



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 13, 2015

The Honorable John Shimkus
Chairman, Subcommittee on Environment
and the Economy
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The U.S. Nuclear Regulatory Commission appeared before the Subcommittee on Environment and the Economy on September 9, 2015, at the hearing entitled, "Oversight of the Nuclear Regulatory Commission". From that hearing, you forwarded questions for the hearing record to Chairman Burns. The responses to those questions are enclosed. If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

A solid black rectangular box redacting the signature of Eugene Dacus.

Eugene Dacus Director
Office of Congressional Affairs

Enclosure:
As stated

cc: The Honorable Paul Tonko, Ranking Member
Subcommittee on Environment and the Economy

The Honorable John Shimkus

Question 1. The NRC's annual fee assessment, which sets how much each operating reactor must pay to fund the agency, stated "the shutdown of the Vermont Yankee decreases the fleet of operating reactors, which subsequently increases the annual fees for the rest of the fleet." This reaction, which does not appear to note a decreased need in overall resources, could result in a spiral of increasing costs on operating reactors, which could force economically distressed sites to close.

a) Should the premature closure of reactors result in a commensurate reduction in resources within the Office of Nuclear Reactor Regulations? If so, what is the total reduction associated with closure of the Vermont Yankee site?

b) Does the Commission recognize the potential domino effect of reactor closures?

Answer.

a) The NRC's licensing, rulemaking, and oversight programs require that a certain infrastructure be maintained in order to support the current fleet of operating reactors. In addition, the Office of Nuclear Reactor Regulation continues to play a significant regulatory role when a plant first enters the decommissioning process. Thus, the closure of a single reactor will not necessarily result in a commensurate reduction in resources within the Office of Nuclear Reactor Regulation. In other words, if ten percent of reactors cease operations, NRR would not automatically be reduced by ten percent. At the same time, the NRC continually assesses its

needs and adjusts resources accordingly. The Office of Nuclear Reactor Regulation does not anticipate any immediate reduction in personnel due to the closure of Vermont Yankee.

b) The Omnibus Budget Reconciliation Act of 1990 requires the NRC to recover 90 percent of its budget from fees. If there are fewer reactors in the United States, the NRC will allocate the program infrastructure costs of the NRC's operating reactor activities across a smaller number of reactors, resulting in increased fees for individual licensees. Under the current statute, the NRC recognizes that there may be a point at which the pool of operating reactors might be considered too small to support funding the agency through the current fee recovery structure.

Question 2. This Committee has repeatedly expressed concerns regarding the use of “qualitative factors” by the NRC staff to justify proposed rulemaking when a quantitative cost benefit is available.

a) How is the Commission assuring NRC staff cost benefit analyses are based on sound, objective data?

b) What is the Commission doing to ensure the NRC is improving its quantitative data analyses?

c) Please list *all* staff activities, such as rulemakings, licensing standards, or guidance development, that are under way which consider the use of qualitative factors?

Answer.

a&b) The Commission has approved the NRC staff's plans for updating guidance regarding the use of qualitative factors to improve the clarity, transparency and consistency of the agency's regulatory analyses and backfit analyses. The guidance will address qualitative factors assessment methodology, cost estimating best practices, and the treatment of uncertainty in regulatory and backfit analyses. This guidance is scheduled to be released in July 2016 following Commission review.

In preparing its rulemakings, the NRC staff performs preliminary high-level cost assessments and backfitting assessments using established methods and data to estimate the potential costs of a proposed regulatory action. These estimates are available for public review at the time the draft regulatory bases are published for public comment. The NRC staff uses additional cost data received during a proposed rule's public comment period to refine its cost estimates for the final regulatory bases. If the Commission decides that rulemaking is the appropriate regulatory decision, then the staff updates the cost estimate using data as it becomes available, explicitly addresses uncertainties, recognizes excluded costs, and conducts an independent review of selected cost estimates to ensure realism, completeness, and consistency.

c) The NRC's current rulemaking activities are listed in the NRC's Unified Agenda. The NRC's major rulemakings are listed in the NRC's Regulatory Plan, posted at

<http://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/unified-agenda.html>.

Question 3. NRC Staff is currently developing a roadmap to “improve NRC’s agility, effectiveness, and efficiency, while also refining the basis for agency planning through 2020 and beyond.” This effort, known as “Project Aim 2020” was initiated in June 2014, but has not yet provided the Commission with its final report.

The implementation plan released on September 8 said NRC staff will develop a plan by June 2016. Given that it will take two full years just to develop a plan, there is the potential that the less relevant the recommendation, such as appropriate staffing levels, will be. When do you expect the Commission will take action on Project Aim and how is the Commission assuring this schedule is strictly adhered to?

Answer.

The staff provided its final report and recommendations on Project Aim January 30, 2015. The Commission provided its direction on how to proceed on the Project Aim 2020 recommendations in June. The staff is implementing the approved recommendations as 19 discrete tasks, with completion dates ranging from August 25, 2015 to March 18, 2018. To date, three have been completed; at the end of 2016, only four tasks will be left to complete. The staff has started work on all tasks except those that are sequenced by resource availability or are contingent on decisions from currently ongoing tasks.

Key among the approved recommendations is the Commission's direction to the staff to undertake a "rebaselining" effort to make the agency more efficient. To complete the "rebaselining" effort, the NRC staff will review the agency's workload, - office by office - and develop a list of activities that could be shed or performed at a reduced level. The Commission has directed the staff to immediately implement efficiencies that do not require prior Commission approval. The staff will provide a comprehensive list of activities that could be shed or performed with fewer resources to the Commission for review and approval in April 2016. This list of activities will inform the formulation of the FY 2018 budget, as well as the implementation of the FY 2017 budget.

The majority of the strategies approved by the Commission will be carried out by individual offices. The Commission directed that the Executive Director for Operations (EDO) and Chief Financial Officer (CFO) be responsible for the Project Aim implementation. The EDO and CFO will ensure successful implementation of Project Aim 2020 recommendations through leadership, coordination, and communication efforts. In addition, the Commission holds regular public meetings to review progress, receives monthly status updates, and engages in ongoing communication with the EDO and CFO on implementation status and issues.

Question 4. The Commissioners cited the importance of the “Mitigation of Beyond-Design Basis Events” Rulemaking to finalizing NRC post-Fukushima safety enhancements. The Commission directed that NRC staff should provide the Commission with a plan and schedule for resolving all remaining “Tier 2” and “Tier 3” items by October 31, 2015.

a) In the Commission’s view, given the actions that have been taken to date, what is the relative safety significance of the remaining actions to be completed?

b) Will this process proceed consistent with the NRC’s Backfit Rule and the Commission’s direction on the use of qualitative factors to ensure that the agency remains focused on those items with the greatest safety benefit that warrant additional costs?

c) What is the schedule for completing any remaining items that are safety significant?

d) How and when will the Commission close out items that do not provide significant safety benefits?

Answer.

a) The Commission recognizes the importance of maintaining a focus on those Fukushima lessons learned that provide the greatest safety benefit. The Commission has directed the NRC staff to provide updated resolution plans for Tier 2 and Tier 3 items to the Commission by the end of October 2015. The Commission will consider the staff's recommendations in forming conclusions about the relative safety significance of the remaining actions to be completed. However, it should be noted that the items evaluated as having the greatest safety significance have been or are being implemented as part of Tier 1 and were designated as Tier 1 in recognition of that significance.

b) Yes, the process for addressing all remaining Tier 2 and Tier 3 items will be consistent with the NRC's Backfit Rule in 10 CFR Part 50 and comparable "issue finality" provisions in 10 CFR Part 52, as well as the Commission's direction on the use of quantitative and qualitative factors.

c). In October, the NRC staff submitted detailed Tier 2 and Tier 3 closure plans for Commission review. Subject to Commission approval, the staff plans to place the remaining Tier 2 and 3 issues in one of three categories: propose to be closed; additional stakeholder interaction planned with work to be completed in March 2016; and further assessment needed before closure with work to be completed by the end of 2016.

d) The Commission will provide direction to the staff regarding the Tier 2 and Tier 3 items following the Commission's consideration of the staff's recommendations.

Question 5. On August 13, the Commission received a briefing from NRC staff and stakeholders about options to dispose of the most hazardous form of low-level nuclear waste, known as "Greater Than Class C" (GTCC) material. NRC Staff recommended the Commission should allow the state of Texas to license and regulate the disposal of GTCC waste at an existing low-level waste facility. However, current regulations governing the disposal of GTCC waste (10 CFR 61.55) state it is not generally acceptable for near-surface disposal and require more stringent disposal methods than other low-level waste classifications. Specifically, the regulations state "such waste must be disposed of in a geologic repositoryunless proposals for disposal of such waste in a disposal site licensed pursuant to this part are approved by the Commission."

a) Is there currently a geological repository licensed in Texas that would meet the existing regulations?

b) Should the Commission accept this recommendation, would that action constitute a licensing decision "approved by the Commission" to fulfill existing requirements?

c) The Energy Policy Act of 2005 requires the Department of Energy to submit a Report to Congress on GTCC disposal and await Congressional action prior to selecting a GTCC disposal alternative. Will the NRC wait to take action on licensing of a GTCC site, particularly given DOE's lack of action thus far, until Congress approves of the best disposal pathway?

Answer.

a) There is no existing geologic repository in the United States licensed to receive GTCC waste. Further, there are currently no near-surface cells licensed to receive GTCC waste in the United States.

b) The Commission's acceptance of the staff's recommendation would not constitute a licensing decision. If the Commission approves the staff's recommendation, Texas would still need to submit a detailed proposal under 10 CFR 61.55(a)(2)(iv) for Commission review and approval before Texas could begin the licensing process for a facility to accept GTCC waste for disposal.

c) Because the NRC does not have an application before it that would permit a disposal facility to accept GTCC, it is premature for the Commission to address when the NRC would take action on licensing of a site capable of accepting GTCC waste. The timing of the submission of a Department of Energy (DOE) report on GTCC disposal and any Congressional action, is beyond the Commission's purview. In addition, regardless of whether the NRC or an Agreement State is the licensing authority, the NRC currently does not know when an application might be submitted or the duration of the associated licensing review.

Question 6. The Nuclear Waste Policy Act uses the phrases "the Secretary shall" and "the Commission shall" at least 100 times.

a) Does the Commission believe that the Act mandates that the Commission take certain actions toward the goal of licensing a permanent repository and specifically, what are those mandatory requirements?

Answer.

The Nuclear Waste Policy Act requires the Commission, in accordance with its duties as an independent regulator, to process the license application for a spent fuel repository at Yucca Mountain submitted by the Department of Energy to the extent that it has funds appropriated for that purpose. See *In re Aiken County*, 725 F.3d 255, 267 (D.C. Cir. 2013). The NRC has been and currently is performing that function consistent with the writ of mandamus issued in *In Re Aiken County*. The NRC provides monthly reports to Congress on its Yucca Mountain-related activities and expenditures.

