

**Additional Questions for the Record**

**Subcommittee on Energy and  
Subcommittee on Environment and Climate Change**

**Hearing on  
“Keeping Us Safe and Secure: Oversight of the Nuclear Regulatory Commission”  
July 14, 2021**

The Honorable Christopher T. Hanson, Chairman, Nuclear Regulatory Commission

**The Honorable Frank Pallone Jr. (D-NJ)**

1. NRC staff has recommended that the Commission initiate a rulemaking to investigate the appropriate training and experience for the administration of radiopharmaceuticals. The staff memo was submitted to the commission in January of 2020. Are you going to act on the staff recommendation, and if so when?

**RESPONSE:**

The Commission is considering the staff's training and experience rulemaking plan SECY-20-0005 (ADAMS Accession No. ML19217A318). The staff's rulemaking plan raises important issues that the Commission will consider as part of its deliberations. As the Commission considers the staff's rulemaking plan, the NRC's current regulations continue to ensure appropriate training and experience for the safe and secure use of radiopharmaceuticals.

**The Honorable Bobby L. Rush (D-IL)**

1. As you know, radiopharmaceuticals are nuclear materials used to produce images of organs or tissues of interest. A radiopharmaceutical extravasation is an inadvertent injection of radiopharmaceutical agents into a patient's arm tissue instead of into the appropriate blood vessel. This can cause the injection to infiltrate underlying tissue and produce high-dose radiation in a patients' tissue.

The NRC has oversight of these materials although it does not classify radiopharmaceutical extravasations as medical events and, therefore, they are not required to be reported to the agency. In March 2020, the Nuclear Regulatory Commission (NRC) developed a report in response to a report language request within the Energy and Water Development and Related Agencies Appropriations Bill, 2020. This report requested that the NRC provide an update on monitoring, classification, and reporting requirements for extravasations, specifically radiopharmaceutical extravasations.

- a. What progress has the NRC made on monitoring, classification, and reporting requirements for radiopharmaceutical extravasations?

**RESPONSE:**

The NRC staff is currently evaluating whether extravasations should be reported as medical events, and, if so, what is the appropriate reporting threshold for these events. The staff is considering whether: (1) extravasation merits regulation considering the objectives of the NRC's medical use policy statement; (2) the dose consequence of extravasation is significant enough to merit reporting, and (3) extravasation can be prevented. In addition, the NRC staff is reviewing a petition for rulemaking, docketed in June 2020, requesting that extravasations resulting in a localized dose equivalent of greater than 50 rem be reported as medical events. The NRC staff also held two government-to-government meetings with the Agreement States in May and July 2020, and one public meeting in December 2020 to obtain feedback on radiopharmaceutical extravasations.

Recently, in April 2021, the NRC staff provided to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee on Extravasations the staff's preliminary evaluation of

reporting extravasations as medical events. The subcommittee provided its draft report to the NRC staff in August 2021. In their report, the subcommittee supports medical event reporting for extravasations that result in radiation injury. On September 2, 2021, the NRC will hold a public meeting at which the full ACMUI will discuss and vote on the subcommittee's recommendation. The NRC staff also plans to hold additional meetings with other stakeholders in the fall of 2021.

The staff plans to provide a recommendation to the Commission, by early summer 2022, on whether extravasations should be reported as medical events, including a recommendation for the disposition of the related petition for rulemaking.

**The Honorable Janice D. Schakowsky (D-IL)**

1. Following up on my question at the hearing, some owners and operators of nuclear power plants that have or will soon be shut down are transferring licenses to companies that specialize in decommissioning of nuclear power plants. Usually, the only asset that these specialized companies hold are the nuclear decommissioning trust funds. You explained that the NRC looks closely at the parent companies and the financial backing for these companies, but by transferring the license to a less financially diversified company (often from a diversified or regulated utility to a private company created solely for the purpose of decommissioning the plant) the NRC loses any ability it may have had to hold a more financially stable parent company accountable for decommissioning costs. How will the NRC ensure that these specialized companies are financially viable?

**RESPONSE:**

According to our regulations (i.e., 10 CFR 50.33, 50.34, 50.75, 50.80, and 50.82), the NRC will approve the transfer of licenses for nuclear power plants entering or in decommissioning if it

determines that, among other things, the applicant has demonstrated that it possesses the funds, or has reasonable assurance of obtaining the funds, necessary to cover the estimated costs of radiologically decommissioning the plant and of managing spent nuclear fuel until it is transferred to the Department of Energy (DOE). As part of this determination, the NRC staff evaluates the funds that would be held by the applicant (the majority of which are typically in a decommissioning trust fund (DTF)), the applicant's plan for decommissioning the facilities (i.e., its site-specific decommissioning cost estimate) and its plan for managing spent nuclear fuel, and whether, when taking into consideration the timing of withdrawals from these funds along with the growth of these funds, there is reasonable assurance that the funds will be sufficient to cover total radiological decommissioning and spent fuel management costs. The staff will also consider as additional financial assurance other sources of funds such as parent company guarantees.

In support of an overall finding of financial qualifications, the NRC staff evaluates an applicant's site-specific decommissioning cost estimate against the criteria in NUREG-1713, "Standard Review Plan for Decommissioning Cost Estimates for Nuclear Power Reactors," dated December 2004. These include:

- Description of the decommissioning cost estimating methodology,
- Description of the overall decommissioning project,
- Summary cost estimate by major decommissioning activity and phase,
- Schedule of the major decommissioning activities,
- Summary of the decommissioning management with support staff levels, and
- Estimate of radioactive waste volume.

The NRC staff then applies guidance in NUREG-1577, Revision 1, "Standard Review Plan on Power Reactor Licensee Financial Qualifications and Decommissioning Funding Assurance," dated December 2001 (ADAMS Accession No. ML013330264), to evaluate the financial qualifications of the applicant to carry out radiological decommissioning and spent fuel management activities. As part of this evaluation, the staff performs an independent cash flow analysis, evaluating projected decommissioning costs and DTF assets over the period of time required for decommissioning, through the anticipated license termination date, further evaluating whether the applicant has reasonable assurance that funds will be available for the entire decommissioning process.

Throughout the decommissioning process, the licensee must also adhere to the requirements of 10 CFR 50.82(a)(8)(i), which states, in part, that licensees may use DTFs if the withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

After the approval of any license transfer, the NRC staff continually reassesses its previous finding of financial qualifications until the license is ultimately terminated. For example, per 10 CFR 50.82(a)(8)(v)–(vii), the NRC requires power reactor licensees that have permanently ceased operations to provide an annual decommissioning financial assurance status report. This report provides a status of decommissioning spending and future funding requirements. If at any time the staff determines that, based on its review of these reports and other inspection activities, the licensee's funds are not sufficient to fully cover both radiological decommissioning and spent fuel management costs, then the licensee must demonstrate that these costs are covered by additional sources of funds, or take other action, such as modifying the decommissioning schedule to allow for sufficient growth of the existing DTF.

It is through satisfaction of these requirements that the NRC has assurance, both before the transfer of a license for a plant in decommissioning and during decommissioning itself, that there will be sufficient funds to complete radiological decommissioning and spent fuel management at the site.

- a. What will the NRC do if one of these companies – which holds no assets other than the shut-down plant and the decommissioning trust fund – files for bankruptcy?

**RESPONSE:**

At all times, the licensee has full responsibility to demonstrate adequate funding for all NRC-required decommissioning activities. The NRC actively oversees the licensee's decommissioning, including decommissioning funding. For example, the NRC staff reviews the licensee's annual decommissioning funding status reports. These reports include information on: the amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon; an estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based; any modifications occurring to a licensee's current method of providing financial assurance since the last report; and any material changes to trust agreements or financial assurance contracts. If the report does not show sufficient funds to cover the estimated cost to complete the decommissioning, then the report must include additional financial assurance to cover the estimated cost of completion.

In the event a licensee files for bankruptcy, the NRC's regulations require that the licensee immediately notify the NRC. A bankruptcy filing does not relieve the licensee of its obligation to complete decommissioning. The NRC participates in bankruptcy proceedings to ensure that licensees continue to comply with NRC requirements, including the requirement to maintain their DTFs. The NRC would continue to actively oversee decommissioning activities for licensees that have filed for bankruptcy throughout the bankruptcy proceeding and throughout decommissioning until the license is terminated. Any violations of NRC requirements, including decommissioning funding assurance requirements, would be subject to the NRC's enforcement authority.

Taken together, the NRC's regulatory framework, which includes annual decommissioning funding status reports from the licensee, and the NRC's enforcement authority allow the NRC to detect DTF shortfalls early and ensure that the licensee corrects these shortfalls.

- b. Will the NRC consider transferring these licenses, but continuing to hold the prior licensee responsible as a backstop in the event this specialized company is financially unstable?

**RESPONSE:**

The NRC does not retain regulatory authority over, nor do NRC regulations apply to, prior licensees that have received approval to transfer their licenses and that have completed transfer to other entities. As part of its required review of license transfer applications, the NRC assesses the applicant's financial qualifications, including a rigorous evaluation to assess the estimated decommissioning and spent fuel management costs at the site and the financial resources of the applicant. Accordingly, when the NRC approves a license transfer, it has

concluded that the applicant meets the regulatory, legal, technical, and financial requirements necessary to qualify as the licensee.

