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United States Nuclear Regulatory Commission
*Protecting People and the Environment*

**NUREG-1650, Revision 8**
**Supplement 1**

# Answers to Questions From the Peer Review By Contracting Parties on the United States of America Ninth National Report For the Convention on Nuclear Safety

Office of Nuclear Reactor Regulation

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NUREG-1650, Revision 8
Supplement 1

# Answers to Questions From the Peer Review By Contracting Parties on the United States of America Ninth National Report For the Convention on Nuclear Safety


Manuscript Completed: September 2023
Date Published: February 2024



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Office of Nuclear Reactor Regulation

# ABSTRACT

The Convention on Nuclear Safety was adopted in June 1994 and entered into force in October 1996. The objectives of the Convention are to achieve and maintain a high level of nuclear safety worldwide. Contracting parties to the Convention have four obligations: submit a national report for peer review, review the national reports of other contracting parties, respond to questions and comments submitted by the contracting parties, and participate in the organizational and review meetings. The United States published its ninth national report for peer review in August 2022 (NUREG-1650, Revision 8, "The United States of America Ninth National Report for the Convention on Nuclear Safety"). Supplement 1 to NUREG-1650, Revision 8, documents the answers to questions raised by contracting parties during their peer reviews of the U.S. Ninth National Report. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations, legislative and regulatory framework, regulatory body, responsibility of the license holder, priority given to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design and construction, operation, implementation of the lessons learned from the accident at the Fukushima Dai-ichi nuclear power plant in Japan, and the principles of the Vienna Declaration.

# TABLE OF CONTENTS

# EXECUTIVE SUMMARY

The objectives of the Convention on Nuclear Safety (CNS) are to achieve and maintain a high level of nuclear safety worldwide. Contracting parties to the CNS have four obligations: submit a national report for peer review, review the national reports of other contracting parties, respond to questions and comments submitted by the contracting parties, and participate in the organizational and review meetings.

The United States published its ninth national report for peer review in August 2022, NUREG-1650, Revision 8, "The United States of America Ninth National Report for the Convention on Nuclear Safety," which is available on the U.S. Nuclear Regulatory Commission's (NRC's) website at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1650/. Supplement 1 to NUREG-1650, Revision 8, documents the answers to questions raised by contracting parties during their peer reviews of the U.S. Ninth National Report.

On receiving questions from contracting parties, the NRC staff categorized them according to the article of the U.S. Ninth National Report that addressed the relevant material. There were no questions on Part 3 of the report, which was developed by the Institute of Nuclear Power Operations. Subsequently, technical and regulatory experts at the NRC provided the answers to the contracting parties in preparation for the ninth review meeting of the CNS.

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# ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| AC | alternating current |
| ADAMS | Agencywide Documents Access and Management System (NRC) |
| ALARA | as low as is reasonably achievable (radiation exposure) |
| AMR | aging management review |
| ANS | American Nuclear Society |
| AP1000 | Advanced Passive 1000 Megawatt (Westinghouse pressurized-water reactor) |
| APR1400 | Advanced Power Reactor 1400 |
| ART | Advanced Reactor Technologies |
| ASME | American Society of Mechanical Engineers |
| ASN | French regulatory authority |
| ATF | accident tolerant fuel |
| BL | bulletin |
| BWR | boiling-water reactor |
| BWROG | BWR Owners' Group |
| BWRX-300 | 300 MWe water-cooled, natural circulation SMR |
| CBT | computer-based training |
| CCA | cross-cutting area or aspect |
| CCI | Cross-Cutting Issues (NRC program) |
| CCSW | containment cooling service water |
| CDF | core damage frequency |
| CFR | *Code of Federal Regulations* |
| CFSI | counterfeit, fraudulent, and suspect items |
| CISF | consolidated interim storage facility |
| CLI | Commission Legal Issuance |
| CNS | Convention on Nuclear Safety |
| CNSC | Canadian Nuclear Safety Commission |
| CNV | containment vessel (NuScale) |
| COL | combined license (combined construction and operating license) |
| COVID-19 | Coronavirus Disease 2019 |
| CP | construction permit |
| CRAFT | Collaborative Research on Advanced Fuel Technologies for Light-Water Reactors |
| CRMP | Configuration Risk Management Program |
| cROP | Construction Reactor Oversight Process |
| CWA | Clean Water Act |
| CY | calendar year |
| DC | design certification |
| DCA | design certification application |
| DEC | design extension condition |
| DG | draft regulatory guide |
| DGSW | diesel generator service water |
| DOE | U.S. Department of Energy |
| DRG | Design Review Guide |

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|---|---|
| DSRS | design-specific review standard |
| DUWP | Division of Decommissioning Uranium Recovery and Waste Programs (NRC) |
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| EA | Enforcement Action |
| EAB | exclusion area boundary |
| ECCS | emergency core cooling system |
| EIS | environmental impact statement |
| ENSI | Swiss regulator |
| EP | emergency preparedness |
| EPA | U.S. Environmental Protection Agency |
| EPRI | Electric Power Research Institute |
| EPZ | emergency planning zone |
| ERDS | Emergency Response Data System |
| ESP | early site permit |
| ETE | evacuation time estimate |
| | |
| FDA | U.S. Food and Drug Administration |
| FEMA | Federal Emergency Management Agency |
| FLEX | diverse and flexible coping strategies |
| FR | *Federal Register* |
| FY | fiscal year |
| | |
| GALL | generic aging lessons learned |
| GALL-SLR | generic aging lessons learned for subsequent license renewal |
| GDC | general design criteria |
| GEIS | generic environmental impact statement |
| GL | generic letter |
| GSI | generic safety issue |
| GSR | General Safety Requirement (IAEA) |
| | |
| HCLPF | high confidence of low probability of failure |
| HI-STORE | Holtec International Storage |
| HMR | hydrometeorological report |
| HR | Human Resources |
| HRO | high reliability organisation |
| | |
| I&C | instrumentation and control |
| IAEA | International Atomic Energy Agency |
| IMC | Inspection Manual Chapter |
| IMPEP | Integrated Materials Performance Evaluation Program |
| INPO | Institute of Nuclear Power Operations |
| IP | inspection procedure |
| IRRS | Integrated Regulatory Review Service |
| IRS | International Reporting System |
| ISG | interim staff guidance |
| ITAAC | inspections, tests, analyses, and acceptance criteria |
| | |
| KI | potassium iodide |
| KM | knowledge management |

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|---|---|
| LERF | large early release frequency |
| LIC | Licensing Office Instruction (NRC) |
| LLC | limited liability company |
| LOCA | loss-of-coolant accident |
| LOOP | loss of offsite power |
| LPZ | low population zone |
| LR | license renewal |
| LWR | light-water reactor |
| MAP | Mission Analytics Portal |
| MD | Management Directive |
| MELCOR | Methods for Estimation of Leakages and Consequences of Releases (severe accident analysis code) |
| MHTGR-DC | modular high-temperature gas-cooled reactor design criteria |
| MOC | Memorandum of Cooperation |
| mSv | millisievert |
| MWe | megawatt electric |
| MWt | megawatt thermal |
| NANTel | National Academy for Nuclear Training e-Learning |
| NEI | Nuclear Energy Institute |
| NEIMA | Nuclear Energy Innovation and Modernization Act |
| NEPA | National Environmental Policy Act |
| NIST | National Institute of Standards and Technology |
| NMP | National Materials Program |
| NNSA | National Nuclear Security Administration |
| NOAA | National Oceanic and Atmospheric Administration |
| NPDES | National Pollutant Discharge Elimination System |
| NPP | nuclear power plant |
| NRC | U.S. Nuclear Regulatory Commission |
| NRIA | Nuclear Radiological Incident Annex |
| NRR | Office of Nuclear Reactor Regulation |
| NUOG | Nuclear Utility Obsolescence Group |
| NUPIC | Nuclear Procurement Issues Corporation |
| NUREG | U.S. Nuclear Regulatory Commission technical report designation |
| NUREG/BR | NUREG brochure |
| NUREG/CR | contractor-prepared NUREG |
| NUREG/KM | knowledge management NUREG |
| NWS | National Weather Service |
| OI | Office Instruction |
| ONT | other new technology |
| OPC | open phase condition |
| ORO | offsite response organizations |
| PAG | protective action guide |
| PDC | principal design criteria |
| PDR | public document room |
| PI&R | Problem Identification & Resolution |
| PMP | probable maximum precipitation |
| PRA | probabilistic risk assessment |

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|---|---|
| PSEG | Public Service Enterprise Group, Inc. |
| PSR | periodic safety review |
| PWR | pressurized-water reactor |
| PWROG | PWR Owners' Group |
| QA | quality assurance |
| QAPD | quality assurance program description |
| QHO | quantitative health objective |
| RCS | reactor coolant system |
| rem | roentgen equivalent man |
| RG | regulatory guide |
| RIDM | risk-informed decision-making |
| RIN | regulation identifier number |
| RIPE | Risk-Informed Process for Evaluations |
| RISC | Risk-Informed Steering Committee |
| RMTS | risk-managed technical specifications |
| ROP | Reactor Oversight Process |
| RTP | rated thermal power |
| RTR | research and test reactor |
| SAMDA | severe accident mitigation design alternative |
| SAMG | severe accident management guideline |
| SAT | Systems Approach to Training |
| SCPS | Safety Culture Policy Statement |
| SCWE | safety-conscious work environment |
| SECY | Office of the Secretary (NRC) |
| SEIS | supplemental environmental impact statement |
| SFP | spent fuel pool |
| SFR-DC | sodium-cooled fast reactor design criteria |
| SLR | subsequent license renewal |
| SMR | small modular reactor |
| SOC | statement of consideration |
| SR | surveillance requirement |
| SRM | staff requirements memorandum |
| SRP | Standard Review Plan |
| SRR | safety review report |
| SSC | structure, system, and component |
| SSG | Specific Safety Guide (IAEA) |
| SSE | safe-shutdown earthquake |
| SSR | Specific Safety Requirement (IAEA) |
| STS | Standard Technical Specifications |
| Sv | sievert |
| TAR | Technical Assistance Request |
| TEDE | total effective dose equivalent |
| TI | temporary instruction |
| TID | technical information document |
| TLAA | time-limited aging analysis |
| TRISO | TRi-structural ISOtropic |
| TS | technical specification |

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|---|---|
| TSTF | Technical Specifications Task Force |
| UHS | ultimate heat sink |
| U.S. | United States |
| USA | United States of America |
| VEGP | Vogtle Electric Generating Plant |
| VIP | Vendor Inspection Program |
| VLSSIR | very low safety-significance issue resolution |
| VR-SECY | Commission Voting Record |
| VRG | Vogtle Readiness Group |
| WBN-2 | Watts Bar Nuclear Plant, Unit 2 |
| WGST | waste gas storage tank |

# STRUCTURE OF THE REPORT

This report documents the answers of the United States to questions raised by contracting parties to the Convention on Nuclear Safety (CNS or "the Convention") during their peer reviews of NUREG-1650, Revision 8, "The United States of America Ninth National Report for the Convention on Nuclear Safety," issued August 2022 (hereafter referred to as the "U.S. Ninth National Report") (ADAMS Accession No. ML22245A090). On receiving questions from contracting parties, the U.S. Nuclear Regulatory Commission (NRC) staff categorized them according to the article of the report that addressed the relevant material. There were no questions on Part 3 of the report, which was developed by the Institute of Nuclear Power Operations. Subsequently, technical and regulatory experts at the NRC answered the questions. Please note that, with the exception of bracketed expansions added for some abbreviations that are not expanded in their answers, this report presents the questions exactly as they were received, without editing for grammar or spelling or in any other way. Also, the NRC's answers to the questions reflect the status as of February 2023, which is when the United States submitted these answers to the International Atomic Energy Agency (IAEA).

This report follows the format of the U.S. Ninth National Report for the CNS. Sections are numbered according to the article of the Convention under consideration. Each section begins with the text of the article, followed by an overview of the material covered by the section, and the questions and answers that pertain to that section. This report begins with an introduction and continues with Articles 6 through 19. Specifically, these articles address the safety of existing nuclear installations, legislative and regulatory framework, regulatory body, responsibility of the licensee, priority given to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design and construction, and operation. To be consistent with the U.S. Ninth National Report, this report does not contain sections for Articles 1 through 5. In accordance with Article 1 of the CNS, the U.S. Ninth National Report illustrated how the U.S. Government meets the objectives of the Convention. It discussed the safety of nuclear installations according to their definition in Article 2 and the scope of Article 3 and addressed implementing measures (such as national laws, legislation, regulations, and administrative means) according to Article 4. Lastly, the submission of the U.S. Ninth National Report fulfilled the obligation of Article 5.

This report cites a number of documents that are contained in the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is a web-based information system that provides access to all documents made public by the NRC since November 1, 1999. ADAMS permits full searching and includes the ability to view document images, download files, and print locally. ADAMS can be accessed from the NRC website (http://www.nrc.gov/reading-rm/adams.html). In addition, documents are available through the NRC's Public Document Room (PDR), which may be contacted in any of the following ways:

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| Telephone: | 1-800-397-4209 or 301-415-4737 |
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| Facsimile: | 301-415-3548 |
| U.S. Mail: | U.S. NRC, PDR, O1F13, Washington, DC 20555 |
| Onsite visit: | 11555 Rockville Pike, Rockville, MD 20852 |
| Internet: | http://www.nrc.gov/reading-rm/contact-pdr.html |

# INTRODUCTION TO THE U.S. NINTH NATIONAL REPORT

This section of the U.S. Ninth National Report for the CNS described the following:

- purpose and structure of the report
- summary of changes since the previous report was written in 2020
- U.S. national policy on nuclear activities
- national nuclear programs
- safety and regulatory issues and regulatory accomplishments
- international peer reviews and missions

Contracting parties submitted the following questions about this section of the report.

| **Question Number (No.) 7** |
|---|
| The report states that the document SECY-18-0113 was withdrawn to allow the staff to consider new information and feedback from internal and external stakeholders, including inspectors, members of the public, and the nuclear industry.<br>1) What were the main technical reasons for this withdrawal? In which parts and how the original text was changed/modified?<br>2) What are the main characteristics of the revised document and the main features of the new “Periodicity of the Reactor Oversight Process”?<br>3) Is the deadline for its approval still end of FY 2022? |
| <u>Answer</u>:<br>(1) Industry indicated publicly in 2019 that it was no longer pursuing licensee self-assessments in lieu of inspections. The NRC staff also reassessed similar information (inspection findings, industry trends, operational experience) that was used to inform SECY-18-0113, “Recommendations for Modifying the Reactor Oversight Process Engineering Inspections,” dated November 13, 2018 (ML18144A567), to ensure that the staff’s other recommendations on changing the engineering inspection program remained the same.<br><br>(2) SECY-22-0053, “Recommendation for Modifying the Periodicity of Reactor Oversight Process Engineering Inspections,” dated June 7, 2022 (ML22060A085), removed the recommendation to demonstrate compliance using a licensee self-assessment in lieu of an engineering inspection and informed the Commission that the staff was shifting to a Comprehensive Engineering Team Inspection. SECY-22-0053 maintained the staff’s recommendation to shift the engineering inspection cycle from a 3-year cycle to a 4-year cycle, with the options of remaining at a 3-year cycle or extending to a 5-year cycle.<br><br>(3) The NRC staff recommended shifting from a 3-year inspection cycle to a 4-year inspection cycle for engineering inspections. In the 4-year cycle, each reactor site would receive a Comprehensive Engineering Team Inspection and three Focused Engineering Inspections. Focused Engineering Inspections can change from cycle to cycle.<br><br>(4) The Commission approved the staff recommendations in SECY-22-0053 on July 21, 2022. Starting in January 2023, engineering inspections will be on a 4-year cycle. |
| **Question No. 8** |
| The correct reference to section is 2.3.1.10 instead of 2.3.10. |

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|---|
| Answer: Thank you for the comment. The correct reference should be section 2.3.1.10. This was an editorial error. Our sincere apologies for the confusion. |
| **Question No. 9** |
| The report referees to four hypothetical future scenarios in which NRC might operate.<br>1) What are the main characteristics/features of the four scenarios?<br>2) Why they are considered hypothetical and to which extend they are realistic.<br>3) What are the preconditions that one of the scenarios will be reality? |
| Answer:<br>(1) The four scenarios consist of narratives that were built on two foundational axes—U.S. nuclear power demand and the level of innovation in nuclear reactors globally—to explore hypothetical futures.<br><br>(2) The narratives for each of the scenarios are considered hypothetical and are used to describe a range of possibilities for the external nuclear environment in the year 2030 and beyond. Given that the future is not certain or fixed, these scenarios are inherently hypothetical. The four futures are used throughout this report to describe market, technology, and policy factors that shape the nuclear industry and its impact on the NRC. By structuring plausible futures within a framework, these narratives provide a systematic approach for exploring the future and generating hypotheses that expand perceptions of what may come. The actual future of the nuclear industry may include aspects of several of the nuclear narratives.<br><br>(3) The NRC uses “signposts” as precursors towards the direction of the future that reflect the broader conditions in the environment being monitored. In addition, the NRC uses a set of markers that provide clues and indications about which signposts the NRC external environment is moving toward. The NRC has identified an initial set of signposts and markers, which the agency continues to refine. The agency uses these signposts and markers in its agency environmental scan, which is used to forecast the environment that may affect the NRC’s capacity over the next 5 years. Many internal and external factors may influence the environment in which the NRC will operate through fiscal year (FY) 2026. These factors include industry operating experience, national priorities, climate change impacts, the security and threat environment, legislation, Federal court litigation, market trends, new technologies, public health emergencies, and resource availability. The environmental scan is then used in a capacity assessment to assess the NRC’s ability and infrastructure to carry out evidence-building activities, such as foundational fact finding, performance measurement, policy analysis, regulatory analysis, and program evaluation. The capacity assessment intends to strengthen the NRC’s statistics, evaluation, research, and analysis efforts and enhance the use of evidence in decision-making across the agency. |
| **Question No. 10** |
| How to understand the statement: “… for optional use by applicants”? Are there the possible options? |

Answer: When discussing its development of a risk-informed, technology-inclusive regulatory framework, the NRC points out that the framework is for optional use by applicants for new commercial advanced nuclear reactor licenses. This means that applicants would continue to have the option of using the existing framework in the NRC's regulations for construction permits and operating licenses (Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities") or the existing framework for combined licenses, design certifications, and other licenses and approvals (10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants").

**Question No. 11**

New technologies like SMR [small modular reactor] are in a design stage and no practical experiences are available with their operation:

(1) What are the main reasons to apply RIDM [risk-informed decision-making] in a different manner for new technologies and for existing NPP [nuclear power plant] designs?
(2) Does it mean that the new technologies get "in the RIDM credit" even with the lack of practical experiences?
(3) The usual application of "conservatism" seems to be missing.

Answer:

(1) RIDM is applied in a similar manner for new technologies and for existing NPP designs. Regulatory Guide (RG) 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," issued January 2018 (ML17317A256), delineates the principles of risk-informed integrated decision-making. These same principles of risk-informed integrated decision-making may still be applied to new technologies to tailor the focus, depth, and scope of reviews with the understanding that there are limitations due to a lack of detailed design information and operating experience. Strategies to address challenges in advancing RIDM, such as those cited in NUREG-1650, include the use of fully integrated reviews to include complementary insights from traditional engineering and risk assessment approaches, are applicable to both new and existing technologies.

The NRC has several documents that provide guidance for addressing these limitations, including the following:

- For advanced light-water reactors (LWRs), DC/COL-ISG-028, "Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application," issued November 2016 (ML16130A468), provides one acceptable approach for using probabilistic risk assessment (PRA) in regulatory decision-making. DC/COL-ISG-028 specifically addresses the expectation for a PRA at the design stage and with a lack of operating experience by clarifying requirements in the American Society of Mechanical Engineers/American Nuclear Society (ASME/ANS) RA-Sa-2009, "Addenda to ASME/ANS RA-S-2008 Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications" (the PRA Standard), as endorsed by RG 1.200, Revision 2, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," issued March 2009 (ML090410014).

- For non-light-water reactors (non-LWRs), Trial Use RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed

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| Activities," issued March 2022 (ML21235A008), provides guidance for a PRA that can be used in regulatory decision-making for non-LWRs and addresses limitations based on the availability of information for use in the PRA. The Trial Use RG 1.247 endorses with clarifications ASME/ANS RA-S-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants."<br><br>(2) RIDM is applicable to new technologies so long as the limitations are understood and accounted for in the decision-making. First-of-a-kind structures, systems, and components (SSCs) present unique challenges that typically lead to a higher level of review effort.<br><br>(3) RIDM is an integrated decision-making process in which risk insights are considered together with deterministic analyses, other factors, and the associated acceptance criteria. RIDM will account for conservatism in the deterministic analyses, best estimate results in the probabilistic analyses, sensitivity studies, the treatment of uncertainty, and other information relevant to the decision. |
| **Question No. 13** |
| It's stated that, "The decision to seek license renewal is voluntary and rests entirely with nuclear power plant owners. The decision typically is based on the plant's economic viability and whether it can continue to meet the Commission's requirements. As of August 2022, 84 of the 92 currently operating units in the United States have had their operating licenses renewed. Based on statements from industry representatives, the Commission expects all but two units to apply for license renewal. As of August 2022, nine additional units have entered the period of extended operation, as seen below. Although 10 units with renewed licenses have shut down, a total of 52 units are currently operating beyond 40 years."<br>(1) After the license of nuclear power units is renewed, will NRC increase the frequency of Periodic Safety Reviews for the plants?<br>(2) Will additional review items be added to ensure the continuing safety operation of the plants?<br>(3) What is the additional consideration to the second operation extension comparing with the first operation extension?<br>(4) How to ensure that the non-replaceable safety important equipment has sufficient safety margin during the operation extension period? |
| <u>Answer</u>:<br>(1) The United States does not perform periodic safety reviews. The PSR objective of maintaining safety throughout the entire operating life of a plant is achieved by the NRC's comprehensive regulatory framework, including the Reactor Oversight Process (e.g., onsite resident and regional inspectors), generic issue identification, systematic evaluation process, and licensee responsibilities under its quality assurance program. License renewal is another component of that framework and is focused on managing the effects of aging that can impede the function of certain SSCs determined to be important to the safe operation of NPPs. Additional information on the NRC's approach can be found in Article 14 of the U.S. Ninth National Report.<br><br>(2) As part of the license renewal process, the licensees develop and the NRC approves aging management programs for passive and long-lived SSCs that may not be adequately addressed under the existing maintenance framework. The NRC provides guidance in NUREG-1801, "Generic Aging Lessons Learned (GALL) Report" (40–60 years), issued December 2010 (ML103490041), and NUREG-2191, Volumes 1 and 2, "Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report" (60–80 years), |

issued July 2017 (ML16274A389 and ML16274A399, respectively), for developing aging management programs, which include monitoring, inspections, consideration of operating experience, and other activities to ensure that safety functions are adequately maintained.

(3) For the second license renewal, no additional considerations are necessary beyond the same comprehensive aging management review process that was implemented for initial license renewal. Since the plant is older, applicants for second license renewal consider potential aging issues that may arise with the extended operating time and greater exposure levels, such as increased neutron fluence levels. The NRC enhanced its aging management guidance for the second renewal (NUREG-2191) by considering recent operating experience, updates to industry codes and standards, audits of plant aging management programs in the first license renewal period, and focused technical evaluation of potential degradation issues associated with the reactor pressure vessel, vessel internals, concrete, and electrical cables.

(4) License renewal applicants are required to perform an aging management review of nonreplaceable safety important equipment and all other components in the scope of license renewal and to identify and implement aging management programs that will ensure continued functionality of those components during the extended operating period. Those components with time-limited aging analyses are updated as necessary to demonstrate that the components are able to perform their safety function(s) with sufficient safety margin through the end of the proposed operation period. If needed, based on this analysis, the applicant puts in place an aging management program. The NRC reviews both the evaluation and the aging management program.

**Question No. 14**

It is stated that "The NRC's siting responsibilities stem from the Atomic Energy Act and the Energy Reorganization Act. These statutes confer broad regulatory powers on the Commission and authorize the NRC to issue regulations that it deems necessary to fulfill its responsibilities under the acts. Also, under the National Environmental Policy Act, which prescribes procedures for environmental reviews of Federal projects, the NRC evaluates the environmental impacts of siting a nuclear facility. As discussed in Article 7 of this report, in 1989, the NRC developed 10 CFR Part 52 as an alternative regulatory approach to licensing new nuclear power plants. This approach provides for certified standard designs and combined licenses that resolve design issues before construction and early site permits that resolve most siting and environmental issues years before construction. The NRC's siting regulations are integral to protecting public health and safety. The NRC's defense-in-depth safety philosophy has, and will continue to, take into account the presence of 186 densely populated areas and the impact of population density on the effectiveness of emergency response actions. The primary factors that determine public health and safety are reactor design and construction and operation of the facility. However, siting factors and criteria are important to ensure that radiological doses from normal operation and postulated accidents will be acceptably low, natural phenomena and manmade hazards will be properly accounted for in the design and operation of the plant and impacts to the human environment during the construction and operation of the plant are appropriately considered."

Question: In view of international controversy on the nuclear waste water treatment methods of Japan after the Fukushima nuclear accident, will the NRC consider appropriate restrictions on approval of inland nuclear power projects to prevent the impact of radioactive material leakage on the surrounding environment (such as rivers) and surrounding public, as well as serious controversy by the public community?

