NEI | TECHNICAL REPORT

Recommendations for Enhancing the Safety Focus of New Reactor Regulatory Reviews

Prepared by the Nuclear Energy Institute
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Executive Summary

This report provides an assessment of new reactor licensing reviews, including information from an ongoing review of a small modular reactor (SMR). The assessment was performed to determine whether the NRC has effectively adapted its reviews to account for the benefits of safer designs. Data was evaluated from NRC standard design certification (DC) and combined operating license (COL) reviews. Data from early site permit (ESP) reviews were included as well since the reviews are an important aspect of the 10 CFR Part 52 process.

Data was collected on the cost of the licensing review, the number of questions asked by the NRC staff through requests for additional information (RAIs), and the number of audits conducted by the NRC staff to seek additional information. In addition, specific instances where NRC new reactor reviews appeared to be overly burdensome were evaluated to better understand the contributing factors. Based on this information, this report identifies measures, beyond the actions that the NRC has already taken, that could be used to enhance the effectiveness and efficiency of NRC reviews.

Data indicate that the costs of NRC reviews have increased substantially over time.

Data taken from the April 7, 2015 letter from the NRC Chairman to Senator Inhofe[1] indicate that over the past 20 years costs of NRC reviews have increased substantially. The costs of DC reviews have increased by more than a factor of four over the last three decades,[2] and the review costs for ESPs issued between 2009 and 2016 have increased by a factor of three. Although there are differences between the designs and proposed sites and it is reasonable to expect differences in the amount of effort the NRC staff dedicated to each review, the clear trend has been an increase in review hours and costs over time. The cost increase for DCs go beyond what would be needed to address new regulatory requirements established during this period. The cost increase for ESPs occurred over a period where the ESP process did not change significantly.

Additional data were gathered for each design certification, using information reported publicly by the NRC, and are current up to November 15, 2017. These data clearly show that that the amount of information required by the NRC to be submitted for conducting its review has increased significantly from 1999 to 2014.

Three years of data were available for the KHNP APR1400 review and approximately one year for the NuScale DC review, both of which are underway as of the date of this report. Beginning in 2015 with the APR1400 DC review, the NRC initiated actions to improve the efficiency of their reviews. The NRC staff shifted to greater use of licensing audits to expedite the review schedule and reduce the number of RAIs. This strategy bears promise if best practices in audits are consistently implemented. Recent experience with the conduct of audits indicates that while some audits are conducted efficiently, in others the NRC staff has requested large volumes of detailed information not directly tied to a regulatory decision. The

[1] Letter from Stephen G. Burns (Chairman Nuclear Regulatory Commission) to the Honorable James Inhofe (Chairman Senate Committee on Environment and Public Works). April 7, 2015.
[2] To compare the costs of the reviews conducted since the late 1980's, the costs were adjusted for inflation and reported in 2017 dollars, as described in Section 4.0.

APR1400 and NuScale reviews also demonstrate that in some cases the NRC staff required information beyond that necessary to provide reasonable assurance of adequate protection of public health and safety.

The advantages of safer designs have not resulted in significantly reduced regulatory review costs.

After 14 months of review, NuScale Power Company has incurred a cost of $29 million, and expects the final cost of the DC review to be $55 - $65 million. This regulatory review cost does not include the $12 million of NRC fees during an 8 year pre-application review. This cost is greater than what should be expected for a demonstrably safer design that contains only one-third the safety systems as the current generation of operating plants.

The examples of staff reviews identified in this report demonstrate a tendency by some NRC staff to regulate to a level beyond reasonable assurance. The examples can be placed in one of three categories. First, examples where the reviewers requested types of information and levels of detail beyond that needed for NRC's safety finding. Second, examples where the staff re-reviewed matters that had been previously reviewed and approved; and third, examples where the staff reviewed applications against redundant regulatory requirements.

For the advancement of safety, NRC organizational doctrines of reasonable assurance that the regulations have been met and efficiency as well as effectiveness need to be reestablished and reinforced by the Commission.

The review identified the need for NRC to initiate additional actions to improve regulatory efficiency. To this end the NRC had previously developed enhanced guidance related to RAIs, audits, and a risk-informed approach to determine the level of staff effort dedicated to a particular structure, system or component. In considering the enhanced staff guidance and potential causes of the inefficiencies identified in this report, best practices were identified for 1) limiting requests for additional information to information required for the agency to find reasonable assurance of public safety; 2) increasing the use of risk insights to enhance the effectiveness and efficiency of reviews; and 3) conducting audits. An important insight from this report is that the identified best practices have not been consistently implemented across reviews for all technical disciplines, and need to be applied to both ongoing and future reviews.

Although not intuitive, the unintended consequences of inefficient reviews are actually counter to safety and negatively impact the use of advanced reactors.

This assessment concludes that NRC reviews of these safer advanced designs have generally required the same if not more detail than was required for the previous generation of designs. Thus, NRC reviews of these safer designs have not evolved to become more efficient. Counterintuitively, the advantages of safer designs do not appear to result in more efficient reviews. Inefficient reviews increase NRC review time and cost, and in many instances also result in increasing the amount of information subject to the NRC change control processes over the life of the plant. As a result, finite resources of the NRC staff and industry are devoted to areas of lesser safety significance; often areas that the regulator does not need to consider when making a safety determination. Ultimately, staff activities not directly tied to a safety finding adversely impact the design, licensing and deployment of advanced reactors.

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1 INTRODUCTION

This report considers the effort and costs associated with NRC reviews of design certification (DC), early site permit (ESP), and combined operating license (COL) applications for new LWRs and SMRs over the last three decades. The objective is to evaluate whether the NRC has, in practice, made its reviews of safer designs more efficient. Data was collected on a number of related measures from ongoing and prior Part 52 reviews. Both the data and the examples obtained from licensees and industry vendors are public.

The examples cover a wide range of technical disciplines. Data were collected on measures such as the cost of the review, the number of questions asked by the NRC staff, and the NRC audits. Following the data and examples, the impacts of the NRC staff's reviews are summarized and then the potential causes and actions that could be taken by both the NRC to improve reviews are discussed.

2 BACKGROUND

The Atomic Energy Act of 1954, as amended, provides that the NRC may issue licenses only if it finds that the applicant's proposed utilization or production of special nuclear material will be in accord with the common defense and security and will provide adequate protection of the health and safety of the public. Sec.182.a. of the Act establishes "adequate protection" of public health and safety as the measure that underpins NRC's regulatory requirements.[3] The NRC's regulations implement this statutory standard and the Commission determines what is necessary to provide adequate protection of public health and safety. NRC regulations in 10 CFR 50.40, "Standards for Licenses, Certifications and Regulatory Approval," provide that the NRC must "have reasonable assurance that the applicant will comply with the regulations in this chapter [10 CFR Part 50], including the regulations in part 20 of this chapter, and that the health and safety of the public will not be endangered." Reasonable assurance is the level of certainty that the staff must have to issue a license. The Commission has provided clarifying statements regarding its interpretation of reasonable assurance of adequate protection. For instance, in 1988 the Commission stated in the final backfit rule, "Revision of Backfitting Process for Power Reactors," that "adequate protection is not absolute protection or zero risk."[4]

Reasonable assurance that the regulations have been met is the level of certainty that the staff must have to issue a license.

The NRC has established goals to be effective and efficient in determining reasonable assurance of adequate protection. The NRC has long recognized that in order to do so, the staff should focus time and attention on issues commensurate with their safety significance. Not doing so is contrary to safety because resources of the NRC staff and the industry are spent on areas of low safety significance that are not needed for a safety determination. In addition, unnecessarily burdensome reviews may hamper the deployment of safer technologies, such as advanced non-LWR designs.

[3] In the case of ESPs, the NRC finding is whether the site meets the requirements of 10 CFR 52.24, "Issuance of Early Site Permit," and the site is suitable, rather than reasonable assurance that the regulations have been met for licensing. However, examples of reviews of ESPs and some data pertaining to ESPs were included in the assessment because ESPs play an important role in the Part 52 process.
[4] See "Revision of Backfitting Process for Power Reactors" Final Rule, 53 Fed. Reg. 20603 (June 6, 1988).

The NRC has issued guidance to the staff to highlight these principles. One document notes that, "requirements that are duplicative, unnecessary or unnecessarily burdensome can actually have a negative safety impact. They also can tend to inappropriately shift the NRC and licensee to focus on "compliance versus safety"[5] issues. The guidance also states that, "since some requirements are more important to safety than others, the Commission should use a risk-informed approach wherever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of licensed activities." However, experience developed over the last three decades with DC, COL and ESP applications indicates that the NRC staff has to a large extent remained deterministic in its licensing reviews, even though regulation and guidance allow the NRC staff flexibility to adjust its review on the basis of safety significance.

The NRC's regulatory approach is not intended to review or oversee every action by the industry, since the industry has the responsibility for safe operation of commercial nuclear power plants. DC applications must comply with completeness and accuracy requirements in 10 CFR 52.6. The work to develop an application is performed under a Quality Assurance program that is reviewed and approved by the NRC staff and is compliant with Appendix B to Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." Additionally, licensing actions (e.g., LARs, ESPs, and COLs) are submitted under oath or affirmation.[6] In consideration of the requirements for applicants to ensure the underlying level of quality of the application, it appears that NRC does not properly credit this when formulating its review. Instead, over time reviews have required increasing volumes of information and greater detail, and the NRC staff has focused its attention and resources on structures, systems, and components (SSCs) beyond what is commensurate with their safety significance. As a result, the volume of information and the level of detail required to be submitted and/or reviewed to obtain required NRC safety findings have in many instances increased beyond what is necessary to provide reasonable assurance that the regulations will be met.

Recently, the NRC staff has taken action to enhance the efficiency of new reactor reviews. In particular, the staff has established 44 and 42 month schedules, not including rulemaking, for the DC reviews for the APR1400 and NuScale designs, initiated in 2015 and 2017, respectively.[7] In addition, to help prepare for these reviews, guidance was issued to the staff pertaining to RAIs, audits, and a risk-informed approach to establish the level of staff effort dedicated to a particular SSC. Although progress has been made, the data presented below indicate that additional actions are necessary to ensure the NRC staff's review practices are consistent with the sound safety-focused regulatory approach directed by the Commission and advocated in the aforementioned guidance documents.