In some cases where the NRC has approved a license transfer, state and local governments have negotiated separate agreements with the applicant that provide additional conditions and commitments. These separate agreements often provide further assurance about the applicant's financial plans and resources in meeting its decommissioning requirements. The NRC has not been a party to these agreements.

2. Some nuclear plant owners and operators are engaged in corporate reorganizations that have the effect of moving nuclear power plants with short operating lives and significant decommissioning liabilities to spinoff companies. This happened in the coal mining industry and allowed many companies to avoid liability for reclaiming coal mines by having those spinoff companies file for bankruptcy. How is the NRC addressing license transfer requests associated with corporate reorganization to ensure that companies are not engaged in the type of strategic maneuvering that is now clear took place in the coal markets?

**RESPONSE:**

NRC regulations provide specific requirements for the transfer of operating licenses. License transfer applicants must meet the requirements of an initial licensee, specifically 10 CFR 50.80, 50.33, and 50.34, as mentioned in the answer to the question above. For an operating plant, non-utility prospective licensees must show that they possess or have reasonable assurance of obtaining the funds necessary to cover estimated operation costs for the period of the license.

The applicant is required to submit annual operating costs for the first five years and indicate the source of the funds to cover those costs.

Also, the DTF must meet regulatory requirements before the license transfer can be granted.

Under 10 CFR 50.75, DTF amounts are reported to the NRC every two years while the nuclear power plant is operating to give reasonable assurance that once the plant is shut down there are funds available to carry out radiological decommissioning, as required by NRC regulations. During decommissioning, the licensee is required to report DTF amounts and spending annually.

- a. Is additional scrutiny being applied to license transfers associated with corporate reorganization?

**RESPONSE:**

The same rigorous analysis is required by NRC regulations for all license transfers, including those associated with corporate reorganizations. The NRC staff may request additional information beyond what is included in the application if needed to support the staff's decision on the transfer request.

In reviewing a license transfer request, the NRC must determine (1) whether the proposed transferees are qualified to be the holders of the licenses and (2) whether the transfers of the licenses are otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission. Specifically, the NRC must evaluate whether the potential transferees have satisfied the NRC's requirements related to financial qualifications; decommissioning funding assurance; foreign ownership, control, or domination; nuclear insurance and indemnity; and technical qualifications.

3. The NRC's medical event reporting requirements on extravasation do not require that patients be told if a mistake happens during a nuclear medicine injection. Is the NRC considering changes to these policies? If so, what is the status of that process?

**RESPONSE:**

The NRC staff is currently evaluating whether to conduct rulemaking to consider whether extravasations should be reported as medical events, and, if so, to determine the appropriate reporting threshold for these events. Relatedly, the NRC staff is evaluating a petition for rulemaking, docketed in June 2020, requesting that extravasations resulting in a localized dose equivalent of greater than 50 rem be reported as medical events. Under NRC regulations, not only are medical events required to be reported to the NRC, but notification of the event must be made to the referring physician and the patient, unless the referring physician determines, based on medical judgment, that telling the patient would be harmful. The staff plans to provide a recommendation to the Commission, by early summer 2022, on whether extravasations should be reported as medical events.

4. In May of 2020, the Nuclear Regulatory Commission received a petition for rulemaking to include extravasations in medical event reporting requirements. During the September 2020 meeting of the Advisory Committee on the Medical Use of Isotopes, NRC staff stated that a decision on whether to accept the petition would be made by June of 2021. The NRC delayed the Advisory Committee's meeting from July 15th until September 2nd, 2021 to consider the NRC staff's evaluation of the extravasation issue. Subsequently, NRC staff stated that they plan to deliver a recommendation on the petition to the Commission in 2022. Millions of nuclear medicine injections are performed every year, underscoring the patient safety implications of this petition. What

is the cause of the delays in evaluating the extravasation petition? Will the NRC commit to considering the petition by March 1st, 2022?

**RESPONSE:**

The staff plans to provide its recommendation to the Commission by early summer 2022. The proposed schedule provides staff sufficient time to consider input from various stakeholders, including the Agreement States.

Since docketing the petition in June 2020, the NRC staff has been actively engaging the public and stakeholders on the matter. The staff has issued a *Federal Register* notice requesting public comments on the petition and held a public meeting in December 2020 to obtain insights from stakeholders, including members of the public and the medical community, on radiopharmaceutical extravasations. The NRC staff plans to hold additional meetings with stakeholders in the fall of 2021. These public perspectives will help inform the staff's recommendation on whether extravasations should be reported as medical events.

**The Honorable G.K. Butterfield (D-NC)**

1. NRC's outside advisory committee (ACMUI) recommended maintaining the status quo on medical event reporting requirements and reclassifying extravasations as the fault of the patient rather than the responsibility of the licensee. ACMUI's patient advocate dissented strongly from this recommendation. How is the NRC balancing these competing views and integrating the perspective of the patient, rather than relying on licensees to determine how they are to be regulated?

**RESPONSE:**

The NRC staff has been actively engaging the public and stakeholders as it evaluates whether extravasations should be reported as medical events. Specifically, since May 2020, the staff issued a *Federal Register* notice requesting public comments on a related petition for rulemaking on extravasations, engaged the ACMUI, held two government-to-government meetings with the Agreement States, and held one public meeting to obtain feedback on radiopharmaceutical extravasations.

Recently, in April 2021, the NRC staff provided to the ACMUI Subcommittee on Extravasations the staff's preliminary evaluation of reporting extravasations as medical events (ADAMS Accession No. ML21102A055). The subcommittee provided its draft report to the NRC staff in August 2021 (ADAMS Accession No. ML21210A351). In their report, the subcommittee supports medical event reporting for extravasations that result in radiation injury. On September 2, 2021, the NRC will hold a public meeting with the full ACMUI, including the ACMUI Patients' Rights Advocate, where the full ACMUI will discuss and vote on the subcommittee's recommendation. The NRC staff also plans to hold additional meetings with stakeholders in the fall of 2021.

2. NRC's regulatory partner the Organization of Agreement States (OAS), of which North Carolina is a member, says the medical event reporting exemption for extravasations is "no longer appropriate" and NRC should "make a policy decision to drastically improve the health, safety, and clinical outcomes for hundreds of thousands of patients a year." Is NRC giving proper weight to the view of its regulatory partner OAS and the 39 states it represents?

**RESPONSE:**

Yes, the NRC staff has been actively engaging with the Agreement States, as well as the public and other key stakeholders, on whether extravasations should be reported as medical events. On September 15, 2020, the staff published a *Federal Register* notice requesting public comments on a related petition for rulemaking, including notification to Agreement States about the request for comment on the petition. The Organization of Agreement States also has representation on the staff working group that is evaluating this petition for rulemaking. In addition, the ACMUI, which is also evaluating this issue, includes an Agreement State Representative position. As part of maintaining a coordinated and compatible national program for the regulation of radioactive materials, the NRC values the insights and concerns raised by each Agreement State.

**The Honorable Scott Peters (D-CA)**

1. What recommendations does the NRC have for Congress for long-term storage of spent nuclear fuel?

**RESPONSE:**

As an independent safety regulator, the NRC's role in the long-term storage of spent nuclear fuel is to provide reasonable assurance of public health and safety and protection of the environment, regardless of the technology or approach chosen. The NRC staff has determined that the current legislative authorities provide a sufficient safety and legal construct for the agency to perform its role with respect to the long-term storage of spent nuclear fuel. Accordingly, at this time, the NRC staff has not identified the need for additional legislation to implement its role with respect to the long-term storage of spent nuclear fuel.

2. Chairman Hanson, at the hearing, you repeatedly asserted that NRC has deemed the current storage of spent nuclear fuel at San Onofre in San Diego is safe.
  - a. In reaching this conclusion, what assumptions have you made about the likelihood and extent of sea level rise?

**RESPONSE:**

The NRC requires licensees and dry cask storage system certificate holders to assess natural phenomena, including flooding events, as part of the safety basis for a storage facility or container design.

As part of its initial licensing review and ongoing regulation of spent-fuel storage systems, the NRC staff ensures that the system provides reasonable assurance of adequate protection of the public health and safety.

Further, as part of the agency's lessons learned from the Fukushima Dai-ichi accident, the staff performed additional evaluations of seismic and flooding hazards. The NRC staff considered scenarios, such as full submersion of the storage system in water, partial flooding around the storage system, and blockage of the cooling vents for the storage system overpacks.

With respect to the spent-fuel storage system at San Onofre, the licensee reevaluated the seismic and flooding hazards at the site in response to the Fukushima Dai-ichi accident. As part of this evaluation, the licensee determined that the maximum flood height is 27 feet (8.2 meters), including wave action. The maximum flood height is below the 31-foot (9.4 meter) elevation of the only openings in the Independent Spent Fuel Storage Installation (ISFSI) at San Onofre where water infiltration would be possible.