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| Answer: Evaluation of siting and the potential for radiological releases is an important part of both the safety and environmental reviews for any NRC licensing action authorizing construction of a proposed new NPP under either 10 CFR Part 50 or 10 CFR Part 52. Before accepting an application for construction of a new reactor under either process, the NRC requires an applicant to identify a proposed site and to evaluate the safety of building and operating the reactor at that site. The applicant must demonstrate that the proposed site meets specific regulatory criteria established in 10 CFR Part 100, “Reactor Site Criteria,” to protect health and safety and the environment. To support the environmental review and the staff’s preparation of an environmental impact statement (EIS), the applicant must also identify a range of alternative sites where the reactor could be safely constructed and meet the purpose and need for the project. When preparing the EIS, the NRC staff evaluates and compares the potential environmental impacts from the reactor at the proposed and alternative sites. The NRC staff documents its safety and environmental reviews in a safety evaluation report and the EIS. Issues involving safety and the risk of radiological releases may also be raised in the adjudicatory hearings required before the Commission can issue the license. If the proposed reactor is found to pose an unacceptable risk of contaminating soil, water, or other environmental resources at the proposed site, the Commission may deny the license. If restrictions are necessary to ensure safe operation of the reactor at the site, the Commission staff may establish appropriate license conditions. The NRC also has regulatory tools that rely on continued monitoring and provide the basis for the minimization of risk of contamination. The process has three important aspects: minimization of contamination of the facility, minimization of contamination of the environment, and minimization of generation of waste. |
| **Question No. 17** |
| “The staff recently implemented the very low safety significance issue resolution process (VLSSIR) to improve existing NRC processes so that certain very low safety significance issues that involve licensing-basis questions are promptly resolved without an excessive use of resources, thereby enabling the NRC and licensees to better focus resources on issues of greater safety significance. The process has been used several times, and an effectiveness review concluded that the process is working as intended.”<br>Can you provide some examples of what was or could be considered as a very low safety significance issue? |

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| Answer: The following is a list of reports that contain all the current very low safety-significance issue resolution (VLSSIR) items identified as of November 15, 2022, which can be found in ADAMS under each accession number:<br>• ML20120A599<br>• ML20134J115<br>• ML21015A000<br>• ML22039A020<br>• ML22213A070<br>• ML20135H234<br>• ML21176A042<br>• ML22301A162<br>• ML21076A113<br>• ML21217A331<br>• ML22138A376<br>• ML20356A076<br>• ML22115A161<br>• ML20135H247<br>• ML22301A010<br>• ML20224A354 |
| **Question No. 18** |
| "As discussed in Section 2.3.2.4 of this report, the NRC is exploring ways to improve the data collection process using Mission Analytics Portal-External as a portal for licensee submission of notifications. In addition, the Data Warehouse provides an onsite repository of data that can be more easily transformed and extracted to allow connections between datasets that had previously been siloed. This has provided a substantial improvement in the structured data readily available for analysis and communication."<br><br>Are the SMR-related data already included in the database? |
| Answer: Yes, most SMR data have been entered into the NRC's tracking systems. Licensing work for several of the current SMR applications is entered and tracked via this method. Some of the exploratory work, such as topical reports, may not be tracked in this manner yet, but the agency is working to include more projects. |
| **Question No. 19** |
| "The NRC's Office of Nuclear Reactor Regulation also established the NRC COVID-19 Coordination Team, which is responsible for the following: [...] - identifying possible efficiencies for addressing COVID-19 public health emergency-related work such as approaches to streamline the review and approval of relief requests for sites with refueling outages."<br>Did you experience any operating hours loss due to the pandemic at the smaller scale nuclear facilities, for example research reactors? |
| Answer: Note—When responding to this question, the NRC assumed that "operating hour loss" means a site had to shut down or derate.<br><br>As indicated in the question, the NRC issued letters in several topical areas that described specific information needs that would support expedited NRC staff review of anticipated requests related to Coronavirus Disease 2019 (COVID-19). These letters facilitated the timely submission of concise, but complete applications for licensing solutions to challenges related to COVID-19. The staff was able to respond to these requests in a timeframe that generally |

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| supported the continued operation of the specific licensees.<br><br>Most research and test reactors (RTRs) at colleges and universities experienced a marked downturn in the number of operational hours as a result of the pandemic. As an agency, the NRC considered those RTR facilities that supported critical infrastructure, such as the National Institute of Standards and Technology, the University of Missouri Research Reactor, and General Electric, as priorities and maintained operator licensing examination activities after a short initial delay at the start of the public health emergency. Similar to the power reactors, the RTRs that needed exemptions from certain 10 CFR Part 55, "Operators' Licenses," and requalification requirements were granted exemptions following an approved process. |
| **Question No. 20** |
| "The NRC staff established and communicated additional criteria describing the conditions under which it would expedite review of licensee requests for relaxation of, or exemption from, certain regulatory requirements. [...] The staff reviewed all requests for COVID-19 temporary regulatory relief on a case-by-case basis and granted the requests only if adequate controls were in place to maintain safety and security."<br>In what percentage of the requests could the regulatory relief be issued based on this criteria? |
| <u>Answer</u>: All the COVID-19 related reviews were held to the same standards and criteria that are used in normal licensing reviews. The expedited review process described specific information needs that should be submitted so that the NRC staff could complete the review in a supportive timeframe. The requests were still evaluated against the existing standards and criteria for approval of such requests. |
| **Question No. 25** |
| It is written in the text: "The agency's goal of ensuring openness explicitly recognizes that the public must be informed about, and have a reasonable opportunity to participate meaningfully in, the regulatory process."<br>(1) What does it mean: reasonable opportunity?<br>(2) What is the procedure for taking into account the public opinion or refusal to take such an opinion into account in Nuclear Regulatory Commission (hereinafter—NRC)? |
| <u>Answer</u>:<br>(1) In this context, "reasonable opportunity" means that the agency must provide members of the public with sufficient time and information to understand the grounds for a regulatory decision and a meaningful opportunity to provide their views before the decision is made. If limits are placed on public participation, they must further legitimate goals such as ensuring timely decision-making or efficiently conducted proceedings. This may include, for example, deadlines for the public to submit public comments on proposed regulations or guidance, standards to ensure that requests for hearings on proposed licensing decisions are sufficiently supported and raise a genuine dispute with the application under consideration, and limits placed on the public availability of sensitive information such as proprietary or security-related information.<br><br>(2) The public primarily participates in the NRC's regulatory processes in two ways: providing comments on NRC proposed rules (see section 6.3.6 of the U.S. Ninth National Report) and intervening in licensing proceedings (see section 7.2.2 of the U.S. Ninth National Report). With respect to rulemaking, the NRC is obligated under Federal law to consider all comments received before making a final decision and to respond to all significant comments in writing when it publishes the rule as final. Members of the public who believe |

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| that the agency did not adequately address their comments can seek judicial review of the agency's decision in Federal court. With respect to licensing hearings, the NRC's rules of procedure require those who seek to intervene in a licensing proceeding to sufficiently demonstrate that they would be adversely affected by the proceeding ("standing") and submit at least one "contention" (a statement of law or fact raising a dispute with the application) that conforms to the NRC's hearing requirements. If both conditions are satisfied, the agency will hold a hearing to determine the merits of the contention. If the agency denies admission to the proceeding for failure to meet these requirements, the denial is appealable to the Commission, as well as to the Federal courts. |
| **Question No. 26** |
| It is written in the text: "The staff recently implemented the very low safety significance issue resolution process (VLSSIR) to improve existing NRC processes…".<br>What are the criteria for referring to "very low safety significance issues"? |
| Answer: The two criteria for VLSSIR are documented in Inspection Manual Chapter (IMC) 0612, Appendix B, "Issue Screening Directions," dated August 8, 2022 (ML22019A175). Either criterion can be met:<br><br>Criterion 1: The following are met:<br>• The inspection staff has not been able to conclude that the issue of concern is a violation or licensee standard, as described in Block 2, after considering any licensee provided supporting information on why the issue of concern is not in its licensing basis and any relevant information developed during the inspection process.<br>• The condition surrounding the issue of concern cannot have any potential to be greater than very low significance (i.e., not greater than Green if the issue was determined to be a finding evaluated using the SDP) nor greater than Severity Level IV if the issue was determined to be a violation subject to traditional enforcement.<br>• The resources required to resolve the current licensing basis question would not effectively and efficiently serve the Agency's mission.<br><br>Criterion 2:<br>The issue of concern was evaluated using Office Instruction COM-106, "Technical Assistance Request (TAR) Process," and recommended for no further action because the licensing basis standing is indeterminate, and the TAR Safety Significance Determination has determined the issue to be of very low significance and the issue would not be subject to escalated enforcement if determined to be a violation. |
| **Question No. 31** |
| It is mentioned in the report "The fiscal year (FY) 2022 management and performance challenges are the following: ensuring safety while transforming into a modern, risk-informed regulator".<br>(1) In the effort to transform into a modern, risk informed regulator, what challenges are foreseen/faced with respect to the role of ensuring safety?<br>(2) Could USA provide further details? |
| Answer: The quoted statement comes from the report OIG-22-A-01, "Inspector General's Assessment of the Most Serious Management and Performance Challenges Facing the Nuclear Regulatory Commission in Fiscal Year 2022," dated October 12, 2021 (ML21285A315). The report provides the following additional details: |

**Why is this a serious management and performance challenge?**
The NRC's increasing emphasis on risk-informed regulation necessitates guidance changes, as well as efforts to raise staff awareness of these changes and ensure regulatory consistency. The NRC must also engage external stakeholders to ensure transparency of resulting changes to its licensing and oversight processes.

**Challenge Synopsis**
It has been NRC policy since 1995 to inform regulatory activities with risk insights, thereby balancing deterministic engineering judgment with quantitative analysis based on operating experience. The agency has emphasized this policy in recent years as risk analysis models have become more sophisticated and nuclear power licensees have increasingly used probabilistic safety risk assessment to support changes to their license conditions. Nevertheless, the NRC and the nuclear industry have methodological differences in their respective approaches to probabilistic risk assessment, and agency staff sometimes disagree on the use of risk analysis in regulatory actions such as license amendments and inspection findings. Additionally, advanced reactor designs present unique challenges given the lack of operating experience data to inform risk modeling.

**Ongoing Actions**
The NRC is assessing the risk of aluminum enhanced high energy arc faults at nuclear power plants, mitigation strategies, and possible regulatory action based on assessment results.

The NRC is engaging nuclear power licensees regarding potential expansion of FLEX strategies for mitigating effects of natural disasters on plant safety.

The NRC is performing nuclear power licensing actions using risk information and developing risk-informed, regulatory guidance for licensees in areas such as fire protection, physical security, and digital instrumentation and controls.

**Completed Actions**
The NRC issued staff guidance for integrating risk insights in regulatory decision making across multiple mission areas, such as reactor and material safety, security, and emergency preparedness (NUREG/KM-0016 [ML21071A238]).

The NRC issued staff guidance known as the Risk-Informed Process for Evaluations (RIPE) for evaluating nuclear power plant licensing issues of very low safety significance.

The NRC issued a draft white paper on the use of probabilistic risk assessment to support advanced non-light water reactor licensing.

**Looking ahead: The Office of the Inspector General will continue to monitor developments in this area throughout the year to inform its audit planning work.**

| **Question No. 32** |
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| It is written “NRC staff evaluated it and concluded that the group had adequately addressed each of the five principles of RIDM in RG 1.174, Revision 3, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” dated January 2018 (ML17317A256). The staff also concluded that the effects of the identified issues would have low risk significance for emergency core cooling system performance.” Could USA share further details on consideration of debris accumulation as a low risk significance issue for emergency core cooling system performance? |
| <u>Answer</u>: This part of the report applies only to boiling-water reactors (BWRs), not to pressurized-water reactors (PWRs). BWRs had addressed issues associated with Generic Safety Issue (GSI)-191, “Assessment of Debris Accumulation on PWR Sump Pump Performance,” dated September 14, 2001 (ML022410135), phenomena before the issue was opened for PWRs. Based on the previous BWR responses, the NRC determined that BWRs had adequately addressed the design- and licensing-basis conditions associated with the effects of debris on core cooling. During later work for PWRs, the NRC recognized that additional knowledge gained during the resolution of the issue for PWRs might invalidate some of the BWR conclusions. The industry’s BWR Owners’ Group (BWROG) voluntarily developed a risk-informed approach to evaluate each of the technical areas of concern identified by the NRC staff. The purpose of the evaluation was to ensure that the previous conclusions remain valid considering lessons learned during the PWR analyses. Disparities in the treatment between BWRs and PWRs were documented in NUREG/CR-7011, “Evaluation of Treatment of Effects of Debris in Coolant on ECCS and CSS Performance in Pressurized Water Reactors and Boiling Water Reactors,” issued May 2010 (ML101400088). The BWROG letter, dated November 20, 2017 (ML17326A393), explains its risk-informed approach and the corresponding results. The NRC staff’s technical evaluation of the risk-informed approach and corresponding results can be found in ADAMS (ML18078A061 and ML18058A602). |
| **Question No. 38** |
| Could your country please share some information regarding the willingness of potential nuclear vendors to share information with the regulatory body especially during the research and development phase of accident tolerant fuel? |
| <u>Answer</u>: The Accident Tolerant Fuel (ATF) Project Plan, issued September 2021 (ML21243A298), outlines an enhanced approach to fuel licensing in which the NRC engages with applicants earlier in their research and development phase on many fronts, including routine vendor status meetings, attendance at industry conferences, and presubmittal meetings. The NRC is actively involved in two Electric Power Research Institute industry research frameworks/groups that are coordinating research on ATF, higher burnup, and increased enrichment limits. The first is the Collaborative Research on Advanced Fuel Technologies for Light-Water Reactors (CRAFT). The second is the Extended Storage Collaboration Program. Participation in both research frameworks/groups better prepares the NRC to review future licensing submittals by heightening agency awareness of vendor plans and research activities. Further, the NRC continues to meet routinely with the U.S. Department of Energy (DOE) to share information on ATF status and research, which helps the NRC staff anticipate future reviews and research strategies. |
| **Question No. 39** |
| It would be appreciated if NRC could describe if the desired changes in the “Reactor Oversight Process” are approved now and could comment on the current status of implementation. |

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| Answer: The NRC staff completed the majority of recommended inspection procedure modifications from SECY-19-0067, "Recommendations for Enhancing the Reactor Oversight Process," dated July 16, 2019 (ML19070A050), during the summer of 2022, and they became effective January 1, 2023. The staff issued SECY-22-0053, "Recommendations for Modifying the Reactor Oversight Process Engineering Inspections Periodicity," on June 22, 2022 (ML22060A085), and the Commission unanimously approved the recommendation to change the periodicity of engineering inspections to a 4-year cycle on July 21, 2022. The new 4-year cycle for engineering inspection begins January 1, 2023.<br><br>The staff proposed additional recommendations to the Commission and is awaiting approval. SECY-22-0086, "Recommendations for Revising the Reactor Oversight Process Assessment Program," dated September 16, 2022 (ML22188A221), suggested changes to the treatment of greater-than-green inspection findings and performance indicators. In SECY-22-0087, "Recommendation for Problem Identification and Resolution Team Inspection Frequency," dated September 20, 2022 (ML22145A448), the staff recommended an inspection frequency for the Problem Identification and Resolution Team. In SECY-22-0089, "Recommendation for Enhancing the Emergency Preparedness Significance Determination Process for the Reactor Oversight Process," on September 22, 2022 (ML22189A201), the staff recommended an enhancement to the emergency preparedness. |
| **Question No. 40** |
| It would be appreciated if NRC could deliver the status of the SECY-22-0001, "Final Rule: Emergency Preparedness for Small Modular reactors and Other New Technologies" and an estimated implementation schedule. |
| Answer: As of January 2023, SECY-22-0001, "Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies," is awaiting a Commission decision. If approved by the Commission, the final rule will be effective 30 days after publication in the *Federal Register*. Further schedule updates can be found at https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/active/ruledetails.html?id. |
| **Question No. 41** |
| Could your country please inform about the status and prospected timescale regarding the review of the preliminary safety analysis report for Kairos Power Hermes reactor? |
| Answer: The Hermes test reactor construction permit application review is proceeding on schedule. The schedule calls for the final safety evaluation report and the final environmental impact statement to be completed in September 2023. Following the issuance of these two reports, the NRC Commissioners will hold a hearing on the application. If approved, a permit would be issued after the hearing with the Commissioners. Schedule and status information are available at https://www.nrc.gov/reactors/non-power/new-facility-licensing/hermes-kairos.html. |
| **Question No. 42** |
| It would be appreciated if NRC could elaborate on the status of Vogtle-3 and Vogtle-4. |
| Answer: Southern Nuclear Operating Co. is building Vogtle Electric Generating Plant, Units 3 and 4, the first new commercial nuclear units in the United States in over 30 years. Southern expects the Vogtle Advanced Passive 1,000 Megawatt (AP1000) units to deliver clean energy to over 2.7 million Americans and power more than 500,000 homes and businesses, while producing zero air pollution. The NRC's critical work ensures that these activities are conducted safely.<br><br>On August 3, 2022, the NRC authorized fuel load at Unit 3, the first time that the agency has reached this point in a combined license process. The NRC authorized the plant to operate |

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| after independent verification that the unit had been properly built and that public health and safety will continue to be protected. The authorization to load fuel is done through the NRC's finding (ML20290A282) under 10 CFR 52.103(g). Following the authorization, Vogtle Unit 3 transitioned from the Construction Reactor Oversight Process (cROP) to the Reactor Oversight Process (ROP). On October 13, 2022, Southern began loading fuel in the Unit 3 reactor core. The company began commercial operations in July 2023.<br><br>Vogtle's Unit 4 is about a year behind, with Southern targeting commercial operations by the end of CY 2023. That unit remains under the NRC's cROP. The NRC continues to perform inspections, tests, analyses and acceptance criteria (ITAAC) inspections and verify ITAAC closure notifications for Unit 4. |
| **Question No. 43** |
| It would be appreciated if NRC could share some practical experiences with the Data Warehouse, the Mission Analytics Portal, and the Dashboard. How is data security and integrity guaranteed? |
| Answer: There are many dashboards available through the Mission Analytics Portal (MAP), the vast majority of which draw their data from the Data Warehouse. One example is a dashboard that was created to gather data and generate visuals for operating reactor end-of-year assessments (see IMC 0305, "Operating Reactor Assessment Program," dated November 25, 2019 [ML061520397]). This dashboard uses past inspection data and future inspection plans that are entered into NRC systems to generate the required reports for these assessments.<br><br>As for the data, the dashboard is only fed data from an authoritative source. For example, inspection information is drawn directly from the official NRC application/platform used to store inspection results. The data entered into this application/platform have already undergone the review and approval process to ensure their accuracy. Data are also stored using a cloud service that follows Government requirements for data security to ensure that any sensitive data are retrievable by authorized users. Additionally, MAP is accessible only by internal NRC users, and the agency has the ability to restrict access to certain dashboards or views depending on the sensitivity of the data. |
| **Question No. 44** |
| It would be appreciated if NRC could share their views why from a technical point of view implementation of hardened safety vents is limited to BWR's with Mark I or Mark II [reactor] containment and why the requirements are not codified in NRC regulations. |
| Answer: The NRC staff provides its reasoning for limiting the implementation of hardened safety vents to BWRs with Mark I or Mark II containment in SECY-15-0137, "Proposed Plans for Resolving Open Fukushima Tier 2 and 3 Recommendations," Enclosure 4, "Proposed Resolution Plans for Tier 3 Recommendations 5.2 and 6: Reliable Hardened Vents for Other Containment Designs and Hydrogen Control and Mitigation Inside Containment and Other Buildings," dated October 29, 2015 (ML15254A016).<br><br>Venting Mark I and II containments can help prevent the loss of, and facilitate recovery of, important safety functions, such as reactor core cooling, reactor coolant inventory control, containment cooling, and containment pressure control. As described in NUREG-0933, "Resolution of Generic Safety Issues," issued December 2011 (available at: https://www.nrc.gov/sr0933/index.html), the NRC staff did not identify generic improvements that would apply to Mark III, ice condenser, or large dry containments. Mark III containments have a diversity of ways to provide water to the core, and therefore, reactors with this type of |

containment have a relatively low estimated core damage frequency related to plant transients and malfunctions (on the order of $1x10^{-6}$ per year). Mark III containments are pressure suppression containments and have system interactions between the core cooling and containment functions, like plants with Mark I and II containments. Suppression pool cooling is an important safety function for the plants with Mark III containments; thus, Mark III containments have the capability to power suppression pool cooling equipment in severe accident conditions as opposed to venting. Ice condenser containments are pressure suppression containments, but like other PWR designs, they do not have direct system interactions between core cooling functions and containment functions, as in BWRs. Venting is not a primary method for protecting ice condenser containments; rather, these plants use the presence of the ice and containment sprays to maintain containment pressure and temperature within limits. Like ice condenser containments, large dry containments do not have direct system interactions between core cooling functions and containment functions, as in BWRs. Venting is a not a primary method for protecting large dry containments. Instead, plants use containment sprays or restore containment cooling functions to maintain containment pressure and temperature within limits.

The Commission's denial of the staff's request for rulemaking provides the reasoning for not codifying the requirements for reliable hardened vents in VR-SECY-15-0085, "Evaluation of the Containment Protection and Release Reduction for Mark I and Mark II Boiling Water Reactors Rulemaking Activities (10 CFR Part 50) (RIN-3150-AJ26)," dated August 19, 2015 (ML15231A524), which states the following:

> Order EA-13-109 required all licensees of BWRs with Mark I and Mark II containments to implement requirements for reliable hardened containment vents capable of operation under severe accident conditions. Implementation of this order is currently underway. As discussed in Chairman Burns' vote, from a legal and enforcement perspective, orders are no less robust than other means of imposing regulatory requirements. As a matter of policy, the NRC often conducts rulemaking to make orders generically applicable; however, there is no requirement to do so. For example, Order EA-06-137, "Order Requiring Compliance with Key Radiological Protection Mitigation Strategies," and portions of Order EA-02-026, "Order for Interim Safeguards and Security Compensatory Measures," are still in place with no plans to conduct rulemaking to codify these orders. In this case, Order EA-13-109 is applicable to only a subset of licensees of a specific design, and there is no expectation for a future application to license a new BWR with a Mark I or II containment. As such, there are no clear benefits to codifying this Order as generically applicable from an administrative perspective and, more importantly, there are no safety benefits to codifying the Order as the safety outcome would be identical.

**Question No. 45**

It would be appreciated if NRC could comment on potential plans for a forthcoming IRRS mission.

Answer: The United States believes that Integrated Regulatory Review Service (IRRS) missions provide a valuable and useful independent review of regulatory authorities, as evidenced by the agency's participation in numerous IRRS missions. The NRC staff intends to perform an IRRS self-assessment and provide the results, along with recommendations, to the Commission within the next 2 years. The Commission will determine its next steps with regard to a potential IRRS mission after reviewing the results of the self-assessment.

| Questions No. 48 and 51 |
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| What specific actions have been undertaken by the United States with respect to the “Main General Issues Identified in the Country Group Discussions” (paras. 25–34 of the Final Report of the 7th Review Meeting)? |
| Answer: Note-In responding to this question, the NRC assumed that the requester is referring to paragraph 33 of the 7th Review Meeting President’s report.<br><br>The NRC addressed all major common issues that emerged from the Country Group discussions during the 7th CNS Review Meeting throughout the U.S. Ninth National Report. Please refer to the most relevant sections listed below:<br><br>• Safety Culture—Section 10.3<br>• International Peer Reviews—Sections 2.4 and 8.1.5<br>• Legal Framework and Independence of Regulatory Body—Sections 7.1, 7.2, 8.1.2.2, and 8.2<br>• Financial and Human Resources—Sections 8.1.6 and 9.5<br>• Knowledge Management—Section 8.1.6.2<br>• Supply Chain—Article 13 and Section 13.6<br>• Managing the Safety of Aging Nuclear Facilities and Plant Life Extension—Article 14 and Section 14.1.4<br>• Emergency Preparedness—Article 16<br>• Stakeholder Consultation and Communication—Sections 6.3.6, 8.1.7, 9.4, 16.2, and 17.5 |
| **Question No. 55** |
| It is written in the text: “On January 3, 2022, the draft final rule package was submitted to the Commission for its consideration as SECY-22-0001, “Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies”:<br>(1) Is the regulation "Emergency Preparedness for Small Modular Reactors and Other New Technologies" currently in force?<br>(2) What number of new nuclear power plants with small modular reactors is planned to be considered in 2023 taking into account this regulation?<br>(3) Will this regulation apply to research and isotope production reactors (current and future)? |
| Answer:<br>(1) No. The draft final rule package is with the Commission for its consideration and decision.<br><br>(2) As stated in “Regulatory Analysis for the Final Rule: Emergency Preparedness for Small Modular Reactors and Other New Technologies,” dated January 3, 2022 (ML21200A079), the NRC expects four applicants in 2023.<br><br>(3) Currently operating nonpower reactors are not within the scope of the rule. Future medical radioisotope facilities and research and test reactors licensed under 10 CFR Part 50 after the effective date of the final rule are within its scope. |
| **Question No. 56** |
| (1) Are emergency I&C systems implemented at nuclear power plants to monitor the reactor plant parameters in case of a severe accident?<br>(2) Are the severe accident management guidelines available at the NPP for all states of the reactor and spent fuel pool?<br>(3) Are there computational (technical) substantiations for severe accident management guidelines?<br>(4) Are the computation software tools for severe accident analysis certified? |

Answer:

(1) In NRC-licensed operating NPPs, emergency instrumentation and control (I&C) systems specifically designed to monitor reactor plant parameters in the event of a severe accident have not been implemented. Instead, as a result of the lessons learned from the accident at the Fukushima Dai-ichi NPP in Japan, the NRC required licensees to provide safety enhancements to specific I&C equipment (i.e., spent fuel pool level instrumentation) for monitoring key plant parameters during severe accident conditions.

In addition, the event response framework for implementing operator-initiated severe accident mitigation actions using the installed design-basis accident event monitoring equipment at operating NPPs was enhanced to address equipment reliability and indication uncertainty during severe accidents. The need for new requirements for enhanced reactor and containment instrumentation to support operator actions during severe accident conditions was considered as part of the rulemaking process for the mitigation of beyond-design-basis events rule (10 CFR 50.155). It was determined that new requirements for enhanced reactor and containment I&C systems were not warranted because several concurrent post-Fukushima event actions were implemented to incorporate enhanced mitigation strategies, such as the addition of diverse and flexible (FLEX) backup power and backup temporary shutdown cooling capabilities, reliable hardened venting capability for BWR Mark I and Mark II containments, as well as the availability of severe accident management guidelines (SAMGs) and an event response framework that integrates the SAMGs with the emergency operating procedures. Operating plant licensees have developed technical support guidance for the SAMGs that include assessment techniques for evaluating the indications of plant parameter values that are presented by design-basis accident monitoring equipment for determining the status of plant safety functions during severe accident conditions.