Question 7. Fundamental to the NRC’s credibility as a reliable regulator is the ability for accurate cost benefit analysis as part of proposed rulemaking. However, both the Government Accountability Office (GAO) and the NRC Inspector General have found deficiencies in this process. What tangible actions is the Commission undertaking to address these criticisms?

Answer.

In accordance with Commission direction, the NRC staff is updating its cost-benefit guidance to incorporate lessons-learned and feedback provided by licensees, the Nuclear Energy Institute, the U.S. Government Accountability Office, the NRC Office of the Inspector General, and other stakeholders. This work is currently underway and release of the draft guidance for public comment is expected in July 2016.

The NRC staff has revised its process to perform preliminary cost assessments using established methods and data to estimate the potential costs of a proposed regulatory action. These estimates are available for public review at the time the proposed rule or draft guidance document is published for public comment. The estimates are set forth in the draft regulatory

basis that is published in support of the proposed rule or draft guidance document. The NRC staff uses the cost data received during the public comment period to refine its cost estimates for the final regulatory bases, which are then used to support the promulgation of the final rule or issuance of the final guidance document.

The NRC recently hired experienced cost estimators, established a pilot program to perform independent cost estimates, and is making enhancements to its existing regulatory analysis training and qualification program.

Question 8. The Commission is currently considering to revise the process by which NRC staff initiate a rulemaking.

a) How will you assure that NRC staff will provide you with a full slate of potential recommendations, which will essentially reduce staff independence?

b) What is the expected timeframe for the Commission to complete this exercise?

c) How will this allow the Commission to more efficiently utilize its resources?

Answer.

a) On August 14, 2015, the Commission directed the staff to propose a plan to increase the Commission's involvement in the rulemaking process with the objective of ensuring early Commission engagement before significant staff resources are expended. In its direction to the

staff, the Commission specified options for the staff to consider; these options, and any staff-identified options, will provide a full slate of recommendations for Commission deliberation. Neither is the Commission confined to selecting solely among options presented by the staff.

b) The staff's proposed plan was submitted to the Commission on October 19, 2015.

c) The Commission's objective is a set of changes that ensure significant staff resources are not expended on rulemaking activities without Commission approval.

Question 9. Last December, the NRC updated its "Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications" in order to increase the quality of information provided by the licensee at the outset of the licensing process. This would minimize the number of NRC "Requests for Additional Information," which are time consuming for license applicants to respond to, and reduce the length of time for NRC to complete licensing actions.

a) Has the Commission examined whether this guidance has produced the intended results?

b) Does the NRC plan to update the Acceptance Review process for license amendment requests and other licensing actions?

i. If so, when will the new guidance be finalized?

ii. If not, why has the Commission not undertaken this process and will you consider doing so?

Answer.

a) The NRC has received only one new application since updating the acceptance review guidance. The NRC used the updated guidance to review the APR-1400 design certification application submitted by Korea Hydro and Nuclear Power Company (KHNP) and Korea Electric Power Corporation (KEPCO). The NRC is now in the pre-application phase for an early site permit (ESP) application being developed by TVA for a site in Tennessee. The NRC will apply the updated acceptance review guidance to this potential ESP application, once received.

In a preliminary review by the NRC staff, the use of the updated guidance resulted in an improved design certification application for the APR-1400 design and, to date, the NRC has seen an overall reduction in the number of requests for additional information. However, the application review is still in the very early stages, and it is premature to draw conclusions about whether the updated guidance has produced the intended results.

b) The NRC is updating the Acceptance Review Process for license amendment requests and other licensing actions. The staff expects to complete the recommendations to be included in the update by the end of 2015. The NRC expects to complete the process changes as well as staff training on the update in early 2016.

In the Office of New Reactors (NRO), the staff has already been applying the principal features of the updated "Acceptance Review Process for Early Site Permit, Design Certification, and Combined License Applications" to all licensing actions submitted by the Vogtle and V.C. Summer licensees. For example, the NRO staff offers pre-application interactions with the licensees to discuss specific technical topics in public meetings that are or will be the subjects of license amendment/exemption requests. These interactions provide licensees with a better understanding of NRC requirements on these issues and encourages a more complete

licensing action request. The implementation of the updated acceptance review guidance to these combined license amendment requests has resulted in the need for fewer requests for additional information and has allowed the staff to set and meet reasonable review schedules.

Question 10. A number of process issues arise where there is a lack of continuity within an organization. Licensees have described the extensive problems in which the NRC staff turnover, multiple times on some occasions, results in substantial delays and increased costs. Has the Commission examined how you can minimize the impact on the license amendment request process?

Answer.

The Office of Nuclear Reactor Regulation (NRR) technical staff and the licensing project manager work together to ensure that the amendment processing plan is complete and that the scope, resources, and schedule are sufficient to perform the required safety review. The branch chiefs are responsible for assigning reviewers, taking into account the required skill set, existing workload, and the relative priority in relation to other actions under review; and for providing oversight to ensure assigned reviewers maintain the agreed-to schedule and milestone dates.

Although the reviewer and project manager initially assigned to the action normally remain through completion of the review, occasionally an assigned reviewer or project manager may need to be replaced due to unforeseen circumstances, such as emergent higher priority work or staff departure. For example, following the events at Fukushima, some NRC technical and project management staff members were reassigned from routine licensing activities to work on Fukushima-related items. For these cases, new reviewers, with the required knowledge and skills, were reassigned to complete the routine license activities. Review staff may also need to

be temporarily reassigned to review an expedited licensing action request to avoid an unnecessary reactor transient or shutdown that could increase risk at the facility. Such safety-related actions are given priority over routine or voluntary licensing actions. In such cases, the technical staff and the licensing project manager work together to assess and minimize the impact on the review schedule of affected licensing actions, to the extent possible.

NRR is currently conducting an initiative to review and evaluate the existing reactor license amendment process with the goal of reinforcing current expectations and best practices. The initiative is intended, in part, to identify issues that may be impeding the timely completion of some reviews and to identify opportunities for improvement. One of the issues the task group identified is that staff turnover may be a contributor to delays in licensing reviews. This and other issues identified through this initiative are still being evaluated. As improvements are identified through this effort, the NRC is taking action to implement the improvements.

Question 11. A senior NRC manager was quoted in a February 2015 audit from the NRC Inspector General, “if the current lead of the spent fuel pool criticality group were to leave NRC, there may not be a viable replacement readily available.” This speaks to a need for a robust knowledge management system, which could provide for a systematic documentation in the event NRC staff leaves a licensing project. What knowledge management system does the NRC have in place to mitigate the potential consequences of staff turnover?

Answer.

The staff laid out the agency’s knowledge management (KM) program in a July 2006 paper, SECY-06-0164, “The U.S. NRC Knowledge Management Program.” KM remains a top priority

and is an integrated part of the agency's Strategic Plan to ensure that we capture and preserve knowledge to assist with employee development and performance. There are four key activities to the KM Program:

1. Provide innovative agency support structures for knowledge management, as further described below.
2. Create communities of practice that enable the sharing of relevant knowledge and critical skills among employees who perform the same job function.
3. Capture operating experience, new information on safety and security issues, and knowledge gained from inspection, research, and licensing activities in regulatory guidance.
4. Capture relevant critical knowledge from employees departing the agency, recapture knowledge from former employees, where possible, communicate leadership expectations for knowledge sharing, formalize knowledge management values and principles, and incorporate knowledge management practices within agency work processes.

A key element of the KM Program's success is the system of governance under the agency KM steering committee and KM staff leads, with program management provided by the Office of the Chief Human Capital Officer. These entities oversee and implement activities across the agency to ensure current and future KM needs of the agency are met. The NRC currently captures knowledge through numerous methods, such as stored technical documents, job aids and desk references, written policies and procedures, regulatory guides, standard review plans, regulatory issues summaries, and statements of consideration for rulemaking. The NRC is employing several strategies to facilitate knowledge transfer, including: training courses; formal and informal mentoring; rotational assignments; short- and long-term details; reemployed annuitants; retention incentives; internal seminars and presentations; invitational seminars and

panel discussions; branch chief and team leader meetings; brown bag sessions; video interviews; newsletters; websites; and online materials.

Question 12. Would you consider adopting an internal policy that once a License Amendment Request is assigned to reviewers, they would own the product for the entire process?

Answer.

We agree that stability in the review process for license amendments is beneficial and desirable. However, as discussed in response to Question 10, an assigned reviewer or project manager may occasionally need to be replaced due to unforeseen circumstances such as emergent higher priority work or departure from the agency. Preventing such changes could result in reduced overall efficiency. Therefore, when changes to review assignments are needed, the technical staff and the licensing project manager work together to assess and minimize the impact on the review schedule of affected licensing actions, to the extent possible.

Also, as mentioned previously, the Office of Nuclear Reactor Regulation is currently conducting an initiative to review and evaluate the existing reactor license amendment process with the goal of reinforcing current expectations and best practices. One of the issues the task group identified is that staff turnover may be a contributor to delays in licensing reviews. This and other issues identified through this initiative are still being evaluated. As improvements are identified through this effort, the NRC is taking action to implement them. The staff also plans to revise internal guidance documents, as applicable, to reflect final recommendations and improvements approved through this effort.

Although there may be some changes in future guidance/internal policy with respect to minimizing staff turnover during license amendment reviews, it is not expected that guidance would be changed to prohibit the reassignment of a reviewer or project manager to address unforeseen circumstances.

Question 13. Last year, the number of licensing actions the Office of Nuclear Reactor Regulation completed in under a year was just 83%, though efforts have increased the performance to 87%. However, there is still a need to improve further as well as assure that the underlying factors that led to the buildup are addressed.

a) Is the Commission committed to clearing the backlog of licensing actions?

b) What steps are you taking to provide licensees with the certainty that the Commission will fulfill its responsibility as a regulator and be responsive in a timely manner on licensing actions?

Answer.

a) Yes. The Commission is committed to clearing the backlog of licensing actions to achieve established performance targets. In November 2014, there were 112 licensing actions in the backlog. As of September 30, 2015, there were 32 licensing actions in the backlog and overall performance in processing licensing actions in less than one year has increased to 88 percent.

b) The NRC continues to prioritize all licensing action reviews in accordance with their safety significance and to engage licensees early in the licensing process to discuss and align on the

timeframes for processing all licensing actions. Further, at a public Commission meeting in August on the Operating Reactor Business Line, the staff presented its progress in improving performance in the processing of licensing actions. The Commission has shown its commitment to improve timeliness by establishing performance metrics in the NRC's FY 2016 Congressional Budget Justification under the Operating Reactor Business Line to drive at least a 2 percent improvement each fiscal year in the percentage of licensing actions completed in under a year. Additionally, the staff takes the opportunity to discuss progress and planned activities to support improvement at various interactions with licensees. Finally, the NRC is reviewing the operating reactor licensing process, including a review of lessons learned from how the backlog originated, as part of a business process improvement review being conducted in the context of Project Aim 2020.