3 SUPPORTING HIGH-LEVEL STATISTICS

Several simple numerical indicators show an overall increase in the level of detail and the volume of information that the NRC deems necessary to make a finding of reasonable assurance that the regulations will be met, and public health and safety will be protected. As a result, the staff is spending more time and effort reviewing the additional information. The most meaningful indicator is the review cost as it reflects

[5] NRC Inspection Manual Part 9900, "Technical Guidance," approved by the Commission in SRM COMSAJ-9708 (ML003753992).
[6] Oath or Affirmation is a solemn and formal declaration of the truth of the statement. The NRC, through the Department of Justice, can take legal action as a result of the inaccuracy of information submitted under Oath or Affirmation and has done so.
[7] See: https://www.nrc.gov/reactors/new-reactors/design-cert/apr1400/review-schedule.html and https://www.nrc.gov/reactors/new-reactors/design-cert/nuscale/review-schedule.html.

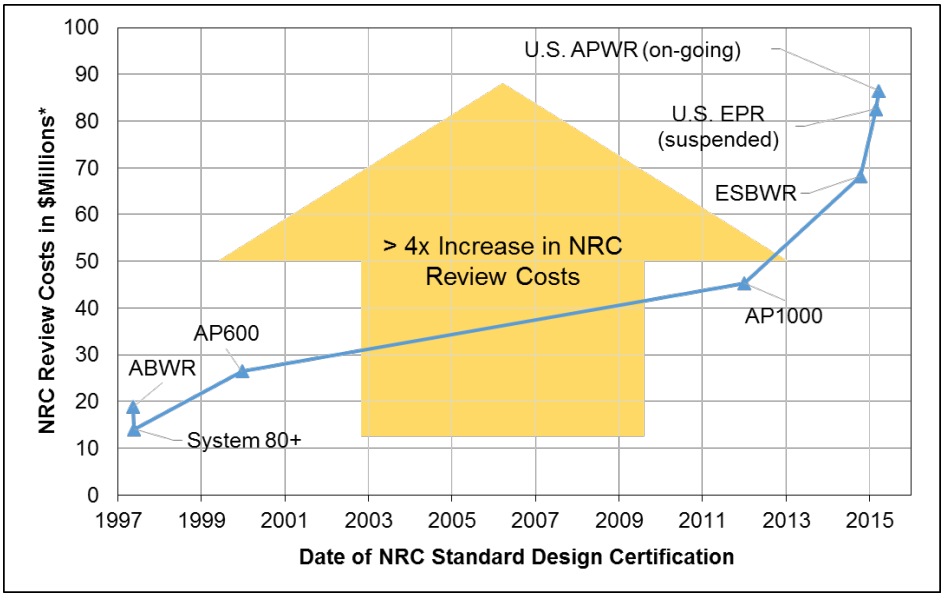
the total staff time dedicated to the review. In some cases the quality of the application submitted to the NRC may prompt a higher level of scrutiny; however, applicants generally model their applications after similar applications that recently received NRC approval. Furthermore, industry's quality assurance programs and procedures are reviewed and approved by the NRC to ensure the quality of the information submitted in the applications. To the extent that following successful precedents and applying 10 CFR 50, Appendix B-compliant Quality Assurance programs produces applications of relatively consistent quality, it is reasonable to conclude that there is a correlation between these measures and the level of review the NRC staff feels is necessary to support its review.

On April 7, 2015, the NRC Chairman responded to a letter from Senator Inhofe, dated March 23, 2015, in which the Senator requested information pertaining to NRC review fees. The NRC's response included statistics on DC, COL, and ESP reviews. Table 1 contains these data as they pertain to NRC review costs for DCs. Because the review of the U.S. APWR is ongoing, Table 1 does not include any costs that were accrued by the vendor beyond the date of the NRC response. Similarly, the duration of the U.S. APWR review is the amount of time the NRC has spent on the review from the submittal date to April 7, 2015. The review costs include the costs accrued during pre-application discussions, but the duration of the review only reflects the time from the date of submission of the DC application. Figure 1 depicts the costs of the reviews in 2017 dollars over the last 20 years. The costs of DC reviews have increased by a factor of more than four since the late 1990's.

Standard Design Certification	Date of Submission	Date of Certification	Calendar Time in Years	Year Used For Inflation Calculation	Cost in $	Cost in 2017 $
ABWR	9/27/1987	5/12/1997	9.6	1993	18.8 M	32.1 M
System 80+	3/30/1989	5/21/1997	8.2	1993	14.1 M	24.1 M
AP600	6/26/1992	12/22/1999	7.5	1996	26.4 M	41.0 M
AP1000**	3/28/2002	12/30/2011	8.4	2006	45.3 M	55.4 M
ESBWR	8/24/2005	10/15/2014	9.1	2009	68.2 M	78.4 M
U.S. EPR	12/11/2007	Suspended on 2/25/2015	7.2 when suspended	2011	82.6 M	90.6 M
U.S. APWR	12/31/2007	Under review	7.3 as of 4/1/2015	2011	86.5 M	94.8 M

Table 1: Cost Statistics for DC Reviews

*** Includes the AP1000 design certification and amendment*



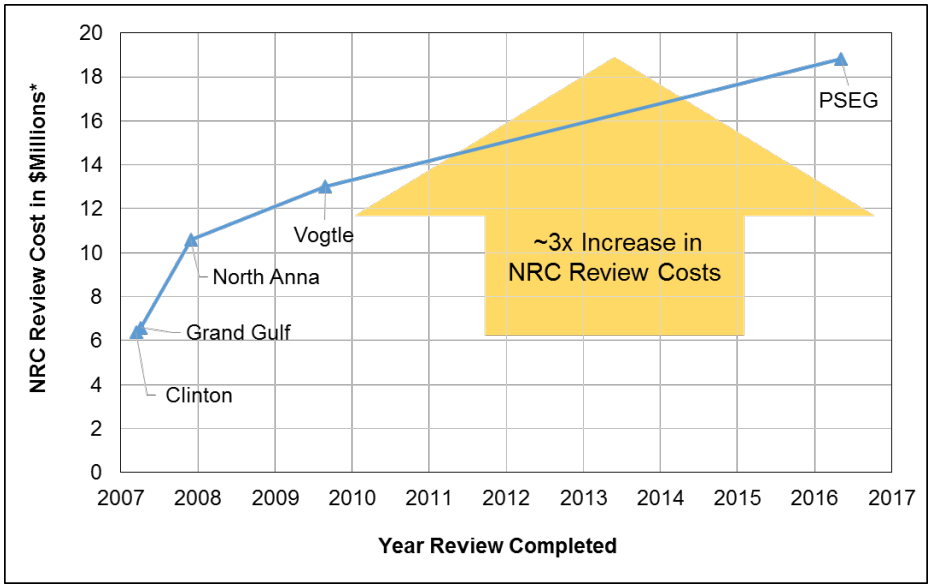
**Cost is reported in 2017 dollars.*

Figure 1: NRC Review Cost of DCs

The reviews of the APR 1400 and the NuScale designs were not included in Table 1, because the former had been underway for only three months and the latter had not commenced by the time the NRC letter was issued on April 7, 2015. NuScale estimates that as of February 28, 2018, the cost of its review for the first 14 months of a 42 month schedule is over $28 million,[8] approximately $2 million per month. This spend rate is expected to decline because the first 1.5 years of the 42 month review involve the most effort by the NRC staff. At the completion of the review and rulemaking, NuScale anticipates that the DC review and rulemaking fees will require $55 - $65 million, and in total $67 - $77 million including NRC pre-application fees. Although this is similar to the costs of several other DC reviews summarized in Table 1, the cost is above that originally forecast by NRC ($40 million) and the NuScale design has one-third of the safety systems as large LWRs. Given that the NRC should focus its review on safety significant systems, a significantly lower review cost for the NuScale design should be expected.

Both the industry and the NRC have substantial experience in the regulatory process governing ESPs, and the process has not changed significantly since its inception. Similar to the practice for DCs, the industry also reviews the most recent NRC Safety Evaluation and Environmental Impact Statement[9] as a guide to what information should be submitted in an applicant's future ESP submittal. Therefore it is reasonable to expect that the cost of ESP reviews would decline over time. However, as shown in Figure 2 this has not happened. In fact, the review costs for ESPs (reported in 2017 dollars using the same approach as was used for DC review costs) have steadily increased by over a factor of three during the last nine years. This is the exact opposite trend of what is expected.

[8] This value does not include the $12 million in fees that NuScale incurred for the pre-application discussions that were conducted from 2008 to 2016.
[9] The ESP process requires a safety evaluation and an Environmental Impact Statement.