For proposed new reactors, requirements (e.g., 10 CFR 50.34(f)(2)(xix) and 10 CFR 52.47(a)(8)) have been implemented for applicants to present a description and analysis of design features for the prevention and mitigation of severe accidents, which includes instrumentation adequate for monitoring plant conditions following an accident that includes core damage.

(2) While the NRC does not require facilities to develop severe accident management guidelines, the industry has committed to developing and updating them. The guidelines are intended for a severe accident with significant fuel damage, and they provide strategies to stop further fuel damage and to limit releases to the environment. The guidelines are strategies, not procedures, so that they provide flexibility to address a broad range of possible conditions regardless of the state of the reactor and spent fuel pool. Following the March 2011 accident at Fukushima Dai-ichi, the industry updated the guidelines.

(3) SAMGs are an industry initiative that all facilities have put in place. The BWROG and Pressurized Water Reactor Owners' Group (PWROG) use industry guidance to develop standalone SAMGs for their respective reactor designs. The development of these guidance documents typically utilizes sophisticated severe accident computer codes to model severe accident phenomenology.

(4) The NRC uses Methods for Estimation of Leakages and Consequences of Releases (MELCOR) to perform confirmatory analyses. MELCOR is a fully integrated,

engineering-level computer code developed by Sandia National Laboratories for the NRC to model the progression of severe accidents in NPPs. MELCOR is developed under strict software quality assurance at Sandia. The code is verified, validated, and maintained under a quality assurance program. MELCOR has a large database as a result of extensive application in the United States and other countries. Documentation reporting on these assessments is available from Sandia National Laboratories.

**Question No. 62**

The Report reads: "…while significant progress was made to minimize the number of plants operating with fuel defects (2021 was a record year), additional effort will be needed to sustain this performance. The Institute continues working closely with industry stakeholders to close these remaining performance gaps." Could you please specify what additional measures are planned to close the remaining performance gaps?

Answer: A 2019 Institute of Nuclear Power Operations (INPO) Event Report contains requirements for closing the gaps identified. INPO is evaluating the implementation of those recommendations by each member. Specific technical assistance and support are being provided to plants that have active fuel defects or have a history of fuel defects. A fuel reliability working group (that consists of member utilities, INPO, fuel vendors, and the Electric Power Research Institute (EPRI)) is focused on further improvements for BWRs. These improvements include engineered features such as improved filtration capabilities, enhanced guidance for below the core plate debris inspection and removal, and fuel bundle bottom nozzle cleaning.

**Question No. 65**

The NRC has been cooperating with the Canadian Nuclear Safety Commission under the memorandum of cooperation.

(1) How cooperation with regard to SMR reviews has been organized between NRC and CNSC?
(2) What are the roles, responsibilities and scopes in cooperative reviews of SMRs?

Answer: On August 15, 2019, the Canadian Nuclear Safety Commission (CNSC) and the NRC signed a memorandum of cooperation (MOC) to increase collaboration on the technical reviews of advanced reactor and SMR technologies (ML19275D578). This MOC further expanded the exchange of technical information and cooperation in nuclear safety matters between the NRC and CNSC under the provisions of the memorandum of understanding signed in 2017. The USNRC-CNSC Steering Committee, which was established by mutual decision by charter dated August 10, 2017, oversees the activities of the MOC. A subcommittee of the Steering Committee called the Advanced Reactor Technologies (ART) and Small Modular Reactors (SMR) Sub Committee coordinates the activities under the MOC. The ART-SMR Sub Committee established a Terms of Reference document in January 2020 that supports the MOC and governs the administration of the ART-SMR Sub Committee, the roles and responsibilities, the desired outputs, and communication protocol (ML21021A265). The ART-SMR Sub Committee reviews and approves new work plans and the work plan deliverables and assesses the progress of the activities associated with the work plans. The collaborative projects under the MOC and the joint reports issued under the MOC can be found on the NRC's public website: https://www.nrc.gov/reactors/new-reactors/advanced/international-cooperation/collaboration-with-canada.html and https://www.nrc.gov/reactors/new-reactors/advanced/international-cooperation/nrc-cnsc-moc/joint-reports.html. On September 2022, the CNSC and NRC signed a charter governing a new project for the collaboration activities associated with General Electric Hitachi's BWRX-300 SMR design (ML22284A024).

| Question No. 70 |
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| (1) Has the NRC made any changes to its staffing structure to accommodate the upcoming SMR licensing process?<br>(2) The change in standards (NUREG-0800) is mentioned, are any changes in regulations planned, and is the approval NuScale design seen as a success story that can be applied to other design?<br>(3) What are the lessons learned from this novel process? |
| <u>Answer</u>:<br>(1) Yes, the NRC has made improvements to the structure and staffing for its upcoming and ongoing licensing reviews of SMRs as (1) the number of applicants has grown, and (2) the agency has incorporated lessons learned and best practices from previous reviews. The NRC is structured with two separate divisions within the Office of Nuclear Reactor Regulation (NRR) for licensing advanced non-LWRs and for licensing large LWRs and light-water SMRs.<br><br>(2) Yes, several changes are planned for the NRC's regulations associated with new and advanced reactor licensing. Currently, the staff has a proposed rule, suggesting policy and regulatory updates to ensure consistency in new reactor licensing reviews, regardless of the licensing process an applicant chooses to use. This would align the regulatory requirements of 10 CFR Part 50 and 10 CFR Part 52 and associated documents, such as regulatory guides and affected chapters of NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP). The rule would bring Part 50 requirements in line with requirements in Part 52 and would update both Parts 50 and 52 with lessons learned from recent Part 52 license application reviews.<br><br>The NRC has also recently proposed establishing an optional technology-inclusive regulatory framework (10 CFR Part 53, "Risk Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors") for use by applicants for new commercial advanced nuclear reactors. The regulatory requirements developed in this rulemaking would use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of ARTs. The NRC staff is expecting to issue the final rule by July 2025.<br><br>The NuScale design certification is a success in that it proved that the current 10 CFR Part 52 regulatory framework can be implemented for a nonconventional reactor design, such as an SMR. Within the 10 CFR Part 52 framework, the NRC staff was able to evaluate and approve regulatory exemptions to requirements that were not needed for certain novel (new) design aspects of NuScale's design. Therefore, the 10 CFR Part 52 framework could be used for non-LWRs with appropriate exemptions as determined through the staff's review, which showed that most, if not all, applicants can also use the process.<br><br>(3) NRC processes and procedures for reviewing new and advanced reactor license applications continues to evolve to ensure that the most risk-significant issues are given the most attention, providing an effective and efficient review of future SMR applications. This builds on the successful review of the NuScale design certification (DC) application with lessons learned that can be applied to future SMR licensing reviews. The NuScale lessons-learned report can be found in ADAMS ML22088A161. |

| Question No. 71 identical to 74 |
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| In this page of the report, it is said: The NRC staff completed a “Comprehensive Review of the Reactor Oversight Process Problem Identification and Resolution Inspection Program,” dated November 12, 2020. Recommended revisions to this inspection program seek to improve inspections to verify that licensees are identifying, evaluating, and correcting issues. These recommendations are being considered for implementation at the beginning of the 2024 Reactor Oversight Process biennial cycle. The staff also completed an effectiveness review of the cross-cutting issues process, recommending minor changes to the process to make it more proactive in identifying cross-cutting concerns before they lead to more safety significant issues. The staff discusses the recommendations in a memorandum entitled “Dispositioning of Cross-Cutting Issues Program Effectiveness Review Recommendations,” dated September 17, 2021. Implementation of those recommendations that were approved is in progress.<br><br>Question: Could you indicate which are the most important recommendations on the Cross-Cutting Issues Program mention in this page of the report? |
| Answer: The full list of recommendations from the Cross-Cutting Issues Program Effectiveness Review appears on pages 12 and 13 of the full report, dated September 21, 2020, and available in ADAMS (ML20239A835 and ML20239A806). The memo dated September 17, 2021 (ML21209A993), documented that two out of the seven recommendations from the full report were approved for implementation. The recommendations in the effectiveness review report were documented in two groups—Group 1 recommendations that would result in minor improvements to the program at a minor implementation cost and Group 2 recommendations that would result in significant program improvements but at a higher implementation cost. The two recommendations approved for implementation were from the list of Group 1 recommendations and would be expected to result in minimal improvement to the Cross-Cutting Issues Program. |
| **Question No. 72 repeat 75** |
| In this page, the report says: NRC regulations provide a strong framework to ensure safety and security. However, the regulations support the current operating fleet of large light-water reactors and do not specifically account for nonlight-water technologies. The NRC wants to ensure that its regulatory framework does not present a barrier to safety enhancements and innovation.<br><br>Question: Could you please indicate if the NRC is working on the development of general design criteria specifically applicable to SMR or non-light water reactors? |
| Answer: Under the provisions of 10 CFR 52.47, 52.79, 52.137, and 52.157, an application for a design certification, combined license, design approval, or manufacturing license, respectively, must include the principal design criteria (PDC) for a proposed facility. The PDC establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. The general design criteria (GDC) in Appendix A to 10 CFR Part 50 were developed for LWRs and provide the minimum requirements for PDC for LWRs, including light-water-cooled SMRs. The GDC also provide guidance in establishing the PDC for non-LWRs. On April 3, 2018, the NRC issued RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors” (ML17325A611), to provide guidance for developing PDC for non-LWRs and include a set of advanced reactor design criteria (ARDC) in appendix A, sodium-cooled fast reactor design criteria (SFR-DC) in appendix B, and modular |

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| high-temperature gas-cooled reactor design criteria (MHTGR-DC) in appendix C. |
| **Question No. 74** |
| In this page of the report, it is said: The NRC staff completed a “Comprehensive Review of the Reactor Oversight Process Problem Identification and Resolution Inspection Program,” dated November 12, 2020. Recommended revisions to this inspection program seek to improve inspections to verify that licensees are identifying, evaluating, and correcting issues. These recommendations are being considered for implementation at the beginning of the 2024 Reactor Oversight Process biennial cycle. The staff also completed an effectiveness review of the cross-cutting issues process, recommending minor changes to the process to make it more proactive in identifying cross-cutting concerns before they lead to more safety significant issues. The staff discusses the recommendations in a memorandum entitled “Dispositioning of Cross-Cutting Issues Program Effectiveness Review Recommendations,” dated September 17, 2021. Implementation of those recommendations that were approved is in progress.<br><br>Question: Could you indicate which are the most important recommendations on the Cross-Cutting Issues Program mention in this page of the report? |
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| **Question No. 75** |
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| Answer: Under the provisions of 10 CFR 52.47, 52.79, 52.137, and 52.157, an application for a design certification, combined license, design approval, or manufacturing license, respectively, must include the principal design criteria (PDC) for a proposed facility. The PDC establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety; that is, SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. The general design criteria (GDC) in Appendix A to 10 CFR Part 50 were developed for LWRs and provide the minimum requirements for PDC for LWRs, including light-water-cooled SMRs. The GDC also provide guidance in establishing the PDC for non-LWRs. On April 3, 2018, the NRC issued RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors” (ML17325A611), which provides guidance for developing PDC for non-LWRs and includes a set of advanced reactor design criteria (ARDC) in appendix A, |

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| sodium-cooled fast reactor design criteria (SFR-DC) in appendix B, and modular high-temperature gas-cooled reactor design criteria (MHTGR-DC) in appendix C. |
| **Question No. 79** |
| (1) What will be basis for review/revision of EAB/LPZ/EPZ distances for SMRs (source inventory or CDF or both)?<br>(2) Is it possible to expect any benefits for advanced large LWRs due to decreased CDF/LERF? |
| Answer:<br>(1) There are separate bases and criteria for determining the respective exclusion area boundary (EAB), low population zone (LPZ), and emergency planning zone (EPZ) distances as they serve different regulatory purposes.<br><br>EAB means the area surrounding the reactor, in which the reactor licensee has the authority to determine all activities including exclusion or removal of personnel and property from the area.<br><br>LPZ means the area immediately surrounding the exclusion area, which contains residents, the total number and density of which are such that there is a reasonable probability that appropriate protective measures could be taken in their behalf in the event of a serious accident. The EAB and LPZ distance requirements are applicable for SMRs. The safety analysis for a power reactor must demonstrate that the offsite radiological consequences of postulated accidents are not in excess of 250 millisieverts total effective dose equivalent (TEDE) to an individual located at any point on the EAB for any 2-hour period following the onset of the postulated fission product release. The analysis must also demonstrates that an individual located at any point on the outer boundary of the LPZ, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage), would not receive a TEDE in excess of 250 millisieverts.<br><br>EPZs are used to simplify protective action decision-making when such decisions may be time constrained. Under the draft final rule in SECY-22-0001, the need for a plume exposure pathway EPZ is determined through the use of two criteria. The first criterion is that the plume exposure pathway EPZ is the area within which public dose is projected to exceed 10 millisieverts TEDE over 96 hours from the release of radioactive materials from the facility, considering accident likelihood and source term, timing of the accident sequence, and meteorology. The second criterion is that the plume exposure pathway EPZ is the area where predetermined, prompt protective measures are warranted. EPZs for SMRs are expected to be scalable in size. However, the EPZ size does not change the requirements for emergency planning; it only sets physical bounds on the planning.<br><br>(2) Decreasing the likelihood of core damage frequency (CDF) and large early release frequency (LERF) in design has the safety benefit of reducing risk, regardless of the EAB/LPZ/EPZ distances. Safety enhancements in design are credited through a graded approach to emergency preparedness in which the requirements adjust commensurate to the risk of the facility. |
| **Question No. 80** |
| Are you expecting any additional siting requirements or additional operation limits introduction for NPPs due to intensification of climate change impact? |
| Answer: The NRC does not anticipate new siting requirements related to presumed changes |

to the climate. Site characteristics specific to meteorological phenomena, among other natural phenomena, are already considered per GDC 2, "Design bases for protection against natural phenomena," in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50, among others. Acceptable frequencies of occurrence of those phenomena are considered for design purposes via specific regulatory guidance. It is important that the occurrence of a single climate-related event be viewed in that context. However, from an operational standpoint, a licensee is obligated to be aware of conditions that may change at its site and adjust the relevant technical specifications, operating procedures, or both accordingly through the license amendment process.

**Question No. 81**

Can you elaborate, on what is meant by the term "scalable approach" in determining the plume phase emergency zone for small modular reactors?

Answer: The term scalable approach means scaling the size of the EPZ to the risk of the facility without unwarranted regulatory burden. The scalable EPZ size has two criteria: (1) a dose versus distance analysis from a spectrum of accidents, tempered by accident likelihood and other considerations, and (2) a functional requirement as the EPZ is the area where predetermined, prompt protective measures are warranted.

**Question No. 113**

The report states that the NRC considers four hypothetical future scenarios in which the NRC might operate in 2030 and beyond in the Futures Assessment effort. Could you share the insights provided by NRC employees and external stakeholders to identify these scenarios?

Answer: "The Dynamic Futures for NRC Mission Areas," issued February 2019 (ML19022A178), describes these four scenarios in greater detail. The external environment in which the NRC will operate is likely to change significantly in the future. These changes extend beyond changes in the nuclear industry that the NRC regulates to changes in other industries such as renewable energy or electric vehicles that have a second-order effect on the work of the NRC. These changes will likely be complex, but to contextualize the hypothetical and to ground the conversation, this report identifies four potential futures or scenarios that hinge on two main axes: (1) the demand for nuclear power in the United States and (2) the level of innovation in nuclear reactors globally.

The four futures are used throughout this report to describe market, technology, and policy factors that shape the nuclear industry and its impact on the NRC. The four futures have titles that are selected simply to reflect the thrust of their narratives and make the scenario easy to remember. The titles are "Nuclear Takes Off," "What's Old Is New Again," "Gone with the Wind," and "Great Idea, But Not for U.S." These are intended to be easy to remember labels; they are not intended to connote "good" or "bad" futures, only to stimulate discussion. The scenarios selected aim to stretch mindsets on how the NRC will face specific challenges and opportunities as it delivers on its mission. These narratives should be recognized as a tool to facilitate the conceptualization of the future of the nuclear industry and its impact on the NRC, rather than as concrete forecasts of the future. By structuring plausible futures within a framework, these narratives provide a systematic approach for exploring the future and generating hypotheses that expand perceptions of what may come. The actual future of the nuclear industry may include aspects of several of the nuclear narrative descriptions.

**Question No. 116**

The section deals with the vulnerability of NPP designs, which is associated with loss of external power supply due to damage, including damage of power supply lines. Modifications are made to minimize the loss of external power supply to maintain safety functions. What modifications are implemented at NPPs for this purpose?

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| Answer: Section 2.3.1.6 of the of the U.S. Ninth National Report describes the design vulnerabilities associated with open phase condition (OPC) in offsite power systems at NPPs and implementation to address these vulnerabilities. This section does not describe the design vulnerabilities associated with loss of external power supply (or loss of offsite power (LOOP)) as mentioned in the question. The OPC may occur concurrently with a LOOP, but it does not necessarily result in a LOOP. Modifications at NPPs to address the design vulnerabilities associated with OPC include installation of equipment to detect an OPC, initiate alarm in the main control room, and isolate the affected offsite power from the safety busses either automatically or manually as appropriate. |
| **Question No. 133** |
| The U.S. report is very comprehensive and provides a lot of detailed information that is useful and interesting both from the perspective of demonstrating the fulfillment of the obligations under the Convention on Nuclear Safety and from the perspective of experience sharing. |
| Answer: Thank you for your comments and observations. The NRC appreciates the positive feedback. |
| **Question No. 134** |
| Highlighting the changes from the previous report is useful in identifying new developments. We consider this a good practice worth of adopting. |
| Answer: Thank you for your comments and observations. The NRC appreciates the positive feedback. |
| **Question No. 148** |
| Have any requirements been changed or improvements been requested to take into account the feedback from the COVID-19 pandemic period? On which topics? |
| Answer: Generally, the approaches that were developed (as described in section 2.3.2.6 of the U.S. Ninth National Report) would be more appropriate for situations where there is a defined externally driven scenario that would likely result in a large, but temporary, spike in licensing requests. As such the approaches developed are generally not as practical to implement for day-to-day licensing activities during normal times. The NRC staff has, however, preserved the approaches developed and implemented during the COVID-19 response so that they are available as models should another similar situation arise. Similarly, for the NRC's inspection process, the use of information technology resources for oversight activities was noted to be an overall improvement to the traditional inspection process. |
| **Question No. 153** |
| All U.S. operating power reactor licensees have completed the implementation of the safety enhancements required by the mitigation strategies, the spent fuel pool (SFP) instrumentation and the reliable hardened containment vent orders. Could NRC specify what are these main safety improvements that have been implemented with regard to severe accident mitigation? |
| Answer: Severe accident mitigation Order EA-12-049, "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," dated March 12, 2012 (ML12054A736), is now codified in the CFR (10 CFR 50.155). This regulation requires operating nuclear power reactors to develop strategies and guidelines for beyond-design-basis external events and extensive damage mitigation guidelines, have equipment (such as portable pumps, generators, associated cabling, and ability to position the equipment) protected from the effects of natural phenomena with sufficient capacity and capability to mitigate beyond-design-basis external events, and train personnel who perform activities related to beyond-design-basis external events and extensive damage mitigation. RG 1.226, "Flexible Mitigation Strategies for Beyond-Design-Basis Events, issued June 2019 (ML19058A012), identifies methods and procedures the NRC staff considers acceptable for |

nuclear power reactor applicants and licensees to demonstrate compliance with 10 CFR 50.155.

Spent Fuel Pool Instrumentation—During the Fukushima Dai-ichi accident, plant operators lost the ability to cool the spent fuel pools and determine water level in the pools. Without sufficient water inventory, spent fuel rods could overheat and potentially release significant amounts of radiation. It was determined that the spent fuel at Fukushima remained covered, but attention and limited resources were diverted from more important tasks during the accident. The NRC required all U.S. NPPs to install water level instrumentation in their spent fuel pools. The instrumentation reports at least three distinct water levels: (1) normal level, (2) low level but still enough to shield workers above the pools from radiation, and (3) a level near the top of the spent fuel rods where more water should be added without delay.

Hardened Containment Venting System—The Fukushima accident disabled the plant's reactor core cooling systems, causing heat and pressure to build within the containment buildings, eventually damaging the buildings and allowing release of radioactive material to the environment. Following the accident, the NRC issued an order requiring all U.S. NPPs similar in design to the Fukushima plants to improve or install a reliable, hardened vent to remove heat and pressure before potential reactor core damage. The agency updated the order to ensure that the vents would also function in conditions following core damage.

**Question No. 154**

IAEA, GSR part 1, requirement 33, states "Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained." Does NRC have internal rules about the periodicity for revising regulations and guides?

Answer: The NRC follows its "Final Plan for Retrospective Analysis of Existing Rules," dated January 24, 2014 (ML14002A441), to review existing significant regulations and identify regulations that can be made more effective or less burdensome while achieving regulatory objectives. The Final Plan addresses the NRC's methodology for prioritizing its rulemaking activities, as well as previous and ongoing efforts to update the agency's regulations on a systematic, ongoing basis. The NRC's Final Plan builds on the agency's longstanding focus on ensuring that its regulations are effective, efficient, and up to date, recognizing the agency's established processes to build a sound regulatory framework.

Additionally, the NRC's rulemaking petition process is the system by which any member of the public can request that the NRC develop, modify, or rescind a regulation. The staff considers applicable international safety and technical standards and relevant operating experience during all stages of prerulemaking and rulemaking. Additional information on this process is available on the NRC's public website: https://www.nrc.gov/about-nrc/regulatory/rulemaking/petition-rule.html.

In addition, in accordance with the NRC's Management Directive 6.6, "Regulatory Guides," approved July 19, 2022 (ML22010A233), the staff reviews regulatory guides every 10 years or sooner to determine whether the guide should be revised, withdrawn, or is satisfactory as it is. As in rulemaking reviews, the staff considers international safety and technical standards during its review of regulatory guides when guidance documents are initially issued and when they are revised.