Question 14. The NRC Inspector General reported extensive deficiencies in the quality and length of time for NRC to consider license amendment requests. In a February 2015 audit of NRC's Oversight of Spent Fuel Pools, an NRC licensee described frustrations with the process, stating:

“it generally took his utility approximately 6 months to complete the initial criticality analysis. NRC would then take anywhere from 6 to 12 months to respond with its initial [Requests for Additional Information]. The licensee said it would take about 1 month to answer the RAIs, and then he would wait to hear from the NRC again. This process would continue until the licensee sufficiently answered all the RAIs, possibly taking up to 3 years before the criticality analysis was approved and the license amendment granted.”

a) What is the Commission doing to assure NRC staff is responsive to licensees and held accountable for their performance?

Answer:

The NRC staff tracks how long it takes to complete license amendment request reviews, with a goal of completing most within one year. The staff is aware that this goal has often not been met in the past for reviews of spent fuel pool criticality analyses, due to a combination of factors, including:

- licensees did not follow established guidance for license amendment requests associated with spent fuel pool criticality analyses;
- licensee analysis practices did not keep pace with changes to fuel design and reactor operation;
- challenges presented in quantifying the reduced credit for neutron-absorbing materials due to degradation and deformation;
- significant variations in the application of criticality analysis methodologies by licensees; and
- an inadequate number of staff members with appropriate expertise.

In response, the NRC has taken or will be taking the following actions:

- doubling the number of staff members with sufficient knowledge of criticality analysis methods;
- development of a generic letter to address degradation and deformation of neutron-absorbing materials in a consistent manner;
- review a guidance document for spent fuel pool criticality analyses (Nuclear Energy Institute document NEI 12-16); and

- continued staff interactions with the major vendors performing criticality analyses for spent fuel pools resulting in license submittals that are more accurate and complete.

These actions are consistent with recommendation 1 from the Office of Inspector General (OIG) audit report, as discussed in the OIG analysis of the proposed actions by the NRC. As a result of these efforts, the staff has made significant improvement in the review time frames for recent license amendment requests associated with spent fuel pools. The NRC will continue to track license amendment request review time frames as the staff completes implementation of the above actions, especially the establishment of the formal regulatory guidance that will replace the existing interim staff guidance document.

Question 15. In a February 2015, NRC IG audit, a licensee “likened the RAI process to a “fishing expedition,” noting that it required a lot of resources and research with little instruction on how to address the question.” Another industry representative said it was a “crapshoot” depending on which NRC reviewer was assigned to the application.

a) What is the Commission’s response to the descriptions contained in the IG Audit?

b) How will you improve the number and quality of RAIs in the licensing process?

Answer.

a) In the time since most spent fuel pools were licensed, there have been significant changes to typical spent fuel characteristics and storage arrangements (e.g., higher enrichment fuel with

more burnable absorbers; more reactive, modern fuel assembly designs; higher density storage configurations; and aging-related changes to neutron-absorbing material permanently installed in the spent fuel pools). The combination of the reactivity impact from these factors resulted in many license amendment requests with significantly less margin to regulatory limits in their spent fuel pool criticality analyses. The NRC staff found that, in some cases, licensees did not follow established guidance and did not adequately address these additional factors. As a result, the staff had to issue more requests for additional information (RAIs) to determine if the licensee amendment request met applicable requirements.

The NRC staff has partnered with licensees and the Nuclear Energy Institute (NEI) to develop more detailed guidance for spent fuel pool criticality analyses. The resulting document, NEI 12-16, is a product of multiple staff-licensee interactions through public meetings and the formal staff review process. Review and acceptance of NEI 12-16, and publication of the associated NRC guidance documents, will address the NRC Office of Inspector General (OIG) recommendation to provide a generic regulatory solution for spent fuel pool criticality analysis. OIG found the agency's response acceptable to close out the recommendation upon completion of the planned activities. The availability of detailed guidance will clarify the NRC's expectations of the scope and acceptance criteria for spent fuel pool criticality license amendments, thereby reducing the need for RAIs through the submission of high-quality applications.

b) In response to efforts to reduce the licensing backlog and consistent with the efficiency and effectiveness goals within the objectives of Project Aim 2020, the Office of Nuclear Reactor Regulation (NRR) has implemented strategies to leverage existing efficiencies in the licensing review processes that will reduce the number of RAIs and the time needed to complete a licensing action, in part, by a renewed focus on adhering to office instruction. For example, our internal instruction specifies that a draft safety evaluation report will be developed with open

items by the staff before RAIs are written and sent to the licensee. In addition, NRR management conducts a review of RAIs before they are issued to ensure that the questions are within the scope of the license amendment request. Where appropriate clarifications can be obtained through dialogue, NRR will rely on public meetings. Lastly, license amendment requests on similar issues will be grouped and processed together to the degree possible, not only to gain efficiency but also to ensure consistency.

NRR has also established a working group to review and evaluate the existing LIC-101 process to identify opportunities to gain efficiencies and improve effectiveness in the process. The staff will implement recommendations from the working group through revision to office instruction and other guidance, as needed.

Question 16. The NRC has a long list of rulemakings in various stages of development, some of which appear to have little to no safety value gain. Will the Commission review all ongoing activities to prioritize and eliminate rulemakings with no safety significant benefits as a part of the Project Aim baselining?

Answer.

Yes. The Commission will review all ongoing rulemaking activities under the Project Aim rebaselining activity. Outside of the Project Aim rebaselining activity, the Commission has recently approved termination of three rulemakings and the staff is developing a proposal for the Commission to terminate additional rulemakings of limited regulatory value.

Question 17. NRC's corporate overhead costs have risen significantly over the previous decade and have now reached \$422 million, or 41% of NRC's total budget

authority, according to the NRC's 2015 Fee Recovery Rule. Ernst & Young assessed NRC's overhead costs and recommended accounting for some overhead costs such as Human Resources, IT, and Financial Management within the NRC's business lines so that the costs attributed to corporate overhead would appear smaller.

a) Does the NRC plan to adopt this recommendation, or is the Commission planning to find ways to tangibly reduce corporate overhead costs?

b) How have staffing for the corporate support functions changed recently and what is the Commission doing to control those costs?

Answer.

a) The Ernst & Young (EY) assessment did not recommend moving corporate human resources management and financial management resources into the business lines, and these resources were not moved in the NRC's budget realignment. Rather, consistent with the EY recommendations, the NRC is re-categorizing some mission support costs, currently budgeted as Office Support, to align those resources to the individual program business lines those resources more directly support. This will align the NRC budget structure with best practices of other similarly situated federal agencies and with general federal budgeting practices.

Specifically, Office Support included senior management positions, administrative assistants, and other mission support staff who work in the program mission areas. The creation of Office Support as part of an earlier budget structure change pulled these mission-indirect resources into a separate business line and had the unintended consequence of increasing the resources the agency identified as corporate overhead in the annual fee rule. The realignment returns

these additional resources to the programmatic business lines to accurately reflect their role in providing mission support to the program offices.

The agency continues to look for ways to reduce Corporate Support. The Commission is committed to making reductions to the Corporate Support budget by finding additional efficiencies—through agency initiatives such as Project Aim 2020, office reorganizations, and by acting on EY’s benchmarking recommendations—that support agency management objectives during a period of ongoing change.

b) Overhead has been a focus of agency cost reduction efforts in recent years, and the NRC staff is actively evaluating ways to achieve further savings. Between the FY 2011 enacted budget and the FY 2016 President's budget, the NRC realized a reduction of 219 full-time equivalents (FTE) or \$36.4 million in overhead resources, primarily through centralization and standardization of Corporate Support functions.

As part of the Project Aim 2020 rebaselining effort currently under way, corporate activities and resources are being examined and prioritized in order to find more cost-efficient ways to perform necessary overhead functions. Specific plans to realize efficiencies identified through the rebaselining will be presented to the Commission for consideration. The NRC is committed to transparency with respect to the proposed realignment of resources, as well as to real reductions in the area of corporate overhead.

Streamlining activities to eliminate duplication of certain overhead functions in the program offices allowed the agency to make significant reductions in Office Support FTE. During this period, Corporate Support FTE resources increased as some of the administrative work shed by the program offices was centralized in the corporate offices. The Commission is committed to

finding new efficiencies and making further reductions in agency-wide overhead, including centralized Corporate Support functions, based both on recommendations stemming from the EY benchmarking report and future results from the agency re-baselining effort currently under way as part of the Project Aim 2020 initiative.

Question 18. Chairman Burns' testimony notes that the outlook of the industry which led to the creation of the Office of New Reactors, has not materialized. Accordingly, NRC staff has recommended the Office of New Reactors be folded back into the Office of Nuclear Reactor Regulation.

a) What is the status of this recommendation?

b) Would expediting this consolidation reduce the overall budgetary and staffing needs of the commission?

Answer.

In June, the Commission approved the staff's recommendation, as part of Project Aim, to develop a plan to conduct a merger of NRO and NRR. In response, the Project Aim 2020 team formed a working group that is currently developing a business case for a merger of NRO and NRR. This business case will include an evaluation of leading resource drivers, proposed timing for a merger, a description of projected efficiencies gained by a merger, and a plan for addressing the challenges that may arise. The staff will provide its transition plan to the Commission by June 8, 2016, for its review and approval. At present, NRR and NRO each have sufficient workloads to support staffing both offices and consolidation at this time could have a detrimental impact to the timely completion of both the ongoing and projected work of each office.

Question 19. The NRC's Committee to Review Generic Requirements (CRGR) was established to review formal action on guidance related to licensing, inspection, assessment, and enforcement that could impose [a] backfits [to be imposed] on NRC's licensees. Specifically, CRGR was intended to provide a quality check to assure that any application of the backfit rule meets strict, well-defined criteria. In a 2007 effort to provide flexibility in the rulemaking process, CRGR was provided the authority to use informal reviews instead of taking formal action. However, instead of CRGR use of informal reviews selectively to improve NRC efficiency, a formal action is now the exception, rather than the rule. Since 2007, out of 122 actions, CRGR has conducted 3 formal briefings, 13 formal reviews, and 95 informal reviews.

a) If CRGR only rarely conducts formal briefings or reviews, how do they actually engage licensees to receive industry perspective on the potential application of the backfit rule?

b) Will you describe specific actions members of CRGR undertake to fulfill their responsibilities? For example, do they have the authority to visit nuclear power plants to understand how the regulatory impacts on licensees are implemented? If so, are you aware if they actually do so?

c) What are your specific recommendations to revitalize CRGR and engage with industry?