**Cost is reported in 2017 dollars.*

Figure 2: NRC Review Costs of ESPs

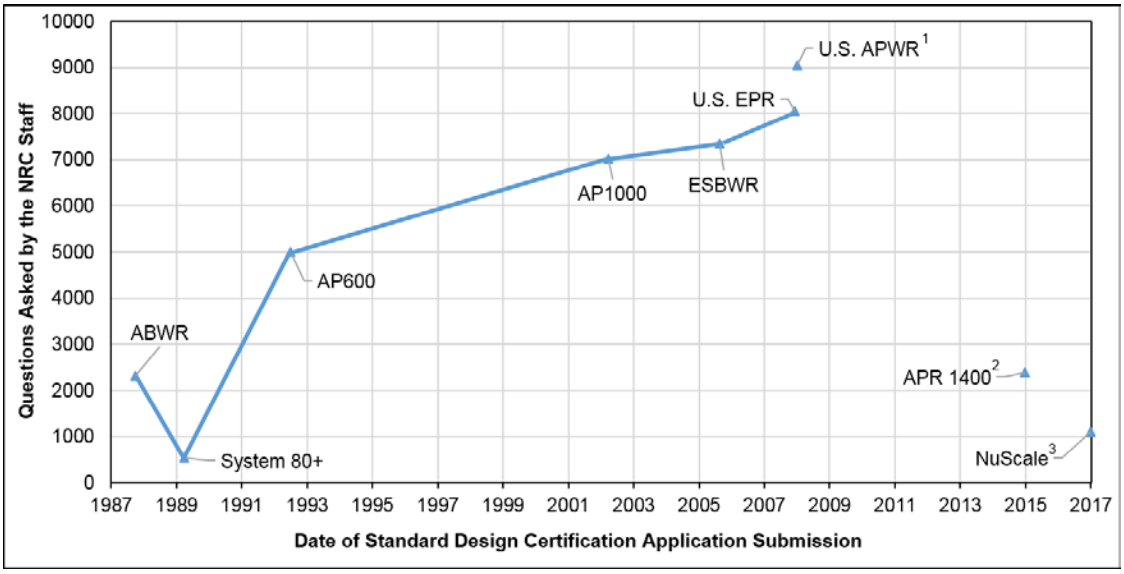
Other statistics were collected to help ascertain whether the level of detail and the amount of information required by the NRC staff when reviewing DCs have increased over time. The NRC question and audit statistics, presented in Table 2, were gathered by accessing publicly available information reported by the NRC on each DC and are current up to November 15, 2017. As a result, three years of data were available for the APR1400, a design that is similar to PWRs currently operating, and approximately one year for the NuScale review. The number of NRC staff questions asked was looked at as well as the number of regulatory audits conducted. Figure 3 shows that the number of questions asked by the NRC staff generally increased from the late 80's to 2015 by approximately a factor of four. Figure 4 shows that the NRC staff increased the number of audits over the same time period.

Beginning in 2015, with the start of the APR1400 DC review, the NRC staff appears to have changed its practices in an effort to enable more efficient reviews. As depicted in Figures 3 and 4, the number of questions asked by the NRC staff and the number of audits declined. In the case of the NuScale review, the data are for the first 9 months of the review and thus are expected to increase. However, since the first 1.5 years of the NuScale review involve the most effort by the NRC staff, the number of questions asked by the NRC staff and the number of audits conducted are not expected to continue at the same rate.

Standard Design Certification	Date of Submission	Date of Certification	Calendar Time in Years	RAIs	Audits
ABWR	9/27/1987	5/12/1997	9.6	2317	5
System 80+	3/30/1989	5/21/1997	8.1	532	10
AP600	6/26/1992	12/22/1999	7.5	5005	15
AP1000**	3/28/2002	12/30/2011	8.4	7022	34
ESBWR	8/24/2005	10/15/2014	9.1	7345	33
U.S. EPR	12/11/2007	Suspended on 2/25/2015	7.2 when suspended	8055	50
U.S. APWR	12/31/2007	Under review[10]	9.9 as of 11/16/2017	9044	41
APR 1400	12/23/2014	Under review	2.9 as of 11/16/2017	2378	29
NuScale	12/31/2016	Under review	0.9 as of 11/16/2017	1111	22

Table 2: Question and Audit Statistics for DC Reviews

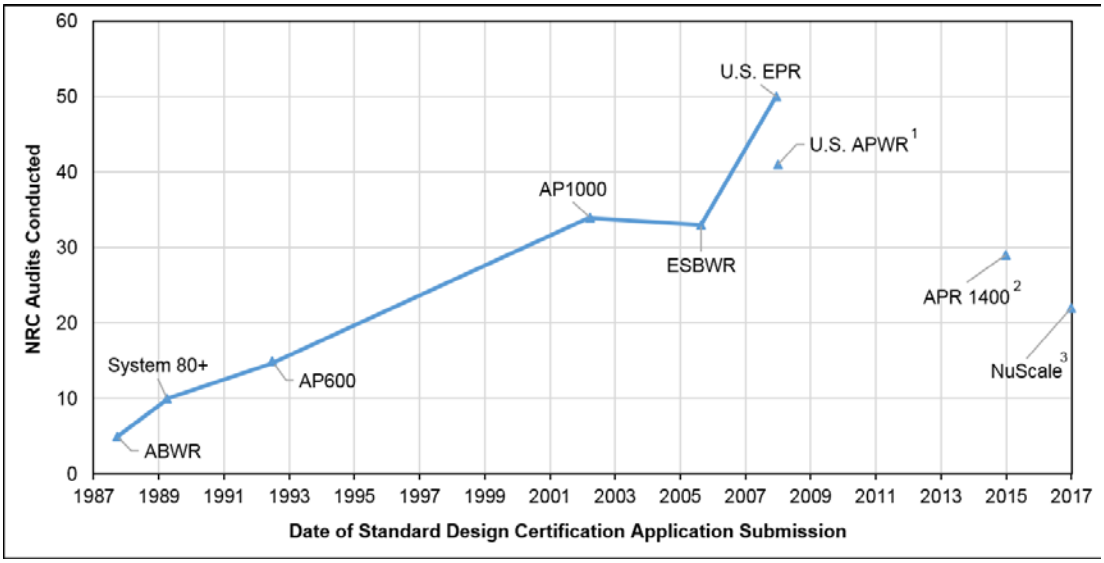
*** Includes the AP1000 design certification and amendment*



1 The U.S. APWR is on-going as of the date of this report.
2 The data are for the first 3 years of the APR1400 review.
3 The data are for the first 9 months of the NuScale review.

Figure 3: Questions Asked by the NRC Staff for DCs

[10] The staff has limited its review activities at the request of the applicant.



1 *The U.S. APWR is on-going as of the date of this report.*
2 *The data are for the first 3 years of the APR1400 review.*
3 *The data are for the first 9 months of the NuScale review.*

Figure 4: Audits Conducted by the NRC for DCs

In a regulatory audit, the NRC staff primarily examines and evaluates non-docketed information. Audits are conducted to understand or verify information, and/or to identify information that will need to be docketed in order to support the NRC staff's decision. Audit plans are made publicly available before the audit and a report of the findings issued after the audit. The NRC staff has increased its reliance on audits rather than written RAIs in an effort to increase the efficiency of reviews. Recent experience with NuScale's DC review and TVA's ESP review has shown that when effectively implemented, audits appear to reduce the total number of RAIs and enable the staff to focus on questions necessary to make a safety finding, rather than asking questions to better understand the material.

NRC use of audits has the potential to increase review efficiency when effectively managed. However audits without a well-defined scope and duration can lose their safety focus and consume significant resources addressing questions not linked to a safety determination.

4 EVALUATION OF REVIEW CONCERNS

The purpose of this section is to identify and evaluate areas of concern with NRC reviews. While addressed separately, the areas are interrelated. For example, audits appear to reduce the number of RAIs. Both audits and RAIs can result in changes to the level of detail in the application.

This section discusses observations and recommended improvements that can be implemented, in some cases for ongoing NRC reviews. Examples to illustrate the concerns are included in the Appendix.

4.1 Licensing Audits

The NRC staff's increased use of licensing audits has helped maintain established review schedules and reduce the number of RAIs. This strategy bears promise if best practices in audits are implemented more consistently. Thus audits and RAIs are intertwined and consistent implementation of best practices would improve the overall review. For example, the NRC staff appears to be adhering to its schedule to complete the DC review of the APR1400 design in approximately 44 months. This schedule does not include rulemaking. Approximately three years into the review, the NRC staff has asked 2,378 questions and conducted 27 audits. The staff established a 42 month schedule for the NuScale DC review, not including rulemaking. One year into the NuScale review the NRC staff has asked 1,111 questions and completed 27 audits with another 8 in progress.

The audit process appears to reduce the number of RAIs issued by the NRC staff. However, when audits are not well planned and efficiently conducted, they can be unnecessarily burdensome. An example of this would be an audit where the NRC staff is permitted by NRC management to conduct exploratory questioning outside the scope of the audit plan. In such cases, a great deal of NRC and applicant time and effort is spent identifying and reviewing excessive volumes of information and detail well beyond the scope of what is necessary to make the applicable regulatory finding.

While there are indications that audits could result in a more efficient, less costly review, it is yet to be demonstrated. The most positive indication is that audits do seem to expedite the review schedule. This has been attributed to the more frequent communications that occur with audits, including face-to-face interactions that result in more effective dialogue and more timely resolution compared to the exchange of correspondence with RAIs.

Whether there are cost savings associated with the use of audits remains unclear in part because the NRC does not track audit costs separate from the associated application or topical report review, and thus NRC costs for this approach are unknown. NuScale does track the costs of supporting NRC audits. To date, NuScale costs to support audits are about $5 million. The total projected NRC review costs at the high range exceed the upper estimate of $60 million for the DCA review that NuScale presented at a Commission meeting on September 16, 2016. With approximately $28 million in fees as of the end of February 2018, the original NRC fee forecast of $40 million no longer seems plausible.

Historically, most audits have been of relatively short duration (days) with a narrow focus and prompt issuance of the final audit report and conclusions. Audits have been viewed as the licensing equivalent of inspections on operating units: a check of a sample of the underlying engineering documents to ensure the statements in the application were supported. In recent applications, audits are more frequently conducted over an extended period of time and in some cases have been over six months in duration. Some of the long duration audits have been effective and well-managed; however, long duration audits are, in general, more difficult to manage for both the applicant and the NRC, and make it harder for the NRC staff to maintain focus on the regulatory issues that the audit was intended to resolve.

As discussed further in the examples provided in the Appendix, some audits are not effective because they have not been appropriately managed. Through more consistent use of good audit practices, the audit process can be significantly improved.

Identified concerns with audits include:

- Instances where the audit plans were developed before the NRC staff reviewed the associated relevant portion of the application (or topical report). This resulted in a poorly defined audit scope and duration. In some cases, the NRC staff tended to review applicant documents without having a clear regulatory need to do so.

- Instances where the audit scope was in many instances expanded with no justification. This problem appears to be in most instances caused by a poorly defined initial audit scope.

- Instances where the interim milestones were not identified and interim audit reports were not issued to ensure progress was occurring at the expected rate.

- Instances where the NRC staff and contractors were routinely late to meetings with the applicant. This resulted in less effective and more costly meetings.