Because potential sea level rises are gradual phenomena that are monitored by the licensee and state and local governments for a variety of public purposes, the NRC is confident that any action that may be necessary to address sea level rise at the San Onofre ISFSI will be taken in a timely manner to ensure the safety of the public. Pursuant to its regulations, the NRC maintains authority to modify, suspend, or revoke a license where necessary to ensure adequate protection of public health and safety.

- b. In reaching this conclusion, what assumptions have you made about the likelihood and effect of a major earthquake?

**RESPONSE:**

The NRC requires licensees and dry cask storage system certificate holders to assess natural phenomena, such as earthquakes, as part of the safety basis for a storage facility or container design. The NRC reviews and independently confirms these assessments as part of NRC's licensing work for the storage system and site. This analysis includes evaluation of the seismic conditions at the site to ensure that the design of the facility exceeds the site's anticipated seismic hazards (in terms of peak ground acceleration, soil-structure interaction, and soil liquefaction potential) with appropriate safety margins. With respect to the San Onofre site, the NRC has performed thorough inspections of the design and construction of the Independent Spent Fuel Storage Installation (ISFSI) to ensure that the facility provides reasonable assurance of adequate protection of public health and safety. The staff will continue to perform its oversight of the facility as long as there is fuel on the site.

- c. In reaching this conclusion, what assumptions have you made about the likelihood and effect of a terrorist attack, whether physical or cyber?

**RESPONSE:**

The NRC requires licensees to have an on-site physical security program to protect against unauthorized access to the spent nuclear fuel and its storage area. The security requirements at NRC-licensed facilities are based on the potential threat level as well as the potential consequences of an event; the NRC works with other government agencies, including the Federal Bureau of Investigation and the Department of Homeland Security, to assess the threat environment and determine if any changes are needed. The NRC reviews and approves licensees' physical security plans and routinely inspects implementation of the physical security program at licensee sites. With respect to the San Onofre site, security requirements are addressed in the licensee's NRC-approved physical security plan. The NRC provides oversight through routine, periodic inspections at the site.

The NRC has evaluated and implemented, where appropriate, risk-informed cyber security measures for classes of licensees commensurate with the safety significance of their nuclear applications. For independent spent fuel storage installations (ISFSIs), the NRC concluded that licensees are adequately protected from a cyber-attack and specific cyber security regulatory requirements are not warranted at this time. The agency routinely interfaces with government partners, and domestic and international stakeholders to share operating experience and best practices on cyber security. The NRC continually evaluates information on evolving cyber threats and from recent cyber-attacks, such as the 2021 Colonial Pipeline attack, to determine the need for any cyber security posture improvements for all classes of NRC licensees.

3. The spent nuclear fuel canisters at SONGS were intended to be short-term. What is the best approach for safe storage of the spent nuclear fuel at SONGS once the canisters reach their shelf life if there aren't long-term storage options available?

**RESPONSE:**

The NRC has established regulatory requirements for the safe storage of spent nuclear fuel that, through routine inspection and oversight, ensure continued safe storage. All storage systems approved by the NRC have been reviewed to ensure they meet all the regulatory safety requirements and are approved for a term of up to 40 years. In addition, the NRC has a license renewal framework that allows for an additional term of up to 40 years. To obtain a renewal, the NRC requires dry storage system licensees to have in place Aging Management Programs to ensure continued safe storage for the duration of the license term. These requirements, together with the agency's oversight and inspection program provide reasonable assurance that the dry cask storage systems will continue to perform their safety functions during the licensed period of operation.

4. What else could Congress be doing to advance the safe and more rapid deployment of advanced and small modular reactors?

**RESPONSE:**

As an independent regulator, the NRC's role regarding the safe deployment of advanced and small modular reactors is focused on establishing and implementing an efficient and effective regulatory framework for licensing and oversight. In accordance with Section 103(e) of the Nuclear Innovation and Modernization Act (NEIMA), the NRC submitted a report to Congress on July 15, 2021, on the NRC's efforts "to complete a rulemaking to establish a technology-inclusive regulatory framework for optional use by commercial advanced nuclear reactor

technologies in new reactor license applications and to enhance Commission expertise relating to advanced nuclear reactor technologies” (ADAMS Accession No.

ML21109A263). In addressing NEIMA Section 103(e)(4)(B), the NRC explained that the NRC staff has evaluated the Atomic Energy Act of 1954, as amended (AEA) and determined that the AEA provides an appropriate safety and legal construct to support the use of risk-informed and performance-based evaluation techniques. In light of that, the NRC staff has not identified additional legislation needed to implement a new regulatory framework at this time.

5. Can you explain the safety benefits of advanced and small modular reactors compared to existing reactors? Would such technology be able to employ spent nuclear fuel like that stored at San Onofre for the production of energy?

**RESPONSE:**

On October 14, 2008, the Commission issued its Policy Statement on the Regulation of Advanced Reactors in the *Federal Register*, which included items to be considered in advanced nuclear power reactor designs. This document reinforced and updated the policy statements on advanced reactors previously published in 1986. As stated in these policy statements, the Commission expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions. The policy statement identifies attributes that could affect the review of a proposed advanced reactor design, including reliable and less complex shutdown heat removal systems; longer time constants before reaching safety system challenges; simplified safety systems that, where possible, reduce required operator actions; reduced potential for severe accidents; and considerations for safety and security requirements together in the design process. The NRC will perform an independent review to ensure the safety and security of advanced reactor designs prior to licensing any design or facility.

With regard to the ability of advanced reactors to utilize spent nuclear fuel, the NRC staff is aware of a limited number of designs that include this option. If the NRC receives a licensing application for a facility designed to utilize spent nuclear fuel, the NRC staff will review any novel design features, special operating characteristics, or other unique issues, as appropriate, in accordance with the Atomic Energy Act of 1954, as amended, and the NRC's rules and regulations to ensure the effective and efficient licensing of such a process.

**The Honorable Cathy McMorris Rodgers (R-WA)**

1. Describe how NRC is using its decades of data and industry operational experience to improve the oversight of nuclear reactors and what is necessary for the Commission to move this process along.

**RESPONSE:**

The NRC has made significant progress in its transformation efforts associated with data-driven decision-making in the past 5 years, especially in the development of tools to inform the reactor oversight process (ROP). The Office of Nuclear Reactor Regulation has deployed an operating experience hub that provides a single site for ROP-related data analysis dashboards to allow internal NRC users to easily explore relevant information important to the oversight and inspection of operating reactors. This hub provides trending and search tools for plant operating experience, industry scram trends, issues of concern, ROP inspection sample completion, and tracking of Congressional ROP metrics. These tools allow NRC staff to efficiently research historical issues and trends in order to inform current inspection and oversight activities. The NRC staff is exploring the use of enhanced analytical tools to leverage historical data to provide insights to support the ROP, reactor licensing, and other regulated activities. The NRC staff is also assessing whether these analytical tools can be used to enhance search capabilities,

automate event evaluation, and incorporate risk insights into reported events. The NRC has recently deployed a public facing ROP analytics dashboard that provides an interactive way to explore data generated by the ROP. This dashboard provides key reactor plant performance information allowing the public direct access to review and filter NRC data (e.g., by licensee, region, plant type, or individual site). The NRC staff has also deployed an accident sequence precursor dashboard that summarizes significant historical operating experience from a risk perspective and is currently working on processes to further incorporate this information into the ROP.

Currently, the NRC staff has the operating experience data it needs to make the reasonable assurance findings for the operating reactor fleet. As a learning organization, the NRC staff continues to monitor the ongoing activities of the nuclear industry to collect and analyze component performance and operating data to support its efforts to more efficiently and effectively operate and maintain its current fleet of reactors. Where the industry's efforts have a nexus to NRC's safety mission, the NRC staff will evaluate how best to leverage the industry's efforts to improve the effectiveness and efficiency of its oversight and licensing responsibilities.

- a. What are the benefits of this process to upgrade how NRC does perform its oversight?

**RESPONSE:**

The most significant benefit is more efficient and effective regulation of the operating reactor fleet by providing clear and easily accessible data to inform decision-making at all levels. The dashboards described in the preceding response assist managers and inspectors in efficient planning for inspections and other oversight activities by allowing NRC staff to access information from multiple systems in a single interface. The dashboards allow for quick search

of operating experience and generic communications, trending of scrams and safety significant system failures, status-at-a-glance information for system-specific inspections, and other important ROP metrics. COVID-related dashboards, which show data from appropriate health authorities, allow managers to monitor local infection rates in the communities surrounding operating plants to assess the appropriate inspection posture to maintain safety for both plant workers and NRC staff. Overall, these dashboards allow for the rapid visualization of a significant amount of data from multiple data sources to not only assist in planning, assessment, and response to plant oversight activities, but also to assess the ROP itself in meeting its goals of being objective, risk-informed, understandable, and predictable.

- b. How will this experience apply to the regulations and oversight for innovative new reactors?