Answer.

a) The Committee to Review Generic Requirements (CRGR) includes NRC senior executives from the Offices of Nuclear Regulatory Research (RES), Nuclear Reactor Regulation (NRR), New Reactors (NRO), Nuclear Material Safety and Safeguards (NMSS), Nuclear Security and Incident Response (NSIR), and from a regional office selected on a rotating basis. By charter, the CRGR reviews selected regulatory requirements, generic correspondence, regulatory guidance, and NRC staff guidance related to licensing, inspection, and enforcement that could impose a generic backfit. The CRGR conducts formal reviews and briefings as needed. Through both formal and informal reviews, the CRGR ensures that any generic backfits proposed by the NRC staff for NRC-licensed power reactors, new reactors, and nuclear materials facilities that fall within its charter are appropriately justified on the bases of the backfit provisions of the applicable NRC regulations and guidelines.

The CRGR's review of staff proposals is an internal review process; as such, the CRGR's communications and meetings with the staff to facilitate its reviews are intended as an internal control and not primarily an opportunity for direct licensee engagement. However, under NRC processes, the staff publishes most, if not all, of its proposals for public review and comment before submitting them to the CRGR for its review. Therefore as part of its review, the CRGR members consider any public comments, paying particular attention to any backfit concerns raised. If the CRGR finds that the staff did not fully address any public comments associated with a backfitting concern, it can request the staff to take additional actions to resolve the concern. As examples, such directed actions could involve an additional comment period with focused questions, a public meeting to discuss the backfitting concern with all interested stakeholders, or both.

The CRGR has also engaged directly with licensees and the industry in response to their requests. A report of CRGR activities is issued annually. As an example, last year, the Nuclear Energy Institute (NEI), after learning about a staff proposal concerning tornado missile protection that could apply to a number of operating reactors, raised a backfit concern and asked CRGR to review the proposed action. In response to NEI's requests, the CRGR Chairman, with support of other CRGR members and staff, held a conference call with NEI and licensee representatives. At the end of the call, NEI stated that the CRGR had addressed its request for CRGR engagement. The CRGR has documented this engagement in SECY-15-0107, "Annual Report of CRGR Review Activities," of August 20, 2015.

Finally, over the years, individual CRGR members have also received perspectives on backfitting from licensees and other stakeholders and have provided NRC perspectives on backfitting and the role of CRGR in a variety of forums, including NRC's annual Regulatory Information Conference and industry conferences, visits to reactor sites and other nuclear facilities, and scheduled meetings with agency officials.

b) With support from appropriate NRC technical and legal staff, the CRGR members fulfill their responsibilities by applying their extensive nuclear and regulatory experience and critical thinking, as well as insights obtained from both internal and external stakeholders, to review regulatory actions proposed by the NRC staff. The CRGR members are NRC senior executives and technical managers who are directly involved in the day-to-day technical and regulatory work of the agency. These executives have an average of 30 years of experience. Most of the CRGR members have first-hand experience and knowledge of nuclear power plant operations, nuclear materials licensees, and some have experience with both. All of the committee members have an in-depth understanding of the regulatory process, including backfitting. Through their technical and regulatory experience, CRGR members all are knowledgeable of

potential impacts of regulatory actions on licensee costs and operations. When they review a staff proposal, the members have direct access to the appropriate NRC staff and managers who provide data, information, and perspectives regarding the issue at hand to allow the committee to conduct a thorough and objective review.

As mentioned above, one CRGR member is a regional senior executive. This member regularly visits nuclear power plants, interacts with licensees and other stakeholders, and coordinates with counterparts at the other regional offices. If needed, the CRGR or individual committee members could visit nuclear power plants to help inform CRGR decisions. During CRGR deliberations, members provide relevant insights gained from their plant site visits and other first-hand interactions with licensee representatives. As an example, in the case of the proposed action regarding tornado missile protection discussed in the response to question 19(a), prior to CRGR engagement on the issue, the CRGR chairman was familiar with the technical, safety, and regulatory issues, including potential regulatory impact and backfitting considerations, because the underlying issue had been found by one of his inspectors while he was a senior executive in an NRC regional office. He had visited several nuclear power plants (before becoming the CRGR chairman) and reviewed the issue with his inspectors and the licensees. The current regional CRGR member also had good insights on this issue that he had gained from his plant site visits, his interactions with licensees, and the insights and perspectives he obtained from his counterparts in the other NRC regional offices.

c) As described in its most recent “Annual Report of CRGR Activities,” the CRGR is appropriately engaging with nuclear industry representatives and other stakeholders. In their roles as senior executives and technical managers, the CRGR members will continue to have opportunities to engage with licensees and industry representatives to discuss the role of the CRGR, the NRC's generic backfit management process, and industry questions and issues

associated with backfitting. In addition, at a recent internal meeting, the committee agreed to meet with all interested stakeholders to discuss the role of the CRGR and generic backfitting. The CRGR will hold this public meeting during 2016.

In addition, the Commission recently directed the NRC staff to provide a proposed plan for increasing the Commission's early involvement in the rulemaking process. The Commission directed that the proposed plan include, among other things, a recommendation for reconsideration of the Commission's 2006 direction with respect to the reviews of proposed rules by the CRGR. The Commission also directed the NRC staff to analyze whether amendments to the CRGR charter to alter its role in the agency's rulemaking process have the potential to better inform the agency's allocation of resources and prioritization of activities. The staff's recommendations are with the Commission for consideration.

Question 20. NRC Inspector General (IG) report "Audit of NRC's Oversight of Spent Fuel Pools (OIG-015-A-06)" detailed extensive reliance on "interim staff guidance" in NRC's safety guidance documents. The IG found that the overreliance on these documents results in an unpredictable review process, which is open to interpretation and unreliable. Please describe the role interim staff guidance plays in NRC's reactor oversight activities.

a) How many interim staff guidance documents are currently in place?

b) Does the Commission have a role in assuring interim staff guidance is limited and appropriate?

c) Will the Commission consider examining the frequency and justification in which NRC staff utilize interim staff guidance?

Answer.

Interim staff guidance documents allow the staff to expeditiously address specific areas until the Standard Review Plan (SRP) or other NRC regulatory guidance documents are updated.

a) There are approximately 100 interim staff guidance (ISG) documents in use today. They can be found on the NRC's public website, organized by technical/subject matter:

<http://www.nrc.gov/reading-rm/doc-collections/isg/>.

b) The Commission does not routinely review issuance of interim staff guidance. Although not involved directly in this process, the Commission retains responsibility for all policy decisions at the agency and, if necessary, could direct the staff to revise or withdraw an ISG.

c) This issue is being considered under the Project Aim rebaselining efforts. The NRC staff plans to submit a SECY paper to the Commission in April 2016, which outlines the priority of staff utilization of these documents.

Question 21. NRC's Principles of Good Regulation rely on transparency embedded throughout the regulatory process.

a) How does the Commission adhere to its principle of openness in its licensing process?

b) Would you consider developing a tracking system for license amendment requests, that would be available for licensees to know in real-time the status of their licensing actions?

Answer.

a) For initial licenses and amendments thereto, the NRC publishes notices in the *Federal Register* notifying the public of the opportunity to comment or request a hearing on the proposed action. The NRC also holds public meetings related to licensing actions, including meetings at NRC headquarters and in the vicinity of the plant sites. Furthermore, through the Agencywide Documents Access and Management System (ADAMS) portion of our website, the NRC makes all non-sensitive licensing publically available. The NRC also maintains information on key licensing activities on its public website, thereby informing members of the public of the status of completed, ongoing, and expected licensing activities.

b) The licensing project managers (PMs) currently maintain a tracking system of all licensing actions for their assigned facilities. In addition to this tracking system, the PMs routinely communicate with licensees regarding licensing actions under review. The PMs also promptly inform both licensees and other stakeholders of licensing decisions and respond promptly to inquiries about the status of licensing actions.

Question 22. The NRC's "backfit rule" (10 CFR 50.109) provides that, before a new requirement can be added to an existing licensing facility, the NRC must demonstrate that the new requirement would result in a "substantial increase" in the protection of public health and safety and that the "direct and indirect costs of implementation for that facility are justified in view of this increased protection." The purpose of this rule is to ensure that, for

facilities already licensed by the NRC, the benefits from any additional modifications exceed the cost. While this analysis has traditionally involved an objective, quantitative analysis there has been a concern that the NRC staff has increasingly shown a willingness to rely on qualitative, subjective factors or has ignored the cost-benefit analysis requirement altogether. This dynamic was seen in two of the recent issues that came before the Commission for consideration: (1) SECY-15-0065, which addressed “Mitigating Strategies” for severe accident scenarios; and (2) SECY-15-0085, which involved “Containment Protection” for certain kinds of nuclear power plants. What limitations or constraints exist on the staff’s authority to base decisions or recommendations to the Commission using qualitative factors in a way that takes precedence over quantitative analyses?

Answer.

The staff’s use of qualitative factors arises when analyses do not lend themselves to purely quantitative evaluations. However, the appropriate weighing of qualitative factors in regulatory decision-making ultimately lies with the Commission. The Commission recently approved the NRC staff’s plans for updating guidance regarding the use of qualitative factors to improve the clarity, transparency, and consistency of the agency’s regulatory and backfit analyses, and this activity is ongoing. The Commission has not authorized, as part of this updating, any expansion of the consideration of qualitative factors in regulatory and backfit analyses. The Commission specifically directed that the revised guidance should ensure that costs are quantified to the extent possible, and use qualitative factors to inform decision making, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data).

Question 23. In its June 2015 report, the NRC Inspector General observed: “the agency may be vulnerable to errors, delays, wasted effort, and flawed decision making because of the limited experience of its cost estimators. It also increases the potential to make less than optimal rulemaking decisions because the NRC Commission uses regulatory analyses to determine whether to move forward with rulemaking.” Has the Commission looked at this issue of the level of experience of the NRC’s cost estimators?

a) How is this concern being reviewed and addressed within the NRC?

b) Would you agree that instances where qualitative factors are relied upon for NRC decision making should be “rare”? When should a qualitative analysis override a quantitative analysis that is available?

Answer.

a) The NRC staff has recently hired experienced cost estimators, established a pilot program to perform independent cost estimates, and is enhancing its existing regulatory analysis training and qualification program.

b) As stated in the response to Question 22, the Commission has directed that the revised cost-benefit guidance should encourage quantifying costs to the extent possible, and use qualitative factors to inform decision making, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data).

Question 24. Chairman Burns' testimony notes that the NRC does not have resources budgeted to review potential applications for an interim storage site, but "could reprioritize work if applications are submitted."

a) What work would be reprioritized to provide the staff and resource time?

b) If Congress provides funding to continue work on the Yucca Mountain license application, would the Commission have to increase staff to conduct work on both the repository and storage applications? If so, how would this be consistent with your efforts embodied in the Project AIM 2020 goal of "right-sizing" the organization?