- Instances where the audit NRC staff and contractors were not in agreement on the issues to be raised during the meeting with the applicant. This resulted in less effective meetings and increased costs.

The following practices are recommended to be added to or emphasized in the NRC's existing staff guidance, NRO-REG-108, "Regulatory Audits," and incorporated into all ongoing and future audits:

- There should be a well-defined scope and purpose, reflected in the audit plan that is based upon an initial review of the relevant portions of the application.

    - Each document requested for audit should be tied to a specific regulatory need and specific dates for its review.

    - The estimated cost of the audit (review hours) should be provided and tracked.

    - If there is a need to change the scope of an audit, a documented revision to the audit plan should be issued including the basis for the new scope and its impact on cost and schedule.

    - For audits greater than one month, the audit plan should have sufficient detail to establish interim milestones to ensure progress is being made at the forecasted rate.

- Interim reports should be published at intervals no greater than one-month, and include an evaluation of the work completed, whether interim milestones were achieved, and whether the costs to accomplish that work matched the original plan. If interim milestones were not achieved an assessment of the causes of the delays, and corrective actions to get the audit back on schedule, should be included in the interim report. The interim report should conclude whether the overall schedule for the audit will be achieved given the current state of the audit. Interim reports should be provided to the applicant within one week of its completion.

- Audit meetings should be conducted consistent with effective meeting principles. Questions planned for discussion should be provided to applicants at least one week prior to the meeting.

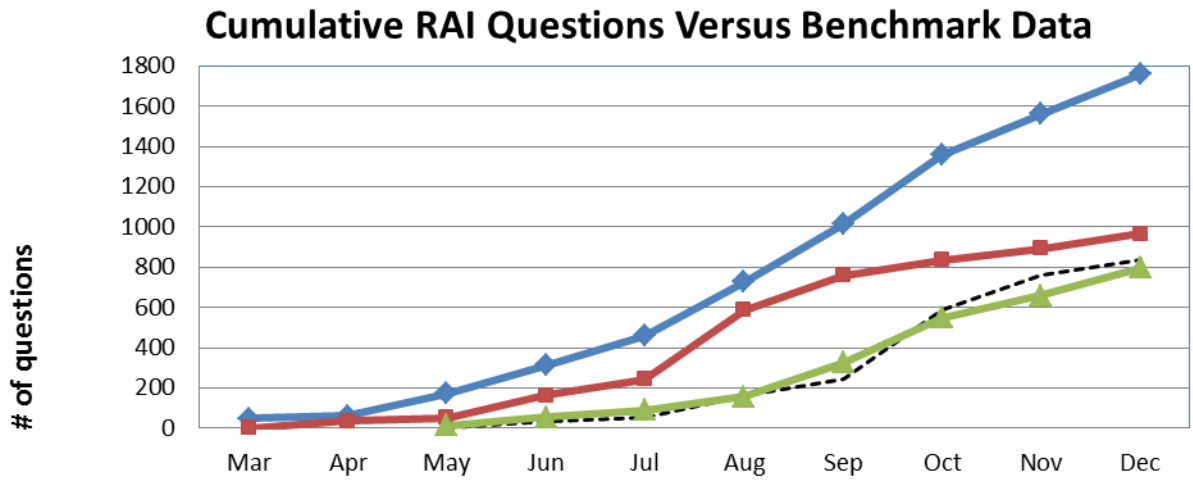
NRC staff and their contractors should arrive on time for audit meetings with alignment on the questions they intend to ask the applicant and the associated regulatory positions.

- Management attention, at the branch chief and senior executive levels, should be provided throughout the audit to ensure progress.

4.2 Requests for Additional Information

In general, the perception is that, overall, for ongoing reviews the RAI process has become more efficient. Management appears to be more involved, and more frequently challenges the need for RAIs, thereby preventing some RAIs that lack regulatory basis from being issued. As noted above, the increased use of audits also contributes to a reduction in RAIs.

NuScale provided the following results for RAIs through 2017. In advance of submittal of its DCA, NuScale developed a benchmark curve for expected RAIs. The curves were developed based on prior DCA reviews, and then modified based on other factors such as: quality of the application, fewer systems to review, reduced multiple round RAIs, and shorter overall schedule. The results, shown in Figure 5, indicate substantial improvement over the forecasted number of RAIs. However, as noted above, the reduction in RAIs is not reflected in reduced NRC review cost, but it appears that the reduction in RAIs is helping maintain the original review schedule.



	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Benchmark	49	61	172	312	458	728	1014	1359	1560	1760
Received	0	36	51	164	243	587	759	835	892	967
60-day Target			0	36	51	164	243	587	759	835
Submitted			13	55	89	156	325	549	661	797

Figure 5: Cumulative RAI Questions vs Benchmark Data

Some areas for additional improvement with RAIs include:

- Despite applicants noting during clarification calls that the information desired by the staff was in the FSAR, and the NRC staff agreeing, the staff still issued an RAI. All RAIs, no matter how minor, represent a substantial cost to issue, respond to, and close. The impact is not only the cost for the applicant to provide an answer but also for the cost for NRC's review.

- Related to above, applicants should not be requested to duplicate information in multiple sections of the FSAR. This adds configuration management burden. Further, the format of an FSAR is defined by guidance, and while convenient to have information where NRC staff prefers, this not needed for the NRC to conclude that the application meets the regulations.

- RAIs that use 10 CFR 52.6 (Completeness and accuracy of information) as a regulatory basis are inappropriate. This basis implies that an applicant intentionally made incomplete or inaccurate statements. If so, the RAI process is not appropriate to resolve this concern. Given the lack of specificity in the regulations and guidance regarding application content, and the size of applications driven by past practice, it is unrealistic to assume that applications will not include some errors and inconsistencies.

- RAIs whose primary or sole regulatory basis is a content requirement such as 10 CFR 52.17(a) (Contents of applications; technical information), 52.47(a) (Contents of applications; technical information), or 52.79(a) (Contents of applications; technical information in final safety analysis report) are also inappropriate. The acceptance review concludes that the application contained sufficient content to conduct the review, including the content specified by applicable regulations. These RAIs give the impression that the staff does not know what is needed to make the associated safety finding; rather, staff appears to just want "more" information.

- RAIs that do not include reference to specific acceptance criteria whether derived from regulation or guidance are difficult to answer. This leaves the applicant speculating as to the information necessary for the staff to make its safety finding. This problem is most common in ESP and DC reviews where the information requested is largely controlled by operational programs that will later be developed and implemented by a COL applicant and licensee. It is unclear how these RAIs consider the safety-significance of the SSCs for the specific design under review. Part of this stems from the Standard Review Plan (SRP) (and Design Specific Review Standard (DSRS) in the case of NuScale) which the staff follows closely and is not risk-informed. Regardless, the SRP and Regulatory Guide 1.206 (Combined License Applications for Nuclear Power Plants) allow the staff to use judgement and account for safety significance. There is evidence that the staff is not taking advantage of this flexibility especially for systems that are not safety significant.

- RAIs that request applicants add information for completeness, where that information duplicates other requirements or guidance. For example, most COL items are duplicative of 10 CFR 50 and 52 requirements, or COL application guidance in RG 1.206.

- Applicants frequently do not receive timely feedback on adequacy of RAI responses. It is not unusual to wait months for NRC feedback. The concern is that if a response is not sufficient, time is lost to correct the deficiency. These "idle times" can impact the review schedule.

Recommended practices to improve the RAI process:

- RAIs should not be issued where the applicant has shown the NRC where the information resides in the application.
- Applicants should not be requested to duplicate information throughout the FSAR.
- RAIs should not reference 10 CFR 52.6 (Completeness and accuracy of information) unless NRC staff has reason to believe the application was intentionally incomplete or the applicant intentionally made inaccurate statements.
- Content-based RAIs (e.g., 10 CFR 52.17(a), 52.47(a), 52.70(a)) should not be issued.
- RAIs should include specific technical acceptance criteria, derived from guidance or regulation, which identify the gaps between the application and the acceptance criteria that the staff needs to close to make their safety finding.
- Feedback on RAI responses should be provided to applicants within 30 calendar days.

4.3 Increasing Level of Detail

Applications have been increasing in level of detail, despite a lack of regulatory changes that would drive significant additions to FSARs (or DCDs, for some design certification applications under 10 CFR 52). The regulations governing content of FSARs have remained largely unchanged. The most significant changes have been the addition of PRA-related content with Part 52. However, these additional content requirements do not explain the level of detail in recent FSARs.

The industry and NRC last addressed this issue in the late 1990s, with the content for updated FSARs as required by 10 CFR 50.71(e). As a result of that effort, NEI 98-03 (Guidelines for Updating Final Safety Analysis Reports) was issued and endorsed by NRC. It acknowledged that much information that was not necessary had been added to FSARs over time, and allowed licensees the opportunity to remove some unnecessary details.

Unnecessary information in an FSAR imposes a burden on applicants, who have to develop and pay for review of unnecessary content, and licensees who must maintain and evaluate changes against that content. Content that is not needed to demonstrate compliance with regulations, and/or lacks a nexus to subsequent NRC oversight, poses a regulatory burden with no benefit to safety. Inclusion of this information during initial certification or licensing is not necessary.

NRC staff requested types of information and levels of detail beyond what could be justified for reasonable assurance; repeated the review of matters that had been previously approved; and added layers of redundant regulatory requirements.

These practices increase licensing review costs without a corresponding increase in safety. The Appendix includes examples where the NRC staff requested types of

information and levels of detail beyond what could be justified as needed to provide reasonable assurance that the regulations would be met, and examples where information was sought concerning matters that were of little or no safety significance.

The NRC has tools to address level of detail, but these tools should be more effectively used. For example:

- Existing guidance in RG 1.206 contains the necessary flexibility concerning level of detail but is not consistently implemented, for example:
  - *Level of detail necessary to resolve all safety issues*
    - C.I.9 Auxiliary Systems

      For systems that have little or no role in protecting the public against exposure to radiation, the description should provide enough information to allow the NRC staff to understand the design and operation and their effect on reactor safety, with emphasis on those aspects of design and operation that might affect the reactor and its safety features or contribute to the control of radioactivity.