**Question No. 155**

Consistent with the requirements of Nuclear Energy Innovation and Modernization Act, the NRC staff is developing a risk-informed, technology-inclusive regulatory framework for

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| optional use by applicants for new commercial advanced nuclear reactor licenses, which it plans to establish by July 31, 2025.<br>(1) Is there a political commitment or support to build or to develop SMRs? If yes, for what use?<br>(2) What are the ongoing projects and what are the perspectives in 2030? 2040?<br>(3) Will these projects rely on proven or on new technologies?<br>(4) Will these projects be first of a kind or reactors with abroad operating experience?<br>(5) Is there a particular type of reactors that is considered in the USA to be more mature or more suited to USA needs? |
| Answer:<br>(1) Consistent with its mission as an independent safety regulator, the NRC does not have a role in promoting nuclear power. The DOE's Advanced Reactor Demonstration Program is aimed at speeding the demonstration of advanced reactors through cost-shared partnerships with U.S. industry. Additional information can be found at https://www.energy.gov/ne/advanced-reactor-demonstration-program. The DOE has also provided funding for light-water SMR projects, including the design certification of the NuScale design. Additional information is available at https://www.energy.gov/ne/advanced-small-modular-reactors-smrs.<br><br>(2) The NRC staff is reviewing two construction permit (CP) applications for nonpower non-light-water reactors (non-LWRs) and is increasing preapplication engagement with prospective applicants for commercial non-LWRs and light-water SMRs. The Kairos Power Fluoride Salt Cooled, High Temperature Non-Power Reactor (Hermes) CP application was docketed for detailed review at the end of 2021. The Abilene Christian University CP application for a molten salt (liquid-fueled) nonpower research reactor was docketed for detailed review in November 2022.<br><br>The DOE would be in a better position to forecast interest in new nuclear projects in the 2030 to 2040 timeframe. However, the NRC is engaged with multiple entities in preapplication discussion for potential applications in the future. Additional information about non-LWR licensing and preapplication reviews is available at https://www.nrc.gov/reactors/new-reactors/advanced/licensing-activities.html and for light-water SMR preapplication reviews at https://www.nrc.gov/reactors/new-reactors/smr/licensing-activities.html.<br><br>(3) A variety of designs are under development in the United States with varying degrees of prior operating experience. In accordance with NRC regulations at 10 CFR 50.43(e), the performance of each safety feature of the design must be demonstrated through either analysis, appropriate test programs, experience, or a combination of these methods. If a prototype plant is used to comply with the testing requirements, then the NRC may impose additional requirements on siting, safety features, or operational conditions for the prototype plant to protect the public and the plant staff from the possible consequences of accidents during the testing period. For these reasons, developers are typically conducting separate effects tests and integral effects tests, and in some cases, planning to construct and operate nonpower test facilities under the licensing of the NRC or the authorization of the DOE to obtain the necessary data to support their safety case.<br><br>(4) The specific designs currently proposed or planned in the United States have not been operated internationally; however, some of these designs build on decades of domestic and in some cases international operation, research, and development; for example, |

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| pebble bed reactors have been operated in other countries.<br><br>(5) There is a range of maturity level of the designs being proposed in the United States. The light-water SMR designs leverage decades of light-water reactor experience in the United States. Non-LWR developers are also leveraging significant experience with non-LWR fuel testing; for example, several non-LWR developers are using the extensive testing of the TRi-structural ISOtropic particle fuel (TRISO) funded by the U.S. DOE to support fuel qualification for gas-cooled and molten-salt-cooled reactor designs that use TRISO fuel. |
| **Question No. 156** |
| In February 2022, NRC Commission issued a decision stating that further environmental review is required for subsequent license renewal applications. What is the context of this decision? |
| Answer: On February 24, 2022, the Commission issued three orders (Commission Legal Issuance (CLI)-22-02, CLI-22-03, and CLI-22-04) addressing subsequent license renewal (SLR) proceedings for 5 operating nuclear plants, affecting a total of 11 units. Specifically, the Commission concluded that NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants" (LR GEIS), which the agency relies on in part to meet its obligations under the National Environmental Policy Act (NEPA), did not consider the impacts of continued nuclear power operations during an SLR term (60 to 80 years).<br><br>The primary purpose of the LR GEIS is to identify all environmental issues for license renewal and evaluate those environmental impacts considered to be generic for all, or a distinct subset of, NPPs. The LR GEIS also identifies and provides information on issues that need to be addressed in plant-specific environmental reviews for NPP license renewals. The NRC documents these reviews in supplemental environmental impact statements (SEISs) to the LR GEIS that is issued for each plant's license renewal.<br><br>Additionally, the Commission issued a Staff Requirements Memorandum (SRM)-SECY-21-0066, "Staff Requirements—SECY-21-0066—Rulemaking Plan for Renewing Nuclear Power Plant Operating Licenses—Environmental Review (RIN 3150-AK32; NRC-2018-0296)," dated February 24, 2022 (ML22053A308), directing the staff to develop a rulemaking plan that aligns with the Commission's Orders in CLI-22-03, CLI-22-02, and CLI-22-04. The SRM also directed the staff to include in the rulemaking plan a proposal to remove the word "initial" from 10 CFR 51.53(c)(3) and to revise the LR GEIS and Table B-1 in Appendix B, "Environmental Effect of Renewing the Operating License of a Nuclear Power Plant," to 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," and associated guidance to fully support SLR environmental reviews. On March 25, 2022, the staff submitted SECY-22-0024, "Rulemaking Plan for Renewing Nuclear Power Plant Operating Licenses—Environmental Review (RIN 3150-AK32; NRC-2018-0296)" (ML22062B643), requesting Commission approval to initiate a rulemaking that would align with the Commission's adjudicatory orders to include revising the LR GEIS and Table B-1 in 10 CFR Part 51. The staff also requested Commission approval to make other needed updates to the LR GEIS to account for changes to applicable laws and regulations, new data, and experience in conducting similar environmental reviews. On April 5, 2022, the Commission issued SRM-SECY-22-0024 (ML22096A035), approving the staff's recommendation to proceed with the rulemaking. The Commission directed the staff to conduct the rulemaking within 24 months. Upon receiving the Commission's approval, the NRC staff immediately began to revise the LR GEIS and Table B-1 on an expedited schedule in accordance with Commission direction. The proposed rule package, including the draft revised LR GEIS, was submitted to the Commission by |

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| SECY-22-0109, "Proposed Rule: Renewing Nuclear Power Plant Operating Licenses—Environmental Review (RIN 3150-AK32; NRC-2018-0296)," dated December 6, 2022 (ML22165A003), and was made publicly available on December 20, 2022.<br><br>The draft revised LR GEIS includes an evaluation of the environmental issues and findings of the 2013 LR GEIS and updates the analysis and assumptions to fully support SLR and continue to support initial license renewal. Lessons learned, knowledge gained, and experience from license renewal environmental reviews performed by the NRC staff since development of the 2013 LR GEIS provided a significant source of new information for this assessment. In addition, new scientific research, changes in environmental regulations and impact methodology, and other new information were considered in evaluating the significance of impacts associated with initial license renewal and SLR. Public comments on previous plant-specific license renewal reviews also were analyzed to assess the existing environmental issues and identify new ones.<br><br>In updating Table B-1 in Appendix B to 10 CFR Part 51, the NRC staff considered the need to modify, add to, or delete any of the 78 environmental issues in the 2013 LR GEIS and codified in Table B-1. This evaluation identified 80 environmental issues, which are considered in detail in the draft revised LR GEIS. The staff determined that 59 belonged in Category 1 (i.e., generically resolved) and would not require additional plant-specific analysis. Of the remaining 21 issues, 20 were determined to be Category 2, and 1 issue remained uncategorized. None of the 78 environmental issues identified in Table B-1 and evaluated in the 2013 LR GEIS were eliminated, but certain issues were consolidated, one issue was subdivided into three separate issues, and three new issues were added. |
| **Question No. 157** |
| Challenge: The last IRRS mission in the USA was hosted in 2010. The USA should consider to host a full scope IRRS mission. |
| Answer: The United States believes that IRRS missions provide a valuable and useful independent review of regulatory authorities, as evidenced by its participation in many IRRS missions. The NRC staff intends to perform an IRRS self-assessment and provide the results, along with recommendations, to the Commission within the next 2 years. The Commission will determine its next steps with regard to a potential IRRS mission after reviewing the results of the self-assessment. |
| **Question No. 158** |
| Good Practice: The report highlights the recent development of data analytics tools and dashboards to summarize and highlight trends in the Reactor Oversight Process. In particular, an operating reactor analytics Web site and several dashboards were deployed in 2021 to give the public access to currently available information but in a format that is much easier to understand. These projects can be considered as a Good practice. |
| Answer: Thank you for your comments and observations. The agency appreciates the positive feedback. |
| **Question No. 159** |
| Area of Good Performance: NRC shared various lessons learned and actions to ensure its readiness to transition new reactors from construction to operations (notably the Vogtle Readiness Group and the Vogtle Project Office) |
| Answer: Thank you for your comments and observations. The agency appreciates the positive feedback. |
| **Question No. 171** |

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| Area of Good Performance: the sub-section 2.3.1.10 of the U.S. Ninth National Report about transformation at the NRC, NRC points out that their regulations support the current operating fleet of large light-water reactors, but do not specifically account for non-light-water technologies. The NRC wants to ensure that its regulatory framework does not present a barrier to safety enhancements and innovation, and has identified the need to become more agile, efficient, and effective. In this process, NRC has engaged the staff in various ways to best benefit of the “collective wisdom of the staff”. The staff engagement to strategic planning of the transformation could be considered as a good performance. |
| Answer: Thank you for your comments and observations. The agency appreciates the positive feedback. |
| **Question No. 172** |
| Area of Good Performance: As part of HR management, the NRC’s competence and knowledge management initiatives can be regarded as an area of good performance. These include e.g., investing in a competency model initiative that helps in identifying development needs, programs for capturing and preserving knowledge, and collaborative platform for learning and knowledge. |
| Answer: Thank you for your comments and observations. The agency appreciates the positive feedback. |
| **Question No. 173** |
| Challenge: It could be expected that:<br>(1) the current fast development of new innovative reactor and fuel concepts (including e.g. micro reactors and TRISO fuel), and resulting licensing demands, and<br>(2) delays caused by the pandemic in some oversight activities, might create challenges for NRC human and financial resources. |
| Answer:<br>(1) To address potential human resource challenges, the NRC included advanced reactor licensing in the same division as nonpower production and utilization facility licensing to allow the staff to leverage synergies and experience in the licensing of novel technologies, such as by using experience gained from the initial licensing of medical radioisotope facilities. Further, to conduct non-LWR application reviews and prepare for applications, the NRC reassigned subject matter experts from critical disciplines to the advanced reactor division to increase capacity, formed a second licensing branch for advanced reactors, and used subject matter experts from across the agency and external contractors to add additional capacity. The NRC continues to identify and fill vacancies to increase organizational capacity for the projected advanced reactor workload.<br><br>More generally, a cross-organizational collaborative effort is underway that engages a broad array of NRC internal stakeholders to expand the agency’s hiring capabilities. This effort, called #HireNRC, is a strategic, proactive, and flexible program that considers and applies innovative techniques to attract and onboard top talent to implement the NRC’s safety and security mission. As of September 2022, the NRC has onboarded more than 200 employees using innovative techniques. These techniques include virtual hiring sessions, social media campaigns, and curated “bite-sized” training videos. Increased hiring continues to be a focus for 2023 and beyond.<br><br>(2) The NRC responded to the COVID-19 public health emergency by exploiting the flexibilities inherent to the Reactor Oversight Process. Inspections were completed, delayed, deferred, or canceled as appropriate based on local conditions and the health and safety considerations of the inspectors. The NRC improved capability to meet mission |

needs through the use of modern communications technology and innovative approaches to inspections (hybrid inspections). In 2020, NRC inspectors completed over 150,000 direct inspection hours at all 59 reactor sites in the United States. This was about 110% of the minimum number of inspections required in the NRC's baseline inspection program. Because of the NRC's ability to exercise the flexibilities above during the pandemic, the agency was able to avoid any backlog in licensing or oversight work that strained human capital and financial resources.

While there is broad agreement that onsite and in-person inspection is the most effective and preferred inspection method for a majority of NRC inspection activities, innovative inspection approaches, along with the continued application of existing program flexibilities and communications technology, proved to be successful and can provide ongoing benefit to agency effectiveness and efficiency going forward.

**Question No. 182**

Would you please give additional clarification on the safety function of drainage system of the reactor refueling shaft (pit) in view of reliable safety system operation according to Generic Safety Issue (GSI)-191 "Assessment of Debris Accumulation on PWR Sump Performance", presented on page 19.

Answer: Note—In responding to this question, the NRC assumes that the requestor is asking: Considering the GSI-191 findings, could the NRC provide insights on possible safety concerns with the safety function of the drainage system of the fuel transfer canal or the draindown done at the end of a refueling outage?

During a refueling outage, the fuel transfer canal drains are closed, and the canal is filled with water to shield and cool the fuel transferred in the refueling process. During normal operation, the fuel transfer canal is drained, and the fuel transfer canal drain valves are locked open. In the event of a design-basis accident, the refueling canal drains are the main return path to the lower compartment for containment spray system water sprayed into the upper compartment. The refueling canal drains also function to help limit the pressure and temperature that can be expected following a design-basis accident. During a loss-of-coolant accident, significant debris may be transported to the refueling canal, depending on the location of break and the insulation materials used, and collect on the refueling canal drain. As a result, the debris on the refueling canal drain is expected to be evaluated in GSI-191 reviews. RG 1.82, "Water Sources for Long-Term Recirculation Cooling Following a Loss-of-Coolant Accident," contains more guidance on GSI-191. RG 1.82 also discusses inspections of drainage flow paths, such as refueling cavity drains and floor drains. In addition, RG 1.82 discusses conducting the inspection of these components, as well as other upstream components late in a refueling outage to ensure the absence of debris generated by construction or maintenance activity. Many licensees have closed this issue, and details regarding drainage systems, modifications to the system to address GSI-191, and analyses of the system are available in their closure letters, which are publicly available. Licensees either installed debris interceptors over the drainlines or evaluated the potential transport of debris to the refueling canal area and determined that debris capable of blocking the drain could not get there. The NRC evaluated that the volume of water assumed to drain to the sump from the refueling canal was justified for each licensee.

**Question No. 185**

(1) How many and what regulatory documents are planned to be developed regarding risk and performance assessment, p.xi (p. 13)
(2) Based on what inspections and analyzes (internal and external) it was concluded that

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| some nuclear units/plants can be operated for another 80 years, page 16 (page 35);<br>(3) What is the strongness of the decisions of the “Risk-Informed” Supervisory Committee (RISC) in the structure of the nuclear regulator, item 2.3.1.8, page 27 (page 47);<br>(4) What regulatory changes will need to be made at the local and federal level in the short term in relation to small modular reactors and is there already such a plan?, pages 18/33/46/50/137/;<br>(5) What are the main (key) elements that are checked during the review of supply programs and what necessitates such checks by the nuclear regulator? section 13.6, p. 147 (p. 166). |
| <u>Answer</u>:<br>(1) The NRC develops a variety of regulatory documents to support risk-informed and performance-based approaches in regulatory activities. These documents include formal rulemaking and regulatory guides. In addition, the NRC regularly updates existing guidance documents to reflect current information. The NRC does not have a fixed number of documents that it plans to develop for risk-informed and performance-based regulations.<br><br>(2) On a generic (or general) basis, the NRC supported the Expanded Materials Degradation Assessment, an expert elicitation process used to identify aging issues that could be relevant for plant operation up to 80 years. The results of the assessment are summarized in NUREG/CR-7153, “Expanded Materials Degradation Assessment (EMDA),” Volumes 1 to 5, issued October 2014 (available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr7153/index.html).<br><br>The NRC also audited the implementation of aging management programs at several plants with renewed licenses (ML13122A009).<br><br>These activities, in addition to public engagements with stakeholders to discuss technical issues and operating experience, resulted in a conclusion that plant operation to 80 years is feasible and led to the development of NUREG-2191, “Generic Aging Lessons Learned for Subsequent License Renewal” (GALL-SLR), and NUREG-2192, “Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants.”<br><br>This general conclusion must be sustained on a plant-specific basis through the license renewal process in 10 CFR Part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants.”<br><br>(3) The Risk-Informed Steering Committee (RISC) was not a regulatory decision-making body. Its purpose was for the NRC’s senior management to engage with their industry counterparts to better understand each other’s priorities and areas that needed attention. The items discussed and identified at the RISC meetings informed NRC decision-making and actions, which were undertaken using established NRC processes. As noted in the U.S. Ninth National Report, the NRC’s RISC has been discontinued.<br><br>(4) There are several changes planned for the NRC’s regulations associated with new and advanced reactor licensing. Currently, the staff has a proposed rule, suggesting policy and regulatory updates to ensure consistency in new reactor licensing reviews, regardless of the licensing process an applicant chooses to use. This would align 10 CFR Part 50 and 10 CFR Part 52 regulatory requirements and associated documents, such as regulatory guides and affected chapters of the SRP. The rule would bring 10 CFR Part 50 |

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| requirements in line with requirements in 10 CFR Part 52 and would update both 10 CFR Part 50 and 10 CFR Part 52 with lessons learned from recent 10 CFR Part 52 license application reviews.<br><br>The NRC has also recently proposed establishing an optional technology-inclusive regulatory framework (10 CFR Part 53) for use by applicants for new commercial advanced nuclear reactors. The regulatory requirements developed in this rulemaking would use methods of evaluation, including risk-informed and performance-based methods, that are flexible and practicable for application to a variety of advanced reactor technologies. The NRC staff is expecting to issue the Final Rule by July 2025.<br><br>(5) Criterion VII, “Control of Purchased Material, Equipment, and Services,” of 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” requires NRC licensees to establish measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. The applicant or designee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services. In practice, licensees describe how they meet these requirements in their NRC-approved quality assurance program descriptions (QAPDs) and develop additional detailed implementing procedures to perform the activities described in their QAPD. While licensees have the ultimate responsibility to ensure the quality of the SSCs they purchase, the NRC established the Vendor Inspection Program (VIP) to verify that reactor applicants and licensees are fulfilling their regulatory obligations to provide effective oversight of the supply chain. The VIP accomplishes this through a number of activities, including vendor inspections to verify the effective implementation of the vendor’s quality assurance program. NRC IMC 2507, “Vendor Inspections,” dated October 3, 2013 (ML13247A725), describes the NRC’s VIP and includes references to several NRC inspection procedures (IPs) that provide detailed guidance for NRC inspectors to use when conducting supplier inspections. Supplier inspections, conducted by the NRC’s vendor inspectors, typically implement IP 43002, “Routine Inspections of Nuclear Vendors,” dated July 15, 2013 (ML13148A361). This IP provides guidance for the inspector to verify implementation of portions of the quality assurance program criteria applicable to the scope of work performed by the supplier. The functional areas of the supplier’s program inspected may include any of the 18 criteria described in Appendix B to 10 CFR Part 50; however, the lead inspector will focus the inspection effort on those Appendix B criteria most relevant to the specific scope of work and activities the supplier is responsible for performing. |
| **Question No. 186** |
| (1) How is the motivation of the staff maintained after the limitations imposed by the COVID-19 pandemic?<br>(2) How is effective knowledge transfer maintained at the change of generations? |
| <u>Answer</u>:<br>(1) The NRC staff leveraged remote communication technologies to continue accomplishing its mission effectively during the pandemic. This included using video and teleconferencing resources to have needed interactions with stakeholders. These interactions allowed the NRC staff to be aware of and respond to topical areas of |

expected licensing needs. Where areas of sufficiently increased need were identified, the NRC staff developed additional, pandemic-specific guidance to facilitate expedited reviews of those requests. As the pandemic progressed, so did the capabilities of the technical and networking tools available to the staff (e.g., updates to Microsoft Teams to support larger meetings), which increased the staff's confidence in its ability to sustain effectiveness in the new work environment.

(2) Knowledge management (KM) remains an integral part of the NRC's internal strategic processes to ensure the capture and preservation of knowledge to assist with employee development and performance for both current and future NRC staff. The agency has a robust KM program and uses a broad and continuously evolving range of KM methodologies for identifying, collecting, and sharing knowledge.

A key element contributing to the NRC's success in KM is its system of governance and delineated roles and responsibilities. The NRC uses a distributed model in managing and implementing the KM program. The responsibility for managing agencywide KM procedures, guidance, training, and infrastructure is centralized in the Office of the Chief Human Capital Officer. This provides for necessary standardization, consistency, and efficiency. The actual implementation of KM practices is decentralized and is achieved through a cross-office network of NRC management and staff and the KM Steering Committee composed of senior management who are Office Champions and their KM staff leads. Decentralizing the implementation process allows tailoring KM strategies and practices to meet the needs of individual offices and regions. It also enables increased innovation and experimentation with KM practices from which "best practices" can be harvested for broader use.

Human capital practices such as the Strategic Workforce Planning process and competency modeling are an integral part of intentionally planning and informing opportunities for KM. For example, KM is integrated into the Strategic Workforce Planning process and is a commonly noted strategy in office and regional action plans when a workforce gap is identified. Competency models provide a means of comparing an employee's current capabilities against the performance requirements of a job and building a development plan to close any identified gaps. Through this process, KM practices such as on-the-job training and skills-based and technical mentoring are frequently used to support employee development or re-skilling, or to close skill gaps.

With a strong focus on ensuring that knowledge transfer and transition occurs, the agency's KM program recently issued a KM Toolkit for Supervisors that was adopted from a benchmarking effort with other agencies and companies. This toolkit is intended to assist supervisors with identifying and implementing KM approaches that will address their organizations' most urgent needs and allow the capture of knowledge from retirees or those leaving the agency. The toolkit focuses on approaches that can be readily implemented, introducing successful KM practices that include step-by-step processes for implementation and templates. In addition, a Best Practices Toolkit for use by all employees was created and is dedicated to sharing common methods used around the agency for transferring, storing, and capturing knowledge.

One of the NRC's key tools for KM is the agency's internal wiki platform, Nuclepedia, which was implemented in January 2020. The NRC's agency knowledge resource repository is where all NRC employees can capture, share, and collaborate on information

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| and learn from one another. Nuclepedia enables collaborative authoring and sharing of information across organizations and facilitates the capture of critical knowledge, significant events, and regulatory issues. The goal of Nuclepedia is to maximize the effectiveness of staff resources by doing the following:<br><br>• capturing knowledge before it is lost<br>• providing less expensive and more efficient training aids that are available on demand<br>• facilitating and capturing the decision-making process<br>• providing efficient access 24 hours a day to knowledge and experts<br>• facilitating location of information, expertise, and subject matter experts in one tool<br>• supporting the workforce on a real-time basis by providing access to resources and support beyond the traditional workplace<br><br>The KM program continues to evolve and explore new modalities for ensuring that critical knowledge is maintained as staff attrition drives the need to keep knowledge transfer in the forefront and integrated into employees' daily operations. |
| **Question No. 187** |
| Do you have a specific definition of an "Advanced Reactor"? There are many different definitions being floated, and the majority of "Advanced Reactor" designs have been demonstrated and licensed under different international frameworks. |
| Answer: In the "Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008, the Commission did not formally define the term "advanced reactor," but described advanced reactors as designs with some or all of several attributes, such as the use of simplified, inherent or passive means to shut down and cool the reactor, longer time constants, less reliance on operator actions, etc. (https://www.nrc.gov/reading-rm/doc-collections/commission/policy/73fr60612.pdf).<br><br>The Nuclear Energy Innovation and Modernization Act (NEIMA) (https://www.congress.gov/115/bills/s512/BILLS-115s512enr.pdf) defines an "advanced nuclear reactor" as a nuclear fission or fusion reactor, including a prototype plant, with significant improvements compared to commercial nuclear reactors under construction as of January 14, 2019, including improvements such as the following:<br><br>• additional inherent safety features<br>• significantly lower levelized cost of electricity<br>• lower waste yields<br>• greater fuel utilization<br>• enhanced reliability<br>• increased proliferation resistance<br>• increased thermal efficiency<br>• ability to integrate into electric and nonelectric applications<br><br>In the 10 CFR Part 53 rulemaking, rather than define "advanced reactor," the NRC staff has proposed using the term "commercial nuclear reactor," which encompasses designs that would be considered advanced reactors as well as other LWR designs. |
| **Question No. 188** |
| Does the NRC's mission extend to fusion as well? |
| Answer: Yes, the NRC's mission includes fusion. The Energy Reorganization Act of 1974 |

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| established the Nuclear Regulatory Commission to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment, as established in the Atomic Energy Act of 1954, as amended (ML15364A497). In SRM-SECY-09-0064, "Staff Requirements—SECY-09-0064—Regulation of Fusion-Based Power Generation Devices," dated July 16, 2009 (ML092230198), the Commission stated, as a general matter, that "the NRC has regulatory jurisdiction over commercial fusion energy devices whenever such devices are of significance to the common defense and security or could affect the health and safety of the public." Additionally, the Commission directed the staff to wait until commercial deployment of fusion technology became more predictable before expending significant resources to develop a regulatory framework for fusion technology.<br><br>NEIMA (https://www.congress.gov/115/bills/s512/BILLS-115s512enr.pdf), directed the NRC to develop the regulatory infrastructure to support the development and commercialization of advanced nuclear reactors. NEIMA's definition of an "advanced nuclear reactor" includes both fission and fusion technologies. Section 103 of NEIMA specifically requires the NRC to "complete a rulemaking to establish a technology inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications" by December 31, 2027. In response, the NRC staff provided options to the Commission for appropriately licensing and regulating fusion energy systems within the NRC's regulatory structure in SECY-23-0001, "Options for Licensing and Regulating Fusion Energy Systems," dated January 3, 2023 (ML22273A178). |
| **Question No. 189** |
| Given that one of the goals is permitting higher levels of enrichment and burn-up, what is being done to manage potential risks in safeguards, and back-end conditions? |
| Answer: The NRC has determined that the regulatory framework is generally broad enough to address safety, security, and safeguards for new types of fuel associated with ATF designs. This understanding is based on a review of the general literature about expected ATF concepts. Modifications of the review process or guidance may be necessary to address new design features, higher levels of enrichment and burnup, as well as different discharge and loading operations associated with ATFs. The staff remains ready to review applications relating to the back end of the fuel cycle for both near-term and long-term fuel concepts based on the information available today. To manage potential risks in safeguards, the NRC staff will use a case-by-case approach when reviewing applications to determine whether supplemental security measures, beyond the graded physical protection requirements in the existing regulations, are needed. The staff will continue to gather available information and develop guidance, as needed, to enhance the efficiency of its reviews. The agency will continue to evaluate the regulatory framework and assess information needs to support its readiness, including potential areas of technical focus such as source-term evaluations, criticality and shielding evaluations, thermal performance, and material degradation, considering both short-term and long-term performance. |
| **Question No. 190** |
| Many of these assessments have covered "as-designed" conditions (e.g., insulation, materials, etc.). How have transient conditions been incorporated to ensure that the conclusions that led to closure remain valid? |
| Answer: The NRC position is that the licensees are responsible for ensuring that they are operating within their design basis. However, during its closeout of the issue for each plant, the NRC staff reviews the foreign material exclusion program, design control practices, maintenance practices, and operational practices related to the control of material in |

containment during both outages and operation. Each plant also has a technical specification to ensure that the emergency sump is operable. Recently, the NRC approved a change to the standard technical specifications, which provides more detailed direction on the inspections required to be completed to ensure operability of the emergency sump. This technical specification change is related to GSI-191 issues but separate from the closure of the issue for each plant. For GSI-191, when the NRC issues a closure letter for the plant, the agency is confident that the licensee has implemented adequate controls to maintain the debris amount that could be generated during a loss-of-coolant accident within the design-basis values.

**Question No. 191**

As written, it would appear that SECY-22-0001 would extend NRC regulation beyond nuclear plants if there is potential to impact emergency plans.

(1) Is this extension intended to regulate the impacts, or only ensure there are adequate emergency plans?
(2) How is the NRC planning to execute this?

Answer:

(1) The draft final rule for the new alternative emergency preparedness (EP) requirements for SMRs and other new technologies (ONTs) in 10 CFR 50.160, "Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities," is with the Commission for review. The draft final rule does not extend NRC regulation beyond nuclear plants; it does, however, consider the potential to impact emergency plans from other nearby facilities. The draft final rule 10 CFR 50.160(b)(2) includes a requirement for a hazard analysis of any facility located contiguous to or near an SMR or ONT that considers any hazard and to include any credible hazard in the licensee's EP program that would adversely impact the implementation of emergency plans, as well as any specific response actions needed.

There are many potential examples of a nuclear power facility that may be located contiguous to or near a facility not licensed by the NRC, such as a nuclear power facility that is used to supply process heat or electrical power to a nearby industrial facility, or an SMR that is used to power a desalination facility located on the same site. Under these scenarios, the hazards of the facility not licensed by the NRC must be factored into the EP program of the nuclear facility to ensure the protection of public health and safety.

Separate from emergency planning, the NRC staff performs a review of manmade site hazards, such as nearby manufacturing facilities, military bases, and transportation routes, to ensure that the NPP is protected against potential accidents at those facilities. This review was done in the past for the operating reactors and will continue to be done in the future for new reactors. See Standard Review Plan, Section 2.2.3, Revision 3, "Evaluation of Potential Accidents," issued March 2007 (ML070460336).

(2) The NRC will be issuing Revision 1 of RG 1.242, Revision 0, "Performance-Based Emergency Preparedness for Small Modular Reactors, Non-Light-Water Reactors, and Non-Power Production or Utilization Facilities," when the final rule is approved by the Commission. The revised RG will include guidance on hazard analyses for contiguous or nearby facilities (ML21238A072).

