its plans to submit an amendment request to the AP1000 DC in the second quarter of 2007.[22] The staff and Westinghouse started discussions on the amendment and on the additional AP1000 technical reports that Westinghouse planned to submit to the NRC for review. The purposes of the additional reports were to provide supplemental information regarding activities required to complete and close COL information items and ITAAC, to describe design changes and changes to the design control document (DCD) identified as a result of design completion activities, and to provide analysis activities to support extension of the design (such as extending the suitability of the design from hard rock foundations to soft soil foundations). Westinghouse intended for these reports to be incorporated into the FSAR referencing the AP1000 DC or incorporated into the DC through a supplemental rulemaking when the 10 CFR Part 52 revision permits such changes.[23] Additionally, in 2011, Westinghouse submitted Revision 19 of the DCD, providing information to (among other topics) address the aircraft impact assessment requirements of 10 CFR 50.150(a) for the AP1000 design.[24]

Although Westinghouse submitted an application to amend the AP1000 design certification rule (DCR) in mid-2007, the NRC delayed its acceptance review until after the promulgation of the

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21 Letter from J.E. Lyons to W.E. Cummins, "Acceptance of the Westinghouse Electric Company Application for Final Design Approval and Standard Design Certification for the AP1000 Design," June 25, 2002 (ADAMS Accession No. ML021760083)

22 Letter dated July 14, 2006, "Westinghouse Response to NRC Regulatory Issue Summary 2006-06," (ADAMS Accession No. ML062010136)

23 Letter dated April 5, 2006, "AP1000 COL Design Change Review" (ADAMS Accession No. ML060970266)

24 Letter dated June 13, 2011, "Westinghouse Electric Company – Updated Application to Amend the AP1000 Nuclear Power Plant Design Certification Rule" (ADAMS Accession No. ML11171A301)

revision to 10 CFR Part 52[25] and continued its review of the submitted technical reports.[26] On January 18, 2008, the NRC docketed the supplemented application [27] and issued a letter stating that, "In its decision to docket, the NRC found that the information provided in most parts of the amendment request meets NRC regulations with respect to completeness and technical sufficiency." Exceptions noted in the letter included the need to address long-term cooling water sources, and coping with debris generation from a loss-of-coolant-accident. These exceptions were identified as areas of uncertainty with regard to the NRC's review schedule, dependent on receipt of additional information from Westinghouse.

In its review of the amendment application, the staff focused on additional information to resolve design-related COL information items, the shield building design, and some design corrections and other vendor-identified design changes.[28] It should be noted that the NRO staff reviewed the amendment at the same time that it was conducting reviews of many COL applications referencing the AP1000 design. On December 30, 2011, the NRC published the AP1000 DC amendment final rule in the *Federal Register.*[29]

Two factors influenced the review of the AP1000 DC amendment: (1) the simultaneous review of the DC application and several COL applications, including the Vogtle, Units 3 and 4, and Summer, Units 2 and 3, applications, and (2) the concurrent licensing and construction of the AP1000 design at two sites in China. Additional design and construction changes were identified during the ongoing international construction of AP1000 plants that impacted standardization of the AP1000 design. These changes were addressed by Westinghouse through the submittal of resulting design changes that impacted the NRC DC amendment review schedule. Refer to Table 1 below for the associated safety review and rulemaking durations and milestones.

4.2.2 ESBWR

The General Electric-Hitachi (GEH) ESBWR is a 1,594-MWe [30] reactor using natural circulation for normal operation with passive safety features.

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25 In 2007, the staff revised 10 CFR Part 52 to make changes throughout the Commission's regulations to ensure that all licensing processes in Part 52 were addressed, and to clarify the applicability of various requirements to each of the processes in Part 52 (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license). See Final Rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," (72 FR 49352), August 28, 2007

26 SECY-06-0220, "Final Rule to Update 10 CFR Part 52, 'Licenses, Certifications, and Approvals for Nuclear Power Plants' (RIN AG24)," October 31, 2006 (ADAMS Accession No. ML062910203)

27 Letter from D. B. Matthews to W.E. Cummins, "Acceptance Review of the AP1000 Design Certification Amendment Application for Revision 16," January 18, 2008 (ADAMS Accession No. ML073600743)

28 Westinghouse submitted several revisions for the staff's review; i.e., Revision 16 (May 26, 2007), through Revision 19 (June 13, 2011).

29 Final Rule, "AP1000 Design Certification Amendment," (76 FR 82079), December 30, 2011

30 The original ESBWR submittal, through Revision 10 of the design control document, rated the design at 1,390 MWe.

Beginning in April 2002, GEH (then GE) requested an NRC preapplication review on the ESBWR standard design. The initial scope of the preapplication reviews included an assessment of the technological basis for passive safety systems and the analysis methods for transients and accidents (e.g., the application of the TRAC-G thermal-hydraulic code to ESBWR loss-of-coolant accidents (LOCAs)). Later, the staff's review expanded to include several technical and regulatory issues, including the reliance on passive systems to perform safety functions credited in the design basis for 72 hours following an initiating event.

While engaged in the specifics of the preapplication reviews, the staff began development of the infrastructure needed to support the upcoming DC application review, such as the development of modeling capabilities for the NRC's thermal-hydraulic system analysis code TRACE to assess the safety features of the ESBWR design.

From August to October 2005, GE submitted and supplemented its application for the standard DC of the ESBWR. The NRC docketed the application on December 1, 2005.[31] The staff requested additional information on unique design features, testing, and analytic codes, similar in scope to the information requested for the AP600 design. In October 2006, the Office of New Reactors was established and assumed licensing responsibilities for the ESBWR, and other Part 52 applications. In 2007, the staff revised 10 CFR Part 52 as previously noted, updated the standard review plan, and published a new standard format and content regulatory guide to support COL applications.[32] The change in reviewers during the Nuclear Reactor Regulation (NRR)/NRO office transition and the influence of updated guidance for applications referencing the design contributed to an increase in the level of effort and time to complete the ESBWR DC review.

Challenges to the schedule arose, and several factors may have contributed, including: (1) the expectations associated with a complete and technically sufficient application changed because of the revision of 10 CFR Part 52 and the update of associated guidance; (2) a large number of RAIs issued over a short period created processing challenges for the applicant to develop responses and for the staff to review the responses; and (3) the assumed applicant response time and staff review schedule did not account for the complexities of the technical issues needing more information nor the level of effort needed by the applicant to prepare the responses and by the staff to review them.