    - C.I.9.5 Other Auxiliary Systems

      The level of information to be provided will reflect the design bases for the system; therefore, the non-safety systems will likely have reduced discussion.

This guidance allows staff to adjust the level of detail of information requested, as well as the depth of review conducted.

Recommended improvements concerning the level of detail in applications include:

- Provide staff guidance and training on the flexibility to substantially reduce the review and depart from review guidance for systems of little or no safety significance.
- Allow applicants to reduce the information in their FSARs to:
  - Give short description of system functions without requiring system drawings.
  - State that the system has been evaluated against regulatory criteria (e.g., General Design Criterion 2, 4 and 5) and that engineers have determined that system operation and failure will not adversely affect performance of a safety function.
- In situations where deemed necessary, use a licensing audit to review a sample of systems to provide assurance that the statements in the application are accurate.
  - Sufficient applicant documentation (at applicant's site) shall be a system design description and functional specification.

4.4 Re-review of Matters Previously Approved

Re-review of matters previously approved involves instances where the NRC staff requested information on a matter that had already been approved by the NRC. The majority of these cases involve the review of a License Amendment Request (LAR) where the NRC staff increased the scope of the LAR to cover matters were not directly related to the change. Often the additional matters had been approved by the staff previously but individual reviewers re-opened the review. Some examples provided in the Appendix pertain to approved topical reports where the NRC staff reviewed additional areas beyond what was approved in the topical report. Whatever the cause, the result was an unnecessary review that increased the cost to the applicant, required additional time for both parties, and distracted the applicant and the NRC staff from more safety significant matters.

4.5 Redundant Requirements

Redundant requirements involve instances where the NRC staff requested information on a matter that would either be reviewed in another regulatory process or was already controlled by another regulation. Examples provided in the Appendix include the NRC staff requesting information during an ESP that would later be reviewed during the COL stage, requiring redundant additional technical specifications, and adding COL items into DC FSARs that are redundant to requirements for COLAs. Such redundant requirements lead to an unnecessarily complex licensing basis which requires time to develop and manage, and more time and attention to manage over the life of the facility.

Recommended improvements include:

- Eliminating the practice of requiring applications to address issues that will not be resolved until a later application. Specifically, ESPs should not need to include information that does not provide finality for the COL review.

- Where an applicant can demonstrate that a proposed technical specification is redundant to other technical specifications, the proposed addition should not be included as it increases operational complexity with no safety benefit.

- Eliminating the practice of including COL items that are shown to be redundant to COL application requirements in DC FSARs or DCDs.

5 CAUSES AND CONTRIBUTING FACTORS

Significant contributors to the current NRC environment include inconsistent management engagement, inefficient decision-making and lack of commitment to risk-informed regulation.

Overall NRC has over time required greater volumes of information, with increasing detail to conduct its reviews. These practices appear to result from the NRC staff's tendency to regulate to a level beyond assuring that the regulations and the associated regulatory limits have been met (i.e., beyond the requirements of NRC regulations). These practices impact safety and the industry's ability to develop and deploy safer, more cost-effective designs. Therefore it is important to understand the factors that have contributed to this situation.

5.1 Efficient decision-making

More efficient decision-making is necessary. Instead of ensuring that differing views are heard and dispositioned respectfully and efficiently, in some cases management appears to expend significant resources in an effort to appease all parties involved. Obtaining consensus often requires devoting an inordinate amount of resources to ensuring that NRC parties involved in the decision-making process are satisfied.

5.2 Commitment to Risk-Informed Regulation

The Commission has long embraced the use of risk-informed regulation, and as noted in this report, existing guidance gives the staff flexibility to consider risk during its review. However, as shown in some of the examples provided in the Appendix, the use of risk information can be better utilized when performing reviews of DCAs, COLs, and LARs. The examples indicate that staff resources are not always allocated to matters commensurate with their safety significance. In industry's view, some staff do not give appropriate consideration of risk-informed insights and have in many instances remained deterministic in their reviews regardless of the safety benefit.

6 RECOMMENDATIONS AND CONCLUSIONS

Attention should be focused on issues commensurate with their safety significance, and risk-informed principles should be utilized in licensing matters to the maximum extent practicable. The NRC and industry share the role of ensuring the safety of new reactors, and implementation of the recommendations discussed in this report will help do so in a more efficient manner. These changes are necessary to facilitate the development and deployment of advanced technologies that provide enhanced levels of safety.

6.1 Safety Focus of New Plant Reviews

The NRC should use risk-informed regulation more consistently in all its activities to ensure that new reactor reviews are more safety focused.

Costs of ongoing reviews remain high leading to the conclusion that the advantages of safer designs appear to be of little benefit in reducing regulatory review costs. Actions should be taken to address the factors that have contributed to this situation. Most importantly, NRC reviews should use risk information as well as deterministic principles of defense-in-depth and the maintenance of safety margins. The Commission has used risk information in its reactor oversight program, when reviewing changes to a plant's licensing basis, when performing regulatory analyses of new requirements, and when considering backfits that are not necessary to ensure adequate protection. The Commission has also modified some regulations to be risk-informed, or promulgated voluntary risk-informed rules as an alternative to deterministic rules. However, the NRC has not adequately applied risk-informed concepts to focus its licensing reviews of new reactors. The NRC should use risk-informed regulation more consistently in all its activities to ensure that new reactor reviews are safety focused.

NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," (SRP) which provides detailed guidance to the NRC staff on how to conduct a review, proposes that NRC staff reviews should focus on matters of highest safety significance. Specifically, Chapter

1 indicates that some information in the application "enables the reviewer or reader to obtain a basic understanding of the overall facility without having to refer to the subsequent chapters. Review of the remainder of the application can be accomplished with a better perspective and recognition of the relative safety-significance of each individual item in the overall plant description." This guidance, if followed, has the potential to significantly improve the efficiency of NRC reviews by applying risk-informed principles to licensing reviews in a systematic manner.

Additionally, the NRC should revise its review guidance to explicitly state that reviews should be conducted in a manner that reflects the relative safety significance of an SSC. Text should be added that summarizes the negative impact of treating all SSCs as equally important. The NRC staff also should change its focus to providing reasonable assurance that the regulations will be met. Therefore, the review guidance should clearly cite the 10 CFR 50.40 requirement of reasonable assurance and should include examples that compare and contrast cases of reasonable assurance versus absolute assurance for every technical discipline covered by NRC reviews of new reactor applications. The NRC staff relies on the SRP as its primary guidance document and as a training tool to support junior staff in conducting a review. For future advanced reviews NRC should consider use of high-level guiding principles for conducting a safety focused review in lieu of revising the SRP as the most cost effective and timely means of effecting change in NRC staff review practices.

6.2 Conduct of Audits and Oversight and Discipline in the use of RAIs

The use of audits has improved the staff's adherence to established review schedules and has reduced the number of RAIs but has not demonstrated that it results in reduced review costs for safer designs. The NRC should consistently implement the best practices identified in this report for controlling the use of RAIs and conducting audits. The use of RAIs has been improved through additional management attention; however additional improvements in the management of and staff discipline in the use of RAIs is warranted. In addition, NRC should establish cost accounting measures and metrics for improving the management of audits.

6.3 Management Engagement in Decision-Making

Management involvement in decision-making is a key factor for implementing changes. Recommended process improvements in Section 5 of this report are intended to increase management involvement and interaction with their staff.

6.4 Issue Resolution Process

Applicants have at times chosen to accede to inappropriate NRC requests for information or detail because challenging the request can often be time consuming and costly, and because there was low confidence that NRC managers would engage effectively.

Industry should raise examples of inefficient reviews to the attention of the level of management that is necessary to achieve resolution as soon as the concern is identified. The licensee's willingness and ability to raise issues will benefit from improvements in the issue resolution process, as discussed above.

Some of the examples in the Appendix demonstrate that, while applicants or licensees ultimately prevailed or believe they were on a success path, the level of effort to achieve the outcome was very high. An improved issue resolution process should reduce the effort.

APPENDIX: NRC REVIEW PROCESS EXAMPLES

This Appendix provides examples of staff reviews that support the findings in the paper. It includes an exemplary RAI as well as additional examples involving NRC's use of audits and RAIs in its regulatory reviews. In addition it includes instances where the NRC has re-reviewed an issue already reviewed and approved and instances where NRC has imposed additional layers of regulatory requirements. In addition other examples are included that illustrate the concerns identified in the report. The examples were selected across a variety of application types (ESP, DC, COL) and technical review disciplines to show that these issues with the reviews exist across the organization. These examples are also not comprehensive; additional examples were identified that were not included in the report. The number of examples was limited to illustrate the concerns. Some of the examples could be placed under multiple concerns but were only included once. Positive examples were included under licensing audits and requests for additional information to demonstrate the recommended practices in Section 4 for those concerns.

Some of the examples also note that satisfactory resolution was ultimately achieved, or is in process. The level of effort described to gain success on some of these issues support the cross-cutting concern in Section 6.0 regarding the need for an improved issue resolution process.

A.1 Model Request for Additional Information

A.1.1 Decay Heat Removal Capability in the NuScale DCA

An example of an RAI that illustrates the recommended practices, noted in Section 4.2. The RAI is associated with the staff review of NuScale's DCA. This RAI has a clear nexus to a specific technical requirement (not content requirement) and the information the NRC staff needs to reach a conclusion is identified.

10 CFR Part 50, Appendix A, GDC 34 requires in part that a system have the capability to transfer decay heat and other residual heat from the reactor such that fuel and pressure boundary design limits are not exceeded. For the NuScale design, the decay heat removal system (DHRS) serves this function. Design Specific Review Standard (DSRS) Section 5.4.7 stipulates that in order to make a safety finding regarding the ability of the DHRS to meet GDC 34, staff should be able to verify the cooling capacity of the DHRS heat exchanger using limiting reactor building pool water temperature. In order to make this determination, the staff evaluates component performance specifications of the DHRS (e.g., tube plugging, fouling, heat removal as a function of flow and temperature on the shell/tube sides of the heat exchanger, expected range of flow rates, condenser performance characteristics).