Answer.

a) The NRC currently reviews a variety of storage and transportation applications each year for spent nuclear fuel and for transport of other radioactive materials. These applications involve domestic as well as non-domestic storage and transportation systems as well as those that are planned to be offered in the future by vendors (i.e., those systems that have not yet been offered or purchased for use). If an application for an interim storage facility were received, the Commission would evaluate the workload at that time and would consider whether the reviews of other applications could be delayed. For instance, the Commission might prioritize the review of storage and transportation systems based on whether the system was designated for domestic use or had immediate, domestic customers.

b) If Congress provides funding, the NRC would continue its review of the construction authorization application for a repository at Yucca Mountain. The necessary staffing level for the repository and for potential storage applications will depend on the specific review activities

necessary for each activity. As a part of the Project Aim 2020 activities, the staff is developing a strategic workforce to ensure the NRC has the efficiency, effectiveness, and agility to complete its mission to protect the health and safety of the public and the environment in a changing environment. Developing a more efficient, effective, and agile workforce will allow the agency to shift available personnel among projects as needs and priorities change.

Question 25. On March 26, a proposed rule was published in the Federal register to revise the standards for low- level radioactive waste (LLRW). Among the major provisions of the proposed rule was the added requirement to provide defense-in-depth protections beyond existing standards - standards that have previously been deemed adequate by the Commission. However, the determination to impose defense-in-depth was a result of a subjective justification by NRC staff and contrary to the Commission's direction contained in the Staff Requirements Memorandum (SRM).

a) Is it the Commission's policy that NRC Staff must adhere to direction provided by the Commission in its staff requirements memoranda?

b) What is the status of the proposed rule for low-level radioactive waste? Will you support a final rule that diverges from the original guidance to the NRC Staff?

Answer.

a) The NRC staff must follow direction provided by the Commission in staff requirements memoranda (SRM).

b) The NRC staff is currently reviewing comments received during the public comment period. The NRC received approximately 90 discrete letters and over 1,000 form letters representing state governments, industry groups, public interest groups, Indian tribes, and individual stakeholders. The NRC staff will submit for Commission consideration a draft final rule that incorporates and explains all changes from the proposed rule that resulted from the stakeholders' comments. The Commission will approve or disapprove the final rule.

Question 26. Chairman Burns' testimony notes that the NRC staff is developing a reactor decommissioning rulemaking to improve efficiency and predictability of the decommissioning process. The Commission's direction to the staff was to issue a final rule by early 2019; however in January, the Executive Director of Operations said "there is a high likelihood that the final rule may not be issued until sometime in calendar year 2020."

a) Why, at the onset to the rulemaking process and four years from the goal, is the senior NRC Staff appearing to change the schedule that has been directed?

b) How will you assure the process is appropriately managed to achieve the schedule the Commission provided to staff?

Answer.

a) In the SRM for SECY-14-0118, “Request by Duke Energy Florida, Inc., for Exemptions from Certain Emergency Planning Requirements,” the Commission directed the staff to initiate the rulemaking process and set an objective of early 2019 for completion. The Commission also directed the staff to continue processing current and pending applications for decommissioning amendments and exemptions until that regulatory work is complete. In SECY-15-0014, “Anticipated Schedule and Estimated Resources for a Power Reactor Decommissioning Rulemaking,” the staff committed to proceed with a rulemaking on decommissioning and stated that it would maintain its focus on the current decommissioning transition licensing actions while proceeding on a schedule to provide the rule to the Commission in 2019, if several key assumptions are met, including that no additional reactors, other than Oyster Creek Nuclear Generating Station, permanently shut down during the rulemaking period.

Once the final rule is provided to the Commission, the Commission would deliberate on the rule and issue direction to the staff. Assuming the Commission approves publication of the final rule, there would be additional steps prior to publication, including the Office of Management and Budget’s review of the Information Collections aspects of the rule. Thus, while the schedule for the rulemaking is to provide the final rule to the Commission in 2019, SECY-15-0014 stated that there was a high likelihood that the rule may not be published in the *Federal Register* until 2020.

b) The staff will provide the regulatory basis, proposed rule, and final rule to the Commission as part of the rulemaking process. Any schedule changes for these products would require Commission approval. As stated in SECY-15-0014, “Anticipated Schedule and Estimated Resources for a Power Reactor Decommissioning Rulemaking,” the staff committed to keep the Commission informed of any issues that could result in delays to the anticipated

decommissioning rulemaking schedule. On October 7, 2015, the staff provided to the Commission a detailed schedule, estimated resource needs, and impacts on other agency work to support completion of the rulemaking in 2019 in SECY-15-0127, “Schedule, Resource Estimates, and Impacts for the Power Reactor Decommissioning Rulemaking.”

Question 27. In a report released September 2, the NRC Inspector General (IG) assessed the efficiency and effectiveness of NRC’s management of change and found the agency “does not have a comprehensive process to manage change because efforts to provide an agencywide change management process are incomplete.” The IG observes that NRC has “missed opportunities to implement change more efficiently and effectively, and will continue to do so without a comprehensive, scalable, agencywide change management process.” The agency managers agreed with the IG’s findings, but opted not to provide formal comments for response.

a) Given the number and significance of the various change initiatives underway, how will the NRC assure that they are implemented effectively?

b) Will the Commission take action in response to the IG’s recommendations?

Answer.

a) The NRC staff has taken several actions to ensure that change initiatives are effectively implemented. To ensure effective implementation, the NRC has established a governance structure and framework for Project Aim that includes senior management, and draws on best practices and lessons learned from recent change initiatives. The framework is a consistent

approach that includes dedicated senior level leadership, measurable milestones to hold staff and management accountable, stakeholder analysis and impact assessments, and efficient decision-making. Another action to support effective implementation is development of the Project Aim 2020 communication strategy, which is intended to enhance understanding of change initiatives and how they fit together. In parallel, the Office of the Chief Human Capital Officer (OCHCO) has provided, and continues to provide, resources that will help our senior leaders, managers, supervisors, and staff-level employees transition through periods of change by providing them with the necessary tools and resources to build change capacity.

b) Yes, the Commission is taking action in response to the IG's recommendations. Specifically, the agency-wide change management framework initiated by OCHCO will undergo additional development to reflect a more comprehensive step-by-step process. To enhance our communication efforts, the agency will use available change management resources, including the updated framework and accompanying tools. The agency will also provide training and training resources to management and staff that is geared specifically to implementing the completed framework.

Question 28. A review of recent NRC budget requests suggests that most, if not all, of the Commission's business lines include "research" activities. In the Commission's most recent budget request, the total funding requested for "Research" exceeded \$90 million, which is a significant figure for an agency with a total budget of approximately \$1 billion.

a) Please provide a report detailing the overall NRC expenditures on research activities, the list of ongoing research projects, and the general process that the NRC follows to select research projects.

b) Does the NRC have plans to take a close look at these research programs to achieve cost savings?

c) For a regulatory agency like the NRC, what portion of overall research spending is geared toward safety significant research projects?

Answer.

a) The NRC formulates its budget at the product level (e.g., in the research product line, some of the products include reactors research, advanced reactors research, and materials research). The NRC executes its budget at the more-detailed cost center level that is driven by the priorities of the regulatory offices at the time of budget execution. The FY 2015 and FY 2016 budget and FY 2015 execution information is included in Attachment 1, "FY 2015 and FY 2016 Budget Information."

Attachment 2, "Regulatory Research Activities by Cost Center," presents the currently ongoing staff-initiated research projects organized by cost center. For each project, the NRC has provided the title, requesting office, scope or description of the research, the regulatory outcome, the expected project duration, and most relevant budget cost center. Since some of the listed research activities are supported by a variety of contracts and staff resources, only the predominant cost center associated with the activity is represented in the table.

In addition to staff-initiated research, some ongoing activities in the Office of Nuclear Regulatory Research (RES) are Commission-directed or congressionally mandated. Attachment 3, "Commission and Congressionally Directed Activities," includes recent examples of these types of activities along with the reasons for undertaking the work.

User need requests are the primary mechanism used by the regulatory offices to request support from RES. These requests typically involve a request for research or analyses to support safety, security, and regulatory decisions. Each user need request is transmitted as a memorandum to the RES Office Director from one or more office directors of NRC regulatory offices.

A large portion of the regulatory program offices' work is reviewing requests to amend operating licenses by utilities. These requests primarily focus on asking the NRC to either allow relaxation of certain license requirements or to request approval of new or different ways to meet NRC regulations, which usually result in financial savings by the licensee.

Most user need requests from the regulatory program offices request that confirmatory research be performed to independently verify that licensee requests can be safely implemented and that adequate protection of the public health and safety is maintained. It is this independent confirmatory research that provides the regulatory office with the independent assurance they need to approve or deny licensee requests.

RES has internal controls and management procedures to ensure that it develops a complete and mutually agreed-upon request and corresponding project plan to support any research work. The process requires that all requests for research articulate clearly defined objectives and deliverables. Priorities are conveyed to RES through the user need requests and through periodic counterpart meetings at various levels of management and staff. The progress of ongoing research and any updated priorities are reviewed quarterly by the RES Office Director. In addition, all research expenditures are reviewed by RES, the Office of the Chief Financial Officer, and the Office of Administration for all work done by contractors and DOE National

Laboratories. Further, research products are also subjected to peer reviews and to reviews by the independent Advisory Committee on Reactor Safeguards.

b) As part of Project Aim 2020, all NRC programs are currently being reviewed for efficiencies, including the NRC's research program.

RES develops its research program in response to Commission direction and input from the regulatory program offices and other stakeholders. It is also reviewed by the Advisory Committee on Reactor Safeguards. Major research activities often include collaborations with other federal agencies, industry research organizations, universities, and international partners that share costs or data with the NRC in order to leverage resources and manage costs.

c) The NRC's entire research budget supports the agency's safety and security mission. RES primarily conducts confirmatory experiments and analyses; develops technical bases that support the NRC's safety and security decisions; and prepares the agency for the future by evaluating the safety and regulatory aspects of new technologies and designs for nuclear reactors, and materials, waste, and security. The NRC does not perform research that is developmental or unrelated to nuclear safety or security.

Question 29. The Commission has a goal of completing 95% of its licensing amendment revisions within one year, however, has struggled lately to meet those goals. Additionally, the length of response time for other licensing tasks has increased, which results in uncertainty for applicants.

a) Has the Commission considered developing performance metrics for different types of licensing actions?

b) Would the Commission consider this exercise concurrent with other organization efficiencies, namely Project Aim?