**RESPONSE:**

The NRC staff incorporates industry operational experience into its day-to-day regulation and oversight activities of all reactors, including activities associated with innovative new reactor designs. The NRC staff performs a systematic, coordinated, and efficient review of domestic and international operating experience gained from the nuclear power industry, research and test reactors, new reactor construction, and applicable significant non-nuclear operating experience. The approach allows for the collection and assessment of operating experience information, and timely communication to stakeholders, including NRC experts in specific disciplines. Each day, the NRC staff assesses new operating experience to identify information that could impact not only the existing operating fleet, but also new power reactors, like Vogtle Units 3 and 4, so that appropriate action is taken. The NRC recognizes that most of its existing information relates to light-water reactor technology. A portion of this information, such as operating experience related to material aging, failure modes for commonly used equipment,

digital instrumentation and controls, emergency preparedness, and human performance provides insights that the NRC uses to improve its regulation and oversight of all reactors regardless of the design. The NRC is working with its international counterparts to promote the timely sharing of operating experience and lessons learned during reviews of first-of-a-kind reactor designs. The NRC supplements these new reactor design reviews with additional analysis and testing, as well as review of operational data during initial testing programs and first operational cycles.

For advanced non-light water reactors, the staff is in the process of developing an Advanced Reactor Inspection and Oversight Framework document that will leverage lessons learned from the current reactor oversight program, which was developed for the operating fleet of large light-water reactors. The Advanced Reactor framework document will be used to develop construction and oversight inspection procedures for these reactors. The framework document considers the likelihood that Advanced Reactors will incorporate advanced safety features, are safe-by-design, or both. This allows the NRC to focus its oversight on the creation and deployment phase of the reactor's lifecycle, ensuring that advanced safety and safe-by-design features are realized at commissioning. This, in turn, allows oversight of the operational phase of the reactor's lifecycle to be risk-informed, technology inclusive, and performance based while still providing reasonable assurance of adequate protection of the public health and safety.

- c. Will the Commission be acting on the policy matters before it on the enhancements for the reactor oversight process?

**RESPONSE:**

On August 5, 2021, the Commission approved the withdrawal of SECY-18-0113, "Recommendations for Modifying the Reactor Oversight Process Engineering Inspection" and

SECY-19-0067, "Recommendations for Enhancing the Reactor Oversight Process." The NRC staff requested to withdraw the two ROP papers because new information and relevant additional staff activities were not considered in developing the basis for several of the recommendations in the papers. The NRC staff plans to consider the new information and activities as it reevaluates the basis for the previous recommendations. As part of this work, staff will reengage internal and external stakeholders, including regional inspection staff, members of the public, and the nuclear industry, on these and any other proposed changes to the ROP, as appropriate. The staff will engage the Commission, as appropriate, with any new recommendations depending on the outcome of the updated staff evaluation.

2. At least one of the Advanced Reactor Demonstration Project (ARDP) demonstration reactors have said they will seek a license under the two-step process outlined in 10 CFR Part 50. As you know, Congress has directed the Department of Energy and the developers to complete their reactors within a 5–7-year timeframe.

a. Can the NRC license these reactors under Part 50 while meeting the timeline established by Congress?

**RESPONSE:**

As an independent regulator, the NRC's role is focused on performing efficient and effective licensing reviews to ensure adequate protection of the public health and safety. Both ARDP awardees are currently engaged in pre-application activities with the NRC to identify issues that could challenge timely submission of applications and completion of the licensing process. Pre-application engagement includes an appropriate mix of technical reports for NRC staff information, white papers for NRC staff feedback, and topical reports for regulatory assessment. This engagement also helps to establish a common understanding of the safety

case for the design, identify first-of-a-kind issues that need to be resolved, and identify gaps in information and data necessary to establish the safety of the design early in the process. These pre-application activities support more efficient and effective licensing reviews.

- b. How long do you anticipate the NRC will need to complete the two-step Part 50 process for the ARDP demonstration projects?

**RESPONSE:**

As directed by the Nuclear Energy Innovation and Modernization Act (NEIMA), the NRC staff established generic milestone schedules for issuing the final safety evaluation for various types of applications, including applications for non-light water reactors, such as the ARDP awardees. The generic schedules for issuing the final safety evaluation for both construction permit applications and applications for operating licenses issued under 10 CFR Part 50 are 36 months each after completion of the acceptance review for the application. When the generic milestone schedules were established, the NRC staff noted that it will work with each licensee or applicant to establish a specific schedule for each request. The schedule may be shorter or longer than the generic milestone schedule based on the specific needs of the licensee or applicant, the NRC staff's resources, and specific circumstances, such as novel design features and the overall complexity of the design. In addition, the NRC staff notes that construction cannot start until a construction permit has been issued and that an operating license cannot be issued until the safety and environmental reviews of the operating license application are complete and the applicant has substantially completed construction.

3. In August 2020, the NRC announced it had completed its 42-month safety review of the NuScale design on schedule. This is a remarkable achievement for the NRC, NuScale,

and the nuclear industry. NRC is now required to issue a final rulemaking to officially certify the design. Unfortunately, the NRC's posted schedule for the certification rulemaking was recently extended to 18 months from design approval – out to March 2022. Further, my staff has learned NRC may extend this schedule to 22 months. I would like to understand this schedule.

- a. Why does it take 18 or more months to issue a rulemaking? What can NRC do to expedite the schedule?

**RESPONSE:**

Rulemaking is a deliberative process that allows meaningful participation by stakeholders and thoughtful consideration of their comments, as well as review and approval by the Commission. The process to issue the NuScale rulemaking is driven by different factors, some outside of the NRC's control. These factors include:

- The length of the public comment period for the proposed rule, which was recently extended in response to a request from stakeholders.
- The number and complexity of public comments received.
- Review and approval by the Office of Management and Budget of the information collection contained in the proposed and the final rules.
- Approval by the Director, Office of the Federal Register, to incorporate by reference the design standard into the NRC's regulations in title 10 of the Code of Federal Regulations.

The NRC has ongoing initiatives to make the rulemaking process more effective and efficient. For this project, the NRC is implementing an expedited concurrence schedule, and the staff plans to expedite the development of the final rule as much as possible.

- b. How does the NuScale design certification compare to prior design certification rulemakings and, where differences exist, why?

**RESPONSE:**

In the past, the NRC used the standard notice and comment rulemaking process for design certification rules. However, for the Advanced Power Reactor 1400 (APR1400) design certification rulemaking, the NRC used the direct final rule process because experience showed that it was unlikely that the NRC would receive significant adverse comments. The direct final rule process was considered appropriate for this design certification because the design was substantially similar to nuclear power reactor designs previously certified by the NRC. The NRC also used the direct final rule process for the first design certification renewal rule (U.S. Advanced Boiling Water Reactor) this summer and plans to use the direct final rule process to extend the AP1000 design certification rule.

Since NuScale is the first small modular reactor design to be certified by the NRC, and because of the potential for significant, adverse public comments on this rulemaking, the NRC is using the standard notice and comment rulemaking process. Because the notice and comment process is a two-step process (i.e., issuance of a proposed rule followed by a final rule), as compared to the one-step direct final rule process, it can take more time to complete but allows for robust public engagement.

c. Is the schedule for this 18-month rulemaking likely to be further delayed? If so, why?

**RESPONSE:**

In July 2021, the estimated schedule for issuing the NuScale final design certification rule was revised to July 2022 to accommodate a Commission-directed 60-day public comment period and to more accurately account for necessary coordination with the Office of Management and Budget and the Office of the Federal Register for issuance of the final rule. As described in the answer to (a) above, there are a number of factors that could potentially lead to further delay in the rulemaking schedule.

On July 27, 2021, the NRC received a request, submitted on behalf of two public interest groups, to extend the public comment period for the NuScale proposed rule by an additional 90 days. The NRC evaluated this request and decided to extend the public comment period by an additional 45 days to allow more time for members of the public to develop and submit their comments. In light of this extension to the public comment period, the NRC staff expect to revise the estimated date for issuance of the final design certification rule.

4. What is the NRC doing to take advantage of the increased flexibility in scheduling and utilizing inspection resources through teleworking technologies demonstrated during COVID?

**RESPONSE:**

Last year, a multidisciplinary team from multiple offices within the NRC evaluated lessons learned and best practices from the implementation of the Reactor Oversight Program during the initial phases of the COVID-19 pandemic. Based on recommendations from that effort, the

NRC staff is working to improve internal information technology capabilities and reliability. Additionally, the NRC staff is working with industry to improve tools and protocols for remote access to important plant information and operational programs. The NRC staff plans to continue to engage with internal and external stakeholders regarding lessons learned during the pandemic.

- a. How has the NRC's teleworking experience during COVID changed the expectations of inspectors for where and how they do their work?

**RESPONSE:**

During the pandemic, the NRC has taken action to ensure the safety of the agency's inspectors by providing guidance for onsite inspection and use of alternative technologies to complete inspections. During the public health emergency, the NRC has effectively implemented the Reactor Oversight Program and Nuclear Materials and Waste Safety oversight programs using remote inspections and other alternative technologies as necessary. The NRC is considering lessons learned from the pandemic regarding remote inspection capabilities. Onsite inspections have resumed and continue to be a vital part of the inspection process.