The staff prepared preliminary SER chapters during its development of the RAIs; however, these working documents did not directly support the RAI concurrence process as a means to better understand the regulatory context of each of the RAIs. This insight led to a lessons learned example as summarized in Section 5.4 of this report.

Similar to the staff's experience in reviewing the AP1000 DC amendment, GEH introduced design changes late in the review process to account for feedback from prospective COL applicants referencing the ESBWR. The re-review of portions of the application related to

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31 Letter from D. B. Matthews to S.A. Hucik, "Acceptance of the General Electric Company Application for Final Design Approval and Standard Design Certification for the Economic Simplified Boiling Water Reactor (ESBWR) Design," December 1, 2005 (ADAMS Accession No. ML053200311)

32 Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 20, 2007 (ADAMS Accession No. ML070630042)

constructability and operation and maintenance (O&M) insights added time and resources to complete the review.

Additional delays occurred when, in late 2011, the NRC notified GEH of the need for more information on the steam dryer design to support its safety findings in the final safety evaluation report (FSER). This issue was raised through operating experience of the power uprated fleet. With the submission of Revision 10 of the DCD, the staff resolved all remaining technical issues. In September 2014, the Commission approved the supplemental FSER and issued the final rule certifying the ESBWR design.[33] Refer to Table 1 below for the associated safety review and rulemaking durations and milestones.

4.2.3 U.S. EPR (DC Review Suspended)

The U.S. EPR is a PWR designed by AREVA NP, Inc. (AREVA). The U.S. EPR design, rated at 1,600 MWe, features four redundant trains of emergency cooling equipment. It should be noted that during the development of the U.S. EPR application and the staff's review of the application, AREVA was also managing the construction of the EPR in Olkiluoto, Finland, and AREVA and Electricité de France (EdF) were managing the construction of another EPR in Flamanville, France. In addition, construction of other EPRs commenced in China (i.e., Taishan, Units 1 and 2, in 2009 and 2010, respectively). Similar to the experience gained during international construction of the AP1000 plants, these ongoing EPR construction activities provided additional information to further inform the staff's review of the application.

In late 2004, AREVA (then Framatome ANP, Inc.) informed the NRC of its intent to submit an application for the U.S. EPR standard DC in 2008. In addition, Framatome expected to offer informational meetings on the design in 2005 and to submit several specific topical reports in 2006. Framatome considered the U.S. EPR design as evolutionary and did not anticipate requirements for new testing or research activities.

Following the preapplication reviews, AREVA submitted an application for certification of the U.S. EPR standard design and the NRC docketed the application on February 25, 2008.[34, 35] In the acceptance review notification and subsequent schedule letter, the staff identified certain technical areas that could challenge the staff's review that included: (1) the approach to justify the amount of post-accident mixing in containment that makes it acceptable to not rely on active containment cooling; (2) the seismic and dynamic qualification of mechanical and electrical equipment; and (3) the emergency core cooling system strainer downstream effects on post-LOCA long-term core cooling with recirculation flow.

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33 Final Rule, "Economic Simplified Boiling-Water Reactor Design Certification," (79 FR 61944), October 15, 2014

34 Letter from G. Tesfaye to S. M. Sloan, "AREVA NP Inc. – Acceptance of the Application for Standard Design Certification of the U.S. EPR," February 25, 2008 (ADAMS Accession No. ML080380357)

35 Letter from G. Tesfaye to S. M. Sloan, "AREVA NP Inc. – U.S. EPR Standard Design Certification Application Review Schedule," March 26, 2008 (ADAMS Accession No. ML080790431)

As the review progressed, delayed and inadequate responses to RAIs from AREVA became common. The causes for the delays may be attributed to one or more of the following:

(1) the applicant's need for more than 30 days to respond to the significant technical issues identified in the schedule letter and shortly after the start of the review;

(2) the applicant's choice to repeatedly revise the FSAR, resulting in more RAIs as the responses affected other sections that had already been reviewed, resulting in substantial effort to re-review those sections, going well beyond such efforts expended on other reviews;

(3) the emergence of additional technical issues not identified in the initial schedule letter, particularly in the area of digital instrumentation and control (DI&C); and

(4) the staff's need for an iterative review to resolve the technical issues due to inadequate RAI responses from AREVA.

Over the next 5 years, the staff issued six supplemental schedule letters and ultimately moved the target date for completion of the FSER to June 2015. In July 2013, after several attempts by AREVA to resolve issues related to DI&C, the staff informed AREVA that they had not provided sufficient basis for the staff to reach the necessary safety conclusion for the U.S. EPR DI&C design. In particular, the staff noted that AREVA had not demonstrated sufficient independence and diversity to meet the regulatory requirements at the current state of design; and that Areva's DI&C design was unnecessarily complex for the performance of safety functions. This complexity was the major contributor to AREVA's inability to demonstrate independence and diversity in the design. The staff committed to continuing the review of other technical issues, but would not issue a revised review schedule until AREVA responded to the DI&C issue.[36]

The NRC has been cooperating with the regulators in Finland, China, France, and other countries on review of the EPR design through the Multinational Design Evaluation Program (MDEP) EPR working group. The working group leverages regulatory resources by sharing information and experience on the safety design review to enhance the safety of the design. Participation in this cooperative efforts enables regulators to make timely licensing decisions through exchanging experience on design-related construction, commissioning, and operating experience. The working group also communicates its views and common positions to vendors regarding the basis of safety evaluations.

The main technical issues consistently raised by the MDEP member countries were the independence of systems and the qualification of the DI&C platform. The working group issued a common position documenting aspects of the EPR design, where the countries had common agreement on the issues in March 2011 and produced a technical report discussing the major outcomes of its discussions in 2013. Through its participation in the MDEP working group, the staff learned of the challenges faced by other regulatory bodies in resolving the DI&C issues for

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[36] Letter from D. B. Matthews to P. Salas, "NRC Staff Conclusions on Aspects of the U.S. EPR Digital Instrumentation and Control Systems Design," July 2, 2013 (ADAMS Accession No. ML13168A571)

the EPR design. Participation in the working group helped all member regulators to address the issues in a cooperative manner.