Answer.

a) The Commission has established performance metrics for licensing actions (95 percent in less than a year) and other licensing tasks (90 percent in less than a year). In addition, the Commission established performance metrics in the NRC's FY 2016 Congressional Budget Justification (CBJ) under the Operating Reactor Business Line to drive at least a 2 percent improvement each fiscal year in the percentage of licensing actions and other licensing tasks completed in less than a year. Further, the Commission recognizes that certain types of licensing actions, such as power uprates, improved standard technical specification conversions, and other unusually complex actions should be completed in different time frames, as noted in the CBJ. Additionally, the staff engages licensees early in the licensing process to discuss and align on the timeframes for all actions, with increased focus on those with schedules that will extend beyond one year.

b) The Commission is reviewing the operating reactor licensing process as part of Project Aim through the completion of phased initiatives to enhance effectiveness and efficiency in the operating reactor program, including the operating reactor licensing process; and through the conduct of a business process improvement review of the operating reactor licensing process to make associated improvements to enhance predictability, timeliness, and efficiency of the reviews.

Question 30. Section 275 of the Atomic Energy Act provides dual authority to both the Nuclear Regulatory Commission (NRC) and the Environmental Protection

Agency (EPA) to regulate the uranium processing industry. EPA is currently considering a proposed rule to establish specific concentration limits for groundwater surrounding uranium in-situ recovery facilities. The Atomic Energy Act requires the EPA Administrator to consult with the Commission and the Secretary of Energy before promulgation of such a rule.

a) Has EPA consulted with the NRC on this issue?

b) Does NRC consider its existing standards with respect to in-situ mining sufficient?

c) What is NRC doing to protect its jurisdiction from EPA?

Answer.

a) Yes. EPA initially informed the NRC in 2010 that it was undertaking the rulemaking and provided the NRC with periodic updates regarding status of the rulemaking during its development. EPA also periodically requested technical information from the NRC during preparation of EPA's draft proposed rule. The NRC staff also reviewed and provided comments on the draft proposed rule during the interagency review process led by the Office of Management and Budget.

b) Yes, the NRC has determined that Criterion 5B(5) of its 10 CFR Part 40, Appendix A regulations sets forth the appropriate standards to be applied to groundwater protection and restoration at uranium in-situ recovery facilities. The NRC supplements these standards by site-specific license conditions to further ensure adequate groundwater protection and restoration.

In the event EPA issues new regulations that create or revise generally applicable standards, the NRC will make conforming changes to its regulations as required by section 275 of the Atomic Energy Act of 1954, as amended.

c) NRC's General Counsel addressed jurisdictional issues in a letter to the EPA's General Counsel, dated July 28, 2015. The NRC and EPA plan further discussions as EPA develops its final rule. The NRC also plans to participate in the OMB-led interagency review process for the draft final rule.

Question 31. What is the NRC's role in licensees' choice of decommissioning strategies?

Answer.

The NRC's power reactor decommissioning regulations (10 CFR 50.82(a)) allow the licensee to determine the decommissioning strategy for its reactor.

The NRC has evaluated the environmental impacts of three general methods for decommissioning power reactor facilities:

- DECON: The equipment, structures, and portions of the facility and site that contain radioactive contaminants are removed or decontaminated to a level that permits termination of the license.
- SAFSTOR: The facility is placed in a safe stable condition and maintained in that state until it is subsequently decontaminated and dismantled to levels that permit license termination. During SAFSTOR, a facility is left intact, but the fuel has been removed from the reactor vessel and radioactive liquids have been drained from systems and components and then processed. Radioactive decay occurs during the SAFSTOR period,

thus reducing the quantity of contaminated and radioactive material that must be disposed of during decontamination and dismantlement.

- ENTOMB: Radioactive structures, systems, and components are encased in a structurally long-lived substance, such as concrete. The entombed structure is appropriately maintained, and continued surveillance is carried out until the radioactivity decays to a level that permits termination of the license. To date, there has not been any interest by NRC reactor licensees to use the ENTOMB option.

The choice of the decommissioning method is left to the licensee. However, the NRC would require the licensee to re-evaluate its decision if the process it chooses: (1) could not be completed as described, (2) could not be completed within 60 years of the permanent cessation of plant operations, or (3) included activities that would endanger the health and safety of the public by being outside of the NRC's health and safety regulations.

Late last year, the Commission directed the staff to initiate a rulemaking on decommissioning. One of the issues that the staff was directed to include in the rulemaking is the "appropriateness of maintaining the three existing options for decommissioning and the timeframes associated with those options." An Advance Notice of Proposed Rulemaking is expected to be published for public comment in the near future.

Question 32. How many power uprate licensing actions are currently pending with NRC Staff?

a) Please provide a list of power uprate requests the Commission has received since 2005, including the type of power uprate, date submitted,

the date approved, number of requests for additional information, and whether the uprate was approved or denied.

Answer.

The NRC is currently reviewing three power uprate license amendment requests; 1) Oconee-1, -2, & -3; the NRC review for this amendment request is currently on hold by request of the licensee. 2) Catawba-1. The NRC anticipates its review for the power uprate request for Catawba will be completed by January 2016; and 3) Browns Ferry-1, -2, & -3; on September 21, 2015, the licensee submitted a license amendment requesting an extended power uprate that would increase to the current licensed thermal power for Units 1, 2, & 3 by approximately 14.3%. This application is under review by the NRC staff for acceptance.

The NRC has established goals for reviewing power uprate applications as follows: 9 months for a measurement uncertainty recapture (MUR) power uprate (power increase of less than 2%), 12 months for a stretch power uprate (or SPU, power increase up to 7%), and 18 months for an extended power uprate (or EPU, power increase as high as 20%). The goals provide an appropriate safety review schedule based on application complexity, support management oversight of the review activities, and meet industry needs for timely reviews.

The NRC public website for power uprates provides linked references to all licensee correspondence, including responses to requests for additional information.

For each power uprate request since 2005, the table below lists the type of power uprate, date submitted, date of final action (e.g., approved, denied, not accepted, or withdrawn by licensee), and the number of applicant RAI letter responses.

Licensee Power Uprate Applications Received by the NRC (since 2005)

	PLANT NAME	POWER UPRATE TYPE¹	DATE SUBMITTED	DATE (FINAL ACTION)	# RAIs
1	Calvert Cliffs 1, 2	MUR	1/31/05	9/27/07 (Withdrawn)	-
2	Monticello	EPU	3/31/05	6/25/08 (Withdrawn)	-
3	Fort Calhoun	MUR	3/31/05	9/27/07 (Denied)	-
4	Hope Creek	EPU	11/7/05	2/10/06 (Not Accepted)	0
5	Susquehanna 1, 2	EPU	3/31/06	5/18/06 (Withdrawn)	-
6	Hope Creek	EPU	9/18/06	5/14/08 (Approved)	39
7	Browns Ferry 1	SPU	9/22/06	3/6/07 (Approved)	1
8	Davis-Besse	MUR	4/12/07	6/30/08 (Approved)	9
9	Crystal River 3	MUR	4/25/07	12/26/07 (Approved)	5

¹ MUR = Measurement Uncertainty Recapture (<2%); SPU = Stretch Power Uprate (</=7%); EPU = Extended Power Uprate (</=20%)

	PLANT NAME	POWER UPRATE TYPE¹	DATE SUBMITTED	DATE (FINAL ACTION)	# RAIs
10	Millstone 3	SPU	7/13/07	8/12/08 (Approved)	35
11	Vogtle 1, 2	MUR	8/28/07	2/27/08 (Approved)	4
12	Comanche Peak 1, 2	SPU	8/28/07	6/27/08 (Approved)	12
13	Cooper	MUR	11/19/07	6/30/08 (Approved)	4
14	Monticello	EPU	3/31/08	6/25/08 (Withdrawn)	-
15	Calvert Cliffs 1, 2	MUR	8/29/08	7/22/09 (Approved)	9
16	Monticello	EPU	11/5/08	12/9/13 (Approved)	71
17	North Anna 1, 2	MUR	3/26/09	10/22/09 (Approved)	3
18	Point Beach 1, 2	EPU	4/7/09	5/3/11 (Approved)	100
19	Nine Mile Point 2	EPU	5/27/09	12/22/11 (Approved)	27
20	Prairie Island 1, 2	MUR	12/28/09	8/18/10 (Approved)	3

	PLANT NAME	POWER UPRATE TYPE¹	DATE SUBMITTED	DATE (FINAL ACTION)	# RAIs
21	LaSalle 1, 2	MUR	1/27/10	9/16/10 (Approved)	2
22	Surry 1, 2	MUR	1/27/10	9/24/10 (Approved)	2
23	Limerick 1, 2	MUR	3/25/10	4/8/11 (Approved)	11
24	Grand Gulf 1	EPU	9/8/10	7/18/12 (Approved)	47
25	Turkey Point 3, 4	EPU / MUR	10/21/10/ 12/14/10	6/15/12 (Approved)	70
26	St. Lucie 1	EPU / MUR	11/22/10	7/9/12 (Approved)	85
27	St. Lucie 2	EPU / MUR	2/25/11	9/24/12 (Approved)	67
28	Harris 1	MUR	4/28/11	5/30/12 (Approved)	15
29	Crystal River 3	EPU	6/15/11	2/7/13 (Withdrawn)	-
30	Braidwood 1, 2	MUR	6/23/11	2/7/14 (Approved)	19
31	Byron 1, 2	MUR	6/23/11	2/7/14 (Approved)	19

	PLANT NAME	POWER UPRATE TYPE ¹	DATE SUBMITTED	DATE (FINAL ACTION)	# RAIs
32	Oconee 1, 2, 3	MUR	9/20/11	See Note ² (On Hold)	-
33	McGuire 1, 2	MUR	3/5/12	5/16/13 (Approved)	9
34	Peach Bottom 2, 3	EPU	9/28/12	8/25/14 (Approved)	28
35	Fermi 2	MUR	2/7/13	2/10/14 (Approved)	5
36	Catawba 1	MUR	6/3/14	Under Review	-
37	Browns Ferry 1, 2, 3	EPU	9/21/15	Under Review	-

² Oconee 1, 2, 3 - (On Hold) [NRC letter dated August 31, 2012, to Duke Energy regarding Oconee Power Uprate.](#)

The Honorable Tim Murphy

Question 1. In light of NRC's Project Aim, what changes is the NRC considering making to the licensing process to make it more safety-focused and efficient? For example, could review plans be risk-informed so that not everything was treated as important?

Answer.

The Office of Nuclear Reactor Regulation (NRR) staff prioritizes licensing action reviews in accordance with safety significance and, whenever practicable, the schedule needs of the licensee. The NRR staff engages licensees early in the review process to discuss the timeframes for processing all licensing actions.

NRR has a number of efforts planned or underway with the goal of making the licensing process more efficient.

The NRC has shown its commitment to improve timeliness with the establishment of performance metrics in its FY 2016 Congressional Budget Justification. Under the Operating Reactor Business Line, the NRC announced its intention to drive at least a 2 percent improvement each fiscal year in the percentage of licensing actions completed in under a year. The NRC staff also routinely discusses steps to make the licensing process more safety-focused and efficient during various interactions with licensees, such as public meetings. In addition, the NRC is reviewing the operating reactor licensing process, including lessons learned from how the backlog originated, as part of a business process improvement review being conducted under Project Aim.