5. Deploying new nuclear reactors and renewing the licenses of existing reactors has environmental benefits. Nuclear energy is the largest source of clean-air energy in the U.S., protects our climate, and avoids air pollution-related health problems.

- a. Does the NRC's current environmental justice policy allow it to consider these benefits when it compares proposed nuclear projects to the foreseeable alternatives to nuclear power?

**RESPONSE:**

Consistent with Executive Order 12898, the NRC's "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions" ([69 FR 52040](#)) explains that the NRC currently considers environmental justice under the National Environmental Policy Act (NEPA). Consistent with its Policy Statement, the focus of the NRC's environmental justice reviews is on whether a proposed agency action will have disproportionately high and adverse impacts on minority and low-income communities. For nuclear power reactor licensing, NRC staff documents the results of its environmental justice review in an Environmental Impact Statement (EIS). In the EIS, the staff describes the human health and environmental effects of the proposed action and alternatives to the proposed action on minority and low-income populations. In addition to the environmental justice review, the NRC considers "the economic, technical, and other benefits and costs of the proposed action and alternatives." (10 CFR 51.71(d)).

6. NRC staff has recommended that the Commission initiate a rulemaking to investigate the appropriate training and experience for the administration of radiopharmaceuticals. The staff memo was submitted to the commission in January of 2020. Are you going to act on the staff recommendation, and if so when?

**RESPONSE:**

The Commission is considering the staff's training and experience rulemaking plan SECY-20-0005 (ADAMS Accession No. ML19217A318). The staff's rulemaking plan raises important issues that the Commission will consider as part of its deliberations. As the Commission considers the staff's rulemaking plan, the NRC's current regulations continue to ensure appropriate training and experience for the safe and secure use of radiopharmaceuticals.

7. Please provide for the record the average number of hours of NRC inspections at a 2-unit Nuclear Power Plant site. In addition:

**RESPONSE:**

The average number of NRC direct inspection hours at 2-unit sites is about 3,000 hours per year. Generally, the number of direct inspection hours excludes items like travel, preparation, and documentation.

- a. Identify how those hours of inspection have changed over the past ten years.

**RESPONSE:**

<b>Year</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>
<b>Hours</b>	2939	3267	3129	3077	3152	3185	3042	3018	2943	2723

The average number of direct inspection hours for 2-unit sites has remained relatively stable at approximately 3,000 hours per year. The exception being 2020 due to the limitations that were in place during the pandemic.

- b. Identify inspections time staff has expended on matters the staff considers low safety significance.

**RESPONSE:**

The majority of direct inspection time is spent accomplishing baseline inspections. These inspections are common to all nuclear plants. The baseline inspection program focuses on

activities and systems that are “risk significant.” The inspection program also reviews the cross-cutting issues of human performance, safety-conscious work environment, and how the licensees find and fix problems. Training and inspection procedures are designed to help inspectors risk-inform the samples they select in accomplishing their inspections.

The NRC evaluates inspection findings for safety significance using a significance determination process and compares performance indicators against prescribed risk-informed thresholds. The agency then determines an appropriate response that is commensurate with the safety significance of the performance issue using preestablished guidelines in an action matrix. Responses can include supplemental inspections for selected issues or enforcement actions on significant inspection findings. In addition, the NRC has implemented a new program to improve internal processes so that low safety significance issues are promptly identified and resolved without an excessive use of resources.

8. During the hearing, Rep. Burgess asked you whether Nuclear Power Plant operators were empowered to make safety decisions in real time.

**RESPONSE:**

Operators and senior operators are empowered to make safety decisions in real time. They are licensed under the regulations in Title 10 of the Code of Federal Regulations, Part 55, “Operators’ licenses.” The protection of public health and safety requires that licensed operators not only be proficient in general operations but be able to safely cope with plant transients and malfunctions. Further, a facility licensee may not permit the manipulation of the controls of any facility by anyone who is not a licensed operator or senior operator (there are certain exceptions to permit training and for fuel movement). The licensing tests administered to potential

operators and senior operators verify the candidate's ability to make safety decisions in real time.

A licensed senior operator is empowered by 10 CFR 50.54(x) and (y) to approve a facility licensee taking reasonable action that departs from a license condition or a technical specification in an emergency. A licensed senior operator can authorize this action if the action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. There is no requirement that senior reactor operators request permission from their management, the Commission, or other outside sources before invoking 10 CFR 50.54(x) and (y).

- a. To follow-up, what is the authority of a senior reactor operator at a plant to take action without consulting the Commission or outside officials to address emergency safety issues?

**RESPONSE:**

As explained in the preceding response, a licensed senior operator is empowered by 10 CFR 50.54(x) and (y) to approve a facility licensee taking reasonable action that departs from a license condition or a technical specification in an emergency. A licensed senior operator can authorize such action if it is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. The senior operator invoking 10 CFR 50.54(x) and (y) is not required to seek pre-approval from the NRC or licensee management.

- b. Can this be likened to the authority of the captain of a ship?

**RESPONSE:**

Yes. In fact, when developing the NRC rules related the authority of licensees to take actions in an emergency, the Commission considered the rules used for sea vessels and for aircraft that similarly empower the captain or pilot to take whatever prudent action is needed to avoid dangers of navigation and collision, and otherwise respond to an emergency.

- c. How does this compare with the authority of the equivalent of senior reactor operators at the Fukushima Daiichi Power Plant leading up to the incident of March 2011?

**RESPONSE:**

The NRC is unaware of the authority granted to senior reactor operators at the Fukushima Daiichi Power Plant at the time of the accident and unable to determine if it was equivalent or similar to that of the senior reactor operators in the United States. International organizations, such as the International Atomic Energy Agency, have guidance for the selection, qualification, training, and authorization of personnel working in all safety related functions in nuclear power plants. Japan is among the community of Member States who participate and benefit from these consensus standards. Subsequent to the accident, extensive international collaborative efforts took place to review all consensus standards to incorporate lessons learned into each country's nuclear regulatory programs, as appropriate. These international consensus standards and NRC requirements are generally in alignment. NRC requirements empower operators and senior operators to make safety decisions in real time, as discussed in further detail in the preceding question.

9. During the hearing Rep. Armstrong noted that applicants need to have a good understanding of how long and how much money to get a license at the beginning of the licensing process. He asked how NRC is putting together workable, predictable project schedules for advanced reactor reviews and you promised to provide additional information. Please provide that information for the record here.

**RESPONSE:**

The NRC staff practice is to develop a review schedule tailored to each advanced reactor application that includes cost estimates, including estimates of NRC staff hours and contractor costs, for the review. This review schedule is informed by the applicant's regulatory engagement plan, if they chose to provide one to the NRC staff, that lays out the applicant's requested schedule, including timeframes for various interactions with and decisions by the NRC. The NRC staff provides the review schedule and cost estimate to the applicant prior to commencing the in-depth review of the application and expending substantial resources and notifies the applicant of any significant changes.

In May 2021, the NRC issued a draft white paper, "Pre-application Engagement to Optimize Advanced Reactors Application Reviews" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21145A106), which describes the benefits of robust pre-application engagement with the NRC staff. The draft white paper proposes a set of pre-application activities that, if utilized appropriately, would enable the NRC staff to offer a more predictable, efficient review of an advanced reactor license application with a potentially shorter schedule. In addition, the NRC staff is optimizing its review process for advanced reactors with the goal of making the reviews more efficient and safety-focused. The NRC staff anticipates that the new process will require fewer resources assuming that the incoming

applications are complete, of high-quality, and address NRC feedback provided during pre-application interactions.

The NRC staff is also developing guidance to address the content of advanced reactor applications (for applications under 10 CFR Parts 50, 52, or 53 using the Licensing Modernization Project (LMP) process) under the Technology Inclusive Content of Application Project (TICAP) and Advanced Reactor Content of Application Project (ARCAP) initiatives to focus its effort and resources on the most risk-significant areas. The NRC staff is engaging extensively with industry and other stakeholders to develop this ARCAP and TICAP guidance and to determine the appropriate level of detail for advanced reactor applications.

### **The Honorable Michael Burgess (R-TX)**

NRC response to COVID-19

1. Did the Nuclear Regulatory Commission (NRC) change how it conducted its regulatory efforts?

#### **RESPONSE:**

The NRC has made several adjustments to licensing, oversight, enforcement, and other activities to maintain reasonable assurance of adequate protection of public health and safety and the common defense and security during the COVID-19 pandemic. The NRC has made these changes in a deliberate manner that preserved openness, transparency, and public engagement as part of the agency's decisionmaking process without compromising its mission. To ensure stakeholder engagement, the NRC has enhanced its use of virtual collaboration tools to conduct public meetings and extended public comment deadlines, as appropriate.

### Licensing

In response to the Department of Health and Human Services' declaration of the COVID-19 public health emergency, the NRC has taken necessary steps to protect public health and safety, including the identification of regulatory requirements that could pose challenges during the pandemic, and the areas where the NRC staff believes that temporary flexibilities, such as exemptions, can be approved without compromising the ability of licensees to maintain the safe and secure operation of NRC-licensed facilities.