In an effort to reduce the number of rounds of RAIs needed to resolve technical issues, the staff introduced a two-phase RAI response protocol. In this new process, the applicant offers a preliminary RAI response to the staff for review and feedback before the submission of the final RAI response. The staff's intent was to ensure that the applicant was addressing the staff's concerns. However, the new process resulted in greater review effort by the staff and did not appear to yield any efficiencies in resolving the outstanding technical issues. Furthermore, the practice of submitting documents directly to the staff in lieu of the NRC's Document Control Desk shifted the responsibility to the staff of ensuring the capture of submittals into ADAMS, which resulted in a greater workload for the project management staff.

In late 2013, the applicant requested the NRC staff to focus its review on those SER chapters with few unresolved technical issues (i.e., the "near-term closure" chapters), while the applicant continued its design work and technical issue resolution for the remaining application chapters.[37] The applicant's plan included issuing FSAR markups of each chapter and "freezing" the design in these chapters to allow the staff to complete its reviews and issue its SER chapters with no OIs. The implementation of the applicant's proposal simplified the schedule and made managing and tracking tasks more efficient. Concurrent with the implementation of this plan, the staff discontinued its use of the two-phase RAI protocol and established a weekly public teleconference call to clarify its RAIs with the applicant.

After reviewing AREVA's plan for closure of the near-term chapters, the staff provided AREVA with a revised schedule date for completion of Phase 4 reviews for those chapters only.[38] Even with the reduced scope, the applicant encountered multiple budgetary challenges that further challenged the schedule. In late 2014, the staff completed a portion of its advance SER for the near-term chapters in accordance with the published schedule.

After issuance of portions of the advance SER for the near-term chapters, the applicant pointed out instances of outdated information. The applicant made many revisions to the FSAR chapters after the staff had completed its reviews. These revisions required the staff to re-review its completed portions of the SER to ensure consistency with the current FSAR revision. The staff considered it prudent to confirm that any changes to the FSAR did not contradict its findings in all issued portions of the SER.

In some instances, standardization of the U.S. EPR design with the units under construction overseas led to delays in AREVA's RAI responses as well as changes to the design for which the technical staff had already completed its review and made a safety conclusion.

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37 Letter from P. Salas to the NRC, "Path Forward for U.S. EPR Design Certification Application," October 21, 2013 (ADAMS Accession No. ML13297A305)

38 Letter from F. Akstulewicz to P. Salas, "Review Schedule for the U.S. EPR Standard Design Certification Application Group A," August 6, 2014 (ADAMS Accession No. ML14161A174)

On February 25, 2015,[39] AREVA requested the NRC to suspend the safety review of the U.S. EPR standard DC application until further notice. Refer to Table 1 for the associated safety review and rulemaking durations and milestones.

4.2.4 US-APWR (DC Review in Progress)

The US-APWR developed by Mitsubishi Heavy Industries, Ltd. (MHI) is based on MHI's Japanese APWR design in use at 24 sites in Japan. This design combines passive and active systems to support a plant rating of 1,600 MWe.

For about 18 months, from July 2006 through December 2007, the staff conducted preapplication reviews of limited scope and duration. During this time, MHI submitted 12 topical reports related to LOCAs, I&C, fuel design, the advanced accumulator, and human factors engineering (HFE).

In late 2007, MHI submitted its application for the US-APWR standard DC, and on February 29, 2008, the staff accepted the application for docketing.[40] In the acceptance letter, the staff noted technical issues (e.g., subcompartment containment analyses and the sump strainer design) that would introduce uncertainty into the review schedule. Because of several meetings with the staff, MHI supplied supplemental information to address these issues.[41]

Initially, the staff's review of the application began slowly because the project was not budgeted, or prioritized with the numerous other applications for DCs and COLs already in the review queue. Thus, the US-APWR review initially had a lack of sufficient, consistent technical resources, challenging the staff's ability to maintain the review schedule.

As the staff completed its preliminary SER and issued RAIs, several issues requiring additional review were identified. First, MHI modified the thermal hydraulic code used in its safety analysis. Therefore, the staff needed to review the modified code prior to reviewing the US-APWR accident analysis. Second, MHI changed the seismic analysis from the soil-spring interaction method to a finite element method, causing additional staff reviews.

Although these and other issues delayed the next phase of the review (i.e., development of the SER with OIs), the NRC continued to work towards completing the review. After 3 years of reviewing the US-APWR application, the staff notified[42] MHI of a delay in completing its review,

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39 Letter from P. Salas to the NRC, "Request to Suspend Review of U.S. EPR Design Certification Application," February 25, 2015 (ADAMS Accession No. ML15061A130)

40 Letter from J. A. Ciocco to Masahiko Kaneda, "Mitsubishi Heavy Industries Ltd. – Acceptance of the Application for Standard Design Certification of the US-APWR," February 29, 2008 (ADAMS Accession No. ML080420261)

41 Meeting Summary, "Summary of the March 25, 2008 Meeting on the US-APWR Design Certification Review Schedule," April 2, 2008 (ADAMS Accession No. ML080910038)

42 Letter from D. B. Matthews to Y. Ogata, "Schedule Change for the United States – Advanced Pressurized Water Reactor Design Certification," April 28, 2010 (ADAMS Accession No. ML100830739)

primarily because of the MHI changes in seismic analysis from the soil-spring interaction method to a finite element method.

The NRC sent subsequent schedule change letters[43, 44, 45] to MHI stating that the staff's reviews would be further delayed due to incomplete information on the DI&C design and MHI's delayed responses to staff's RAIs; and MHI's failure to address inconclusive test results supporting the Generic Safety Issue (GSI) -191 design commitments.

Although the staff made progress in the review of several areas, the seismic review caused changes to the plant layout, and the new methods for addressing sliding stability of the nuclear island ultimately led to a significant delay in the review schedule. MHI submitted 163 technical reports (including test plans, test results, and other reports) in support of its application. MHI submitted 47 technical reports during the preapplication review period or within the first year of the staff's review. Of the 116 technical reports submitted after the first year of the review, MHI identified an additional 75 technical reports to be submitted in support of its application and developed 41 technical reports to support the staff's review.

