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ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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October 5, 2015

The Honorable Stephen G. Burns  
Chairman  
U.S. Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, MD 20852

Dear Mr. Burns:

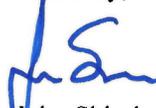
Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, September 9, 2015, to testify at the hearing entitled "Oversight of the Nuclear Regulatory Commission."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, October 19, 2015. Your responses should be mailed to Will Batson, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed to [Will.Batson@mail.house.gov](mailto:Will.Batson@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



John Shimkus  
Chairman

Subcommittee on Environment and the Economy

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

Attachment

## Additional Questions for the Record

### The Honorable John Shimkus

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 increase 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 Regulation? 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?
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 analysis 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 development which consider the usage of qualitative factors?
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 recommendations, such as appropriate staffing levels, will be. When do you expect to the Commission will take action on Project AIM and how is the Commission assuring this schedule is strictly adhered to?

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 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?
5. On August 13, the Commission received a briefing from NRC staff and stakeholders about options to dispose of 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 repository....unless 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?
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?
7. Fundamental to the NRC's credibility as a reliable regulator is the ability for accurate cost benefit analysis as a 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?
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?
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 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?
10. A number of process issues arise when there is a lack of continuity within an organization. Licensees have described the extensive problems in which NRC staff turnover, multiple times on some occasions, results in substantial delays and increased costs. Has the Commission examined how you can minimize this impact on the licensing amendment request process?
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?
12. Would you consider adopting an internal policy that once a Licensing Amendment Request is assigned to reviewers, they would own the product for the entire process?
13. Last year, the number of licensing actions the Office of Nuclear Reactor Regulation completed in under a year was just 83 percent, though efforts have increased the performance to 87 percent. However, there is still 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 certainty that the Commission will fulfill its responsibility as a reliable regulator and be responsive in a timely manner on licensing actions?
14. The NRC Inspector General (IG) 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?
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?
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 benefit as a part of the Project AIM baselining?
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 FY 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?
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?
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 backfit 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?
20. NRC Inspector General (IG) report "Audit of NRC's Oversight of Spent Fuel Pools (OIG-15-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?
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?
22. The NRC's "backfit rule" (10 CFR 50.109) provides that, before a new requirement can be added to an existing licensed 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, 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?
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 analysis 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 quantifiable analysis that is available?
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?
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?
26. Chairman Burns' testimony notes that 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 outset of 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?
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?
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?
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 actions 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 organizational efficiencies, namely Project AIM?
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?
31. What is the NRC's role in licensees' choice of decommissioning strategies?
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.

**The Honorable Tim Murphy**

- 1. In light of NRC's Project Aim, what changes is 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?
- 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?

3. NRC staff has 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?
4. NRC regulations permit 20-year extensions to the original 40-year operating license. So far, 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 upon the technical and regulatory success of the first license renewals. The FY2016 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 NRC be ready to process the applications expected to be submitted in 2018-19 timeframe?

#### **The Honorable Billy Long**

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?

#### **The Honorable Kathy Castor**

Crystal River 3 shut down for a planned refueling outage on September 26, 2009. One of the major work activities planned for this outage was a steam generator replacement. In order to take the old steam generators out and put the new steam generators in, Progress Energy (now Duke Energy) created a construction opening in the side of the containment building. Workers discovered a crack in the containment wall while cutting a hole through the concrete and created a second crack while attempting to repair it. As a result, Duke Energy decided to retire Crystal River 3 and is seeking to recover costs of the stranded power plant to the tune of up to \$1.3 billion from retail customers over the next 20 years.

The containment building, which is the final barrier keeping deadly radiation from the reactor from reaching the atmosphere, is made of concrete and is 42 inches thick. Inside the containment wall are metal “tendons” that tighten around the structure, reinforcing its strength. Before cutting into the concrete to remove the steam generators, engineers loosen the tendons in the area they plan to cut.

A 2011 *Tampa Bay Times* article states that of all the previous 34 steam generator replacement projects at U.S. nuclear power plants, all of which were successful, at least 13 had involved cutting into the containment building. Only two companies, Bechtel and SGT, had managed these projects.

In an attempt to save \$15 million, however, Progress Energy decided to self-manage the project.

Essentially, Progress Energy loosened fewer tendons than is customary and loosened them in sequential order instead of nonsequentially. Further, at other plants, workers de-tension all the proposed tendons and then cut the wall open. At Crystal River 3, only 27 of the 65 tendons were loosened before the cut was made. “De-tensioning the tendons is a very expensive and time-consuming effort,” said a Progress Energy contractor.

Of the nation’s 100 operating nuclear reactors-31 reactors are greater than 40 years old, 35 reactors are between 30-39 years and 33 reactors are between 20-29 years old. The operating license for 33 reactors is expiring in the next 15 years.

Ill-conceived steam generator replacements led to the retirements of Crystal River 3 and the San Onofre Nuclear Generating Stations and more steam generator replacements may be needed as our nuclear reactor fleet continues to age.

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.
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.
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?”
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?

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?
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 at \$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?
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?

### **The Honorable Peter Welch**

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 emitter treatments as an "Authorized User".

My understanding is that prior to 2006, NRC regulations required 80 hours of training & 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?

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 & experience requirements?
  
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?