**Question No. 192**

It is good news that the NRC has completed its review of all of these requirements. Can the NRC comment on the adequacy of the responses from the licensees and how many (if any) still have outstanding actions? (The link in the report is broken)

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| Answer: All applicable licensees have completed the required safety enhancements resulting from the lessons learned from the Fukushima accident, to include flooding and seismic hazard reevaluation, and all licensee reports, and the NRC has reviewed the assessments and found them to be acceptable. The table in the document "Post Fukushima Flooding and Seismic Hazard Reevaluation Status," dated January 8, 2021 (ML21055A556), shows the status of flooding and seismic reevaluation for operating reactors in the United States. Of note, since the document was published, Indian Point Nuclear Generating, Units 2 and 3, and Palisades Nuclear Plant have permanently shut down and ceased operations. This document also contains additional information on the scope of the flooding and seismic evaluations performed by licensees.<br><br>Additionally, at the following link (corrected broken link in the report), a copy of the NRC's documentation of completion of required actions is available for each plant.<br>https://www.nrc.gov/reactors/operating/ops-experience/fukushima.html<br>For example, a copy of the October 11, 2019, letter issued to Beaver Valley Power Station to document completion of actions is available on the public website (ML18302A208). |
| **Question No. 193** |
| In the "Robustness of Defense in Depth" principle, one of the concepts is siting away from population. Has the NRC considered the implications of this principle in terms of some of the currently proposed SMR concepts? A later paragraph seems to contradict this statement, so some clarity could be helpful. In 17.2.2, there are seemingly prescriptive rules that may not deliver the graded/performance-based approach. |
| Answer: The NRC addresses the siting of NPPs in relation to populations within its regulations and guidance. NRC regulations require that exclusion areas, LPZs, and appropriate distances from population centers be defined for each NPP site. However, the criteria used to establish these areas and distances are informed by calculated offsite doses from postulated accidents and therefore allow for a graded or performance-based approach. Insofar as proposed SMRs may have limited offsite consequences in comparison to earlier generations of NPPs, the sizes of the exclusion areas and LPZs could be reduced accordingly and could hypothetically be reduced to the site boundary. NRC guidance documents describe an acceptable approach to achieving the NRC's preference for NPPs to be sited in areas of low population density. The guidance used for the current and recently licensed large LWRs specifies that the population density in the area surrounding an NPP should be less than 500 persons per square mile (193 persons per square kilometer) from the plant. The NRC is currently revising the guidance to incorporate a performance-based approach such that the area in which population density is considered for siting reviews depends on the calculated offsite consequences from postulated accidents in a manner similar to that used for determining exclusion areas and LPZs. For more information refer to SECY-20-0045, "Population-Related Siting Considerations for Advanced Reactors," dated May 8, 2020 (ML19262H055), and the related Commission decision in the SRM dated July 13, 2022 (ML22194A885). |

## ARTICLE 6. EXISTING NUCLEAR INSTALLATIONS

**Each Contracting Party shall take the appropriate steps to ensure that the safety of nuclear installations existing at the time the Convention enters into force for that Contracting Party is reviewed as soon as possible. When necessary, in the context of this Convention, the Contracting Party shall ensure that all reasonably practicable improvements are made as a matter of urgency to upgrade the safety of the nuclear installation. If such upgrading cannot be achieved, plans should be implemented to shut down the nuclear installation as soon as practically possible. The timing of the shutdown may take into account the whole energy context and possible alternatives, as well as the social, environmental, and economic impact.**

This section explains how the United States ensures the safety of nuclear installations in accordance with the obligations in Article 6. It covers the reactor licensing and major oversight processes in the United States. This section also discusses programs for rulemaking, fire protection regulation, decommissioning, research, and generic communications. Finally, this section addresses the 2015 Vienna Declaration on Nuclear Safety.

| **Question No. 3** |
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| It is mentioned in the report, that licensing process for Watts Bar NPP Unit 2 under 10 CFR Part 50 completed in 2015 after issuance of construction permit in 1973. NRC may like to share information about major issues encountered during the licensing process with the focus on changes in regulatory requirements from 1973 to 2015. |
| Answer: Watts Bar Nuclear Plant, Unit 2 (WBN-2), has a unique licensing history. As stated, the construction permit was issued in 1973. The operating license application was submitted and docketed by the NRC in 1976. The NRC published a safety evaluation report NUREG-0847, “Safety Evaluation Report Related to the Operation of Watts Bar Nuclear Plant, Units 1 and 2” (ML072060490), and four supplements in the 1980s documenting its review of the WBN-2 operating license application when construction stopped in 1985. When the licensee (Tennessee Valley Authority) notified the NRC in 2007 of its intention to complete construction of WBN-2, one of the major issues to be resolved was which regulations, standards, and guidance would be applicable to the operating license review. WBN-2 was required to meet all applicable regulations, though some regulations are tied to certain milestones such as construction permit submittal, construction permit approval, or operating license submittal dates. A regulation may also say to do “X” if the operating license application is before 1999 but do “Y” if after 1999. Since WBN-2 submitted its application in 1976, it was required to meet “X” even if “Y” was newer. However, WBN-2 was required to meet some more recent regulations because no such milestone was included in the rulemaking processes. An example of this would be cybersecurity. WBN-2 was also included in the orders the NRC issued following the events at Fukushima. As such, WBN-2 was required to complete all actions in the orders, and the NRC staff had to complete its evaluations of those actions before issuing the operating license. Given the licensee’s project timeline, this meant WBN-2 was ahead of most of the industry in coming into compliance with the orders.<br><br>Regarding standards and guidance documents, in SRM-SECY-07-0096, “Staff Requirements—SECY-07-0096—Possible Reactivation of Construction and Licensing Activities for the Watts Bar Nuclear Plant Unit 2,” dated July 25, 2007 (ML072060688), the Commission directed the NRC staff to use the current licensing basis of Watts Bar Nuclear Plant, Unit 1, as the reference basis for the review and licensing of WBN-2. Simply put, |

whichever standard or guidance document that was acceptable for Unit 1 should be used by the staff when reviewing Unit 2, provided the structure, system, or component was the same. Where systems differed significantly (e.g., some instrument and control systems), the licensee and the staff followed current standards and guidance documents.

Another major issue to resolve was determining how much of what was previously reviewed in the original safety evaluation report and supplements could be credited and which sections needed additional information and NRC review. The licensee and the NRC staff agreed on the issue, and the staff published the list of items in Supplement 21 to the safety evaluation report, issued February 2009 (ML090570741), which outlined the portions of the review the staff considered complete and the portions still under review. This assisted both the licensee and the staff to focus their resources and effectively complete the review.

**Question No. 12**

It's stated that "In 1989, the NRC adopted a single-step process, which is specified in 10 CFR Part 52, and provides direction for issuing a combined license for construction and operation of a new reactor. The NRC has issued 14 combined licenses since 2012, authorizing the construction and operation of 14 new units at eight nuclear power plant sites in the United States. Six of the licenses at three sites were subsequently terminated at the licensees' request. Eight licenses at five sites remain in place. Currently, the NRC has no combined license applications under review."

Question:

(1) From the practical experience of the COL regulation of recent years, what are the advantages and disadvantages of new licensing regulation when compared with the previous one?

(2) What is the attitude of the operators to the COL regulation?

<u>Answer</u>:

(1) When the NRC published the proposed 10 CFR Part 52 (53 FR 32060, 32062) on August 23, 1988, the agency stated that its purpose was to improve reactor safety and to streamline the licensing process by encouraging the use of standard designs and by permitting early resolution of environmental and safety issues related to the reactor site and design. As a result, the scope of the combined license (COL) proceeding for a facility can be far more limited than the scope of the two-step licensing process under 10 CFR Part 50. However, the licensing process under 10 CFR Part 50 allows an applicant to begin construction with preliminary design information instead of the final design required for a COL under 10 CFR Part 52. Although the two-step licensing process provides flexibility and allows a more limited safety review before construction, the design has less finality before the applicant commits to construction of the facility.

(2) While the NRC cannot speak directly to the attitude of the operators, different applicants have pursued both licensing paths (10 CFR Part 50 and 10 CFR Part 52) in recent years. Applications planned in the near future are expected to use both paths. Therefore, the NRC infers that different applicants have different opinions of 10 CFR Part 52 and the COL regulations.

**Question No. 22**

How was the graded approach applied in the supervision with the results as of August 1st, 2022?

<u>Answer</u>: The phrase "graded approach" is meant to reflect how the NRC's action matrix dictates the agency's oversight response. Identification of a significant performance deficiency typically corresponds to a move in the action matrix (for example, from Column 1 to

Column 2 or Column 3). As a licensee moves from Column 1, more and additional inspection and oversight are warranted. The licensee needs to address the causes of the performance deficiencies before the NRC returns the plant to Column 1 of the action matrix. IMC 2515, Appendix B, "Supplemental Inspection Program," effective September 28, 2022 (ML22189A179), details how the NRC responds to shifts in the action matrix.

**Question No. 23**

(1) Please provide extra explanations about the origin and initiation of staff-submitted recommendations.
(2) Is this the result of the activities of NPP managing organizations, operators or others?
(3) How does this reveal the shortcomings of the NRC's supervisory activities and what are the next steps to change the NRC's supervisory activities?

Answer:

(1) The recommendations from staff were developed from the Transformation Team that the NRC formed in 2018 (ML18029A106).

(2) Additional recommendations did come from the Nuclear Energy Institute, which represents a significant majority of the NPP management organizations and operators.

(3) Note: When responding to this question, the NRC assumed that the term "supervisory activities" is equivalent to "oversight activities."

The NRC staff's recommendations were the result of a staff-initiated transformation effort to enhance the Reactor Oversight Process to be more risk informed and performance based. The staff completed most of the recommended inspection procedure modifications from SECY-19-0067 (ML19070A050) during the summer of 2022, and the changes became effective January 1, 2023. In response to SECY-22-0053, on July 21, 2022 (ML22202A507), the Commission unanimously approved the NRC staff's recommendation to change the periodicity of engineering inspections to a 4-year cycle. The new 4-year cycle for engineering inspection began January 1, 2023.

The staff proposed additional recommendations to the Commission and is awaiting approval. SECY-22-0086 recommended changes to the treatment of greater-than-green inspection findings and performance indicators. SECY-22-0087 suggested options for the Problem Identification and Resolution (PI&R) team inspection frequency. SECY-22-0089 recommended a revision to the emergency preparedness significance determination process.

**Question No. 24**

It is written in the text: "The NRC has determined that spent fuel can safely remain stored in the SFPs or in dry cask storage facilities until a geologic repository is built and operating."
(1) Are there any projects other than Yucca Mountain?
(2) What are the design storage periods for spent nuclear fuel in the SFP and in dry cask storage?

Answer:

(1) For the past 10 years, Congress has appropriated no funds to the U.S. Department of Energy (DOE) for a permanent disposal facility at Yucca Mountain or to the NRC for the Yucca Mountain licensing proceeding. The NRC's adjudicatory proceeding on the Yucca Mountain license application is currently suspended. The DOE continues to work on a disposal research and development program as part of developing a path forward for a comprehensive waste management system. In addition, it is anticipated that the consent-based siting approach being developed by the DOE to site Federal interim

storage facilities could be adapted to site one or more repositories at such time that the DOE receives authorization and funding from Congress to pursue development of repositories.

The NRC received two applications for consolidated interim storage facilities (CISFs) for the storage of spent nuclear fuel. The NRC issued a materials license to Interim Storage Partners, LLC, to construct and operate the Waste Control Specialists, LLC, CISF in Andrews County, Texas, after the agency completed its safety, environmental, and security reviews in September 2021. A summary of the Waste Control Specialists CISF licensing actions can be found in ADAMS (ML21188A096). The second CISF application was submitted by Holtec International for its proposed HI-STORE CISF in Lea County, New Mexico, and it is still under NRC review. A summary of the Holtec International CISF licensing actions can be found at https://www.nrc.gov/waste/spent-fuel-storage/cis/holtec-international.html.

Additional information on the CISFs can be found at https://www.nrc.gov/waste/spent-fuel-storage/cis.html.

(2) Technical understanding and operational experience continue to support the technical feasibility of safe storage of spent fuel in spent fuel pools and in dry casks over long periods of time (e.g., slow degradation of spent fuel during storage in spent fuel pools and dry casks; engineered features of storage pools and dry casks to safely withstand accidents caused by either natural or manmade phenomena).

Spent fuel pools are massive structures constructed from thick, reinforced concrete walls and slabs designed to be seismically robust. The engineered features of storage pools are designed to withstand accidents caused by either natural or manmade phenomena. Based on the technical information and national and international experience with wet storage of spent fuel, it is technically feasible to safely store spent fuel in wet storage with only routine maintenance during the period of reactor operations and the completion of decommissioning (i.e., no large-scale replacement of spent fuel pools during this time period).

Storage in dry casks may persist after the reactor facility is fully decommissioned and the spent fuel pool is removed. Dry cask storage systems can be initially licensed for up to 40 years with possible renewals of up to 40 years, with no restriction on the number of renewals. The 40-year licensing period does not necessarily equate to a design life for a specific system. Rather, spent fuel storage applicants can apply for a term of up to 40 years but must demonstrate the safety of the storage system design for the requested license term. The requirements for spent fuel storage renewal include demonstration that aging and degradation will be addressed by either (1) time-limited aging analyses that demonstrate that the SSCs continue to perform their intended functions, or (2) aging management programs to manage issues associated with aging that could adversely affect SSCs. Aging management programs consist of condition monitoring, performance monitoring, inspections, mitigation, repair, or replacement activities for each of the SSCs, upon consideration of its material of construction, service environment, condition, and any related operating experience.

**Question No. 27**

According to the second sub-paragraph of para. 6.1: “The NRC’s licensees are responsible for designing, constructing, and operating nuclear facilities safely, while the NRC is

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| responsible for the regulatory oversight of the licensees."<br><br>Para. 6.3.1 Reactor Licensing stipulates as follows: "To construct and operate a new nuclear reactor, an entity must apply to the NRC for a license". There is no mentioning of the design here.<br><br>Paragraph 3 of 6.3.1 states that "Regulations in 10 CFR Part 52 also provide for the issue of design certificates...."<br><br>What is the difference between a design certificate and a license, and a process for issuing design certificates and a licensing procedure? |
| <u>Answer</u>: A design certification (DC) is an NRC-approved standard nuclear plant design, issued under Subpart B, "Standard Design Certifications," of 10 CFR Part 52. An NRC-approved DC does not authorize construction or operation; only an NRC-issued license can authorize construction and operation. An application for a combined license (COL) under Subpart C, "Combined Licenses," of 10 CFR Part 52 generally would reference an NRC-approved DC and provide site- and plant-specific attributes for Commission approval in a one-step licensing process. |
| **Question No. 28** |
| What are the criteria for transfer of a nuclear facility from "operation" to "decommissioning" state? |
| <u>Answer</u>: The regulation in 10 CFR 50.82(a)(1)(i) states: "When a licensee has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 50.4(b)(8)."<br><br>The regulation in 10 CFR 50.82(a)(1)(ii) states: "Once fuel has been permanently removed from the reactor vessel, the licensee shall submit a written certification to the NRC that meets the requirements of § 50.4(b)(9)."<br><br>The regulation in 10 CFR 50.82(a)(2) states: "Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the 10 CFR part 50 license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel." |
| **Question No. 29** |
| What measures are undertaken by NRC if the licensee does not have the necessary funds for decommissioning at the decommissioning stage? |
| <u>Answer</u>: At all times, NRC licensees have full responsibility to provide adequate funding for all agency-required decommissioning activities. Reactor operators are required to provide reasonable assurance of decommissioning funding by establishing a secured trust fund at the time of initial operations. The NRC evaluates the adequacy of the fund throughout the life of the license. Operating reactors report on the status of their trust funds every other year; decommissioning reactors must report annually.<br><br>Companies have a variety of mechanisms available to address decommissioning fund shortfalls, including parent and self-guarantees, letters of credit, surety bonds, and the contribution of additional funds into the trust fund. They also may extend their schedule for completing radiological decommissioning, thereby delaying expenditures so assets may appreciate. To ensure that adequate funds are available for decommissioning, the licensee is required to periodically adjust and reevaluate decommissioning costs for its facility during |

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| operations, through decommissioning, and until license termination. If a licensee identifies a decommissioning fund shortfall, the NRC will require the company to obtain additional financial assurance to cover the shortfall and discuss its strategy for addressing the shortfall in its next report to the Commission. Reactors in decommissioning must address the shortfall immediately. |
| **Question No. 54** |
| Will the United States impose restrictions or a ban for reprocessing by the third countries of the SNF produced from the nuclear fuel supplied by to Eastern Europe (Czech Republic, Bulgaria, Ukraine...) by Westinghouse? |
| Answer: The Atomic Energy Act, as amended (section 123.A7), requires all bilateral civil nuclear cooperation agreements (commonly known as "Section 123 Agreements") to stipulate that prior U.S. consent is required before a country reprocesses any U.S.-obligated material. The United States would review any request for such consent on a case-by-case basis. |
| **Question No. 88** |
| Following the Fukushima accident, the world has heightened concerns about a severe accident in NPPs. Most operating NPPs were not subject to regulatory requirements on severe accidents when they were built. Some argue the operating NPPs should be applied with the safety or regulatory requirements of the same level as the new NPPs.<br>(1) Does the U.S. put in place the same regulatory requirements for mitigation of severe accidents for both operating and new NPPs?<br>(2) If the requirements for operating and new NPPs are different, what are the legal grounds or justification for this? |
| Answer: After the accident at Three Mile Island, the NRC developed its "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138; August 8, 1985) https://www.nrc.gov/reading-rm/doc-collections/commission/policy/50fr32138.pdf). The policy statement states the Commission's expectations that future plants would assess the potential for severe accidents and use a combination of deterministic engineering judgment and PRA to identify and, where appropriate, incorporate design features to prevent or mitigate the severe accident conditions. Operating NPPs implemented some design changes (e.g., hydrogen monitoring) and developed response procedures (e.g., severe accident management guidelines) but were not otherwise required to make major changes to the plant designs to address severe accidents. Following Fukushima, the NRC issued orders to all operating plants and to licensed new reactors not yet constructed to take certain actions. This was followed with a rule that codified most of those orders imposing the same requirements on the existing fleet and future applicants. Some of the measures taken by operating NPPs to provide flexible approaches to the mitigation of beyond-design-basis external hazards following the Fukushima accident could contribute to reducing the risks from severe accidents. |

| **Question No. 170** |
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| The NRC is faced with different reactor designs to review.<br>(1) How long does it take for the NRC in average for the design certification and the technical review?<br>(2) Are the construction permit and the operation license included in this process?<br>(3) How many people are normally involved in these review processes? |
| <u>Answer</u>:<br>(1) A DC application can be reviewed and approved within 42 months. To complete the process, a rulemaking has to be undertaken, which could take an additional 12 to 24 months.<br><br>(2) No, a DC review does not include a construction permit or the operating license. A DC is typically used as part of a COL application using the one-step licensing process of 10 CFR Part 52. A construction permit application could also be based on an approved DC, followed by a COL at the end of construction using the 10 CFR Part 50 two-step licensing process.<br><br>(3) Up to 100 technical and project staff may be involved, depending on the scope of design and scope of review. |
| **Question No. 174** |
| At least two resident inspectors are stationed at each operating nuclear power plant site to monitor plant status, perform routine inspections, and respond immediately to events. Additional inspectors from the NRC's regional offices and headquarters perform more specialized inspections in areas like fire protection, operator licensing, security, and other aspects of plant design and operation.<br><br>Question: What is the ratio between the number of full-time employed inspectors who work on inspection of reactors and the number of running reactors (92)? |
| <u>Answer</u>: The ratio of inspection staff to operating units for the NRC is on the order of four inspectors per unit. |
| **Question No. 195** |
| "using a graded approach" was added to this document; however, the description of what this actually means and how it is implemented is not clear. |
| <u>Answer</u>: The phrase "graded approach" is meant to reflect how the NRC's action matrix dictates the agency's oversight response. Identification of a significant performance deficiency typically corresponds to a move in the action matrix (for example, from Column 1 to Column 2 or Column 3). As a licensee moves from Column 1, more and additional inspection and oversight are warranted. The licensee needs to address the causes of the performance deficiencies before the NRC returns the plant to Column 1 of the action matrix. IMC 2515, Appendix B (ML22189A179), details how the NRC responds to shifts in the action matrix. |
| **Question No. 196** |
| Given the large number of different reactor types under development/consideration for submitting licenses in the next couple years, how does the current Fire rule set apply? |
| <u>Answer</u>: The current fire rule sets apply as they always have. For applicants using them (under 10 CFR Part 50 and 10 CFR Part 52 and the associated guidance documents), the applications must request exemptions from portions of the rule or deviations from portions of the guidance that do not apply to, or are otherwise inappropriate for, their designs. These requests would be resolved during the regulatory reviews using the associated processes, as is done for LWRs. |

Additionally, the NRC is developing 10 CFR Part 53 (rule and guidance), a risk-informed, technology-inclusive regulatory framework for advanced reactors.

## ARTICLE 7. LEGISLATIVE AND REGULATORY FRAMEWORK

1. **Each Contracting Party shall establish and maintain a legislative and regulatory framework to govern the safety of nuclear installations.**

2. **The legislative and regulatory framework shall provide for:**

   **(i) the establishment of applicable national safety requirements and regulations**

   **(ii) a system of licensing with regard to nuclear installations and the prohibition of the operation of a nuclear installation without a license**

   **(iii) a system of regulatory inspection and assessment of nuclear installations to ascertain compliance with applicable regulations and the terms of licenses**

   **(iv) the enforcement of applicable regulations and of the terms of licenses, including suspension, modification, or revocation**

This section explains the legislative and regulatory framework governing the U.S. nuclear industry. It discusses the provisions of that framework for establishing national safety requirements and regulations and systems for licensing, inspection, and enforcement.

| **Question No. 63** |
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| The NRC staff is developing a risk-informed, technology-inclusive regulatory framework for optional use by applicants for new commercial advanced nuclear reactor licenses by July 31, 2025.<br>(1) Could NRC please share, what is the current status of this rule making?<br>(2) Could NRC present some examples of technological advances already been recognized for advanced reactor designs and how these are considered in the rulemaking process? |
| Answer:<br>(1) The NRC staff is on schedule to submit the 10 CFR Part 53 proposed rulemaking package to the Commission in February 2023. Following review by the Commission and implementation of any Commission-directed changes by the NRC staff, the proposed rule will be published for public comment. The staff plans to provide the final rulemaking package, including key guidance documents, to the Commission by December 2024. The staff is expecting to issue the final rule by July 2025, which is well ahead of the date of December 2027 directed by the U.S. Congress in the Nuclear Energy Innovation and Modernization Act.<br><br>(2) Examples of areas where technological advances in reactor designs are being recognized include the following:<br>(a) The use of PRA for non-LWRs to identify licensing-basis events and design-basis accidents and to establish the safety classification of structures, systems, and components, which the NRC endorsed in RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” issued June 2020 (ML20091L698). This |

approach is embodied in the 10 CFR Part 53 rulemaking package described above.

(b) Changes to emergency preparedness requirements contained in a draft final rule (currently with the Commission) that will be incorporated into 10 CFR Part 53, based on Commission direction.

(c) The concept of "functional containment," as discussed in SECY-18-0096, dated September 28, 2018 (ML18114A546), being incorporated into 10 CFR Part 53 and NRC guidance documents.

(d) Fuel qualification guidance for nontraditional fuel types as addressed in NUREG-2246, "Fuel Qualification for Advanced Reactors," issued March 2022 (ML22063A131), which could support applicants being licensed under 10 CFR Part 53.

(e) NRC-published guidance in Draft Regulatory Guide 1380 (RG 1.87, Revision 2), "Acceptability of ASME Section III, Division 5, High Temperature Reactors," issued August 2021 (ML21091A276), which would endorse the American Society of Mechanical Engineers (ASME) Section III, Division 5, "High Temperature Reactors" (2017 edition), which could support the construction and licensing of nuclear reactors operating above 425 degrees Celsius (°C) (800 degrees Fahrenheit (°F).

**Question No. 76**

Were there any situations of application for combined licence without prior certification of the design? If yes did this lead to the prolongation of the licensing process.

Answer:

(1) Yes, most applications for a combined license (COL) were reviewed in parallel with the review of the referenced reactor design. Both the AP1000 and the advanced boiling-water reactor designs were certified before any COL applications were submitted that referenced the designs; however, both these standard designs were modified in the course of review of the COL applications.

(2) This dual review approach could have caused some delay in the final COL licensing process, but there was also a time savings in that the final design certification reflected actual COL licensed plants, streamlining to some extent the rulemaking process for the design certification.

**Question No. 89**

The national report (page 79) mentions the principles of the Atomic Energy Act of 1954.
(1) What are these principles? How are they specified in subordinate statutes of the Act?
(2) How are these principles related to the principles of good regulation of NRC?

Answer:

(1) The principles of the Atomic Energy Act of 1954, as amended, are specified in Chapter 1, "Declaration, Findings, and Purpose." Broadly speaking, this chapter of the statute articulates the view of the U.S. Congress that atomic energy is capable of peaceful uses and should be developed to improve the general welfare, and that the possession and use of nuclear materials must be regulated in the national interest in order to provide for the common defense and security and ensure public health and safety. This chapter also states that the purpose of the Act is to effectuate these policies by creating national programs for, among other things, conducting and fostering research and development; utilizing atomic energy for peaceful purposes to the maximum extent consistent with public health and safety; and international cooperation to make available the benefits of peaceful applications of atomic energy to cooperating nations in the interest of common defense and security. These broad declarations of findings and purpose are then effectuated in more detail by the ensuing chapters of the Act.