In late 2013, MHI informed the NRC of its intent to put into place a coordinated slowdown of its DCD licensing activities to focus its resources on the restart of the Japanese utilities since the Fukushima-Daiichi accident.[46] MHI committed to working with the staff to sustain the ongoing review; however, it projected its reduced support to start by March 2014, for an indeterminate period dependent upon the success of bringing units in Japan on line and on the availability of the necessary expertise to refocus on the project. Therefore, the staff limited its review to a single chapter or two at a time starting with HFE, followed by I&C. As a result of MHI's request, the project priority has been lowered within the NRC, and there may be future configuration management challenges associated with reviewing chapters one at a time rather than using an integrated review approach.

Because of the limited availability of MHI resources to support the review, work remains to complete the review, including (1) completion of the HFE SER and an ACRS review, (2) completion of the seismic SER with OIs and an ACRS review, (3) completion of the introduction and plant description chapter, and (4) closure of OI's in other remaining FSER chapters.

The staff has not scheduled the latter phases of the review because of the technical issues it identified early in its review and the limited available resources from the applicant since the Fukushima-Daiichi accident. Refer to Table 1 for the associated safety review and rulemaking durations and milestones.

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43 Letter from D. B. Matthews to Y. Ogata, "Schedule Change for the United States – Advanced Pressurized Water Reactor Design Certification," February 24, 2011 (ADAMS Accession No. ML110240150)

44 Letter from D. B. Matthews to Y. Ogata, "Schedule Change for the United States – Advanced Pressurized Water Reactor Design Certification," October 27, 2011 (ADAMS Accession No. ML112430036)

45 Letter from D. B. Matthews to Y. Ogata, "Schedule Change for the United States – Advanced Pressurized Water Reactor Design Certification," June 4, 2012 (ADAMS Accession No. ML12130A078)

46 Letter from Y. Ogata to D. B. Matthews, "Adjustment to Ongoing Efforts for US-APWR Design Certification Application," November 5, 2013 (ADAMS Accession No. ML13311A109)

4.2.5 APR1400 (DC Review in Progress)

The APR1400 designed by Korea Hydro & Nuclear Power Co., Ltd. (KHNP) and the Korea Electric Power Corporation (KEPCO) is an evolutionary two-loop PWR design rated at 1,400 MWe. The design is based on the System 80+, with revised design features to enhance safety.

KHNP initially submitted the APR1400 application in December 2013. After completing its acceptance review, the staff determined the APR1400 application did not meet docketing requirements for completeness. KHNP resubmitted its application in December 2014, and it was accepted by the NRC for docketing in early March 2015.[47]

To assist in meeting the goal of submitting an acceptable DC application, the staff conducted a preapplication audit and extensive additional preapplication discussions with KHNP. To further support the goal of receiving a high-quality application, the staff updated NRO Office Instruction NRO-REG-104 in late 2014 for the conduct of preapplication readiness assessments.

The APR1400 DC review project is currently on schedule. Some challenges associated with KHNP RAI response times are beginning to emerge, in part due to the volume and timing of RAIs being sent to KHNP. At this point, the overall schedule has not been impacted.

Discussions with the applicant have emphasized the importance of improving RAI response time. Lessons learned from previous projects for RAI management are being applied to the APR1400 review and are discussed further in Section 5. The staff has also adopted a set of review process strategies to support safe and timely completion of the review (see Attachment). Refer to Table 1 for the associated safety review and rulemaking durations and milestones.

4.3 Summary of Design Certification Reviews

Table 1 summarizes the DC reviews conducted by the staff. The impacts of the various factors described above in the DC review summaries are clearly reflected in the overall review durations shown in Table 1.

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[47] Letter from J. A. Ciocco to Dr. Ha-Hwang Jung, Korea Hydro and Nuclear Power Co., Ltd, and Dr. Hee-Yong Lee, Korea Electric Power Corporation – “Acceptance of the Application for Standard Design Certification of the APR1400,” March 4, 2015 (ADAMS Accession No. ML15041A455)

Table 1 Summary of Design Certification Reviews

Proposed Design	Duration of Acceptance Review (months)*	Date DC Application Submitted	Duration of Safety Review (months)*	Duration of Rulemaking (months)*	Date Certified
ABWR	36	03/1989 [a]	61	34	05/1997
System 80+	26	03/1989	39	33	05/1997
AP600	6	06/1992	69	15	12/1999
AP1000	3	03/2002	27	19	01/2006
AP1000 amendment	8	05/2007	43	17	12/2011
ESBWR	4	08/2005	63	43	09/2014
U.S. EPR	2	12/2007	Suspended at request of applicant, 2/2015	N/A	N/A
US-APWR	2	12/2007	Review slowdown initiated by applicant, 11/2013	TBD	TBD
APR1400	2	12/2014 [b]	42	13 (8 months after issuance of the safety review)	TBD

* Durations shown may not reflect the actual staff level of effort because they may include schedule delays for a variety of reasons including resolution of technical and policy issues, applicant response delays or pause requests, the quality of applications, and other factors. See individual design summaries in Section 4 for additional information. Rulemaking activities may begin prior to completion of the safety review, so the net project duration is generally less than adding the safety review duration and the rulemaking duration together.

[a] GE submitted the ABWR design certification application in piecemeal fashion from 09/1987–03/1989.

[b] KHNP initially submitted the APR1400 application in 12/2013. After completing its acceptance review, the staff determined the APR1400 application to be unacceptable. KHNP resubmitted its application in 12/2014.

5.0 INCORPORATION OF LESSONS LEARNED IN DC REVIEWS

Shortly after issuing the COLs for Vogtle, Units 3 and 4, and Summer, Units 2 and 3, the NRC conducted a lessons learned review to identify potential enhancements to its 10 CFR Part 52 licensing processes to support more effective and efficient reviews of future applications.[48] That report considered experiences from all types of Part 52 application reviews conducted by the staff. All of the short-term actions identified in the 2013 report were completed in January 2015. The three remaining items are longer in duration: (1) update Regulatory Guide (RG) 1.206, "Combined License Applications for Nuclear Power Plants (LWR [light-water reactor] Edition);" (2) incorporate Interim Staff Guidance (ISG)-11, "Finalizing Licensing-Basis Information," into the RG 1.206 update; and (3) update NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants." [49] These three remaining items are being addressed by the staff, consistent with NRO's work prioritization and available resources.

For this report, the staff revisited selected lessons learned identified in that 2013 report and identified additional areas for review that seemed likely to reveal additional opportunities for process improvements in the context of performing DC reviews. These lessons learned are discussed below.