The NRR staff is also reviewing and evaluating the existing license amendment process with the goal of reinforcing current expectations and best practices. This initiative is intended, in part, to identify issues that may be interfering with the timely completion of some reviews and to identify opportunities for improvement. Although issues identified through this initiative are still being evaluated, the staff is taking actions to implement improvements as they are identified.

On August 25, 2015, the Commission directed the NRC staff to use its existing authority to ensure the NRC's regulatory actions are properly prioritized, taking into account risk information and other factors. The Commission also directed the NRC staff to use existing agency processes under 10 CFR 50.12 and 10 CFR 50.90 to apply risk-informed decision-making in its review of relief requests such as licensee exemption requests.

Question 2. The recent Cumulative Effects of Regulation (CER) pilot has shown that the NRC continues to issue new regulations that generate relatively low safety-benefit at a significant cost to create the rule and still more for licensees to implement the rule. What changes will NRC make to ensure that new rules will actually increase safety and that accurate cost-benefit ratios are applied in the decision making?

Answer.

The NRC will review all ongoing rulemaking activities under the Project Aim rebaselining activity. This effort will review the agency workload, which has evolved over the past decade, including current and planned rulemakings, and develop a list of activities that could be shed or performed at a reduced level to help focus our efforts on activities that can provide the most safety benefit. The NRC will consider many aspects, including risk insights (where available) to screen out rules with no or relatively low safety benefit. The NRC will continue to use the

management review process to ensure that new rules reflect agency priorities and result in an efficient rulemaking process. The NRC will continue to use the management review process to ensure that new rules reflect agency priorities and result in an efficient rulemaking process.

In addition, the staff engaged with the industry on case studies to review the accuracy of cost and schedule estimates used in NRC's regulatory analyses. Based on NEI and industry recommendations, the staff is performing preliminary high-level cost assessments and backfitting assessments, on a case-by-case basis as part of the regulatory basis. These preliminary assessments provide an opportunity for the NRC staff to receive public input during the comment period on the technical merits of prospective actions and its estimated costs and benefits before prospective regulatory actions proceed into rulemaking.

Question 3. NRC staff had difficulty consistently and fairly applying the backfit rules that exist for various types of licensees. Fortunately, the Commission has re-directed the staff in a few cases. What will the Commission do to ensure the staff respects the backfit rule going forward?

Answer.

The Commission has directed the staff to develop updated cost-benefit guidance to improve the clarity, transparency, and consistency of the agency's analytical processes, including its backfit analyses. The Commission has also provided the staff with a set of high-level principles for this update that emphasizes quantification using realistic estimates and uncertainty analysis as well as the evaluation of qualitative factors in a judicious and disciplined manner. As an additional matter, the Commission will continue to scrutinize backfit analyses, as part of its review of future staff proposals, to ensure that backfit analyses comply with these principles and that any departures from prior agency practice are justified.

Question 4. NRC regulations permit 20-year extensions to the original 40-year operating license. So far, the NRC has issued 74 renewed licenses for the nation's 100 operating reactors. A number of licensees are actively planning to pursue a second 20-year license extension. In FY 2015, Congressional report language identified the importance of NRC having a fair, effective, predictable, and efficient process for second license renewal that builds up on the technical and regulatory success of the first license renewals. The FY 2016 budget request does not mention planned activities for second license renewal. Can you discuss the NRC's readiness for receipt of second license renewal applications expected to be submitted in the 2017 timeframe? Will the NRC be ready to process the applications expected to be submitted in the 2018-2019 timeframe?

Answer.

The NRC anticipates being ready to process applications for second, or "subsequent," license renewals expected to be submitted in the 2018-2019 timeframe. The NRC has established a focused license renewal process with the clear requirements needed to assure safe plant operation for extended plant life, both for initial renewal, and for extensions beyond 60 years of operations. For the first license renewal period, the staff issued documents to guide applicants and staff reviewers: the "Standard Review Plan for the Review of License Renewal Applications for Nuclear Power Plants," or SRP, and a "Generic Aging Lessons Learned Report," or GALL Report. These documents describe methods acceptable to the staff for implementing the license renewal rule, as well as techniques used by the staff in evaluating applications for license renewals to ensure a quality and uniform review for all applications. The staff is currently developing the license renewal guidance framework for license renewal for operation

from 60 to 80 years. The NRC staff is nearing completion of a new revision of the GALL Report and the SRP to address the issues that nuclear power plants may experience for operation to 80 years. The staff plans to issue these documents for public comment by the end of calendar year 2015 and expects to finalize the guidance documents needed to review subsequent license renewal applications prior to the anticipated receipt of the first application in the 2018 to 2019 timeframe.

The Honorable Billy Long

Question 1. Radioactive sources play a crucial role in our country's industrial, agricultural, and health care sectors. One source in particular, the Cobalt-60 isotope, has many uses. One of its most significant uses is in the delivery of cost-effective, life-saving radiosurgery for patients suffering from brain cancer and other complex neurological disorders. Hospitals throughout the country treat thousands of cancer patients each year with medical devices using Cobalt-60.

a) The Nuclear Regulatory Commission (NRC) has jurisdiction over the licensing and use of Cobalt-60 sources. In spite of an exemplary safety record and critical role that Cobalt-60 plays in delivering health care services, some recent policy proposals have suggested a need for increased oversight through additional federal agencies and resources. Would you please share the Commission's current and future activities to implement the revised 10 CFR Part 37 regulations in a manner that balances patient access to Cobalt-60 clinical treatment applications with continued adequate oversight of source security?

Answer.

The NRC and Agreement States have created a robust regulatory framework that provides strong safety and security for radioactive materials used in medical applications, including those medical applications utilizing Cobalt-60. Since 2005, medical facilities have been required to secure risk-significant radioactive materials in accordance with the Increased Controls Orders issued by the NRC, or equivalent requirements issued by the Agreement States. In 2013 the

NRC incorporated the requirements in the Increased Controls Orders into its regulations found in 10 CFR Part 37. The Agreement States have been transitioning from these Increased Controls requirements as well, with a deadline of March 2016 to complete the transition to requirements compatible with 10 CFR Part 37.

The regulatory framework in 10 CFR Part 37 utilizes a risk-informed, multi-layered approach to ensure the safety and security of radioactive materials used in medical applications. This mix of performance-based and prescriptive requirements enables the medical community to adopt the least burdensome and most flexible alternatives to securing NRC-licensed material. At the same time, the requirements in Part 37 ensure protection that is commensurate with the threat environment and the risk associated with the material. To aid licensees with implementation of the 10 CFR Part 37 requirements, the NRC published complementary sets of implementing guidance in 2013 and 2014.

The Honorable Kathy Castor

Question 1. There are 65 pressurized-water reactors that require the use of steam generators. Please list the number of these reactors that have operated between 20-29 years, 30-39 years and 40 years or longer.

Answer.

There is one reactor that has operated less than 20 years, 18 reactors that have operated between 20 and 29 years, 25 reactors that have operated between 30 and 39 years, and 21 reactors that have operated 40 years or longer.

Question 2. The NRC currently has rules for inspections, maintenance and repair of steam generator tubes. Do these rules also pertain to steam generator tube replacement projects? If not, does the NRC believe it would be appropriate to set minimum standards or guidelines for steam generator tube replacement projects? Please explain your reasoning.

Answer.

The NRC has rules for the inspection, maintenance, and repair of steam generators that are applicable to both original and replacement steam generators; however, the requirements may vary based on the materials used for the steam generator tubes. For example, a longer inspection interval may be allowed if the replacement steam generator is made from more corrosion-resistant materials. The NRC inspects steam generator replacement projects under the guidance provided in the NRC Inspection Manual. A specific inspection procedure in that manual verifies, on a sampling basis, that engineering evaluations and design changes associated with a steam generator replacement are completed in conformance with

requirements in the facility license, applicable codes and standards, license commitments, and NRC regulations.

Question 3. The NRC's own inspection report on the Crystal River 3 steam generator replacement states that the "root cause analysis determined that the delamination was caused by scope and sequence of this tendon detensioning in preparation for making the opening." Did the NRC review and approve then Progress Energy's plan to replace the steam generator tubes? Did the steam generator replacement project require a license amendment? Does the NRC agree that the cracks were an unforeseen consequence of the repair or that the cracks "could not have been predicted?"

Answer.

Progress Energy was not required to have the replacement plan approved by the NRC and the NRC did not review and approve Progress Energy's plan to replace the steam generators. An inspection of the steam generator replacement project was performed and a publicly available inspection report was issued.

For steam generator replacement projects, licensees follow NRC rules regarding which actions require NRC approval (10 CFR 50.59). NRC inspection procedures note that a temporary opening can be made in containment without NRC approval under the provisions of 10 CFR 50.59, provided that the process does not raise any unreviewed safety questions or require a change in technical specifications. The temporary opening at Crystal River 3 met this criteria and thus did not need a license amendment.

The 10 CFR 50.59 process is also used in evaluating whether design changes in the steam generator require prior NRC approval. If the replacement steam generator is designed to similar codes/standards as the original steam generators, an amendment is not needed for the replacement steam generators. Most steam generators in NRC-licensed power plants are designed to the American Society of Mechanical Engineers Boiler and Pressure Vessel Code and to quality assurance requirements in NRC regulations.

Although the steam generator replacement project did not require a license amendment, an amendment was needed to remove inspection and repair criteria and methods from the Crystal River-3 technical specifications that were applicable to the original steam generators, but were no longer applicable to the replacement steam generators.

The NRC's responsibility is to ensure the health and safety of the public by ensuring the plant systems, structures, and components meet established standards. Therefore, the NRC's review focused on safety and provided reasonable assurance that the containment would meet the same requirements as it did before the replacement project began, and that the licensee had appropriate programs in place to detect any additional degradation during the repair process or during future operation of the plant. The NRC review did not focus on whether the cracks could have been predicted or avoided; however, the NRC inspection report did note that the corrective actions taken by the licensee to prevent recurrence or propagation were appropriate. The same report further noted that impact of the tensioning process may be significant in causing stress concentrations and may require further research.

Question 4. On February 10, 2012, the NRC issued Combined Operating Licenses (COLs) to Southern Nuclear Operating Company (Southern) for Vogtle Units 3 & 4. Southern submitted its application for combined licenses for

two AP1000 advanced passive pressurized-water reactors on March 28, 2008.

On July 30, 2008, Duke Energy (then Progress Energy) submitted its application for a COL for two AP1000 advanced passive pressurized-water reactors designated as Levy County, Units 1 & 2.

On June 30, 2009, Florida Power and Light submitted its application for a COL for two AP1000 advanced passive pressurized-water reactors designated as Turkey Point, Units 6 & 7.