Based on industry and public engagement, the NRC issued a series of letters describing specific criteria and conditions under which it would expedite the review of licensee requests for temporary exemptions from certain regulatory requirements, such as for work hour controls, operator training and qualification, and medical device calibration and testing. The staff also issued temporary staff guidance to guide the staff's review of COVID-19-related licensing requests. These letters and guidance are available on the NRC public Web Page at <https://www.nrc.gov/about-nrc/covid-19/index.html>. Lastly, the staff developed online submission portals to standardize and streamline the submission of these requests to the NRC. The agency's standard for granting regulatory relief remains unchanged, and each request is reviewed on a case-by-case basis. The NRC's expeditious review and, if warranted, approval of these requests during the pandemic enables licensees to take necessary measures to follow Federal, State, and local public health guidelines. To date, the NRC has reviewed and approved over 250 licensing requests in support of licensee response to the pandemic.

### Oversight

Throughout the pandemic, the NRC has executed a risk-informed oversight approach that maintains reasonable assurance of adequate protection of public health and safety and promotes the common defense and security, while protecting the health and safety of

inspectors, site personnel, and the community, in accordance with Federal, State, and local guidelines. The scope, objectives, and requirements of the NRC's inspection procedures have not changed; however, a flexible approach was developed enabling Regional Administrators to balance local health conditions and risk profiles to determine the appropriate onsite presence of inspectors (detailed guidance available at ADAMS Accession Nos. [ML20097E538](#), [ML20106F226](#), [ML20143A281](#), and [ML20079E700](#)).

While not onsite as much as before the pandemic, NRC inspectors are able to independently monitor some licensee activities remotely using technology to access facility information necessary to perform the agency's independent oversight role. NRC inspectors have also increased their communication with licensees since the start of the pandemic. Together, these efforts have allowed the NRC to continue its independent oversight of NRC-licensed facilities.

As COVID-19 restrictions began to ease across the country, the NRC issued updated guidance that included goals for the reactor inspection program (e.g., completion at the minimum allowed by the baseline inspection program for each site in CY 2020 and return to pre-COVID-19 levels in CY 2021) (ADAMS Accession Nos. [ML20141L766](#) and [ML21027A274](#)). The NRC is continuously monitoring site-specific conditions, including COVID-19-related conditions onsite and in surrounding communities, and adjusting the method of inspection as necessary.

### Enforcement

The NRC issued enforcement guidance memorandum (EGM), EGM-20-002 (ADAMS Accession No. [ML20083K794](#)) on April 15, 2020, to provide guidance for exercising enforcement discretion in certain situations where NRC licensees encounter compliance issues caused by COVID-19-related impacts. Attachments to this memorandum (ADAMS Accession Nos. [ML20091L385](#), [ML20136A085](#), and [ML20143A066](#)) provide further guidance for the disposition of violations

related to completion periodicities associated with security training and requalification requirements, licensee suspension of the use of licensed material and material placed into safe storage, and non-compliance of radiological emergency response plans.

#### Agreement State Coordination

The NRC staff has worked closely with the Agreement States, the Organization of Agreement States, and the Conference of Radiation Control Program Directors to ensure reasonable assurance of adequate protection for all materials licensees and compatible approaches across the National Materials Program while managing COVID-related impacts. The NRC has adjusted Integrated Materials Performance Evaluation Program (IMPEP) schedules in partnership with the affected Agreement States. The staff also has been conducting remote periodic meetings, IMPEP reviews, and Management Review Boards. The NRC coordinated with the Agreement States to issue a temporary instruction (ADAMS Accession No. [ML20188A382](#)) in October 2020 to address IMPEP team evaluation of performance indicators for actions taken by radiation control programs during the pandemic.

2. Did these changes improve the efficiency of the NRC's operations?

#### **RESPONSE:**

Many of the changes the NRC has made during the COVID-19 pandemic to maintain reasonable assurance of adequate protection of public health and safety and the common defense and security also have improved the efficiency of NRC operations.

For example, successful application of web-based portals for COVID-19-related licensing requests led to the development of a web-based relief request (WRR) portal for submission of any (both COVID- and non-COVID-related) relief requests and a similar enhancement to the

Web-Based Licensing (WBL) system for materials licensees. These external online portals establish the foundation and framework for future process enhancements such as online responses to requests for additional information. Online submissions have the potential to enable future capabilities that are likely to result in efficiencies, such as enabling streamlined document sharing, electronic tracking of review status, and standardized formatting and automation of administrative aspects of review documentation.

To process the COVID-19-related licensing actions on short timelines while focusing on safety and security, the NRC staff have implemented a number of changes resulting in efficiencies, including a tiger team approach to develop and implement guidance to industry, temporary staff guidance, and templates for staff use. Additionally, the staff has worked with the Federal Emergency Management Agency (FEMA) to use the FEMA Prep Toolkit to reduce the review time between the NRC and FEMA for exemptions related to emergency preparedness. As a result of its effectiveness, the NRC and FEMA plan to continue to use the Toolkit for non-COVID-related reviews, including changes to Alert and Notification Systems.

The NRC staff is assessing lessons learned and long-term changes that can increase both effectiveness and efficiency without compromising the agency's important safety and security mission. For example, the staff is assessing whether and how long-term efficiencies can be gained in the implementation of NRC reactor and nuclear materials and waste safety oversight programs (ADAMS Accession No. ML20308A389 and ML21158A231). The staff intends to conduct a more comprehensive review of lessons learned and best practices that will consider the additional experience gained from conducting inspections during the pandemic. This review will include engagement with internal and external stakeholders and will explore the pandemic-related effectiveness and efficiency improvements that the NRC made to its inspection programs to determine whether any of these improvements should continue. The

staff also plans to evaluate whether any lessons learned during the agency's response to the pandemic could be applied to other program areas, such as licensing and enforcement.

3. Was power plant safety impacted?

**RESPONSE:**

No. The agency's standard for granting regulatory relief remains unchanged, and each request is reviewed on a case-by-case basis; the NRC may only grant exemptions that meet the relevant requirements. Granting temporary relief from certain regulatory requirements does not relieve a licensee of its obligation to ensure the safe and secure operation of its facility. The NRC's expeditious review and, if warranted, approval of these requests enables licensees to take necessary measures to follow Federal, State, and local public health guidelines. All requests from licensees for temporary regulatory relief in response to the pandemic are approved only if adequate controls are in place to maintain safety and security.

A majority of NRC inspections in CY 2020 were performed using a hybrid approach, where NRC inspectors performed onsite, in-person inspections and monitoring of plant activities as well as offsite or remote inspection of plant records and documents. The NRC has maintained reasonable assurance of safe plant operation through this approach.

4. Did more virtual work create new cyber vulnerabilities?

**RESPONSE:**

The enhanced virtual work environment and reliance on technology throughout the pandemic has resulted in new cyber vulnerabilities and malware risk; cyber-attacks have increased in

frequency as well as sophistication. These vulnerabilities and related threat actors seek to capitalize on weaknesses aligned to virtual communication technologies as well as the potentially susceptible human element through targeted phishing campaigns aimed at NRC staff and the agency's information technology (IT) systems. While virtual work has increased the complexity and cadence of patching active vulnerabilities on IT assets, the expanded use of telework has also enabled the agency to improve its overall cybersecurity program through appropriate investments. The following are examples of technologies and mitigations the NRC has invested in to further secure its enterprise and respond to the evolving threat landscape.

- The NRC implemented several solutions to adapt to increased telework, including a new Virtual Private Network (VPN) solution, which provides increased security and data protection; a Data Loss Prevention technology to reduce, and in many circumstances prevent, NRC data exfiltration, data loss and data spills; and new software on NRC workstations that provides an enhanced security scanning capability to detect vulnerabilities and configuration compliance.
- The NRC adopted and implemented the Cybersecurity and Infrastructure Security Agency (CISA)-sponsored Vulnerability Disclosure Policy (VDP) program to give security researchers guidelines for conducting vulnerability discovery activities and to convey the NRC's preferences in how to submit discovered vulnerabilities. The NRC's VDP policy defines how the NRC handles incoming alerts (legally and technically), how the NRC communicates with researchers, and how the NRC's internal teams validate, mitigate, and externally disclose a security vulnerability.

Throughout the pandemic, the majority of prior NRC Federal Information Security Management Act (FISMA) metrics remained consistent and one area improved.

5. Can some changes be made permanent, to maintain safety standards while reducing NRC fees on ratepayers?

**RESPONSE:**

The NRC staff plans to continue to examine the tools and processes leveraged to respond to the COVID-19 pandemic and to adopt improvements and efficiencies into existing processes where appropriate.

Last year, the NRC established a team from multiple offices to identify lessons learned and best practices and to make recommendations to improve NRC readiness for future emergencies and non-emergency conditions. The team's findings were published on January 11, 2021, "Initial Report on Challenges, Lessons Learned and Best Practices from the 2020 COVID-19 Public Health Emergency - Focus on Regulatory Oversight of Operating Nuclear Reactors" (ADAMS Accession No. ML20308A389). The team concluded that the NRC's continued oversight of nuclear power reactors during the pandemic has been appropriate considering the circumstances and reflected NRC staff and management's ability to adapt to the challenges the pandemic presented. NRC inspectors, staff, and management have learned a great deal in a very short time, and while the pandemic continues, these lessons learned and best practices should prove highly beneficial for future emergencies that limit or prevent access to nuclear plant sites.