Finally, the report describes the specific lessons learned actions now being applied by the staff to the APR1400 DC review.

5.1 High-Quality Applications that Fully Address Relevant Regulatory Requirements and Staff Guidance Support the Conduct of the Review within a Predictable Timeframe

The DC review experiences described in Section 4 of this report provide examples of applications that challenged schedule and resource assumptions. While the DC applications accepted for docketing met the existing standard at the time of acceptance (i.e., the application was sufficient to "begin" the review), the need for a higher standard of application completeness became apparent. In response to the related lesson learned, as discussed in the 2013 report, the staff changed its acceptance standard from "sufficient to begin the review" to sufficient to "conduct" the review. This change is expected to provide significant review efficiency gains for both the staff and the applicant.

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48 Memorandum from R. W. Borchardt to Chairman MacFarlane, et al, "New Reactor Licensing Process Lessons Learned Review," April 18, 2013 (ADAMS Accession No. ML13059A240)

49 Memorandum from Michael E. Mayfield and Scott C. Flanders to Glenn M. Tracy, Director of the Office of New Reactors, "Completion of Near Term Actions in Response to the New Reactor Licensing Process Lessons Learned Review: Title 10 of the Code of Federal Regulations Part 52 Report," April 23, 2015 (ADAMS Accession No. ML15091A398)

The change was implemented in the latest revision of NRO Office Instruction NRO-REG-100, "Acceptance Review Process for Design Certification and Combined License Applications." [50] The staff applied this revised standard to the initial acceptance review for the APR1400 application submitted by KEPCO and KHNP and determined the APR1400 application to be unacceptable for docketing due to a lack of completeness.[51] As a result of the staff's determination and over the course of several months, the applicant engaged the staff to address the application weaknesses identified and to revise its application to meet the standard of "sufficient to conduct the review." After reviewing the resubmitted application, the NRC accepted and docketed the application, consistent with the revised acceptance review standard.

5.2 Applicants and NRC Staff Must Commit Resources to Promptly and Thoroughly Respond to Requests for Additional Information and Substantive Technical Matters to Support a Predictable Review Schedule

Section 4 of this report describes the staff's experiences with DC applicants in which significant delays in the review schedule resulted from the applicant's inability to respond to RAIs and substantive technical issues within the assumed 30-day response timeframe. Reasons for these delays included corporate decisions to refocus application review timing and scope, underestimation of resource needs for complex technical issue resolution, and in one case, the impacts of a natural disaster on an applicant's operations. In each of these cases, the NRC staff made efforts to accommodate the needs of the applicants. These examples demonstrate the staff's flexibility in working with applicants with special circumstances during the DC review.

However, absent special circumstances, applicants must be prepared to commit the necessary resources to respond to RAIs and to resolve complex technical issues promptly. This support is especially critical during Phases 1 and 2 of the review, when the staff's technical review efforts are highest. To support planned schedule milestones, the applicant must be prepared to support the response timeliness and technical sufficiency planning goals. One way the staff assists applicants in this regard is to communicate NRC staff support expectations to the potential applicant early in the preapplication period. The potential applicant can then examine these expectations in the context of their own organizational capacities and make adjustments early in the application review process, if needed. The EPM platform and the NRO planning and scheduling instruction [52] are being used to identify schedule risks and staff resource impacts resulting from delays associated with the applicant's organizational capacities.

For future DC reviews, the staff continues to evaluate the merits of revising the planning and scheduling baselines to ensure that schedule goals are realistic and experience based. One such change under consideration is to plan for a range of expected response times for

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50 NRO Office Instruction NRO-REG-100, "Acceptance Review Process for Design Certification and Combined License Applications," Revision 2, December 18, 2014 (ADAMS Accession No. ML071980027)

51 Letter from D. B. Matthews to B. Cho and H. Lee, "Korea Hydro and Nuclear Power Co., Ltd., and Korea Electric Power Corporation – Non-Acceptance of the Application for Standard Design Certification of the APR1400," December 19, 2013 (ADAMS Accession No. ML13351A417)

52 See NRO Office Instruction NRO-REG-116, "Planning and Scheduling," Revision 0, May 9, 2013 (ADAMS Accession No. ML12132A159 (Package) – NONPUBLIC)

RAIs and complex technical issues, on the order of 45–60 days for the most complex issues, considering feedback from the applicant in making the duration determination.
The staff believes that the best way to minimize the applicant support requirements in the early phases of the application review is to ensure that the proposed design is mature and the application has the content and detail needed by the staff. As seen in the APR1400 review, this minimizes RAIs and unforeseen technical issues. Frequent communications between prospective applicants and the staff during the preapplication phase activities are key to achieving this goal.

5.3 Early Identification and Timely Resolution of Complex Technical and Policy Issues Minimize Impacts on the Review Schedule

When developing a new reactor review schedule, the staff assumes that the DC application contains sufficient details to resolve all safety issues. The staff also relies on preapplication discussions and early topical/technical report reviews to identify policy and technical issues for early resolution. Ideally, policy and technical issues will be resolved by the prospective applicant and the staff prior to application submission. This will enhance regulatory certainty and minimize application review schedule impacts. As the staff learns more about applicants' plans to identify and address policy and technical issues related to their specific designs, the staff will engage with the Commission, as appropriate, to reach the earliest possible resolution of these issues. The staff will also continue to independently identify technical and policy issues that may be applicable to multiple reactor designs to improve the efficiency of future reviews.

Examples of complex technical issues that required significant schedule adjustments during previous DC reviews include DI&C issues (U.S. EPR and US-APWR), structural design methodology changes (US-APWR), and system design issues (ESBWR). Section 4 of this report provides additional information on these issues. For each of these issues, the NRC staff proactively identified areas where the applications did not furnish information sufficient to reach a safety finding, and worked or is working with each applicant to obtain the required supplementary information.

In order to achieve an efficient review, prospective applicants intent on pursuing a DC application should commit to working with the NRC staff to resolve technical issues (such as DI&C and seismic/structural challenges) early, and to reaching resolution before submitting an application. With its emphasis on preapplication communications, the revision to the NRO office instruction on acceptance reviews, and with the issuance of the NRO office instruction on preapplication readiness assessments, the staff has implemented the supporting elements of this lesson learned.