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| (2) Through the Atomic Energy Act, Congress has established the principles governing the use and regulation of nuclear activities within the United States. The NRC's Principles of Good Regulation are the principles articulated by the NRC itself concerning how it intends to engage the public and regulated industry when exercising its authority as the Nation's independent nuclear health and safety regulator. Thus, although the NRC's Principles of Good Regulation are not contained within the statute, they represent the NRC's self-expressed commitment to demonstrate certain values when exercising the responsibilities the statute has entrusted to the agency. |
| **Question No. 197** |
| Should a description of the basis for the Part 53 process be described here? |
| Answer: Section 7.2.2 of the U.S. Ninth National Report covers the current regulations for licensing commercial NPPs. As discussed in section 2.3.2.1, 10 CFR Part 53 is a proposed rule, which has not yet been approved by the Commission. The NRC hopes to establish the new regulation by mid-2025. If 10 CFR Part 53 is promulgated and included in the *Code of Federal Regulations*, the NRC staff will update section 7.2.2 accordingly. The NRC appreciates the suggestion. |

## ARTICLE 8. REGULATORY BODY

1. **Each Contracting Party shall establish or designate a regulatory body entrusted with the implementation of the legislative and regulatory framework referred to in Article 7, and provided with adequate authority, competence, and financial and human resources to fulfill its assigned responsibilities.**

2. **Each Contracting Party shall take the appropriate steps to ensure an effective separation between the functions of the regulatory body and those of any other body or organization concerned with the promotion or utilization of nuclear energy.**

This section explains the establishment of the U.S. regulatory body (i.e., the NRC). It also explains how the functions of the NRC are separate from those of bodies responsible for promoting research, development, and advancement of nuclear energy (e.g., the U.S. Department of Energy). It discusses financial and human resources, the regulatory body's international responsibilities, its ethics rules, and its policy for maintaining openness and transparency.

| **Question No. 138** |
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| Does NRC have exchanges with EPA on chemical discharges of nuclear plant in the event of arbitration between safety and chemical-radiological discharges? If possible, give examples of such discussions |
| Answer: Nonradiological chemical discharges by nuclear plants are regulated by the U.S. Environmental Protection Agency (EPA), or the State under EPA-delegated authority. Radiological discharges are under NRC regulatory jurisdiction. Oversight is coordinated but does not overlap, so arbitration is not needed. |
| **Question No. 151** |
| (1) In the USA, how and by whom are hot water discharges into the environment (river, lake or sea) from nuclear power plants regulated? If possible, give examples of limit values, specifying whether or not the nuclear power plant has cooling towers and the kind of the receiving environment (river, large lake or sea).<br>(2) How are the effects of climate change on the regulatory framework for hot water discharges into the environment taken into account by the licensee or the regulatory body?<br>(3) Are specific environmental monitoring plans implemented on the thermal impact of the nuclear power plants on the environment, by whom are they carried out, and are the results available?<br>(4) Climate change will change the operating context of power plants, particularly for plants located on rivers. To what extent are the installations already equipped with retention systems in case of low water?<br>(5) How is climate change taken into account in the design and operation of new nuclear power plants?<br>(6) Same question for existing power plants. To what extent are the installations already equipped with retention systems in case of low water? |
| Answer:<br>(1) Thermal effluents of NPPs are regulated under the Clean Water Act (CWA), which is implemented by the U.S. EPA or delegated to States or Tribes (collectively, "permitting authority"). The National Pollutant Discharge Elimination System (NPDES) program |

addresses water pollution by regulating the discharge of potential pollutants to waters of the United States. Section 402 of the CWA established the NPDES program, which regulates point source discharges of pollutants, including cooling water discharge from all facilities, including thermoelectric power plants. NPDES permits set specific technology-based or water-quality-based discharge limits, prescribe monitoring and reporting requirements, and set special conditions applicable to each discharger. Section 316(a) of the CWA addresses the adverse environmental impacts associated with thermal discharges into waters of the United States. Under this section, the permitting authority establishes thermal surface water quality criteria for waters of the United States within their jurisdiction. Under section 316(a), the permitting authority may also impose alternative, less stringent, facility-specific effluent limits (called "variances") on the thermal component of individual point source discharges. If the permitting authority sets limitations on the thermal component of a facility's effluents, these are specified in a plant-specific NPDES permit. NPDES permits for NPPs can impose maximum heat rejection limits, temperature limits for effluents (which may vary by season), a maximum temperature increase above the ambient water temperature (referred to as "delta-T," which also may vary by season), or some combination of these limits. Other aspects of the permit may include the compliance measuring location and restrictions against plant shutdowns during winter to avoid sudden temperature changes in surface water bodies. Limits and operational parameters specified in NPDES permits are plant specific and therefore vary from site to site.

To operate an NPP, licensees must comply with the CWA, including associated requirements imposed by the EPA or authorized State, as part of the NPDES permitting program. The permitting authority, not the NRC, sets the limits for effluents and operational parameters in plant-specific NPDES permits and enforces the conditions stipulated in the permit. NRC operating licenses are subject to conditions deemed imposed by the CWA as a matter of law. The NRC does not duplicate the EPA's or authorized States' or Tribes' water quality reviews.

The list below provides some plant-specific discharge effluent temperature or thermal limits specified for NPPs in their respective NPDES permits:

- Peach Bottom Atomic Power Station—Cooling Type: Hybrid: once-through (Unit 2); Limit: once-through and cooling towers (Unit 3); the NPDES permit currently limits thermal effluent to a maximum water temperature of 110°F (43.3°C) at the end of the discharge canal; Effluent Discharge Receiving Environment: Conowingo Pond
- Point Beach Nuclear Plant—Cooling Type: once-through; Limit: Wisconsin Pollutant Discharge Elimination System permit limits heat rejected to Lake Michigan to 8,273 million British thermal unit per hour; Effluent Discharge Receiving Environment: Lake Michigan
- River Bend Station—Cooling Type: mechanical draft cooling towers; Limit: Louisiana Pollutant Discharge Elimination System permit imposes a monthly average temperature limit of 105°F (40.6°C) and a daily maximum temperature of 110°F (43.3°C) to the Mississippi River; Effluent Discharge Receiving Environment: Mississippi River
- Surry Power Station—Cooling Type: Once-through; Limit: Virginia Pollutant Discharge Elimination System permit limits heat rejected to the James River to $12.6 \times 10^9$ British

thermal units per hour; Effluent Discharge Receiving Environment: James River

(2) As discussed in the response to (1) above, the U.S. EPA implements the CWA. Therefore, the NRC cannot speak to consideration of the effects of climate change on the implementation of the CWA. However, as part of the NRC's environmental reviews when evaluating a licensing action, the staff considers the potential effects of climate change on the environment affected by the licensing action. The National Environmental Policy Act (NEPA) requires Federal agencies (including the NRC) to evaluate the impacts of proposed Federal actions on the human environment. The NRC complies with NEPA through its regulations in 10 CFR Part 51. The regulations form the basis for the NRC's NEPA compliance and direct the staff in how to perform environmental reviews. The NRC's NPP license renewal supplemental environmental impact statements (SEISs) and new reactor environmental impact statements (EISs) document the potential overlapping impacts from climate change on environmental resources, including surface water resources and aquatic biota. The analysis considers how projected climate change can alter the environmental resources that are impacted by license renewal or construction and operation of a new NPP. For example, the surface water resource climate change analysis for the Point Beach subsequent license renewal draft SEIS (NUREG-1437, Supplement 23, Second Renewal, issued November 2021 (ML21306A226)) discusses how warmer surface water temperatures can result in a decrease in cooling efficiency and therefore have the potential to increase the use of cooling water and result in a slightly larger volume of heated water discharged. Another example is in appendix I to NUREG-2176, "Environmental Impact Statement for the Combined Licenses for Turkey Point Nuclear Generating, Units 6 and 7," issued October 2016 (ML16337A147), which discusses the "new" affected environment as a result of potential changes in the region because of climate change and the potential changes in impacts to water resources and aquatic ecology as a result of climate change.

(3) Current plants have considered meteorological conditions in their design of the ultimate heat sink (UHS) to ensure sufficient cooling with respect to the controlling parameter(s) and critical time periods unique to the specific design of the UHS. The NRC requires a high level of assurance that the UHS's water sources will be available when needed. As described in RG 1.27, "Ultimate Heat Sink for Nuclear Power Plants," the NRC indicates a UHS with at least two water sources should be considered and each source should be capable of performing the UHS safety functions, unless it can be demonstrated that there is an extremely low probability of losing the capability of a single source. Plants using river water as their UHS are typically on large rivers and have a high level of assurance that the water sources for the UHS will be available when needed. Examples of UHSs that the staff has found acceptable are a large river, a large lake, an ocean, two spray ponds, a spray pond and a reservoir, a spray pond, and a river, two mechanical draft towers with basins, a mechanical draft tower with a basin and a river, a mechanical draft tower with a basin and a lake, a cooling lake with a submerged pond, and two wet/dry forced draft towers.

RG 1.27 defines criteria for the UHS complex. Whether supplied by single or multiple water sources, the UHS should be capable of withstanding, without loss of the UHS safety functions, all of the following events: (1) the most severe natural phenomena expected at the site, (2) the site-related events (e.g., river blockage, river diversions, reservoir depletion, ship collisions, airplane crashes, oil spills, fires) that have occurred or may occur during the lifetime of the plant, (3) appropriate combinations of less severe natural phenomena, site-related events, or both, (4) failure of reservoirs, dams, and other manmade water-retaining structures both upstream and downstream of the site including the potential for resultant debris to block water flow, and (5) potential changes in ocean, river, or lake levels as a result of severe natural events, or possible changes in climatological conditions in the site region resulting from human or natural causes that may occur during the plant lifetime.

For UHSs where the water supply may be limited or the temperature of plant intake water from the UHS may become critical (e.g., ponds, lakes, cooling towers, or other UHSs where recirculation between plant cooling water discharge and intake can occur), RG 1.27 suggests analyses be performed to provide assurance of a 30-day supply availability throughout the 30 years of meteorological data. The 30-day capacity of the UHS is assumed sufficient to provide cooling for the time necessary to evaluate the situation and take corrective action.

In additional to UHS design, plants are required to monitor temperature, river water levels, or both with respect to analyzed plant system requirements. The importance of the UHS to nuclear safety is such that, if during plant operation, the capability of the UHS is threatened (e.g., to permit necessary maintenance or as a result of damage), restrictions are placed on plant operation. When inventory reaches any critical parameter (i.e., low water level or elevated UHS temperature), the plant is required to be placed in safe mode of operation or shutdown until parameters meet operational requirements. The list below provides plant examples of technical specification (TS) and surveillance requirements (SR) for plant monitoring on river UHSs.

**Beaver Valley—Ohio River, TS 3.7.9**

- SR 3.7.9.1 Verify water level of UHS is > 654 ft mean sea level.
- SR 3.7.9.2 Verify average water temperature of UHS is < 90°F (Unit 1) < 89°F (Unit 2).

**Cooper—Missouri River, TS 3.7.2**

- SR 3.7.2.1 Verify the river water level is > 865 ft mean sea level.
- SR 3.7.2.2 Verify the average water temperature of UHS is in accordance with < 95°F.

**Dresden—Kankakee River and Cooling Lake, TS 3.7.3**

- SR 3.7.3.1 Verify the water level in the CCSW and diesel generator service water (DGSW) pump suction bays is > 501.5 ft mean sea level.
- SR 3.7.3.2 Verify the average water temperature of UHS is < 95°F.

**Monticello—Mississippi River, TS 3.7.2**

- SR 3.7.2.1 Verify the water level in the intake structure is ≥ 899 ft mean sea level.
- SR 3.7.2.2 Verify the average water temperature of UHS is ≤ 90°F.
- Or be in MODE 3 (12 hours) and MODE 4 (36 hours).

(4) Current plants are designed and required to monitor temperature and inventory of water with respect to intake. When inventory reaches a critical parameter (i.e., lower water level, elevated UHS temperature beyond that analyzed), the plant is required to be placed in safe mode of operation or shutdown until parameters meet operational requirements.

(5) The NRC considered the effects of global warming and changing climate in the EIS guidance for evaluation of new reactors (available at: https://www.nrc.gov/reactors/new-reactors/new-licensing-files/new-rx-license-process.pdf). Explicit in the EIS guidance is

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| the premise that climate over the period of operation of facilities should not be considered constant, but rather changing in accordance with projections that consider the influence of greenhouse gas emissions. The evaluations from the NRC EIS will affect the staff review of SSC protection against natural phenomena.<br><br>The NRC has regulatory criteria applicable to a new application for a construction permit or operating license under 10 CFR Part 50, or an application for a standard design certification, combined license, or standard design approval under 10 CFR Part 52. Specifically, 10 CFR Part 50, Appendix A, GDC 2, requires the design for the UHS and supported systems to address (1) appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated, (2) appropriate combinations of the effects of normal and accident conditions with the effects of the natural phenomena, and (3) the importance of the safety functions to be performed.<br><br>The suggested UHS criteria of RG 1.27 should be applied when the water supply makes up part of the UHS (including rivers). RG 1.27 describes methods and procedures acceptable to the NRC staff that NPP facility licensees and applicants can use to establish UHS features of plant systems required by NRC rules and regulations. The UHS complex, whether supplied by single or multiple water sources, should be capable of withstanding, without loss of the UHS safety functions, potential changes in ocean, river, or lake levels as a result of severe natural events, or possible changes in climatological conditions in the site region resulting from human or natural causes, that may occur during the plant lifetime. This includes those necessary water-retaining structures (e.g., a pond, a reservoir with its dam) and the canals, aqueducts, or piping systems connecting those cooling water sources with the essential or safety-related cooling water intake structure of the nuclear power units.<br><br>(6) Se response to item (4) above. |
| **Question No. 198** |
| (1) What is done to ensure that the Chair has adequate qualifications and provisions to serve in this function?<br>(2) Is there a list of attributes or qualifications that the chair must possess? |
| <u>Answer</u>: The Energy Reorganization Act of 1974 does not list any specific attributes or qualifications that the NRC Chair must possess. Any member of the Commission may be designated by the President to serve as the Chair. The professional qualifications of all members of the Commission would be considered by the President before nominating the individual, and by the United States Senate, which must confirm the nomination. The professional background of the NRC Chair has varied over the years, including nuclear engineers, attorneys, academics, and officials with prior experience in other areas of government. |
| **Question No. 199** |
| (1) Can the NRC speak to the results of the performanced-based reviews of the Agreement States, and if this structure is continuing to have the desired outcomes?<br>(2) Should this be a model for other countries to focus the parent administrator only on the most important topics? |

Answer:

(1) Since 1995, the NRC has used the Integrated Materials Performance Evaluation Program (IMPEP), as described in Management Directive 5.6 (ML19213A024), to evaluate the individual members of the National Materials Program (NMP)—NRC and Agreement States radiation control programs—to determine if their programs are adequate to protect public health and safety and compatible with NRC requirements. The IMPEP program has four main objectives:

- Establish the process in which the NRC and the Agreement States conduct a periodic assessment to determine the adequacy of the NRC and Agreement State programs and to determine the compatibility of Agreement State programs in order to have an orderly pattern of regulation throughout the United States.
- Provide NRC and Agreement State management with a systematic and integrated approach to evaluate the strengths and weaknesses of their radiation control programs.
- Provide significant input to the management of the regulatory decision-making process and indicate areas in which the NRC and Agreement States should dedicate more resources or management attention.
- Provide training and development for IMPEP team members and team leaders to meet minimum knowledge, skill, and ability qualification standards through a standardized methodology.

Each member of the NMP is evaluated at least every 4–5 years. The IMPEP process evaluates six to nine performance indicators depending on the scope of the NRC/State program focused on technical quality and status of the inspection program, technical quality of licensing actions, technical quality of responses to incidents and allegations, and staffing/training. The IMPEP review team typically consists of three to eight NRC and Agreement State members depending on the scope of the program under review. In addition to inspector accompaniments, the onsite portion of the review usually lasts 1 week. To ensure timely feedback of the results to the reviewed agency, the entire review process is approximately 120 days long, from the start of the onsite review to the issuance of the final report. Each IMPEP review is subject to an independent evaluation and approval by a Management Review Board consisting of NRC senior management and an Agreement State representative.

The NRC and Agreement States have found the IMPEP effective in identifying the cause(s) of performance issues with individual NMP programs so that actions can be identified and implemented to improve performance. These actions can be taken by the program alone, or with the assistance of NRC or other Agreement States. The focus on the performance of major activities under each performance indicator ensures that the review team can evaluate potential impacts on adequacy (health and safety) and compatibility (national consistency). This focus also gives the review team flexibility to make recommendations for effective performance improvements across multiple performance indicators. For these reasons, other countries could use IMPEP to evaluate the effectiveness of their national programs.

The NRC and Agreement States periodically conduct a self-assessment of the IMPEP program. The last review, completed in 2018, included recommendations to streamline and integrate the review of the NRC program which was implemented in 2021. A new

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| self-assessment began in December 2022 and is expected to be completed in 2023.<br><br>(2) Yes, the NRC and Agreement States have found the IMPEP effective in identifying the cause(s) of performance issues. The focus on the performance of major activities under each performance indicator ensures that the review team can evaluate potential impacts on adequacy (health and safety) and compatibility (national consistency). For these reasons, other countries could use the IMPEP to evaluate the effectiveness of their national programs. |
| **Question No. 200** |
| The role of the National Nuclear Security Administration (NNSA) is not specifically clear, nor the interface with the NRC. The NNSA rule making and policy have significant impacts on the ability to effectively implement international collaboration, harmonization, etc. Please clarify how this is managed. |
| Answer: The National Nuclear Security Administration (NNSA) is part of the U.S. Department of Energy. NNSA maintains and enhances the safety, security, and effectiveness of the U.S. nuclear weapons stockpile; works to reduce the global danger from weapons of mass destruction; provides the U.S. Navy with safe and militarily effective nuclear propulsion; and responds to nuclear and radiological emergencies in the United States and abroad. NNSA does not have regulatory oversight over civilian nuclear facilities or materials. While NNSA and the NRC have two separate and distinct missions, there are many areas in which the two work closely together to ensure appropriate coordination and avoid duplication of effort or confusion about roles and responsibilities. These include export control and nonproliferation activities and international cooperation and assistance activities. |

## ARTICLE 9. RESPONSIBILITY OF THE LICENSE HOLDER

**Each Contracting Party shall ensure that prime responsibility for the safety of a nuclear installation rests with the holder of the relevant license and shall take the appropriate steps to ensure that each such license holder meets its responsibility.**

The NRC, through the Atomic Energy Act, ensures that the primary responsibility for the safety of a nuclear installation rests with the licensee. Steps that the NRC takes to ensure that each licensee meets its primary responsibility include the licensing process, discussed in Articles 18 and 19; the Reactor Oversight Process, discussed in Article 6; and the Enforcement Program, the Petition for Enforcement Process, and the Allegation Program, discussed below. This section provides an update on the licensee's responsibility for maintaining openness and transparency and for maintaining resources for managing accidents.

| **Question No. 132** |
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| 10 CFR 50.120, "Training and Qualification of Nuclear Power Plant Personnel" sets requirements for several categories of personnel with jobs important for nuclear safety, but these do not include management personnel with various responsibilities and authority in decision-making on safety-related matters. Please provide information on requirements and practices for the implementation of the systematic approach to training and qualification for personnel selected for managerial and supervisory positions important to nuclear safety. |
| <u>Answer</u>: NRC RG 1.8, Revision 4, "Qualification and Training of Personnel for Nuclear Power Plants," issued June 2019 (ML19101A395), provides guidance for the training and qualification of personnel selected for managerial and supervisory positions important to nuclear safety. RG 1.8 addresses the following regulations:<br>• 10 CFR 50.120, "Training and qualification of nuclear power plant personnel," requires that each applicant for and each holder of an operating license issued under 10 CFR Part 50 and each holder of a combined license issued under 10 CFR Part 52 for an NPP establish, implement, and maintain a training program that is derived from a systems approach to training and provides for the training and qualification of specific categories of NPP personnel.<br>• 10 CFR 50.34(b)(6)(i) requires that each application for a license to operate an NPP include information concerning the applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements.<br>• 10 CFR 52.79(a)(26) requires that each application for a combined license include information concerning the applicant's organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements for operation.<br><br>NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," provides guidance for the staff's review of information describing the applicant's implementation of policy, organization, training, and design.<br><br>Positions important to nuclear safety that are not directly covered by the systems approach to training rule in 10 CFR 50.120 are included in RG 1.8, which establishes minimum training and experience requirements for those positions. |

| Question No. 161 |
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| Switzerland has studied with interest the “mechanisms to enforce the licensee’s responsibility to maintain safety”. They contain interesting aspects (e.g., mediation, allegation program, openness and transparency) which also could to be discussed in the context of implementing an error and feedback culture at the regulator’s organization. |
| <u>Answer</u>: Thank you for your comments and observations. The agency appreciates the positive feedback. |
| **Question No. 181** |
| What is the training of the NRC management, staff and inspectors on the mechanisms for the application of the Allegation programme like? |
| <u>Answer</u>: Online computer-based training, taken by all NRC employees and contractors, addresses allegation intake and routing (i.e., information to gather when contacted by a concerned individual and instructions for sending that information to a designated team of employees who follow up on the concerns raised). A second course is taken by those who participate in allegation follow-up. The second course includes instructions for coordinating and tracking the NRC’s handling of the evaluation (e.g., opening an allegation file, assigning a point of contact for the concerned individual, maintaining a database to track the evaluation’s progress), assigning actions to address the concerns based on their safety significance (e.g., inspect, request information from the licensee, investigate alleged wrongdoing), and finally providing closure to the concerned individual. Subject matter and instructional system design experts develop these courses.<br><br>After initial training, refresher training is required for most employees and contractors (i.e., those in positions likely to receive an allegation), and additional instructor-led training is provided as needed. |
| **Question No. 201** |
| Does the NRC have any comment on the trend of violations and enforcements, and the potential drivers for these? Violations seem to be trending in the negative direction, significantly. The NRC seems to be executing its role in nuclear safety; however, the concern would be in the trend and causes. |
| <u>Answer</u>: The total number of escalated enforcement actions in CY 2021 across all regulatory oversight programs slightly decreased from the total number (63) reported in CY 2020, and the total number remains smaller than the 5-year average (CY 2017–CY 2021). Operating reactors and nuclear materials users continue to account for most escalated enforcement actions. Please refer to “Enforcement Program Annual Report: Calendar Year 2021,” page 5, section I.B.1 (ML22136A108), for additional information on trends in enforcement actions. Several factors could be influencing the trend of violations and enforcement actions, including the cessation of operations at some power plants in the past 5 years or improved licensee performance, but no clear, discernible cause has been determined. |

## ARTICLE 10. PRIORITY TO SAFETY

**Each Contracting Party shall take the appropriate steps to ensure that all organizations engaged in activities directly related to nuclear installations shall establish policies that give due priority to nuclear safety.**

The NRC's mission is founded on nuclear and radiological safety, and regulatory activities pertaining to nuclear installations reflect the risk-informed, performance-based approach that the agency takes to fulfilling its mission. The NRC has several policy statements that describe the Commission's perspective on nuclear safety (e.g., PRA policy statements and policies that apply to licensee and NRC safety cultures). Other articles (e.g., Articles 6, 14, 18, and 19) also discuss activities to achieve safety at nuclear installations.

| **Question No. 6** |
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| USA may like to share few examples of safety-security interface issues faced by NRC regarding regulatory oversight of licensees and measures adopted to resolve them. |
| Answer: In 10 CFR 73.58, "Safety/security interface requirements for nuclear power reactors," the NRC requires that licensees assess and manage the potential for adverse effects on safety and security before implementing changes to plant configurations, facility conditions, or security. RG 5.74, Revision 1, "Managing the Safety/Security Interface," issued April 2015 (ML14323A549), provides licensees with guidance on assessing and managing safety and security activities to prevent or mitigate potential adverse effects to either plant safety or security at power reactors.<br><br>Additionally, in the area of cybersecurity, NRC guidance and licensee cybersecurity plans provide operators with the ability to implement alternate security measures if the original security control could negatively impact plant safety. Section 3.3, "Security Controls," of RG 5.71, Revision 0, "Cyber Security Programs for Nuclear Facilities," issued January 2010 (ML090340159), states in part the following:<br><br>A security control should not be applied if the control adversely impacts [safety, security, or emergency preparedness] functions or performance (e.g., unacceptable change in system response time, undesirable increase in system complexity). When a security control is determined to have an adverse impact, alternate controls should be used by the licensee to protect the [critical digital asset] from cyber attack up to and including the [design basis threat] consistent with the process described above. Any residual vulnerability in a [critical digital asset] as a result of not implementing a security control for concern over its impact to [critical digital asset] function or performance should be eliminated or mitigated by alternate controls.<br><br>The following are examples of safety/security interface issues that NRC licensees could face:<br><br>• When installing a physical modification to the plant for safety purposes, the licensee must ensure that impacts to the line of sight of armed responders do not prevent them from effectively protecting the plant from an attack.<br>• When installing a security modification to prevent intrusion into vital areas of the plant, the licensee must ensure that the modification does not prevent plant operators or emergency responders from carrying out their safety functions. |

- To prevent safety issues and other operational disruptions, licensees have deferred the application of software updates on digital systems until a refueling outage or another time when the system could be removed from service, ensuring in the interim that any vulnerabilities are adequately protected through other cybersecurity controls.

In addition to reviews conducted by licensees, the NRC also evaluates safety/security interface issues, both as part of the licensing program and as part of the inspection program.

**Question No. 21**

The US NRC Reactor Oversight Process (ROP) applies a graded approach, i.e., the usual (routine) level of inspections is guaranteed in a prescribed manner during normal operation at capacity. However, if the licensee's performance declines, it entails the increased number of inspections of the enterprise operation. ROP allows licensees to independently diagnose and implement corrective actions for their performance issues before the NRC performs subsequent inspections ("The United States of America Ninth National Report for the Convention on Nuclear Safety," p. 121)

(1) What percent of the reduction in the power plant capacity becomes an indisputable reason for an additional check?

(2) Is any unplanned capacity decrease or increase a reason for a response from the NRC and explanations from the licensee?

Answer:

(1) A reduction in capacity does not typically result in an NRC response unless it is the result of a scram. If a licensee reduces power by more than 20 percent because of an off-normal condition within the plant, this is reported as an input to the Unplanned Power Changes performance indicator. If there is an off-normal condition, inspectors will look at the issue using a baseline inspection procedure. If a licensee has more than six inputs to this performance indicator in 7,000 critical hours, the performance indicator exceeds a safety-significant threshold, and the licensee will be subject to a supplemental inspection.