Based on the information provided in the FSAR, staff is unable to verify the maximum cooling capacity of the DHRS heat exchanger. Nor can the staff verify the system characteristics perform as depicted in the cooldown analyses in Figures 5.4-11 through 5.4-15 in the FSAR. Provide, in the FSAR, the necessary selection of parameters (including, but not necessarily limited to: the number and area of tubes in the condenser HX, the design maximum flow rate, heat transfer and corresponding condenser inlet and outlet temperature values) such that the staff can evaluate the DHRS system performance during the design basis limiting transient.

A.2 Licensing Audits

Some licensing audits reflect the good practices identified in Section 4.1.

- The staff conducted a four month audit to support the NuScale DCA review of the Final Safety Analysis Report Chapter 19 on Probabilistic Risk Assessment (PRA). As a result of this audit, only 61 RAI questions were issued against Chapter 19. These questions were focused on additional information the Staff needed in the DCA to support the NRC's safety evaluation rather than general questions intended to help with understanding of the PRA. This audit was successful in reducing the number of RAIs because the staff defined the scope of the review prior to initiating the audit. The audit was also successful because there was clear communication on the progress of the audit and information needed to finish the review. As part of the Chapter 19 audit, there were weekly engagements with the applicant and the staff, periodic status updates with NuScale and NRC management to discuss the remaining review items, and when an extension was needed to review additional scope, a revised audit plan with the new scope was provided to the applicant. This clear communication through frequent engagements, status updates, and revised audit plans ensured there was convergence with both the staff and applicant on what was needed to complete the review.

- The Tennessee Valley Authority (TVA) concluded that the NRC staff's use of audits in the review of the ESP for Clinch River NRC was more efficient than relying solely on RAIs. Specifically, 28 representatives from the NRC staff and its contractors participated in an audit of environmental matters conducted between May 15 and May 19, 2017. TVA concluded that the participants were well prepared and the audit resolved the majority of NRC's issues and questions. As a result, the NRC staff issued no follow up RAIs to TVA on environmental matters.

NuScale declined to offer specific examples of audits that were less effective. NuScale did provide the following assessment of the 35 licensing audits currently associated with its design certification review in consideration of the concerns regarding audits identified in Section 4.

- Audit plans all identified a regulatory basis and schedule for the audit. The majority of these audit plans generically cited 10 CFR 52.47 as the regulatory requirement governing the audit, and did not specifically identify the acceptance criteria or regulatory need for the audit.

- In general, long duration audit plans did not include interim milestones.

- Audit plans cited that meetings would be scheduled with the applicant on a weekly or monthly basis to discuss the status of the audits. In general, status meetings were not scheduled on frequency of the audit plan, and were not documented.

- Interim status reports were not provided for long duration audits (note: this comment is made given recommendations in Section 4, the audit plans did not include interim plans as a commitment).

- Staff questions for the applicant to discuss were rarely provided a week in advance, one to two business days was typical.

- Of the 35 total scheduled audits of the NuScale DCA and associated topical reports, about half of the audits were completed on the original planned schedule.

- Seventeen audits were extended beyond the original dates. Updated audit plans were provided for two of those audits, the other 15 were extended verbally or through emails. Three of the extended audits do not have a targeted completion date at the time of this report. The majority of these audits were extended by greater than 30 days, with a few audits approaching 12 months in duration.

A.3 Staff Reviews Requiring Unnecessary Detail

A.3.1 Tritium Production in NuScale Reactor Pool

According to the RAI, "The staff acknowledges that there is some validity to the statement by the applicant that the small amount of neutron activation products in the reactor pool water may be insignificant when compared to the amount of primary coolant radionuclides released to the reactor pool water during refueling outages." Despite this acknowledgement, the applicant was requested to explain how tritium production due to neutron activation will be addressed to account for the change in atomic abundance of deuterium.

The resultant increase of tritium production in the pool water due to deuterium activation following 60 years of operation was 0.4%, from 5.53E-8 µCi/s to 5.55E-8 µCi/s. This production rate, when added to the production rates of tritium from other reactions, does not result in a reportable change. The total production rate of tritium from activation of the ultimate heat sink is 4.37E-05 µCi/s, almost three orders of magnitude larger than the tritium production from deuterium activation in the pool water.

This example illustrates that the application as submitted provided the information needed to demonstrate reasonable assurance that requirements were met without requesting the additional analysis. The expected value for tritium was well below regulatory limits. The NRC acknowledged its engineering judgement was that the requested additional information was a minor change. The NRC should have recognized that it was not plausible for the additional information to affect its safety finding. The staff's requests associated with the issue demonstrate a lack of discipline in its review and the tendency to require additional detail beyond that needed to make its safety determination.

A.3.2 Foundation Design in the APR 1400 Design Certification Review

In the Standard Design Certification process, certain information must be submitted to the NRC by the vendor to support the NRC's review of the design. The certified design does not include all the details of the design, only those required to make a safety finding. For example, in the civil structural engineering area, the certified design includes design parameters, analysis methods, referenced codes and standards for detailed design and construction, and the description of critical sections. Critical sections are those sections of safety-related structures that are typically repeated throughout the design. They may include areas of high stress ratios, require unique methods of evaluation, or use novel design techniques. By reviewing the structural design and analyses of the critical sections, the NRC staff can assure that the vendor is applying appropriate codes and standards to its design and is adhering to the code and standard specifications. Therefore, the NRC staff does not review every detail of the plant's structural design.

On December 1, 2017, the NRC staff issued an RAI under the Standard Review Plan Chapter 3.8.5, "Foundations," relating to foundation design and critical sections. In its request, the NRC staff requested KHNP to include, as DCD Tier 1 material, design information for critical sections including design details (welds, reinforcement size and spacing, concrete strength, plate stiffeners, etc.). As justification, the staff claimed that "even minor changes to these critical sections could, when applied to the entire safety-related structure, result in significant changes to the overall performance of the structure, and therefore, invalidate the basis for the staff's approval." The staff also stated that the information must be designated as Tier 1 information to support the staff's reasonable assurance finding.

Industry structural engineering experts have reviewed this APR1400 RAI and have found that the supporting regulatory basis is inaccurate with respect to the scope and intent of DCD Tier 1 material. High-level descriptions of buildings and associated Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) should be categorized as Tier 1, but the staff's position of designating detailed design information as Tier 1 material is inconsistent with (1) current regulatory guidance (Regulatory Guide 1.206), (2) approaches taken by previous DC applications (e.g., AP600, AP1000), and (3) the lessons-learned from on-going new reactor construction, where appropriate flexibility in design is needed during construction.[11]

In contrast to the staff's position, the current NRC public website (New Reactors/Design Certification Applications/USAPWR) clearly states that Tier 1 material provides high-level information on the plant design that is approved and certified by the NRC. The website further describes that Tier 1 includes principal performance characteristics and safety functions of the plant's SSCs. ITAAC are also included to provide reasonable assurance that the as-built plant will operate in conformance with the COL and applicable NRC regulations.

Regarding critical sections, the industry believes that the existing regulatory model specifies that high level descriptions are contained in Tier 1 information, and more detailed design descriptions are contained in ITAAC and Tier 2 information. The industry also believes that the Part 52 change process, which is similar to the change process for operating reactors under 10 CFR 50.59, provides reasonable assurance that the detailed design and construction of critical sections will be performed in accordance with staff-approved methods of design and relevant codes and standards.

While this example is the subject of ongoing discussions at the time the report was issued, it nonetheless demonstrates the staff's tendency to request design details that go beyond that needed to provide reasonable assurance that the regulations will be met and to seek a degree of control over changes not needed to ensure safety. Recent discussions with NRC indicate that progress may occur on this specific issue; however, the broader issue remains regarding sufficiency of downstream requirements like the "50.59 – like" process and ITAAC to provide assurance the constructed plant meets NRC requirements.

A.3.3 Vogtle ESP and Limited Work Authorization Interpretation

During the site preparations under the ESP and the limited work authorization (LWA), Southern Nuclear Company (SNC) planned to conduct significant excavations of existing soil and replace this material with "Engineered Backfill." The ESP/LWA contained criteria that the Engineered Backfill had to meet in order to

[11] *New Reactor Licensing Process; Lessons Learned Review 10 CFR Part 52* [ML13059A239]

be used. However, to further ensure the Engineered Backfill was of appropriate quality, the NRC staff believed it was necessary for SNC to identify in the ESP/LWA the specific locations on the site where SNC would obtain the Engineered Backfill. As SNC began the excavations, it was clear that additional soil would need to be obtained from alternative locations on the site because the five example locations did not contain adequate amounts of suitable soil. However, before excavation of the alternative locations commenced, the NRC staff stopped the work citing that according to the ESP/LWA, SNC could only use Engineered Backfill from those five specified locations.

Instead of relying on the criteria specified in the ESP/LWA to ensure that the additional soil was of appropriate quality to be used as Engineered Backfill, the NRC staff required submittal of a license amendment request to modify the ESP/LWA in order to add these locations. This decision halted the work at the site and delayed the related project activities for six weeks. The NRC review of the submittal was essentially bureaucratic and took only four days to review. The staff approved the amendment without any change or RAI. In this example, both staff actions of: 1) requiring an excessive level of detail in the original ESP/LWA and 2) not allowing the use of structurally equivalent soil from alternate locations without need of an LAR needlessly delayed the project. This example demonstrates the NRC staff's tendency to regulate in an overly conservative and unnecessarily burdensome manner.

A.3.4 Reliability of the Raw Water System in the AP1000 Design Certification Review

The Raw Water System in the AP1000 design is a non-safety system which the design does not rely on in any anticipated operational occurrence or postulated accident scenario. The primary function of the Raw Water System is to provide water to the Demineralized Water System which chemically treats the water and stores it in a Demineralized Water Tank. Certain non-safety systems play a role in mitigating beyond design basis accidents as evaluated using PRA. However, the Raw Water System has no impact on safety as evaluated in the PRA for the AP1000 design.