5.4 Improvements to All Aspects of Requests for Additional Information Can Contribute to a More Efficient Review

The staff's DC review experiences have illustrated opportunities for improvement of RAIs across the RAI life cycle, including content quality, process management, eRAI platform enhancements, applicant responsiveness, technical sufficiency, closure criteria, and knowledge

management. Section 4 of this report describes some of the RAI challenges faced by the staff and applicants for DC applications for new nuclear plant designs.
In the 2013 Lessons Learned report, the staff attributed the large number of RAIs to: (1) the lack of information in the application to support the conduct of the review; (2) the insufficient response to the RAIs that resulted in numerous, iterative RAIs; (3) the substantive RAIs related to testing, new computer analyses, or novel modeling methods to support new analyses that would typically take more than 30 days for the applicant to develop and submit a response to the staff for review; and (4) the lack of staff discipline in determining that subsequent RAIs would result in a timely resolution to the issue.

In its 2013 report, the staff determined that improvements to the RAI management system would support a more efficient review by ensuring consistency and timely communication of issues to both management and the applicant. The staff has implemented improvements to its RAI management system and implementation guidance. These improvements include: (1) updated definitions and guidance on the status of the RAIs, including the capture of documentation supporting the closure of an RAI, but with the issue still unresolved; (2) more clearly defined roles and responsibilities for staff and managers; and (3) an updated office instruction on the purpose and use of the RAI management system.[53]

The staff is also working to improve the efficiency of the RAI process through several means other than those identified in the 2013 report. These include: (1) internally focusing on the quality and clarity of RAIs; (2) ensuring that an RAI is needed to reach a safety finding; (3) improving internal coordination to prevent duplicative RAIs; (4) applying an increased level of executive oversight of RAIs prior to issuance; (5) clearly communicating RAI response time and technical sufficiency expectations with applicants; (6) preparing preliminary or draft SERs before issuing RAIs, as learned during the ESBWR DC review; and (6) reviewing project schedule templates to include more realistic timeframes for RAI responses and resolution of related complex technical issues.

Finally, the staff is making parallel efforts to minimize the need for RAIs. Example activities include: (1) early engagement with potential applicants to identify and clearly communicate NRC application requirements, guidance, and completeness and technical sufficiency expectations; and (2) an expanded use of informational conversations to enhance staff and applicant understanding of particular topics prior to the formal generation of RAIs.

The staff anticipates that the combined effects of the improvement efforts noted above will support the interests of the applicants in maximizing the efficiency and effectiveness of the review process, and the interests of the staff in bringing specific reviews to closure in a structured and predictable manner. The staff continues to evaluate the impacts of implementing these improvements during its review of the APR1400 application by collecting and analyzing detailed process data for the RAI workflow.

5.5 Living Our Mission

[53] NRO Office Instruction NRO-REG-101, “Processing Requests for Additional Information,” Revision 1, July 10, 2014 (ADAMS Accession No. ML14091A802)

In 2015, NRO published an internal guidance document for staff use entitled "Living Our Mission: An Enhanced Approach to New Reactor Reviews" (see Attachment). This document includes expectations for success for the staff and applicants, and strategies that support timely application review project execution. Important aspects of this document include an emphasis on the development of high-quality RAIs by the staff, and on other available methods to obtain needed information, such as meetings and audits.

5.6 Summary of Lessons Learned Being Applied to the APR1400 DC Review

NRO management established a 42-month goal review schedule for the APR1400 DC review, excluding rulemaking and the acceptance review. In summary, the management "best practices" and lessons learned being used for the staff's review include:

- implementing the revised NRO Office Instruction for RAIs for more rigorous acceptance review requirements (NRO-REG-101, published in July 2014);
- implementing the NRO Office Instruction for conducting preapplication readiness assessments (NRO-REG-104, published in October 2014);
- implementing the revised NRO Office Instruction for conducting acceptance reviews (NRO-REG-100, published in December 2014);
- using an integrated, resourced project schedule that captures the key phases and review activities for all stakeholders and support organizations;
- fine-tuning the level of detail in the schedule activity to optimize the balance between project management control and task assignment control (TAC) discipline;
- using an officewide work prioritization system in order to coordinate review needs with available staff and with supporting Centers of Expertise (COEs);
- optimizing the management of technical resources to support reviews and minimize turnover of technical reviewers;
- maintaining appropriate focus on the information needed to reach safety findings for the most safety-significant areas (RAI discipline) when creating NRC RAIs and reviewing KHNP responses;
- maximizing the use of the eRAI system to manage RAI correspondence, approval workflows, and status;
- communicating the NRC expectation for RAI response times to applicants, and providing the opportunity to hold clarification calls on individual RAIs to ensure the applicant understands what information the staff is requesting and why;
- maintaining appropriate review phase discipline as described in current NRO policy and guidance; [54]
- placing additional emphasis on the project management functions of the review, including the collection and analysis of review workflow metrics that could reveal additional process improvement opportunities;

[54] Memorandum from F. Akstulewicz to NRO Division Directors and Deputy Division Directors, "Clarification of Phase Discipline Policy," April 7, 2010 (ADAMS Accession No. ML100950260 – NONPUBLIC)

- preparing draft (preliminary) SERs before generating associated RAIs;
- using applicant audits and confirmatory calculations when needed and appropriate; and
- using the “Living our Mission” internal guidance document as a tool to reach review schedule goals safely.

6.0 CONCLUSIONS

The staff developed this report in response to the Commission's request for answers to two questions:

(1) Can the NRC capture greater efficiencies in the Part 52 review process?

(2) Should the NRC update the metrics for the length of time it will take to perform new reactor reviews under Part 52 based on experience?

This report provides a historical summary of the staff's DC application review experiences submitted under Part 52, and an analysis of how those experiences and other factors contribute to impacts on DC review schedules. The staff's analysis concludes that lessons learned from review experiences are being appropriately identified and implemented. Additionally, the staff is working continuously to identify and communicate factors, which may cause review durations to extend beyond established goals.

6.1 Part 52 DC Review Efficiencies

The staff has determined that the Part 52 DC review process is sound and allows for an efficient review, as long as an applicant submits a high-quality, technically sufficient application, commits to providing the resources necessary to support the staff's review, and addresses key policy and technical issues during preapplication discussions with the staff. Additionally, the staff has made considerable efforts to implement the lessons learned from previous reviews and to implement other new changes to improve review efficiency.