(2) There are many reasons why a licensee requires a power reduction or increase. If the power change is due to an off-normal condition, an inspector will review the condition to determine if there is an issue of concern that may require additional inspection under the baseline inspection program. If a power reduction results from a safety-significant event, the event will be assessed for risk significance, which may result in a reactive inspection conducted by additional inspectors.

**Question No. 33**

It is mentioned that Risk-Informed Technical Specification Initiative 4b enables licensees to make one-time changes to the allowable outage times of safety-related equipment using inputs from PRA models factoring in the real-time status of equipment availability.

(1) Could USA elaborate how the real-time status of equipment availability is factored in the PRA models?

It is also mentioned that Risk-Informed Technical Specification Initiative 5b enables licensees to use inputs from PRA models to modify the surveillance interval of some safety-related equipment using PRA inputs.

(2) Could USA also clarify how Safety-Related equipment is selected for which the surveillance interval can be changed using PRA inputs?

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| <u>Answer</u>:<br>(1) As part of the Risk-Informed Technical Specification Initiative 4b program, the power plant operators maintain a software interface, named the Configuration Risk Management Program (CRMP), as referenced in the associated guidance documents, Nuclear Energy Institute (NEI) 06-09-A, "Risk-Informed Technical Specifications Initiative 4b: Risk-Managed Technical Specifications (RMTS) Guidelines," issued November 2006 (ML122860402), and Technical Specifications Task Force (TSTF)-505, "Provide Risk-Informed Extended Completion Times—RITSTF Initiative 4B" (ML18269A041). The CRMP is built on the plant-specific PRA models and provides an intuitive graphical user interface, which allows the operators to capture and reflect the real status of equipment in the plant. During operations, the CRMP is used continuously to monitor the real-time risk at the plant and to effectively plan maintenance activities. When plant equipment changes status, operators mark the respective equipment as unavailable/available, and the software requantifies the plant risk providing updated estimates for CDF, LERF, and associated risk-informed completion time estimates. One example of software used as CRMP in the United States is the Phoenix Risk Monitor, developed by EPRI.<br><br>The NRC staff reviews the licensee's approach before approving the use of the risk-informed completion time program at each site. Typically, for most licensees, the CRMP reflects the risk from internal events, internal flooding, and fire PRA models, while other external hazards are either screened out or captured with a bounding penalty, as necessary. The licensees also have a requirement for PRA configuration control to maintain the plant-specific PRA to reflect the as-built and as-operated plant.<br><br>(2) Select surveillance frequencies from the plant TS are licensed for the Risk Informed Surveillance Frequency Control Program. The candidate surveillance frequencies are specified in TSTF-425, Revision 3, "Relocate Surveillance Frequencies to Licensee Control—RITSTF Initiative 5b," issued March 2009 (ML090850642), and are reviewed and approved by the NRC with the issuance of the TSTF-425 license amendment for the licensee. As specified in the TSTF document, some frequencies are not included in the scope. These include items such as frequencies that are purely event driven (e.g., "Each time the control rod is withdrawn to the 'full out' position") or frequencies that are event driven but have a time component for performing the surveillance on a one-time basis once the event occurs (e.g., "within 24 hours after thermal power reaching ≥ 95% RTP [rated thermal power]"); frequencies that are related to specific conditions (e.g., battery degradation, age, and capacity); or frequencies that reference other approved programs for the specific interval. NEI 04-10-A, "Risk-Informed Technical Specifications Initiative 5b: Risk-Informed Method for Control of Surveillance Frequencies," issued April 2007 (ML071360456 and ML072570267), describes the underlying risk-informed methodology and uses a combination of deterministic considerations and PRA risk insights. The methodology allows for qualitative or bounding assessments of risk when components are not explicitly modeled in the PRA. |
| **Question No. 49** |
| It is stated that NRC approved the equipment risk-based standardization procedure.<br>(1) Does this procedure provide for specific values of probabilistic risk indicators?<br>(2) If yes, what are quantity values of such indicators for specific equipment categories? |
| <u>Answer</u>: The NRC did not approve a risk-based standardization procedure. Rather, the NRC approved risk-informed Technical Specifications Initiative 4b, which enables licensees to make one-time changes to the allowable outage times of safety-related equipment using inputs from PRA models factoring in the real-time status of equipment availability. |

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| The NRC also approved a risk-informed Technical Specifications Initiative 5b, which enables licensees to use inputs from PRA models to modify the surveillance interval of some safety-related equipment using PRA inputs. RG 1.177, Revision 2, “An Approach for Plant Specific Risk-Informed Decisionmaking: Technical Specifications,” issued January 2021 (ML20164A034), provides regulatory guidance on risk-informing TS. The NRC also endorsed implementing guidance developed by the NEI. NEI 04-10 provides implementing guidance for Technical Specifications Initiative 5b. NEI 06-09 provides implementing guidance for Technical Specifications Initiative 4b. These guidance documents provide significant details on the implementation of these risk-informed initiatives, including “probabilistic risk indicators” applicable to these initiatives. |
| **Question No. 50** |
| (1) What is the purpose of developing Level 3 PRA (i.e., obtaining a license for a specific type of activity, etc.)?<br>(2) What are the probabilistic risk indicators to be standardized and what are their target quantity parameters? |
| Answer:<br>(1) As stated in section 10.2.2 of NUREG-1650, Revision 8 (CNS Report), the NRC developed the Level 3 PRA to extract new risk insights to enhance regulatory decision-making and help focus limited agency resources on the issues most directly related to the agency’s mission to protect public health and safety; enhance and improve the PRA staff’s capability, expertise, and documentation to make PRA information more accessible, retrievable, and understandable; and obtain insight into the technical feasibility and cost of developing new Level 3 PRAs. At this time, there are no risk-informed activities for operating plants to develop and use Level 3 PRAs to support any specific licensing or oversight activities. In the future, plants that volunteer to adopt other licensing frameworks such as the Licensing Modernization Project, which is documented in NEI-1804, Revision 1, “Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development Report,” issued August 2019 (ML19241A472), and endorsed in RG 1.233, Revision 0,“Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” issued June 2020 (ML20091L698), will be required to develop Level 3 PRAs and use those results in support of a broad range of regulatory activities.<br><br>(2) When Level 3 PRA results are used to support risk-informed decision-making, the NRC will most likely use “probabilistic risk indicators” provided in the Commission Safety Goal Policy (51FR30028; August 21, 1986), such as qualitative and quantitative health objectives as “target quantity parameters” or acceptance criteria, together with other factors that are important to meet mandatory and discretionary authorities/responsibilities of the Commission. |
| **Question No. 90** |
| Section 10.3.2 of the national report (page 122) states that as part of the safety culture assessment process, NRC may ask the licensee to conduct a safety culture self-assessment if it has safety culture issues on the same common theme over three consecutive assessment periods.<br>(1) In this case, how does the licensee conduct its safety culture self-assessment?<br>(2) Please specify how NRC provides feedback to the process or outcome of the licensee self-assessment. |

Answer:
The NRC has asked licensees to perform third-party independent safety culture assessments on multiple occasions before supplemental inspections for licensees in Column 4 of the ROP Action Matrix for repetitive degraded cornerstones, multiple degraded cornerstones, multiple yellow inputs, or one red input (NRC Inspection Procedure 95003). The outcomes of NRC reviews of third-party safety culture independent assessments can be found in NRC inspection reports, such as the following:

- Browns Ferry Nuclear Plant 95003 Inspection Report, dated August 22, 2013 (ML13234A539)
- Arkansas Nuclear One 95003 Inspection Report, dated June 9, 2016 (ML16161B279)

The licensees conduct these using third-party consulting companies that have experience in performing safety culture assessments. The NRC reviews these assessments as part of its inspection activities and provides feedback through both verbal debriefings and inspection reports such as the ones listed above.

**Question No. 91**

The national report section 10.3.3 (page 123) explained that the regulatory body and nuclear operators may pursue different safety culture because of the different nature and mission of the organizations.
(1) What does NRC emphasize to enhance its own safety culture, different from the licensee's safety culture?
(2) Please elaborate on the background against which these differences were identified.

Answer:
(1) The NRC emphasizes and relays the importance of safety culture as an inherent component of the broader NRC organizational culture that is complementary to, but distinct from, the agency's work regulating licensees' safety culture; thereby, the NRC focuses attention on organizational health. The agency recognizes the importance of individually and collectively connecting to its safety mission so that safety is every employee's responsibility. When each NRC employee demonstrates a level of responsibility for their behaviors and attitudes that support a positive organizational culture, safety culture also improves. Previous studies conducted at the NRC have revealed that key safety culture indices result in an engaged, innovative, and inclusive workforce—all of which contribute to a healthy organization. Thus, when safety culture indices rise, employee engagement also increases. For this reason, the NRC emphasizes fostering a healthy organization as strategic goal #2 in its 5-year Strategic Plan (2022–2026):

Organizational Health:

2.1 Foster an organizational culture in which the workforce is engaged, adaptable, and receptive to change and makes data-driven and evidence-based decisions.

2.2 Enable the workforce to carry out the agency's mission by leveraging modern technology, innovation, and knowledge management to support data-driven decisions in an evolving regulatory landscape.

2.3 Attract, develop, and maintain a high-performing, diverse, engaged, and flexible workforce with the skills needed to carry out the NRC's mission now

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| and in the future.<br><br>(2) The NRC fosters a culture in which all employees live the NRC's values, demonstrate a positive safety culture, and adhere to the Principles of Good Regulation to support the agency's mission to protect public health, safety, and the environment. The NRC culture includes a system of shared values, beliefs, and behaviors that demonstrates a collective commitment to emphasize safety as the overriding priority in the agency's regulatory decision-making and that recognizes the important role each employee plays in the NRC's success. NRC employees are committed to creating and sustaining a positive work environment to ensure that the agency remains a model regulator.<br><br>Nuclear operators are governed by the Safety Culture Policy Statement (SCPS), which the NRC promulgated in 2011. The SCPS defines nuclear safety culture as the core values and behavior resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. The SCPS includes a list of nine traits further defining a positive safety culture. These traits describe patterns of thinking, feeling, and behaving that emphasize safety, particularly in goal conflict situations, such as when safety goals conflict with production, schedule, or cost goals. Those traits identified in the SCPS overlap with NRC cultural artifacts (e.g., NRC Values, Principles of Good Regulation, and the agency's Leadership Model) that serve as guideposts for the continued development of the desired culture. |
| **Question No. 162** |
| (1) The report states that the NRC has identified a number of traits of a positive safety culture, among them is the trait: Continuous learning. Safety research (e.g., research in the context of high reliability organisations HRO), reveals that the focus on positive, every day performance also gives good indications on how to improve or strengthen safety. Is the issue of Safety-I vs. Safety-II (Safety-I [focus on error] vs. Safety-II [focus on positive performance]) also discussed in the context of the before mentioned trait in the USA, at the NRC? |
| <u>Answer</u>:<br>The NRC does not specifically refer to Safety I and Safety II in its SCPS. The NRC recognizes that the licensee can learn from many kinds of knowledge, events, analysis, and experiences, based both on positive performance and errors, so does not distinguish between the two in the SCPS.<br><br>The NRC's SCPS defines "continuous learning" as "opportunities to learn about ways to ensure safety are sought out and implemented." Examples of behaviors related to this trait are provided in the "Trait Talk on Continuous Learning," issued February 2015 (ML15050A092), and included below. As can be seen, these examples do not distinguish between events, assessments, or experiences focused on positive performance or on errors or poor performance. In developing a positive safety culture, licensees should consider a wide range of data and analysis from operating experience, self-assessment, and benchmarking, and incorporate both positive and negative examples as appropriate, into their training and organizational best practices.<br><br><u>**Operating Experience**</u>: **The organization systematically and effectively collects, evaluates, and implements relevant internal and external operating experience in a timely manner**—A process is in place to ensure a thorough review of operating experience provided by internal and external |

sources. Operating experience is implemented and institutionalized effectively through changes to processes, procedures, equipment, and training programs. Operating experience is used to understand equipment, operational, and industry challenges and to adopt new ideas to improve performance. Operating experience is used to support daily work functions, with emphasis on the possibility that "it could happen here." Operating experience is shared in a timely manner.

<u>Self-Assessment</u>: **The organization routinely conducts self-critical and objective assessments of its programs and practices**—Independent and self- assessments, including nuclear safety culture assessments, are thorough and effective and are used as a basis for improvements. The organization values the insights and perspectives assessments provide. Self-assessments are performed on a variety of topics, including the self-assessment process itself. They are performed at a regular frequency and provide objective, comprehensive, and self-critical information that drive corrective actions. Targeted self-assessments are performed when a more thorough understanding of an issue is required. A balanced approach of self-assessments and independent oversight is used and periodically adjusted based on changing needs. Self-assessment teams include individual contributors and leaders from within the organization and from external organizations when appropriate.

<u>Benchmarking</u>: **The organization learns from other organizations to continuously improve knowledge, skills, and safety performance**—The organization uses benchmarking as an avenue for acquiring innovative ideas to improve nuclear safety. The organization participates in benchmarking activities with other nuclear and nonnuclear facilities. The organization seeks out best practices by using benchmarking to understand how others perform the same functions. Benchmarking is used to compare standards to the industry and to make adjustments to improve performance. Individual contributors are actively involved in benchmarking.

<u>Training</u>: **The organization provides training and ensures knowledge transfer to maintain a knowledgeable, technically competent workforce and instill nuclear safety values**—The organization fosters an environment in which individuals value and seek continuous learning opportunities. Individuals, including supplemental workers, are adequately trained to ensure technical competency and an understanding of standards and work requirements. Individuals master fundamentals to establish a solid foundation for sound decisions and behaviors. The organization develops and effectively implements knowledge transfer and knowledge retention strategies. Knowledge transfer and knowledge retention strategies are applied to capture the knowledge and skill of experienced individuals to advance the knowledge and skill of less experienced individuals. Leadership and management skills are systematically developed. Training is developed and continuously improved using input and feedback from individual contributors and subject-matter experts. Executives obtain the training necessary to understand basic operations and the relationships between major functions and organizations.

| Question No. 163 |
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| The Swiss regulator ENSI created the position “coordination officer for the ENSI’s safety culture” in spring 2022. In the chapter “the NRC safety culture”, ENSI has read many interesting aspects on how to promote its own safety culture. Thank you for these insights and your presentation. |
| Answer: Thank you for your comments and observations. The agency appreciates the positive feedback. |
| **Question No. 178** |
| (1) What type of acceptance guidelines and rules do you use for allowable risk changes (CDF-ΔCDF & LERF-ΔLERF)?<br>(2) Do you distinguish separate rules for instantaneous, average and cumulative risk for risk-informed applications?<br>(3) Do you include statistical and dynamic components of the risk in these applications? |
| Answer:<br>(1) Acceptance guidelines used to support various applications are described in detail and in the appropriate context (e.g., how they are used with other qualitative factors to support risk-informed decision-making (RIDM)) in various NRC guidance documents such as regulatory guides (RGs), management directives (MDs), and inspection manual chapters (IMCs). For example, RG 1.174 provides guidance on how CDF-ΔCDF and LERF-ΔLERF values are used to evaluate the acceptability of proposed changes to a licensees’ licensing bases. IMC 609, “Significance Determination Process,” dated April 29, 2015 (ML14153A633), provides guidance on how CDF-ΔCDF and LERF-ΔLERF values are used to support the risk-informed oversight process. NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Draft Report for Comment,” issued April 2017 (ML17100A480), provides guidance on how CDF-ΔCDF and LERF-ΔLERF are used in regulatory analyses that support the rulemaking process.<br><br>(2) NRC guidance documents distinguish separate rules for instantaneous, average, and cumulative risk for risk-informed applications. For example, RG 1.174 provides guidance on how cumulative risk is used in RIDM.<br><br>(3) “Statistical” or average and “dynamic” or instantaneous risk is used in some NRC risk-informed applications. For example, the NRC’s office instruction LIC-504, Revision 5, “Integrated Risk-Informed Decisionmaking Process for Emergent Issues,” effective March 9, 2020 (ML19253D401), demonstrates how the elevated risk level that is attributed to a potential degraded condition at a plant is used to support RIDM, using the risk-metric conditional core damage frequency. |
| **Question No. 202** |
| The Level 3 PRA project seems to being seeing annual pushes to the end date. Given the perceived importance, how is this being addressed? |
| Answer: The NRC has continued its progress towards completion of the Level 3 PRA project, despite various resource challenges that affected its schedule. Currently, the NRC plans to complete all analyses and publish all the reports during CY 2023 and CY 2024. To meet that goal, the NRC has begun issuing various parts of the completed Level 3 work for public comment. To that end, in April 2022, NRC issued the Level 3 PRA results on at-power and internal events (drafts of Volumes 2, 3x, 3a–3d). |
| **Question No. 203** |
| Has the NRC given any thought to combining safety and security culture, similar to what INPO has done? |

Answer: The NRC specifically addresses safety and security in its Safety Culture Policy Statement (SCPS).

The SCPS states the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. The Commission agreed that an overarching safety culture addresses both safety and security and does not need to single out "security" in the definition. However, to ensure that security is appropriately encompassed within the statement of policy, the staff added a preamble to the traits and retained the robust discussion of security, including the importance of considering the interface of safety and security that was included in the draft SCPS, as follows:

> Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC regulated activities.
>
> Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, e.g., production, schedule, and the cost of the effort versus safety. It should be noted that although the term "security" is not expressly included in the following traits, safety and security are the primary pillars of the NRC's regulatory mission. Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy.

In November 2017, the NRC provided a paper, "U.S. Nuclear Regulatory Commission: Safety and Security—Policy and Oversight" (ML17248A421), for the International Conference on Physical Protection of Nuclear Material and Nuclear Facilities at the IAEA in Vienna, Austria. This paper discusses how the NRC addresses safety and security for NRC licensees, applicants, and vendors through policies, programs, and regulations, including the SCPS, the ROP, and the Allegation and Enforcement programs. This paper also describes how the SCPS addresses both safety and security and how safety and security performance is assessed through the ROP for operating power reactors, and through the Allegation and Enforcement programs for material users and vendors, as well as operating power reactors. Finally, this paper includes illustrative examples of security/safeguards inspection findings tagged to ROP safety culture aspects and security/safeguard findings resulting in alternative dispute resolution.

**Question No. 204**

The process for assessing NRC Safety Culture and oversight of licencees seems really good. Can the NRC speak to the results and trends of safety culture?

Answer:
Licensee Safety Culture: The NRC reviews safety culture on a licensee-specific basis. No adverse industrywide trends have been noticed. No cross-cutting issues have been opened in the past 5 years. The NRC has qualified safety culture assessors at headquarters and in the regional offices who have completed the qualifications in IMC 1245, "Qualification Program for the Office of Nuclear Reactor Regulation Programs," Appendix C-12, "Safety Culture Assessor" (ML19263C895). These assessors are trained to perform safety culture inspections and assessments at licensed facilities.

On the NRC public website, the operating reactor analytics dashboard allows the user to plot inspection findings by cross-cutting aspects assigned. Please refer to this dashboard link for more information on the assigned cross-cutting aspects:
https://www.nrc.gov/reactors/operating/oversight/analytics.html.

NRC Safety Culture: To support continuous improvement of the NRC's safety culture, self-assessment and self-reflection practices are routine. Organizational development experts, skilled and reputable in designing questionnaires and assessing both organizational climate and culture, collect agencywide data for the review and analysis of leadership, engagement, and satisfaction. At the office level, each office supplements these results with actions that are pertinent to their organizational environment. In addition, the agency uses the Office of the Inspector General's routine Safety Culture and Climate Survey to help assess organizational health.

Declining trends in several qualitative and quantitative datasets over the past decade draw attention to organizational health as a priority for NRC leadership and even more so since the global pandemic in order to invest additional resources and attention towards making improvements. The NRC recognizes the need for continuous improvement to maintain a positive work environment and a healthy organization and is not complacent with the results. Complacency lends itself to a degradation in safety culture when new information and historical lessons are not processed and used to enhance the NRC and its regulatory products.

## ARTICLE 11. FINANCIAL AND HUMAN RESOURCES

1. **Each Contracting Party shall take the appropriate steps to ensure that adequate financial resources are available to support the safety of each nuclear installation throughout its life.**

2. **Each Contracting Party shall take the appropriate steps to ensure that sufficient numbers of qualified staff with appropriate education, training, and retraining are available for all safety-related activities in or for each nuclear installation, throughout its life.**

This section explains the requirements for financial resources that licensees must have to support the nuclear installation throughout its life and the regulatory requirements for qualifying, training, and retraining personnel.

| **Question No. 57** |
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| Could you please show the statistics (starting with 2017) of NPP operating events associated with erroneous actions of operators? |
| Answer: In tracking operating experience, the NRC staff reviews licensee event reports, which contain root causes and corrective actions undertaken by licensees. These reports can be found on the NRC public website: https://www.nrc.gov/reading-rm/doc-collections/event-status/index.html.<br><br>Events can have multiple causes, and while the NRC staff makes note of events with operator error as a significant contributing factor, this is directly addressed by inspection follow-up on a licensee-by-licensee basis rather than being compiled statistically. |
| **Question No. 77** |
| (1) Are the operators of NPPs obliged to implement the knowledge management programmes in their organizations?<br>(2) If yes, does NRC verify those programmes and their implementation. |
| Answer:<br>(1) Yes. All current facilities use the systems approach to training (SAT) for operators, required by 10 CFR 55.59(c). The SAT, defined in 10 CFR 55.4, includes trainee participation. Licensees use operating experience in training when appropriate, as specified in the SAT process.<br>(2) The NRC inspects operator requalification programs with Inspection Procedure 71111.11, “Licensed Operator Requalification Program and Licensed Operator Performance,” effective January 1, 2022 (ML21257A202). In addition, NRC inspectors observe operator performance in the plant with a variety of ROP inspection procedures to verify that operators have sufficient knowledge to safely operate the plant. NRC inspectors also verify that licensees evaluate operating experience and incorporate lessons learned when applicable. |
| **Question No. 92** |
| Article 11.2 Regulatory Requirements for Qualifying, Training and Retraining Personnel in the national report (page 132) describes the qualification requirements for licensed operators, training hours, and retraining. Regarding this, please expound:<br>(1) who gives training on access to nuclear facilities to (radiation) workers who are not licensed operators;<br>(2) requirements for completing training; and |

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| (3) what are taught during training. |
| Answer:<br>(1) Most stations assign a specific individual the responsibility to guide workers through general orientation training. This includes showing them how to log on to the industry's electronic training system, National Academy for Nuclear Training e-Learning (NANTeL), checking their progress, and proctoring exams. In some cases, this is a training person, and in other cases it can be a knowledgeable person from another station department.<br><br>(2) General orientation training for nuclear plant workers is normally provided via computer-based training (CBT) through NANTeL. This training is completed before an individual is permanently badged for access.<br><br>(3) Site-specific CBTs exist across the industry and differ from plant to plant. However, a standard curriculum of generic orientation training CBTs would be similar to the following across the industry:<br><br>Course Requirements for Access to the "Protected Area":<br>Generic Fitness for Duty and Behavioral<br>Generic Plant Access Training<br>Generic Foreign Material Exclusion<br>Generic Material Handling<br>Generic Electrical<br>Generic Awareness<br>Generic Cybersecurity Awareness<br>Generic Asbestos Awareness<br>Generic Lead Awareness<br>Generic Human Performance Modules<br><br>Additional Course Requirements for "Radiation Workers" (those with access to a radiologically controlled area):<br>Generic Rad Worker<br>Radiation Protection Dress Out—this is normal done by site personnel (often the instructor or similarly qualified individual) and specific requirements vary from site to site<br><br>Additional Courses that May Be Required by Some Sites:<br>Generic Respiratory Protection<br>Generic Scaffold Safety<br>Generic Fall Protection<br>Generic Confined Space |
| **Question No. 117** |
| If a licensed employee, for some reason, had a break in work at a nuclear facility, then after what time is the license canceled and retraining (relicensing) carried out? |
| Answer: The answer depends in part on why there was a break in work at the facility. If the licensed operator terminated employment with the facility and later came back to the facility to work, the license expires as soon as the operator terminates their employment, as described in 10 CFR 55.55, "Expiration." The operator would then have to either redo the initial licensing process, including another examination, or would have to follow the waiver process of 10 CFR 55.47, "Waiver of examination and test requirements," to request a waiver of the examination. The operator would have to show how the requirements for the waiver provided in 10 CFR 55.47 are met. If the operator continued to be employed at the facility but was not |