The team developed recommendations that can be used to help improve implementation of the Reactor Oversight Process (ROP) during the continuing COVID-19 pandemic; ensure the inspection program is adequately prepared for future emergencies; and identify those processes and actions taken during the COVID-19 pandemic that can be used during normal operations to

enable the NRC to become a more modern, risk-informed regulator. A follow-on effort, which will include engagement with external stakeholders, will further identify lessons learned and best practices and will include an assessment of ROP practices.

### Interim Waste Storage

6. What is the status of the Waste Control Systems application to the NRC for consolidated interim storage in Andrews, TX?

#### **RESPONSE:**

The NRC staff is conducting a detailed review of the application by Interim Storage Partners to construct and operate a consolidated interim storage facility located at the Waste Control Specialists site. The staff is reviewing the application to determine whether the proposed facility meets the NRC's safety and security requirements. In addition, the staff conducted a review of the potential environmental impacts of the proposed action under the National Environmental Policy Act. After a detailed review of the application, the NRC staff will publish a safety evaluation report that will discuss its findings on the safety and security of the proposed facility. With respect to the environmental review, on July 29, 2021, the NRC staff issued its final environmental impact statement assessing the potential environmental impacts from the construction, operation, and decommissioning of the proposed facility (ADAMS Accession No. ML21209A955). The NRC staff anticipates making a licensing decision in September 2021.

7. Can you explain the NRC's role in the licensing of private interim storage facilities?

**RESPONSE:**

Under the Atomic Energy Act of 1954, as amended (AEA), the NRC has authority to license and oversee the construction and operation of private ISFSIs. The NRC regulates ISFSIs (including consolidated interim storage facilities, which are one type of ISFSI) through a variety of regulatory requirements related to licensing, safety and security oversight, inspection, and enforcement. The NRC staff performs detailed safety and security reviews of applications submitted for an ISFSI and publishes its findings in a safety evaluation report. The purpose of the review is to assess whether the facility can be constructed and operated in a manner that provides reasonable assurance of adequate protection of public health and safety. The NRC staff also performs an environmental review of the proposed facility in accordance with the National Environmental Policy Act. Additionally, the NRC provides an opportunity for affected members of the public to request a hearing on the proposed licensing action. If the facility is found to meet the applicable regulations, the NRC issues the license, as required by the AEA.

8. Would this facility be paid for through federal funds?

**RESPONSE:**

NRC funds would not pay for the construction or operation of this facility, if approved. All the costs of the NRC's licensing and oversight of such facilities are paid for by the applicants or licensees and the NRC recovers its expenses through fees charged to the applicants or licensees.

In addition, an applicant for an ISFSI is required to submit information showing that the applicant either possesses or can obtain the necessary funds to construct, operate, and decommission the proposed facility. For the NRC to grant a license, it must find that the applicant is financially qualified to engage in the proposed activity. Once licensed, the licensee must continue to

demonstrate financial assurance to decommission the facility by providing updated estimates of the cost to decommission the facility, providing annual financial statements to the NRC, and maintaining financial records that are subject to NRC inspection. The ISP application relies on private funding for initial capitalization and indicates that funding for construction and operation will be through contracts with customers of ISP.

9. Could the facility in Andrews, TX become a permanent spent fuel storage location?

**RESPONSE:**

The current national policy for the disposal of spent fuel, as expressed in the Nuclear Waste Policy Act, is for permanent disposal to occur in a deep geologic repository. The NRC issues licenses for above-ground independent spent fuel storage installations for interim storage, which would not permit permanent disposal.

The current application under review by the NRC staff requests a license to store material for a period of 40 years. NRC regulations allow the license to be renewed for another 40 years, as long as all applicable regulatory requirements are met. The NRC requires the applicant to provide a preliminary decommissioning plan as part of its license application. Additionally, in its license application, the applicant is required to submit information showing that the applicant either possesses or can obtain the necessary funds to construct, operate, and decommission the proposed facility.

Advanced Nuclear Reactors

10. What is the status of the NRC's Part 53 rulemaking process?

**RESPONSE:**

Consistent with Section 103 of the Nuclear Energy Innovation and Modernization Act (NEIMA), the NRC staff is actively working on the development of the proposed rule for the risk-informed, technology-inclusive regulatory framework for optional use by applicants for new commercial advanced nuclear reactor licenses. Upon completion, the rule will be codified in Part 53 of Title 10 of the Code of Federal Regulations. To facilitate discussion with stakeholders, the staff has iteratively released the Part 53 preliminary proposed rule language as it is developed for discussion at public meetings and to solicit written comments. Numerous stakeholders, including industry, trade groups, nongovernmental organizations, the public, and the Advisory Committee on Reactor Safeguards (ACRS), have provided comments. To date, the NRC staff has held seven public meetings and met with the ACRS eight times to discuss this topic. The proposed and final rules are currently scheduled to be provided to the Commission in May 2022, and March 2024, respectively. Key documents related to the Part 53 rulemaking, including preliminary proposed rule language and stakeholder comments, are available at [Regulations.gov](https://www.regulations.gov) under Docket ID No. NRC-2019-0062.

In response to NEIMA, the Commission directed the staff to consider appropriate treatment of fusion reactor designs in the NRC's regulatory structure and to develop options for Commission consideration on licensing and regulating fusion energy systems. The staff's development of options for the Commission to consider will include assessing the potential risks posed by various fusion technologies and possible regulatory approaches for fusion facilities, which may be modeled on the existing regulatory structure for reactors, materials licensees, or a combination thereof. The draft proposed Part 53 rule to be provided to the Commission in 2022 will be developed with the aim of accommodating fusion technologies as much as possible. However, accommodation of fusion technologies within Part 53 may require a separate rulemaking that could extend beyond 2024 but would be completed before 2027.

11. Have any entities submitted applications for the licensing of advanced nuclear reactors utilize designs other than light water reactors or pressurized water reactors?

**RESPONSE:**

Yes. On March 11, 2020, Oklo Power LLC (Oklo), a subsidiary of Oklo Inc., submitted a combined license (COL) application for its Aurora micro-reactor design, proposed to be constructed and operated at the Idaho National Laboratory site. This is the first COL application for a non-LWR submitted to the NRC. The Aurora is a 4-megawatt thermal compact fast reactor that utilizes heat pipes to transfer heat from the metallic fuel core to the power conversion system and is designed to produce 1.5 megawatts of electricity. The NRC staff is conducting this review in two steps. Step 1 involves the review of certain key issues and Step 2 involves the completion of the safety and environmental reviews of the application. The Step 1 review is still underway and will be considered closed once the NRC staff completes its review of two remaining key issues, maximum credible accident methodology and classification of structures, systems, and components.

12. In recent years, Congress has appropriated federal funding to Department of Energy (DOE) for the construction of a Versatile Test Reactor. Would such a facility improve NRC's ability to assure the safety of new nuclear technologies, materials, and fuels?

**RESPONSE:**

Experimental data obtained from the Versatile Test Reactor (VTR) could be used to develop the technical bases to support licensing of new nuclear technologies. For example, experiments at the VTR could lead to a better understanding of the effects of the fast neutron fluence on the properties of materials and fuels used in the design, construction, and operation of new nuclear

technologies and how those properties change over time. Additionally, experimental data could be used to validate physical models in reactor safety computer codes to support safety assessments and licensing of new nuclear technologies. The NRC has been closely engaged with DOE's Office of Nuclear Energy and the Electric Power Research Institute regarding materials activities to ensure the NRC's research needs are addressed.

13. In 2019, the DOE and the NRC signed a Memorandum of Understanding (MOU) to develop and deploy the VTR. What is the status of this work?

**RESPONSE:**

In September 2019, the NRC entered into a Memorandum of Understanding (MOU) with the Department of Energy (DOE) on Versatile Test Reactor (VTR) Engagement, which is still active. In addition, in October 2019, the NRC entered into a MOU with DOE on Nuclear Energy Innovation, including through the National Reactor Innovation Center. DOE is responsible for carrying out the National Reactor Innovation Center, a program aimed at enabling the testing and demonstration of reactor concepts to be proposed and funded, in whole or in part, by the private sector. The VTR is part of this program. The NRC, consistent with its role as an independent safety and security regulator, is responsible for providing DOE and the nuclear energy community with accurate, current information on the NRC's regulations and licensing processes.

The NRC stays in frequent communication with DOE and monitors progress of the VTR project. The VTR design, construction, and authorization for operation provides a unique opportunity for cooperation and information exchanges between DOE and the NRC regarding DOE authorization, lessons learned from DOE's application of the Licensing Modernization Project (an approach leveraged by the NRC in licensing advanced reactor technologies), and NRC staff

development of expertise on sodium fast reactor technology. The MOUs contain provisions for DOE and the NRC to share information, as appropriate, relating to ensuring that DOE and the NRC have sufficient technical expertise to carry out their respective missions. Additionally, through these MOUs, the NRC has obtained information and training on the VTR's design and the basis for its safe operation.