The staff will continue to monitor DC review efficiency improvements gained by implementation of the actions identified in this report, and will continue to look for additional opportunities to gain additional DC review efficiency.

The staff has also improved project schedule assumptions that have been used for many years in order to better reflect the NRC's accumulated DC review experience. The use of improved assumptions, such as a more realistic RAI response time and a more accurate picture of staff resource capacities and availabilities, should lead to more accurate modeling of review projects and the associated resource requirements. This is particularly important in the NRC's current operating environment in order to obtain the best possible match between staff critical skills, capacities, and review project resource demands. Better schedule assumptions should also provide project managers and technical staff with additional look-ahead time to mitigate schedule change impacts.

6.2 Updates to Part 52 DC Review Duration Metrics

The staff fully recognizes the value and importance of establishing challenging but achievable review timeliness goals, and the contribution of doing so to regulatory certainty. The staff also recognizes that, based on experience, fact-of-life changes during the review period, such as emerging technical issues or requests for review schedule changes by the applicant, can and often do occur.

The analysis of DC review experience has affirmed the staff's approach of setting challenging, but achievable review duration goals and metrics, such as the 42-month DC safety review goal for large LWRs (like the KHNP APR1400) and the 39-month DC application review goal for small modular reactors (SMRs).[55]

From a communication perspective, the staff will place additional emphasis on explaining the planning and scheduling assumptions that support DC application review duration goals to all stakeholders in order to establish realistic review expectations. The review assumptions used for establishing the KHNP APR1400 review schedule provide the most up-to-date assumptions to be communicated.

NUREG/BR-0468,[56] "Frequently Asked Questions about License Applications for New Nuclear Power Reactors," provides a specific estimate of the time required for the staff complete a COL review. The document says, "Generally, the NRC performs an acceptance review in 60 days, followed by a nominal 30-month detailed review for an application that references a certified design. Noncertified designs would take 48 to 60 months to review. The NRC also allows 12 months for completion of the hearing."[57]

There is no similar estimated timeline provided for DC reviews, either in the NUREG cited above or on the NRC public Internet Web site or in ADAMS. As noted above, the LPP, which did provide estimated review durations for DCs, is a nonpublic document used for staff planning purposes. While estimated DC durations for large LWRs have been discussed in various NRC forums, in Congressional testimony, and in independent reports by the Government Accountability Office (GAO),[58] there is no public NRC document that provides this information in a detailed, consistent manner.

In summary, the staff believes that the goal for the length of time it should take to perform new DC safety reviews under Part 52 has been set appropriately at 42 months. The staff will undertake efforts to communicate its review assumptions and expectations to stakeholders in a comprehensive manner.

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55 Public Meeting Slides "Baseline Schedule for SMR Design Certification Reviews," February 24, 2014 (ADAMS Accession No. ML14050A063)

56 NUREG/BR-0468, "Frequently Asked Questions about License Applications for New Nuclear Power Reactors," December 2009 (ADAMS Accession No. ML092370545)

57 Since NUREG/BR-0468 was issued in 2009, the NRC has issued COLs for Vogtle Units 3 and 4 (AP1000), Summer Units 2 and 3 (AP1000), Fermi Unit 3 (ESBWR) and STP Units 3 and 4 (ABWR). Total review and licensing times for these applications ranged from 47 months (Vogtle) to 101 months (STP). Acceptance review and hearing durations were within the NUREG estimated durations for all of these applications. Safety review durations for all COLs except STP have been adversely affected by significant delays with completing the safety reviews of the referenced design certifications. The STP review was delayed because of changes in the DC application reflecting a change in the nuclear steam supply system vendor from GE to Toshiba, and for policy matters related to foreign ownership and financial qualifications of the applicant.

58 GAO Report No. GAO-15-652, "Nuclear Reactors Status and Challenges in Development and Deployment of New Commercial Concepts," July 2015. Note that this report cites the NRC's published small modular reactor (SMR) DC review estimate of 41 months (39 months plus a 2-month acceptance review), but incorrectly applies the estimated duration to any new LWR.

For large LWR DC reviews, the following review timeliness goals are being adopted:

- 2 months for completion of the acceptance review

- 42 months for completion of the safety review (factors such as the uniqueness of the design, the need for and extent of vendor testing required, and whether technical or policy matters are effectively addressed in pre-application reviews, will affect the ability of the staff to apply this goal in some cases)

- 8 months after completion of Phase 4 of the safety review for completion of rulemaking (total rulemaking duration of 13 months)

For SMR DC reviews, the recently established goal of 39 months from acceptance of the application to completion of rulemaking will continue to be used. This goal will be periodically reviewed as licensing experience for these reactors is accumulated.

Further, the staff intends to review the existing published internal and external review duration guidance for each type of Part 52 application and to update the guidance as necessary to bring alignment with the review duration goals discussed above.

6.3 Changing How Review Timeliness Goals and Schedules Are Calculated and Communicated

As described in this report, application review durations can exceed the planned durations for a variety of reasons. Recognizing that some project delays are not attributable to the NRC staff, the staff intends to change the way project total project durations are calculated and communicated to provide clearer information on the cause of schedule changes. For example, an applicant's request for a 1-year pause or slow-down to allow time to resolve a technical issue in a 42-month review schedule could be described as an "NRC safety review duration" of 42 months and a "total review duration" of 54 months. In circumstances in which an applicant is not able to commit to or to provide the level of support resources necessary to accomplish a timely review, the NRC would consider formally suspending the application review. Similarly, if review delays are attributable to staff actions, that would be more clear.

The staff will further develop the approach for capturing and presenting this information in a way that balances the needs of stakeholders to better understand the complexities of Part 52 application review schedules, with the regulatory efficiency that the NRC commits to in its Principles of Good Regulation.

The staff plans to inform stakeholders of these changes through a Regulatory Issue Summary (RIS) and to communicate review schedule expectations, by updating NUREG/BR-0468, and by discussing this broadly in meetings with prospective applicants and in appropriate public meetings and presentations.

The staff plans to issue the RIS and revision to NUREG/BR-0468 by the end of 2016. Discussions of and presentations on the proposed update to the guidance are expected to begin in the summer of 2016 and continue as the update is finalized.