Contrary to what the PRA revealed about safety significance and the fact that the system played no role in defense in depth or maintenance of safety margins, the NRC staff spent a great deal of time confirming the reliability of the Raw Water System. In addition, the staff spent time determining whether the Raw Water System would need to be treated as a non-safety system of elevated importance. In order to make this decision, the staff held several meetings and issued numerous RAIs to Westinghouse, only to ultimately accept the design as is. In this example, the NRC staff was seeking a level of detail on a system of no safety significance that was not needed to ensure that the AP1000 design provides reasonable assurance that the regulations will be met.

A.3.5 Cooling Tower Inventory in the NuScale Design Certification Review

In the NuScale design, the cooling towers are not safety-related because they play no role in mitigating a design basis event. They also play no role in mitigating beyond design basis events. The ultimate heat sink of the design is a very large pool of water in which the nuclear power modules are placed. During an accident, the core is cooled by passively transferring heat to this pool.

Despite there being no connection to public health and safety, the NRC staff requested additional information to verify that there is adequate water in the cooling tower basin. This example demonstrates that the staff did not consider the risk significance of the system and adjust their review accordingly.

A.3.6 Construction Tolerances of Critical Sections at Vogtle 3

In the AP1000 DC review, the NRC staff required detailed information pertaining to the structural design of critical sections that may have been beyond what was necessary to provide reasonable assurance that the regulations will be met. In one example, instead of referencing a particular code or standard, the NRC staff required that the Westinghouse AP1000 DCD include the thickness of the rebar and its spacing in a portion of the basemat (foundation). The DCD indicated that the rebar be spaced one foot apart with a tolerance of plus or minus ¼ inch. When performing an inspection of the basemat as it was being constructed, the NRC staff noted that the spacing of some rebar sections was not exactly one foot plus or minus ¼ inch. The evaluation of minor deviations in rebar spacing is addressed explicitly in the applicable code. In addition, using engineering judgment SNC concluded that the structural capacity of the basemat is not impacted by this small deviation in rebar spacing. Nonetheless, the NRC staff required SNC to either perform a revised structural analysis or remove the concrete and reposition the rebar. SNC chose to remove the concrete and reposition the rebar.

Another example relates to the design of a critical section for the containment internal structures (CIS). During the AP1000 DCD review, the NRC staff required that the Westinghouse AP1000 DCD include a figure showing the size and spacing of headed studs that were to be attached to steel face plates. The DCD indicated the design spacing of headed stud trusses, and channels in the wall modules in locations away from openings and penetrations in the walls.

When performing an inspection of the CIS modules during construction, the NRC staff noted that in some limited areas near obstructions (e.g., near leak chases and embedments), the spacing of some headed studs exceeded the DCD spacing. Although engineering judgment and construction practices would conclude that the structural capacity of the CIS was not impacted by the increased spacing of a limited number of studs near obstructions, the NRC staff required SNC to halt construction and submit a license amendment request to clarify in the UFSAR what the stud spacing should be adjacent to obstructions. To address this, SNC submitted a LAR to better describe the headed stud design which delayed the construction and increased construction costs. The NRC approved the existing configuration as being acceptable without change.

These examples illustrate the staff practice of requiring an excessive amount of detail in the DCD and regulating to a level that is beyond that needed to ensure reasonable assurance that the regulations will be met. This level of detail resulted in unnecessary delays to obtain regulatory approval for minor deviations that had no impact on structural capacity. NRC treatment of this as a compliance issue did not adequately consider the low safety significance of the deviation and the real world consequences in terms of unnecessary delays in construction.

A.3.7 Analysis of Alternative Sites for an ESP

In the review of the Tennessee Valley Authority's (TVA's) ESP, the NRC staff requested traffic accident data around the Redstone Arsenal, which TVA had reviewed as a potential alternative site to Clinch River. TVA had already determined that the Clinch River, rather than the Redstone Arsenal, was the appropriate site based on factors other than traffic patterns. Obtaining the traffic data required a non-disclosure agreement (NDA) with Alabama's Department of Transportation. Further, the NDA prohibits transfer or publishing of data, so it was necessary to provide the data to the NRC as Withheld Information requiring an affidavit.

Due to this burdensome process, TVA questioned whether traffic accident data around this alternative site was really necessary or if TVA could develop the data in an alternative manner. NUREG-1555, Section 9.3, states that the staff "should determine whether the reconnaissance-level information…was complete enough and of sufficient depth commensurate with the level of screening to support the decisions that were made." It should be noted that several other factors aside from traffic patterns around the Redstone Arsenal site made Clinch River the appropriate site, rather than the Redstone Arsenal. As a result, the traffic information was superfluous. Given the numerous other factors that supported the selection of the Clinch River site, the additional burden associated with the staff's request was not justified. However, the NRC staff indicated this information was necessary and that the Alabama Department of Transportation was the appropriate source.

This case demonstrates the staff's tendency to require a level of detail that goes beyond what is necessary to make its regulatory finding that the requirements of Section 52.24, "Issuance of Early Site Permit," are satisfied and the site is suitable. In this case of an ESP, the NRC staff was evaluating whether an alternative site was superior to Clinch River under the National Environmental Policy Act of 1969, as amended.

A.3.8 Request for Corporate Procedures for an ESP Application Review

As the NRC staff was reviewing issues pertaining to the National Environmental Policy Act of 1969, as amended, a part of the review of the Clinch River ESP, the NRC staff requested that TVA's corporate procedures that pertain to hazardous waste management, the contractor occupational safety program, and excavations and trenching be submitted on the docket. The docket is a collection of documents that are used in an adjudicatory proceeding. Information submitted on the docket by an applicant or licensee must be provided under Oath or Affirmation and is publicly available.

TVA indicated that since these procedures are not publicly available, it would not docket the material but would make it available to the staff for their information, as needed. After several lengthy discussions with TVA, the NRC staff agreed that the procedures did not need to be docketed. During these discussions, it became clear that while not a requirement, the NRC staff preferred to quote excerpts from a document on the docket rather than justify that a requirement is met based on the staff's summary of the document.

This example demonstrates the NRC staff's tendency to require a level of detail that goes beyond that necessary to support its regulatory finding that the requirements of Section 52.24, "Issuance of Early Site Permit," are satisfied and the site is suitable.

A.3.9 Computer Code Input and Output Files

During the review of TVA's ESP, the NRC requested as part of an audit that input and output files for the CALMET and CALPUFF (meteorological modelling) codes be submitted on the docket. The DVD submitting them contained over 59 gigabytes of data. The NRC did not have the codes and therefore needed to procure the software to run the cases. These codes are used by the U.S. Environmental Protection Agency to assess long range transport of radionuclide species and some near field applications under complex meteorological conditions. Nonetheless, the NRC staff felt it was necessary to run its own analyses with these codes rather than rely on the results provided by TVA.

In these cases, the NRC staff was seeking an amount of information that appeared to be beyond that necessary to make its regulatory finding. Since docketing is done by electronic means, and vendors do generate numerous gigabytes of information, including the input and output of a great deal of computer codes, the NRC staff considers this information to be readily available. However, the NRC staff should only be requesting information that is necessary to make its regulatory findings and should not be dedicating time to reviewing information that is not significant to the review.

A.4 Re-Review of Resolved or Previous Reviewed and Approved Issues

A.4.1 Common Q Platform Upgrade

In the AP1000 design, the Protection and Safety Monitoring System (PMS) is used for safety-related instrumentation and control. The PMS is based on the Common Qualified (Common Q) platform. SNC needed to request a license amendment for Vogtle 3 and 4 to upgrade to the newer version of Common Q that had already been approved by the NRC, and submitted a license amendment request to do so. During the NRC review, the staff issued RAIs that required SNC to submit additional information that went beyond what was necessary for the NRC to approve the LAR.

For example, the staff requested that SNC show how the newer version met the latest digital I&C regulatory guides even though these guides were different from those committed to in SNC's license. In addition, the staff asked SNC to describe how the newer version met other IEEE standards, even though the staff had previously concluded that other standards were satisfied during its generic review of Common Q that had already been completed.

The staff also requested that SNC document in the LAR how the Westinghouse corrective action program captures suggestions for improvements and best practices. The LAR had nothing to do with the Westinghouse corrective action program beyond a name change from CAP to CAPAL. Furthermore, the staff asked SNC to explain how the human factors engineering design provides for reliable and feasible performance of operator actions, even though the staff previously accepted the human factors engineering design process during the review of SNC's license.

The use of topical reports is intended to enhance efficiency in that once the document has been approved, it can be used by other applicants provided they meet the conditions of the approval. In this case, although the conditions needed to apply the topical report were met, the staff expanded the scope of the review into areas that were not affected by the LAR and areas that had previously been reviewed and approved. The staff's requests associated with the LAR exhibited a lack of discipline in its review and the tendency to repeat the review of a report or issue that has been previously approved.

A.4.2 Electrical Design in the Design Certification Amendment Review

During the AP1000 Revision 19 review, the NRC staff raised concerns regarding compliance with the offsite power criteria of General Design Criteria 17, "Electric Power Systems." Westinghouse highlighted to the NRC staff that the NRC had previously verified compliance with GDC 17 in the DC for AP1000, Revision 15, in 2005, and Westinghouse had not made significant changes to that aspect of the design as a part of Revision 19. Furthermore, the passive design of the AP1000 does not rely upon ac power sources to cool the core in design basis accidents. Instead of recognizing that their concerns had been appropriately

addressed, the NRC staff issued RAIs and requested public meetings on this topic. In order to get the NRC to complete the review of Revision 19, Westinghouse agreed to some of the staff's demands.

This issue consumed significant industry and NRC resources and is an example where, without technical justification, the NRC staff re-opened an issue that had been previously reviewed and approved.

A.4.3 Spent Fuel Pool Criticality Analysis

In June of 2006, Westinghouse submitted a topical report during the AP1000 amendment review to obtain NRC approval of the spent fuel criticality analysis. The review of this topical report progressed in parallel with the overall DCD review. In July 2009, three years into the review, the NRC required justification for the adequacy of the percentage uncertainty for burnup that was credited. This justification should not have been required since the NRC had previously issued guidance in 1998 that specifically allowed the use of the assumptions Westinghouse used in its topical report.