This information is valuable because it supports NRC computer code development and validation activities, a key element of the NRC's strategy to enhance its preparedness for licensing and evaluating the safety of commercial sodium fast reactors. All of these interactions help support the NRC's readiness efforts to review and license sodium fast reactor technologies.

**The Honorable Debbie Lesko (R-AZ)**

1. The U.S. nuclear industry is performing at all-time high levels, the best in the world. Given this performance and the levels of safety that go with it, how is the NRC working to effectively focus on its safety mission without unduly burdening the operating fleet?

**RESPONSE:**

The NRC applies risk insights from well-established methods, models, and operational data used independently by the NRC and the U.S. nuclear industry to focus its efforts on those issues that are of the greatest safety significance in its oversight and licensing of NRC-regulated activities. The NRC's regulatory framework for reactor oversight, the Reactor Oversight Process (ROP), is a risk-informed, tiered approach to inspect, measure, and assess plant safety. The NRC measures nuclear plant performance by monitoring objective performance indicators and by conducting the NRC inspection program. Through the inspection program, any findings that are discovered proceed through a risk-informed significance determination process to evaluate

the importance of the finding as input to determining the appropriate level of NRC response.

The agency also assesses plant safety using significance-based performance results and findings to determine an appropriate response using established and published criteria. The agency's response can include baseline inspection, supplemental inspections for selected issues, or enforcement actions on significant inspection findings. In this way, the ROP ensures that plant oversight is appropriate for the level of plant performance. In addition, the NRC has implemented the Very Low Safety Significance Issue Resolution Program to improve internal processes so that very low safety significance issues are promptly identified and resolved without an excessive use of resources.

The NRC continues to enhance the integration of risk-informed decision-making in licensing reviews. The NRC also continues to review and approve a high volume of risk-informed licensing actions that increase plant operational flexibility while maintaining staff and licensee focus on issues of greater safety significance, such as programs implementing risk-informed completion times for out-of-service equipment.

2. The nuclear industry has embraced ways to become more efficient and cost effective while maintaining high levels of performance and a stellar safety record. What is the Commission doing to embrace efficiencies while maintaining the highest safety standards and thereby curb the continued budget increase year over year for operating reactors?

**RESPONSE:**

The NRC maintains its high safety standards and implements efficiencies by cross training its staff, applying risk insights into its decision-making, simplifying and improving our internal processes, and leveraging technology to obtain better data to inform decision-making. These

efforts have helped maintain a generally decreasing budget, with the FY 2022 budget request including only slight budget increases for the Operating Reactors Business Line, which are primarily due to salaries and benefits adjustments consistent with Office of Management and Budget guidance. Additionally, these efforts are part of the agency's journey to becoming a more modern, risk-informed regulator by streamlining work processes and focusing resources on safety significant areas, as well as the efforts discussed in the previous response to more fully integrate the use of risk information in the agency's decision-making processes.

The NRC continues to find innovative ways to improve its internal processes to support industry and public needs through continued outreach and engagement. For example, the NRC is in the final stages of issuing a revision to the process for licensing of operators for nuclear power plants with Revision 12 to NUREG-1021, "Operator Licensing Examination Standards for Power Reactors." This revision will support improved efficiency in operator licensing by integrating the generic fundamentals examination into the final licensed operator examination, minimizing the need for multiple tests given by the NRC in a way that better supports the licensees' operator training and qualification programs while maintaining the high standards the NRC has established for operators licensed to operate nuclear power reactors. Another example relates to the modernization of inspections through the development and deployment of an Operating Experience Hub for staff use. This internal information source provides trending and search tools that allow NRC staff and management the ability to review findings, operating experience, industry scram trends, ROP inspection sample completion, plant ROP action matrix, licensee event notifications/reports, and ROP-specific resource information. For the public, the NRC has developed sites like the Operating Reactor Analytics and Accident Sequence Precursors dashboards. These dashboards provide the public and the NRC staff with information that can be easily searched and organized related to operating reactor findings, ROP action matrix standing, performance indicators, and risk data on accident precursors. These activities have

improved the efficiency of sharing, internally and externally, information that contributes to more efficient and effective decision-making, transparency, and public communication.

3. Utilities in Arizona and across the country are focused on meeting their long-term clean energy and emissions goals through innovation. What role does the NRC have in licensing any part of the process of producing hydrogen using nuclear energy?

**RESPONSE:**

Currently, there are no applications before the NRC for nuclear reactors to be used to produce hydrogen. If such use is contemplated for a commercial nuclear reactor or other NRC-regulated nuclear reactor, the NRC would have the role of licensing and regulating the reactor to ensure adequate protection of the public health and safety and the common defense and security, but the NRC would not license or regulate the hydrogen production facility co-located with the nuclear reactor.

The potential hazard posed by any hydrogen production facility co-located with the nuclear reactor would, however, need to be considered under the NRC's regulatory requirements. Specifically, the NRC's regulations require that licensees for current operating nuclear reactors assess and address potential hazards posed by the postulated addition of a hydrogen production facility through the established change process to update the plant's licensing basis. For a new reactor to incorporate hydrogen production, this analysis would be included in the plant site characteristics and parameters analysis. This analysis would address how the plant would operate with an acceptable degree of safety in the event of an accident caused by the presence of hazardous materials (i.e., additional hydrogen) on site, or activities and materials off-site at nearby industrial or transportation facilities (e.g., hydrogen pipelines).

- a. Which federal agency currently regulates the licensing process for hydrogen production from nuclear energy?

**RESPONSE:**

There is not currently a single agency that regulates the licensing process for hydrogen production from nuclear energy. The reactor that would be used to produce the heat for the hydrogen production process would be regulated by the NRC. However, the NRC notes that as described in a March 2021 report issued by Sandia National Laboratories (Federal Oversight of Hydrogen Systems, SAND2021-2955, March 2021), many other agencies and regulatory schemes would be involved in the total hydrogen cycle. These agencies may include:

- Department of Energy,
- Environmental Protection Agency, Department of Transportation,
- Department of Labor,
- Federal Energy Regulatory Commission, Department of the Interior,
- Department of Homeland Security, and Federal Aviation Administration

4. I understand that many experts in the nuclear power industry believe the newer Advanced Nuclear Reactors (ANRs) offer great potential to restore the United States to world dominance in the nuclear energy sector – moving us ahead of China and Russia. How do advanced nuclear reactors complement existing, fully successful generating plants like Palo Verde?

**RESPONSE:**

Advanced reactor vendors are proposing many different designs and business models. Most of the advanced reactor designs that the NRC has seen are smaller than the large units at Palo Verde. According to the industry, these smaller designs could complement the existing fleet of operating nuclear power reactors by providing options for replacing existing coal or natural gas plants; providing reliable, distributed electricity production; providing process heat for industrial facilities; providing electricity and district heating for remote towns and villages; and allowing reactor electrical output to better follow real-time grid demand. As an independent regulator, the NRC does not promote nuclear power or a specific reactor design; the NRC reviews licensing applications to determine whether there is reasonable assurance that a proposed facility will not pose an undue risk to public health and safety or the environment.

5. Assuming you agree that these newer, Advanced Nuclear Reactors do in fact represent important steps forward in the US regaining world dominance in the nuclear sector, what steps are you taking to ensure there is a sufficient quantity of the specialized fuel needed to operate these innovative reactors (“high-assay, low enriched uranium fuel” or HALEU)? How far have you progressed in creating the regulatory structure needed to safely produce and transport this specialized fuel?

**RESPONSE:**

The NRC’s role with regard to production of fuel for advanced reactors is limited to ensuring the safety and security of the fabrication and transportation of fuel. The NRC is proactively working on the agency’s regulatory readiness to enable the safe and secure use of advanced reactor fuels. The NRC has experience with licensing reviews for fuel fabrication and transportation package designs with varying enrichments from low enriched fuel for existing light-water reactors to high enriched fuel for use in research reactors and by Naval Reactors. The NRC

examined the regulatory framework (10 CFR Part 70 and 71) and concluded that the current regulations are sufficiently broad and flexible to accommodate the advanced reactor fuel cycle (including production of HALEU); the fuel cycle encompasses fabrication of advanced reactor fuel and shipment of unirradiated advanced reactor fuel.

In order to support more efficient licensing and certification, and to enhance the NRC's ability to identify any potential information needs related to advanced reactor fuel technology, the NRC is sponsoring and conducting research activities, literature reviews, and technical evaluations related to fuel facilities, transportation, storage, and disposal of advanced fuel, including HALEU. The NRC participates in periodic stakeholder public meetings to inform the public about the agency's progress on readiness activities, including research activities, with the goal of providing regulatory clarity and transparency.

Additionally, the NRC staff is actively engaged in multiple forums with industry, DOE, licensees, and future applicants to ensure that the NRC maintains awareness of future developments and initiatives in these areas and encourages potential applicants to engage with the NRC staff early in the process to ensure an efficient review.