By communicating a more holistic picture of the overall schedule, all stakeholders should gain a better understanding of the staff's level of effort. This picture could include the major review activities and durations, applicant response times, and other unique circumstances associated with each review project.

The staff concludes that the changes discussed above, and other recent and on-going initiatives discussed in this report regarding the Part 52 reviews, provide a sound basis for high quality safety, security and environmental reviews which are consistent with the NRC's mission and responsive to applicant and stakeholder needs and expectations.

ATTACHMENT – "LIVING OUR MISSION" (2 Pages)

Living our Mission: An Enhanced Approach to New Reactor Reviews

KEY MESSAGES

• Our reviews serve the public interest by enabling the safe, secure, and environmentally responsible use of nuclear power; and we conduct those reviews consistent with NRO's Vision of Success.
• We have established new commitments for delivering this service on a predictable schedule. These commitments require a strong organizational will to achieve this goal. As such, all levels of the organization will be accountable to conduct the reviews in an efficient manner and focus on safety and regulatory issues essential to our findings.
• We recognize we'll have to do some things differently to deliver our products on a faster schedule than we have in the past, while still meeting all of our safety review responsibilities. Our Expectations for Success clarify how we will work as One NRC to execute our projects and what the applicants need to do to make all this work. We have also developed strategies and good practices that will enable us as a team to implement this goal.
• We are well poised to tackle new projects: we have appropriate guidance in place to focus and execute our reviews—including a more rigorous application acceptance review—and an experienced staff.
• **Specific to the APR1400 design certification review**, our preparation will help us meet our 42-month goal.
  ○ APR1400 is a known design, subject to 2 rounds of pre-application interactions and acceptance reviews.
  ○ The applicant has made good progress on many complex issues.
  ○ We have prioritized the project so that staff will be available to support its review.
  ○ We are reaching out to leverage the knowledge and experience from our international counterparts.

EXPECTATIONS FOR SUCCESS
Expectations of Our Applicants • The applicant will deliver high-quality documents that fully address relevant regulatory requirements and staff guidance. • The applicant will provide requested materials on the agreed-upon schedule. • The applicant will engage the staff early to discuss any areas where deviations from NRC guidance are proposed, such that a mutually understood rationale and review approach can be determined. • The applicant will commit its own resources to support the published schedules and communicate changes in their resource availability early. • The applicant will use established processes (e.g., ISG-11) to determine whether late-stage, self-initiated changes to their application are warranted. For changes that will require significant rework by the staff, the applicant will communicate the scope and purpose of the change as early as appropriate to enable rescoping the review. **Expectations of the NRC** • We will raise issues to project managers and our line management; identity paths forward, where appropriate; and communicate them to the applicant as quickly as possible. • We will develop high-quality RAIs on safety-significant or required review aspects that support completion of our technical evaluation of the design. We will apply the appropriate regulatory tools to resolve issues expediently being clear about our expectations, including RAIs, audits, and public meetings. • We will work as a team across technical and project groups to peer-review RAIs and SERs, ensuring clear regulatory findings and identifying and addressing cross-cutting issues. • We will write succinct SERs that document the staff's findings on the design and the basis for each finding. Technical divisions will determine the scope and level of detail needed to reach the regulatory findings. • We will continue to be open and transparent both within the NRC and to the applicant at all stages of the review though frequent communications on technical, regulatory, and schedule expectations. • We will clearly communicate to project managers, our line management and the applicant the schedule risk and impact if the applicant changes the design (other than addressing or eliminating problems) during the review process. • We will prioritize our work and reduce distractions to staff caused by inquiries on issues of low significance or outside our review scope.

STRATEGIES[1]

Raising Issues

- Raise safety and regulatory issues early.
- Remember that requests for additional information (RAIs) are not the only way (nor the timeliest way) to get the information we need. ***Thus, evaluating the significance of an issue and optimal resolution path (meeting, audit, RAI, etc.) before creating an RAI could add efficiencies to the overall review.*** This should not preclude issuance of early RAIs (before the end of Phase 1).
- Follow the NRO guidance for writing RAIs and ensure that RAIs have a sound basis, i.e., are needed to support a required regulatory finding.
- Ensure technical division BC review and approval of all RAIs. RAIs identified after Phase 1 that identify new technical issues or that significantly change the scope of a review will require technical division director engagement.
- Review RAI responses ***with a prompt acceptance review*** and full technical review within 30 days or provide justification if more time is needed.

Making and Documenting Our Findings

- ***Start writing early in Phase 1; complete preliminary safety evaluation report (SER) to identify all "holes" that could turn into RAIs.***
- ***Follow OGC "tips" on writing SERs in Phase 1 and in Phase 2.*** Incorporate these tips when drafting the SER.
- Coordinate and communicate with secondary review organizations and reviewers when starting to write the SER.
- Focus SER on what is needed to explain the basis for the staff's regulatory findings (i.e., you do not need a chronology of all RAIs, but it's helpful to highlight the nature of the staff's independent review).
- **For APR1400,** use the APR1400 Reviewer's Guide to develop the SER (includes draft format, style, and standard language to be updated during the review process).

Overseeing the Project

- ***Work as a team and hold each other accountable by embracing our Expectations for Success.***
- Develop and implement a schedule that supports the established review duration.
- Follow the change control process for all schedule and/or resource extensions or contractions and include a strong justification for extensions.
- Record time spent (HRMS) and review progress (EPM status updates) in an accurate and timely manner.
- Raise issues early internally and externally (e.g., resolution of technical issues, quality of submittals), and document unresolved issues in formal communications to the applicant. In some cases, it may be more productive to suspend a portion of a review until the applicant provides an acceptable approach.
- Regularly communicate project progress internally with the project team (e.g., monthly meetings with branch chiefs, division and office level management) using NRO's methods of measuring and reporting project performance (e.g., leading indicators, earned value management).
- Conduct regular project management progress tracking meetings with the applicant, addressing schedules, plans, and issues.
- ***Streamline ACRS interactions through: (1) one round of technical presentations for chapters with no open items at Phase 2; (2) bundling many chapters in the second round; and (3) reaching a common understanding with the ACRS about the scope and level of detail of the staff's review.***

[1] Many of these strategies are already in use and are documented here so that everyone is aware and uses them. **Bold, italicized text** is used to highlight strategies that will enhance the reviews for our new projects.