While the NRC ultimately determined that the assumptions used in the Westinghouse topical report were appropriate, this resolution did not occur until February 2010 after significant time and effort. This example demonstrates the NRC staff's tendency to repeat the review of a matter that had previously been approved.

A.4.4 Automatic Depressurization System (ADS) Blocking Device

In order to further reduce the potential for a spurious actuation of the ADS in the AP1000, a blocking device is used in the Protection and Monitoring System. The ADS blocker in the AP1000 design was part of the design certification document, with preliminary details included. Westinghouse developed subsequent design changes to the blocking device to provide design detail that was not available during the design certification process. Therefore, as required, for Vogtle 3 and 4 SNC submitted this information in a license amendment to the NRC to add this detail to the COL.

The staff noted that it was unclear to them what effect this amendment would have on operators during certain scenarios associated with the manual operation of the ADS. They asked if the amendment would add steps which may negatively affect operators. SNC responded by stating that the human factors consideration of this design feature had been addressed under the 5 human factors engineering inspections, tests, analyses, and acceptance criteria (ITAAC) in the COL.[12] SNC also stated that the blocking device had already been inspected by the NRC staff as part of an ITAAC inspection. Nonetheless, the NRC staff requested the results of this inspection and associated reports to review this information again, even though the ITAAC was not changed in the LAR. The staff re-reviewed the approved report and subsequently re-approved it.

This example demonstrates the tendency of the staff to re-review information that had already been approved and widen the scope of the review.

[12] As required by 10 CFR 52.97(b), the ITAAC identified in the COL are necessary and sufficient, when successfully completed by the licensee, to provide reasonable assurance that the regulations have been met that the facility has been constructed and will operate in conformity with the combined license, the provisions of the Atomic Energy Act, as amended, and the Commission's rules and regulations.

A.4.5 Evaluation of Fire Analysis

This SNC LAR for Vogtle 3 and 4 formally added the Protection and Monitoring System (PMS) cabinets and the PMS interdivisional cables located in the four PMS divisional rooms to the fire analysis in Chapter 9 of the FSAR. The previous evaluation of these four rooms had not included these particular cabinets and cables. These cables are routed in other fire areas other than the four PMS divisional rooms and the fire analysis of these other areas did include the cables. The LAR concluded that if a PMS divisional room was adversely impacted by a fire, the other 3 divisional rooms would provide adequate redundancy and a means to safely shutdown the plant, if needed. Therefore, this aspect of the design was shown to provide reasonable assurance that the regulations will be met in the event of a postulated fire.

Instead of constraining the review to evaluate the four PMS divisional rooms, the NRC staff asked SNC to provide cable routing design documents to show the complete routing of the PMS interdivisional cables through all of the areas, not just the four PMS divisional rooms. In addition, an existing ITAAC, which was not part of the change, requires verification of the independence of the PMS interdivisional cables so that a fire in a given fire area would not adversely impact the capability of the PMS to provide sufficient redundancy.

This is another example of the staff expanding the scope of a review and repeating the review of analyses that had already been approved.

A.5 Imposition of Redundant Requirements

A.5.1 COLA Action Item

In the review of SNC's Vogtle 3 and 4 COLA, the NRC requested a description of how the inspection, testing and monitoring program would detect degradation of inaccessible or underground control and power cables that support equipment and other systems within the scope of 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," referred to as the Maintenance Rule. However, a description of how the Maintenance Rule program incorporates industry operating experience was already provided in the COLA. SNC indicated that the COLA referenced a generic letter issued by the NRC, and indicated that the program would consider the issues identified in it. In addition, the Maintenance Rule is the regulatory vehicle by which the NRC would ensure the program was adequate through inspection. SNC also responded that the specific information necessary to provide the requested detail would not be available until after more detailed design and procurement information was developed.

In this example, the staff did not appear to recognize that the commitment to have such a program was acceptable and that the Maintenance Rule provided the regulatory vehicle to ensure its acceptability through inspection. The staff was either not aware of or not willing to rely on another regulatory requirement to provide reasonable assurance that the regulations will be met.

A.5.2 Security in an ESP Review

Tennessee Valley Authority (TVA) submitted an application to the NRC to obtain an ESP. In the NRC staff's review of an ESP, the NRC resolves site safety, environmental protection, and emergency preparedness issues, in order to approve a proposed site for a nuclear power plant. The ESP is independent

of a particular nuclear power plant design and the review is conducted using an envelope of the future plant's characteristics called the bounding plant parameter envelope (PPE). The PPE bounds the characteristics of designs that may be located on the site and does not depend on issuance of a construction permit or combined license.

As part of the ESP application, TVA provided a PPE that was representative of a number of small reactors. TVA identified a 28-acre land mass where the power plant would be located within a 94-acre plant area. TVA stated that this additional land mass would be sufficiently large to accommodate the security boundaries of the plant and a security program that would be consistent with the security regulations under 10 CFR 73.55.

The NRC staff requested that the specific coordinates of the power plant be identified in order to justify that the plant design would be bounded by the PPE. In addition, the NRC staff requested that TVA confirm that the plant designs could be located on the proposed location.

Information needed to identify the exact location of the power plant is not developed until an applicant has selected the actual plant design and has developed detailed geo-technical information to support the structural evaluation of the plant. This information is obtained much later in the process and is only used in the construction permit or COL stage. Furthermore, the NRC does not review the security plan until the COL.

The NRC staff's request for this information during an ESP review is an example of the staff requiring detail that goes beyond what is necessary to support its regulatory finding that the requirements of Section 52.24, "Issuance of Early Site Permit," are satisfied and the site is suitable. In addition, the staff was not comfortable relying on the fact that this information would be submitted and reviewed at the construction permit or COL stage.

A.5.3 Technical Specifications on Flowrate

The NRC staff requested that a core flow rate technical specification be included in the NuScale DCD. The NuScale design is natural circulation and does not use pumps. Flow rate through the core is dependent on thermal driving head generated by the difference in density between the fluid in the core and the cooled fluid after heat has been removed by the steam generator. Flow rate through the core is a function of the power produced in the core and removed by the steam generators.

The NRC staff requested, and NuScale ultimately agreed, to add a technical specification for the required flow rate through the core as a function of power. This technical specification is redundant to reactor protection system setpoints that automatically shut down the reactor as a result of the increase in core exit temperature. Despite the existing protective design feature, the NRC staff requested this redundant technical specification.

A.5.4 Geotechnical Analyses in an ESP Review

During the NRC staff's review of TVA's ESP at Clinch River, the NRC staff requested detailed geotechnical information that would not be available until the COL stage of the licensing process. The geology of the Clinch River site includes limestone which can dissolve in groundwater and develop voids or karsts. To

ensure that karsts would not impact the structural stability of the future plant, TVA proposed that NRC include a condition in the ESP to ensure that karsts would be addressed adequately in the COL application. Such a condition could require that TVA perform geotechnical investigations such as borings to ensure that no structurally significant karsts would exist under the proposed plant location. It is more appropriate to include this information in the COL application because plant design details used in these analyses are not necessarily available at the ESP application stage. In addition, time consuming and costly site geotechnical studies are conducted once the applicant proposes to use the site in a COL application, develops the data, and proposes the actual plant location on the site.

However, the NRC staff requested that this information be submitted as part of the ESP rather than the COL application. After further discussions with the NRC staff during which TVA indicated that this information would not be available until the COL, TVA was required to perform a detailed finite element analysis of the maximum karst size that could be located under a foundation at the Clinch River site. Since TVA planned to site a SMR on the site and no SMR had been certified, TVA used the design of the Westinghouse AP1000 foundation to determine the maximum hypothetical karst void size that it could withstand. This additional detail took time, added significant cost, and served no lasting value as the work will need to be entirely redone as part of the COL application once the SMR design is certified.

This example demonstrates the NRC staff requiring information that goes beyond what is necessary to support its regulatory finding that the requirements of 52.24, "Issuance of Early Site Permit," are satisfied and the site is suitable. Furthermore, the NRC staff was not comfortable relying on the review that is conducted as part of the COL, making the evaluation as ESP a redundant requirement.

A.5.5 COL Items Included in FSAR

Applicants tend to use precedent applications as templates for content. Therefore, NuScale's FSAR includes many of the same COL items as prior DCAs. In addition, the NRC frequently requests additional COL items in the course of the review. NuScale recognized that COL Items included in the initial submittal and items requested by staff are duplicative of COL content guidance (RG 1.206) and regulation (10 CFR 52.79). This trend creates an unnecessary burden during DCA review and will create significant administrative burden at COL application/post-license phases.

Examples of requests for further detail in this area include the request for additional information regarding PRA assumptions to be verified by the COL applicant. This information is duplicative of RG 1.206, Section C.I.9. Further RAI have requested additional detail be added to COL items regarding qualification requirements for management and technical staff and operator training programs that is duplicative of RG 1.206 guidance for COL applicants.

Consistent with NUREG 0800, it is not NuScale's intent to identify, as COL action items, all the requirements that a COL applicant needs to meet to demonstrate compliance with 10 CFR Part 52, "Subpart C – Combined Licenses." NUREG 0800 also notes that "the COL applicant must demonstrate compliance with all the regulatory requirements in 10 CFR 52.79 and 10 CFR 52.80 whether they are addressed by a COL action item or not."

COL items should be used to identify particular, design-specific significant items and ensure they are tracked and considered during the COL application phase. COL items should focus on matters that may be a

significant issue in any COL application. Except when needed to address specific considerations unique to the NuScale design, COL items should not duplicate regulation or regulatory guidance for COL application content. For instance, the NuScale application includes COL items to address site specific items necessary for finalization of the design of certain structures (such as waterproofing) that are not specifically addressed in regulatory guidance.

NuScale raised the concern with duplicative requirements in the form of COL items with the NRC staff early in 2018. The NRC indicated a willingness to reconsider the approach to COL items. NuScale is to provide a proposed definition for COL items, and specifically identify the COL items proposed for removal from the FSAR on the basis of the definition.