It took Southern Company almost 4 years to receive its COL. Duke Energy and Florida Power and Light have not yet received their COL. Why is it taking the NRC and the companies this long to pursue a COL?

Answer.

Under the regulation for licensing new reactors (10 CFR Part 52), the agency cannot issue a combined license until the NRC makes the final safety finding that the applicable standards and requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations for both construction and operation have been met. The Commission must also complete an environmental review to comply with the requirements of other statutes, such as the National Environmental Policy Act.

During the NRC's reviews of several pending combined license applications, the applicants and the NRC have routinely identified new information relevant to safety or environmental matters, such as updated information about potential seismic or flooding hazards. These developments

have required the applicants to evaluate the significance of the new information. As a notable example, all combined license applicants needed to evaluate the applicability of the NRC's post-Fukushima regulatory enhancements to their sites and designs. Additionally, some applicants have made substantive changes to their applications (such as selecting a new reactor technology or altering the location of the nuclear island), necessitating NRC review to determine whether the revised application meets NRC requirements. In many of these instances, it has taken applicants longer than expected to address NRC's resulting technical questions. However, the NRC has continued to openly communicate with applicants regarding the information that is needed. When the applicants submit their revised analyses, the NRC has set realistic schedules for reviewing them in a timely manner.

Several COL applications, including those for Southern's new units at the Vogtle site, reference the amended Westinghouse AP1000 design. While a number of site and technical issues had been previously resolved, the Vogtle COLs could not be issued until the final certification of the amended design was issued, which the Commission approved in December 2011. The NRC then issued the combined licenses for Vogtle in February 2012, after the mandatory hearing on the application was completed. While the Levy County, Lee, and Turkey Point applications likewise reference the amended AP1000 design, the applicants have also had to address a variety of safety and environmental matters (such as emergency plans, seismic analyses, water use, etc.) that are specific to their proposed plans and sites.

More recently, the NRC has been engaged with Westinghouse and the combined license applicants referencing the amended AP1000 design to address emergent design issues that Westinghouse has identified in the process of constructing AP1000 facilities at the Vogtle and Summer sites and in other parts of the world. Westinghouse and the combined license applicants have been evaluating these issues and have submitted information to address them.

The COL applicants are in the process of responding to NRC questions in order for the NRC to assess the safety significance of these issues and their impact on the NRC's review.

In sum, while combined license review schedules are set with a goal of 42 months, they have been affected by emergent issues and technical challenges in the applicants' ability to complete required evaluations in support of their applications. The NRC is continuing to work in a timely and transparent manner to reach final licensing decisions. In addition, valuable lessons learned from design implementation and construction in the U.S. and around the world are being addressed as part of the Lee, Levy, and Turkey Point COL applications.

Question 5 In its Dec. 2, 2013 Post Shutdown Decommissioning Activities Report (PSDAR) decommissioning schedule summary, under period 1 called "planning and preparations," Duke Energy expects to complete this phase by July 1, 2015. What is the status of this work? Has Duke Energy completed this phase?

Answer.

Duke Energy has completed the Phase 1 activities for Crystal River Unit 3 to prepare the plant for decommissioning by draining and de-energizing systems and making modifications to the plant. Phase 2 activities for decommissioning Crystal River-3 involve preparations for the transfer of the spent nuclear fuel to onsite dry storage.

Question 6. In its PSDAR, Duke Energy expects the total costs of decommissioning to reach \$1.18 billion. The costs for license termination are \$861.9 million, \$265.5 million for spent fuel management, and \$52.7 million for site

restoration. As of March 28, 2014, the Crystal River 3 Decommissioning Trust Fund was \$824.8 million in 2013 dollars. This results in an expected shortfall of nearly \$300 million. Where does the NRC expect the rest of the funds to originate from?

Answer.

In its Post-Shutdown Decommissioning Activities Report provided to the NRC in December 2013, Duke Energy indicated that it would decommission Crystal River Unit 3 over 60 years, a decommissioning timeframe allowed by NRC regulations. During this timeframe, annual radiological decommissioning expenses will be paid through withdrawals from the Crystal River Unit 3 Decommissioning Trust Fund (DTF) and interest accrual and growth of investment will contribute to the funds within the DTF. These interest and growth contributions, compounded during the 60 year decommissioning time period, reasonably ensure funding will be available for site decommissioning, spent fuel management, and site restoration. NRC regulations allow licensees to assume up to a two percent real rate of return on DTF balances in projecting their estimates, which means that interest accrual and gains from DTF investments are assumed to exceed inflation by two percentage points. Under these assumptions, and based on cash flow analysis performed by the NRC staff, the real purchasing power of the Crystal River Unit 3 DTF will be preserved and is estimated to grow over time to adequately cover radiological decommissioning activities required for license termination, in addition to spent fuel management and site restoration activities.

In general, licensees are authorized to use their DTFs for expenses associated with radiological decommissioning as defined in NRC's regulations, and are not authorized to pay for spent fuel management, site restoration, or other non-radiological decommissioning expenses using DTF

funds. Licensees may plan to pay for spent fuel management and other non-radiological decommissioning expenses with DTF funds, but such withdrawals must be authorized by the NRC through an exemption and are limited to funds in excess of the licensee's estimated site-specific radiological decommissioning cost requirements. By letter dated March 28, 2014, Duke Energy requested an exemption to use DTF funds for irradiated fuel management and site restoration for Crystal River-3 decommissioning. The NRC granted Duke's request by letter dated January 26, 2015.

Question 7. The NRC focuses on the safety and the security of people and the environment, leaving most cost considerations to the states. Over the past few years, however, mistakes at different nuclear power plants have led to the retirement of Crystal River 3 and the San Onofre Nuclear Generating Station, costing consumers billions upon billions of dollars in project costs, cost recovery of stranded assets, decommissioning costs and the costs of replacing lost power. Plant retirements also threaten grid reliability and a community's well-being.

In his oral testimony, Commissioner Ostendorff stated that the "NRC does not, from a regulatory standpoint, go in and micromanage exactly how the licensee conducts its maintenance."

While no one is advocating that the NRC approve the use of every nut and bolt used in every project, is there a point where the NRC considers the financial ramifications to consumers or the impacts on

grid reliability of a major project such as a steam generator tube replacement gone awry?

Answer.

No. By statute, the NRC's primary focus is the protection of public health and safety. As such, financial impacts to consumers, electric grid reliability, or other impacts on commerce are not considerations in the NRC's oversight of licensees.

The Honorable Peter Welch

Question 1. In its Notice of Proposed Rulemaking on Medical Uses of Byproduct Material, the NRC has specifically requested comments on whether its regulations "discourage licensees from using certain therapy options or otherwise adversely impact clinical practice, and if so, how." We have heard from stakeholders who are very concerned about the impact of current NRC regulations on patient and provider access to certain therapeutic radiopharmaceutical anti-cancer treatments that are approved by the Federal Drug Administration (FDA) and are also regulated by the NRC as beta emitters. These stakeholders are concerned that the current NRC regulations require that oncologists and hematologists who regularly see patients with non-Hodgkin's lymphoma must undergo 700 hours of training and experience requirements to be able to possess and then administer these anti-cancer beta emitting treatments as an "Authorized User."

My understanding is that prior to 2006, NRC regulations required 80 hours of training and experience to administer these treatments as an Authorized User but then that was changed to 700 hours for these and other radiopharmaceutical treatments. Would you please explain the reason for the change to 700 hours?

Answer.

In 2002, the NRC revised its training and experience regulations that apply to physicians using radioactive drugs that require a written directive for parenteral administration (currently Yttrium-

90 (Zevalin), Iodine-131, Phosphorus-32, and Radium-223 radioactive therapy drugs). These regulations were subsequently revised in 2006. The new regulations for these physicians appeared in 10 CFR 35.390 and 10 CFR 35.396. The NRC increased the classroom and laboratory experience hours for these physicians from 80 to 200 hours and specified a total of 700 hours of training and experience because these physicians would be responsible for the occupational and patient radiation safety of a wider range of therapeutic radionuclides (i.e., more than just Iodine-131). These radionuclides have different radiological properties that require special dosage measurement procedures, different survey equipment to detect contamination, and if administered in the wrong dosages, could cause greater harm to patients. Additionally, the NRC established its training and experience criteria to allow physicians to be recognized, not only as authorized users for a specific medical use, but also as the radiation safety officer if requested.

Question 2. Also, it is my understanding that NRC regulations at that time in 2006 maintained 80 hours of training for one low risk product, the oral administration of Iodine-131. These same stakeholders wishing to provide this beta-emitter anti-cancer treatment with a high safety profile don't understand why 80 hours are not appropriate for its administration. Is there a reason new therapeutic radiopharmaceuticals with similar risk profiles to I-131 do not have equivalent training and experience requirements?

Answer.

The radiation safety risks to occupational workers, members of the public, and patients from the oral administration of sodium iodide I-131 are different from those of parenteral radioactive drugs containing Yttrium-90 (Zevalin), Radium-223, and Phosphorus-32. The parenteral

radioactive drugs have different properties that result in a more complicated medical application when compared with sodium iodide I-131. With the exception of the oral administration of sodium iodide I-131, NRC regulations do not specify specific isotopes or routes of administration for their medical use. A physician administering a parenteral radioactive therapy drug needs training and experience applicable to isotopes with different radiological characteristics and risk profiles.

Question 3. Targeted radioimmunotherapy is an active area of research and development with the potential for new life saving therapies in this decade. It is expected in the future that there will be more innovative therapeutic radiopharmaceutical agents. We have heard from stakeholders who are concerned that the current regulatory framework may be too burdensome for physicians to administer these treatments. They are additionally concerned that if the regulatory framework is not adjusted to account for the appropriate training and experience requirements for these therapies, it may impact future innovation of new targeted cancer treatments. As part of this rulemaking, will NRC be reviewing the impact of its seeming “one size fits all” approach to “authorized user” status to ensure that modifications to the regulations to address the levels of training and experience requirements are appropriate to the particular safety risk of the products?

Answer.

The NRC’s medical use regulations are performance based, which means that the criteria for the safe use of certain radioactive products for medical use are stated as objectives and a licensee has a number of ways to meet those objectives. This means that a product, while new

to the medical community, may not need special consideration to be licensed under the regulatory requirements already in place for the medical use of byproduct material (10 CFR Part 35). This also means that physicians who are fully authorized for a specific medical use can use the new products that fit under that medical use. There is also a provision under Part 35 that allows NRC to license the medical use of new products having unique properties that are not addressed in other sections of the regulations. While radio-immunotherapy may be an active area of research, the new products that are being developed may already meet the licensing criteria in Part 35, and thus may be used under the current authorizations (with associated training and experience requirements) for medical use licensees. If there are unique properties, the NRC's regulations under 10 CFR 35.1000 are sufficiently flexible for the NRC to develop licensing criteria to authorize their use without the need for additional rulemaking.