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| able to participate in the requalification program under 10 CFR 55.59, then there is a provision under 10 CFR 55.59(b) to do additional training. This is further described in NUREG-1021, Revision 12, "Operator Licensing Examination Standards for Power Reactors," issued September 2021 (ML21256A276), further describes this in ES-5.3, section A.1.c. In this case, the facility is expected to notify the NRC if any licensed operator is unable to participate in the requalification program and provide details of how the facility will make sure that the operator is qualified before resuming licensed duties. In this case, the license is not canceled, as long as none of the license expiration criteria under 10 CFR 55.55 are met. |
| **Question No. 205** |
| Can the NRC comment on any insights on potential considerations/changes to insurance policies for smaller reactors? |
| <u>Answer</u>: The regulation at 10 CFR 140.12, "Amount of financial protection required for other reactors," identifies financial protection requirements for nuclear reactors not addressed in 10 CFR 140.11, "Amounts of financial protection for certain reactors." Reactors that generate in excess of 10 megawatts thermal (MWt) but do not generate electrical power, and reactors that generate less than 100 megawatts electric (MWe) are required to carry an amount of liability insurance between \$4.5 and \$74 million. The exact amount is determined by a formula described in the regulations, which is based on thermal power and on a site's population factor. Because the power level for each reactor module is less than 100 MWe, these reactors are not required to participate in the secondary retrospective premium plan.<br><br>In 10 CFR 140.11, the NRC also allows a combination of facilities above 100 MWe but below 300 MWe each, with a combined rated capacity of no more than 1,300 MWe, that are located at a single location to be treated as a single facility for assessing the financial protection requirements.<br><br>Given that nuclear reactors below 100 MWe are not required to participate in the secondary layer of financial protection, the Price-Anderson Act and the NRC's regulations are silent as to a combination of facilities below 100 MWe participating in the secondary retrospective premium plan.<br><br>The NRC has noted that, based on this approach, an SMR facility with multiple reactors below 100 MWe would be required only to purchase primary insurance despite a significantly higher overall capacity of the facility (SECY-11-0178, "Insurance and Liability Regulatory Requirements for Small Modular Reactor Facilities," dated December 22, 2011 (ML113340133)). Such an approach could be an issue if events affecting multiple units resulted in the risks of offsite consequences being significantly higher than the risk posed by a single unit. The NRC assesses multiunit risks as part of the licensing process for nuclear reactors, including SMRs and future advanced reactor designs. The assessments are used to ensure appropriate treatment of important insights related to multiunit design and operation.<br><br>The information gathered through the licensing process for specific designs and facilities, together with the analysis performed for the development of a regulatory framework for advanced reactors (SECY-21-0010, "Advanced Reactor Program Status," dated February 1, 2021 (ML20345A240)), will inform future decision-making relating to Price-Anderson Act coverage of SMR facilities. At this time, the staff does not recommend changes to the Price-Anderson Act framework to address different designs of SMR facilities and will monitor the progress of SMR technology and operational experience to further assess this topic for future consideration as it relates to Price-Anderson Act coverage. |

## ARTICLE 12. HUMAN FACTORS

**Each Contracting Party shall take the appropriate steps to ensure that the capabilities and limitations of human performance are taken into account throughout the life of a nuclear installation.**

This section discusses human factors regulatory review and control activities of items such as plant design and modifications, organizational issues, staffing, and fitness for duty. This section also explains how human factors activities are integrated into the Reactor Oversight Process and how feedback and experience in human factors is considered in the regulatory program.

| **Question No. 58** |
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| (1) How are the skills of NPP operators trained and tested in case of multi-unit accident caused by beyond-design basis external events at the NPP site?<br>(2) Have procedures been developed to respond to beyond design external events at the NPP site?<br>(3) How do nuclear power plants document information on control over the limits and conditions of safe operation, are there appropriate procedures in place?<br>(4) How do nuclear power plants control compliance with safe operation limits and conditions established in technical specifications and safety review reports (SRR), are there appropriate procedures available? |
| Answer:<br>(1) The NRC requires that facilities train operators for multiunit accidents caused by beyond-design-basis external events in accordance with 10 CFR 50.155(d). All current facilities use the systems approach to training (SAT) for operators, as required by 10 CFR 55.59(c). As defined in 10 CFR 55.4, the SAT process includes evaluation of trainee mastery of the objectives during training. For emergency preparedness, Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities,” to 10 CFR Part 50, IV.F.2.j.(iii)(4), requires an exercise scenario at least once per 8-year exercise cycle that implements strategies, procedures, and guidance related to 10 CFR 50.155(b)(2) criterion.<br><br>(2) The NRC requires in 10 CFR 50.155(b) that facilities develop strategies and guidelines for beyond-design-basis external events.<br><br>(3) and (4) Facilities have limiting conditions for operation, defined in 10 CFR 50.36(c)(2) as the “lowest functional capability or performance levels of equipment required for safe operation of the facility” in TS. In accordance with 10 CFR Part 50, Appendix B, Criterion V, “Instructions, Procedures, and Drawings,” the NRC requires, in part, that activities affecting safety shall be prescribed by procedures and shall be accomplished in accordance with these procedures. In addition, facilities are required to establish and implement procedures required by TS, including procedures for log entries, record retention, and review procedures. Operators document compliance with requirements in records and in logs. |
| **Question No. 66** |
| (1) Was remote operation of multiple units part of the NuScale licensing documentation?<br>(2) Has there been SMR design reviews involving remote operation concepts?<br>(3) How NRC perceives the significance of this topic in the development of a risk-informed, technology-inclusive regulatory framework? |

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| Answer:<br>(1) The NuScale plant uses licensed operators in an onsite control room. Remote operations were not considered and were not a part of the DC.<br><br>(2) The NRC has not licensed any SMRs involving remote operation concepts. Existing regulations do not allow for remote operations.<br><br>(3) The NRC is considering the impact of remote operation during the development of new regulations for advanced reactors (10 CFR Part 53). However, the draft rule does not explicitly address remote operations at this time. The NRC is conducting research that will be used to inform future positions related to remote operations. |
| **Question No. 69** |
| The NRC has assessed NuScale staffing plan, where multiple units (up to 12) are controlled from a single main control room. In their topical report, NuScale requested that the staff approve a control room staffing plan with a minimum control room crew of three licensed operators and no shift technical advisor. What were the main findings and conclusions regard to this assessment and approval of NRC? |
| Answer: The NRC staff's review of the NuScale topical report TR-0420-69456, "NuScale Control Room Staffing Plan," Revision 1, issued December 2021 (ML21012A361), focused on whether the proposed three-person control room crew could successfully accomplish the most demanding tasks under conditions that reflect real-world challenges, including the demands of multitasking. The staff assessed the methods NuScale used to conduct the staffing plan validation tests, including the scenarios NuScale developed to create challenging, high-workload conditions for the test operators in the simulator and reviewed the task performance, workload, and situational awareness measurement results. The staff found that task performance was successful, workload scores were relatively low, and situational awareness scores were relatively high. Even when measured workload reached relatively high levels, task performance was not negatively affected during the scenarios. Also, situational awareness remained high during peaks in measured workload, which demonstrates that test participants maintained awareness of plant conditions even during the most challenging scenarios. The NRC staff concluded that the staffing plan validation test results show that the staffing proposal is acceptable. As part of this review, the staff also determined that the shift technical advisor role is not necessary for the safe operation of a NuScale plant. The staff based this determination on the following:<br><br>• The NuScale plant system design has lower operational complexity (compared to operating reactors), does not require operator actions during design-basis events, and provides an overall improvement in safety.<br>• The NuScale control room human-system interface design reflects state-of-the-art human factors engineering principles and includes features that alert the crew when a critical safety function is challenged, a plant parameter has exceeded an emergency action level, and a system or component may be inoperable.<br>• The results of the staffing plan validation tests demonstrate that operators can interpret the indications provided on the human-system interface with adequate performance across a variety of measures, without a shift technical advisor.<br>• Operators at a NuScale plant will receive training on the engineering concepts that are relevant to operating a commercial NPP and mitigating core damage, in addition to other plant-specific training.<br>• The staffing plan includes the availability of a second senior operator on shift to assist the |

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| control room supervisor and provide advice, assistance, and an independent assessment of events.<br>• The control room operators have time, without challenging plant safety functions, to get assistance from other off-shift resources, if faced with a situation that is not covered by training or procedures. |
| **Question No. 93** |
| In page 137 of the national report, NRC issued Order EA-12-049 after the Fukushima accident to require nuclear operators to establish mitigation strategies against beyond design basis external disasters. Regarding this order:<br>(1) How are the follow-up measures proceeding after NRC Order EA12-049?<br>(2) What types of physical reinforcements have been made, such as mobile generators?<br>(3) What was the budget for the whole follow-up measures and the budget for each unit? |
| <u>Answer</u>:<br>(1) As of June 18, 2018, all operating power reactor units are in compliance with Order EA-12-049, "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," dated March 12, 2012 (ML12054A735). The NRC staff performed its inspections in accordance with NRC Inspection Manual Temporary Instruction 2515/191 (TI-191), Revision 2, "Inspection of the Implementation of Mitigation Strategies and Spent Fuel Pool Instrumentation Orders and Emergency Preparedness Communication/Staffing/Multi-Unit Assessment Plans," dated July 2018 (ML18191B074), at units declaring compliance to verify that required FLEX equipment and connections are in place. As of June 28, 2019, TI-191 inspections at all operating power reactor sites were complete.<br><br>(2) RG 1.226, Revision 0, "Flexible Mitigation Strategies for Beyond-Design-Basis Events," issued June 2019 (ML19058A012), endorses, with clarifications, methods and procedures in Nuclear Energy Institute (NEI) technical document 12-06, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide," issued December 2016 (ML16354B421), for complying with 10 CFR 50.155, which codifies Order EA-12-049. FLEX capabilities vary from plant to plant based on plant-specific evaluation performed by the licensee, but will typically include mobile generators and associated cabling, portable pumps and hoses, and necessary equipment to facilitate moving and placing these into operation (trucks, forklifts, portable lighting, etc.). Additionally, FLEX equipment is stored on site in areas protected from potential natural hazards. NEI 12-06 also provides guidelines for storage configurations to prevent failure of FLEX capabilities because of external events. In addition to onsite FLEX equipment, additional FLEX equipment is stored at two national response centers and is capable of being delivered to any plant in the United States within 24 hours.<br><br>(3) FLEX strategies are funded by and vary according to the licensees/owners of the units who implemented the strategies. The NRC does not require reporting of such cost information and has not tracked such figures. |
| **Question No. 118** |
| Is there an assessment of personnel commitment to the principles of safety culture (procedure, criteria, frequency)? |
| <u>Answer</u>: Through a safety culture common language initiative with the U.S. nuclear power industry, the NRC and industry agreed to various attributes that describe each of the safety culture traits in a more behavior-based way. These attributes can be found in NUREG-2165, "Safety Culture Common Language," issued March 2014 (ML14083A200). Inspectors use these attributes within the NRC's Cross-Cutting Issues (CCI) Program to determine whether |

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| inspection findings have cross-cutting causal factors related to safety culture. In the CCI Program, the safety culture attributes are referred to as "cross-cutting aspects." Inspection Manual Chapter 0310, "Aspects within the Cross-Cutting Areas," dated February 25, 2019 (ML19011A360), provides a crosswalk between the cross-cutting aspects and safety culture traits and attributes. In addition, for plants in Columns 3 and 4 of the NRC's action matrix, the agency will perform its own assessments of a licensee's safety culture using the attributes described in NUREG-2165. |
| **Question No. 119** |
| (1) Is the Blame-Free policy in implemented?<br>(2) What role does it play in ensuring nuclear and radiation safety? |
| Answer: The NRC does not use the term "blame-free policy." The NRC does have a similar policy called "safety-conscious work environment" (SCWE). SCWE is defined as an environment in which employees feel free to raise safety concerns to management (or a regulator) without fear of retaliation. The NRC has a policy statement outlining the Commission's expectations for licensed facilities to maintain an SCWE. This policy contributes to nuclear safety by allowing employees to raise nuclear safety concerns through multiple avenues available to them (corrective action programs, employee concerns programs, allegations raised to the NRC, etc.) without fear. |
| **Question No. 206** |
| In the second sentence, you have added the clarification around "the people who form the plant staff." This might be taken to mean that people outside of direct plant operations are not considered. Could you clarify? |
| Answer: The prior revision of the report stated, "…the NRC began focusing on protecting the people that form the plant staff and ensuring that they have adequate training to perform their assigned tasks." This revision changed that statement to "…the NRC began focusing on ensuring that the people who form the plant staff have adequate training to perform their assigned tasks." This change was made to clarify that the NRC's focus is on ensuring the adequacy of the training of these persons.<br><br>This statement is in reference to 10 CFR 50.120 and 10 CFR Part 55, which provide requirements for the training and qualification of certain categories of facility personnel. These categories include licensed operators, nonlicensed operators, shift supervisors, shift technical advisors, instrument and control technicians, electrical maintenance personnel, mechanical maintenance personnel, radiological protection technicians, chemistry technicians, and engineering support personnel. Individuals working in any of these categories are required to be adequately trained and qualified to perform their tasks. |

## ARTICLE 13. QUALITY ASSURANCE

**Each Contracting Party shall take the appropriate steps to ensure that quality assurance programmes are established and implemented with a view to providing confidence that specified requirements for all activities important to nuclear safety are satisfied throughout the life of a nuclear installation.**

This section describes quality assurance requirements and guidance for design and construction, operational activities, and staff licensing reviews. It also describes quality assurance programs and regulatory guidance.

| **Question No. 2** |
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| (1) What is the scope of components inspected by the NRC?<br>(2) Is there a certification given by the US NRC to Vendors who pass the inspection?<br>(3) What are the obligations of reactor operators in inspecting the Vendors and Manufacturers? |
| <u>Answer</u>:<br>(1) The United States inspects suppliers of safety-related structures, systems, and components (SSCs), commonly referred to as “basic” components, consistent with those SSCs that meet the definition in 10 CFR 50.2:<br><br>*Basic component* means, for the purposes of § 50.55(e) of this chapter:<br><br>(1) When applied to nuclear power reactors, any plant structure, system, component, or part thereof necessary to assure<br>(i) The integrity of the reactor coolant pressure boundary,<br>(ii) The capability to shut down the reactor and maintain it in a safe shutdown condition, or<br>(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.<br><br>(2) When applied to other types of facilities or portions of such facilities for which construction permits are issued under § 50.23, a component, structure, system or part thereof that is directly procured by the construction permit holder for the facility subject to the regulations of this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.<br><br>(3) In all cases, *basic component* includes safety related design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or other supplier.<br><br>(2) The NRC performs a limited number of inspections of vendors annually as it is the responsibility of NRC licensees to oversee the international supply chain. The NRC does not provide any certification to suppliers as a result of inspections; however, the agency |

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| does develop an inspection report to document the results of that inspection. Within the inspection report, the NRC states, in part, that "This NRC inspection report does not constitute NRC endorsement of your overall quality assurance (QA) or 10 CFR Part 21 programs."<br><br>(3) In accordance with Criterion VII of 10 CFR Part 50, Appendix B, NRC licensees are obligated to assess suppliers on their Approved Supplier List on a periodic basis commensurate with the importance, complexity, and quantity of the product or services. In practice, this interval shall not exceed 36 months, with the potential for a 9-month additional interval under exigent conditions only. |
| **Question No. 47** |
| [Para.13.2.2 states: "Appendix B specifies 18 quality criteria that must be addressed in a licensee's quality assurance program description. These criteria cover such topics as organizational independence, design control, procurement, procedures, document control, test control, special processes, calibration, corrective action, quality assurance records, and audits."] Could you please provide more detailed information on aforementioned 18 criteria? |
| <u>Answer</u>: Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 defines the 18 criteria of the quality assurance program to be applied to the design, fabrication, construction, testing, and operation of the facility's SSCs. Each criterion describes the specific requirements to ensure the quality assurance functions, including (1) ensuring that an appropriate quality assurance program is established and effectively executed and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. Overall, the 18 criteria of Appendix B cover the structure and organizational responsibilities necessary to carry out the quality assurance program, the training and qualification of key individuals, and the roles and responsibilities for program implementation. The criteria also address the specific activities associated with designing, fabricating, testing, and implementing those SSCs and activities such as services defined as safety related. Importantly, Appendix B also provides for the identification, documentation, evaluation, and disposition of nonconforming materials, items, and services, as well as a structured robust process for correcting identified nonconforming conditions and programmatic weaknesses. Finally, the criteria also cover the required oversight activities to evaluate implementation of suppliers' quality assurance programs, as well as internal quality-related activities of the licensees. |
| **Question No. 94** |
| Could you introduce the NRC's major activities and regulatory requirements to prevent and detect CFSIs? |
| <u>Answer</u>: The NRC's regulations are designed to protect both the public and workers from radiation hazards resulting from regulated activities. Regulated entities' compliance with NRC regulations provides reasonable assurance that these entities operate safely such that there is no undue risk to public health and safety. Consistent with these requirements, regulated entities are responsible for preventing and mitigating certain risks associated with counterfeit, fraudulent, and suspect item (CFSI) hazards as related to the safe operation of the regulated entities. Regulated entities' own oversight of suppliers through use of audits and evaluations and the NRC's oversight activities verify the proper implementation of these measures and add confidence that the risk from CFSIs in NRC-regulated activities is minimized.<br><br>The NRC issues regulatory guidance, security advisories, and other forms of generic |

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| communication to provide its regulated entities with guidance and information for preventing and mitigating CFSI risks that could challenge the safe operations of regulated entities. NRC oversight programs are designed to ensure compliance with the agency's requirements, in part, through inspection, investigations, and enforcement. The NRC's current regulatory framework provides reasonable assurance that CFSI hazards are prevented or mitigated and ensures that adequate quality assurance (QA) controls are established by NRC-regulated entities. The NRC oversight programs provide a means to measure and assess industry performance to verify that the presence of CFSIs is appropriately identified by regulated entities. The NRC issues inspection guidance and provides training to its staff to enhance awareness of CFSI risks. |
| **Question No. 95** |
| It is described that the NRC has specified that quality assurance controls (typically called "augmented quality control") are warranted for equipment determined to be more important than commercial-grade equipment (important to safety, yet non-safety-related equipment). Could you provide more detailed information about the regulatory requirements and regulatory activities with regard to "augmented quality control" for the equipment classified as non-safety-related but still important to safety? |
| Answer: The NRC has applied the term "augmented quality" to SSCs that are not safety related but are credited for meeting certain regulatory events. Examples include anticipated transients without scram equipment credited to meet 10 CFR 50.62, "Requirements for reduction of risk from anticipated transients without scram events for light-water-cooled nuclear power plants"; fire protection equipment credited to meet 10 CFR 50.48, "Fire protection"; and station blackout equipment credited to meet 10 CFR 50.63, "Loss of all alternating current power." This equipment must function reliably, and thus, quality controls beyond those typically applied to commercial items are applied to them. This additional quality focus is termed "augmented" and is described in licensees' QAPDs. Typically, each licensee determines the implementation of these controls in accordance with the importance to safety of the SSCs covered under those provisions. Licensee programmatic controls are typically similar to but less stringent than those for safety-related SSCs subject to Appendix B requirements. Alternative approaches to determining the special treatments that apply to SR SSCs also exists under 10 CFR 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," and RG 1.233, both of which rely on PRA to show that these SSCs are of low safety significance. |
| **Question No. 96** |
| It is described that industry initiatives to promote effective and efficient standardization of audit activities of suppliers have resulted in licensees sharing their technical resources through joint audits of suppliers. How does the NRC verify the adequateness of licensees' joint audit program and their audit activities such as NUPIC? (i.e., does the NRC review the NUPIC QA audit program manual and/or verify if the NUPIC QA audit activities are implemented in accordance with the regulatory requirements?) |
| Answer: The NRC routinely participates in the Nuclear Procurement Issues Corporation (NUPIC) general membership and vendor conferences and shares experiences with NRC supplier oversight inspections and NUPIC audit activities. NUPIC was formed in 1989 as an organization comprising domestic and international commercial NPP utilities to provide an industrywide standardized approach for the performance of supplier audits by its members. In addition, the NRC developed Inspection Procedure (IP) 43005, "NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements," issued June 2022 (ML22077A380), to guide the NRC vendor inspection staff in observing licensee oversight activities of the supply chain, including NUPIC audit activities. The agency typically performs two to three observations annually and documents those observations in NRC reports, which |

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| are available on the NRC public website: https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance/nupic-industry.html. |
| **Question No. 97** |
| It is described that vendors should comply with 10 CFR Part 21 as well as Appendix B to 10 CFR Part 50. With regard to 10 CFR Part 21, could you provide more detailed information about the NRC's follow-up activities after a defect or noncompliance is reported by licensees/suppliers? |
| Answer: In 10 CFR Part 21, "Reporting of Defects and Noncompliance," the NRC requires vendors of safety-related SSCs to adopt procedures for the evaluation of deviations and failures to comply associated with potential substantial safety hazards and to report those instances to the NRC. When the NRC receives a Part 21 report, whether from a supplier or licensee, an internal task group at the agency will review the report and determine if any specific follow-up actions are needed including, but not limited to, development of generic communications to inform the industry of the reported issues, consideration of inspection at the vendor's facility, and in cases where wrongdoing may be identified, evaluation of the issues through the NRC Allegations Program. |
| **Question No. 98** |
| 13.6 Vendor Inspection Program of the national report (page 147) specifies the manufacturers and suppliers of safety-related components as part of the vendor inspection program. Are the equipment qualification testing laboratories included in the vendor inspection program?<br>* For your information, in Korea, not only designers and manufacturers but equipment qualification testing laboratories are included in the vendor inspection program.* |
| Answer: Yes, activities associated with equipment qualification testing and analysis for safety-related SSCs, are considered safety-related services subject to the requirements of 10 CFR Part 21 and selected portions of Appendix B to 10 CFR Part 50. Because these are considered safety-related services, the NRC vendor inspection program would apply to vendors providing such services. |
| **Question No. 99** |
| With reference to Article 14, in page 150, it is stated that the NRC applies a graded approach. Do all cycles (from construction to decommissioning) use a graded approach? Please explain the criteria and application. |
| Answer: The phrase "graded approach" is meant to reflect how the NRC's action matrix dictates the agency's oversight response for operating reactors. Inspection Manual Chapter 2515, Appendix B (ML22189A179), details how the NRC responds to shifts in the action matrix for operating reactors. Inspection Manual Chapter 2505, "Periodic Assessment of Construction Inspection Program Results," dated February 18, 2022 (ML21307A038), details how the similar construction action matrix is implemented.<br><br>Identification of a significant performance deficiency typically corresponds to a move in the action matrix (for example, from Column 1 to Column 2 or Column 3). As a licensee moves from Column 1, more and additional inspection and oversight are warranted. The licensee needs to address the causes of the performance deficiencies before the NRC returns the plant to Column 1 of the action matrix.<br><br>Decommissioning does not use an action matrix and therefore does not have a similar graded approach system. |
| **Question No. 100** |
| According to the section 14.1.4 of the national report, USNRC uses several guides (e.g., NUREG-1800, NUREG-1801, NUREG-2191, NUREG-2192, etc.) to evaluate the |

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| acceptability of the license renewal application. The main focus of these guides is the aging issue of the physical structures, systems, and components of nuclear power plants. Please explain how to address human factor issues related to license renewal application. (For background: IAEA Specific Safety Guide (SSG)-25 includes “human factors” as a safety factor in PSR.) |
| Answer: Human factor issues are not considered within the scope of license renewal because they are a part of the normal, continuous regulatory process for operating reactors.<br><br>Chapter 18 of NUREG-0800 and several other documents incorporated by reference in that document (such as NUREG-0711, NUREG-0700, and NUREG-1764) address human factor issues. |
| **Question No. 149** |
| Appendix B to 10 CFR Part 50 requires licensees that procure safety-related material, equipment, or services from contractors or subcontractors to perform audits.<br>(1) How is the supervision of manufacturing operations of nuclear equipment carried out, particularly when manufacturing is carried out abroad?<br>(2) Does NRC conduct specific inspections on this subject?<br>(3) If applicable, how are on-site inspections of contractors and sub-contractors carried out? |
| Answer:<br>(1) In accordance with Appendix B to 10 CFR Part 50, licensees are required to perform oversight of all their safety-related contractors or subcontractors. This is accomplished through a combination of direct observation of manufacturing at the contractors’ facilities during periodic audits or surveys, and through source verification activities conducted by the licensee or their delegees, such as contractors, agents, or consultants. These oversight activities may include any international contractors or subcontractors identified on the licensee Approved Supplier List.<br><br>(2) Yes, the NRC vendor inspection program does have guidance on the inspection of fabrication, manufacturing, and testing processes at vendor facilities.<br><br>(3) NRC inspections of international contractors and subcontractors are conducted in accordance with NRC inspection procedures. For example, Inspection Procedure 43002, provides guidance for the inspector to verify implementation of portions of the quality assurance program criteria applicable to the scope of work performed by the supplier, including fabrication and manufacturing activities. NRC vendor inspections are performed without the licensee being present, as the requirements of 10 CFR Part 21 allow the NRC to inspect at a vendor facility that has a safety-related procurement with one or more licensees or their contractors. |
| **Question No. 164** |
| The NRC interacts with manufacturers and suppliers of safety-related components through the NRC Vendor Inspection Program, which inspects compliance with quality assurance and defect reporting requirements. Vendor inspections are conducted at vendor facilities to examine whether the vendor has been complying with ...<br>(1) Are also key suppliers of safety relevant products part of the Vendor Inspection Program what criteria are used?<br>(2) Does NRC oversee the suppliers audit programme of the licensee? |
| Answer:<br>(1) No, “safety relevant” in this context is considered to be non-safety-related SSCs. In general, the vendor inspection program does not inspect the quality assurance activities associated with non-safety-related SSCs. |

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| (2) Yes, supplier oversight activities performed by licensees are evaluated as part of the NRC's vendor inspection program. The NRC routinely participates in NUPIC general membership and vendor conferences and shares experiences with NRC supplier oversight inspections and NUPIC audit activities. NUPIC was formed in 1989 as an organization comprising domestic and international commercial NPP utilities to provide an industrywide standardized approach for the performance of supplier audits by its members. In addition, the NRC developed IP 43005 to guide the NRC vendor inspection staff in observing licensee oversight activities of the supply chain, including NUPIC audit activities. The NRC typically performs two to three observations annually and documents those observations in NRC reports, which are available on the agency's public website: https://www.nrc.gov/reactors/new-reactors/how-we-regulate/oversight/quality-assurance/nupic-industry.html. |
| **Question No. 165** |
| The NRC reviews descriptions of quality assurance programs and performs onsite inspections to verify aspects of the program implementation.<br>(1) How often are these inspections performed?<br>(2) Can you provide more information regarding the scope of these inspections? |
| Answer:<br>(1) For new applicants under 10 CFR Part 52, including early site permits, design certifications, and combined licenses, the vendor inspection branch conducts IP 35017, "Quality Assurance Implementation Inspection," effective July 29, 2008 (ML20259A220), to verify that the applicant is performing construction and preconstruction activities in accordance with its NRC-approved Quality Assurance Program Description. This inspection is performed at least once during the construction or preconstruction phases with additional inspections conducted on a case-by-case basis. During preparation for operation, a one-time inspection, IP 35101, "QA Program Implementation Inspection for Operational Programs," effective January 1, 2022 (ML063410272), is conducted. This inspection is conducted while an early site permits, design certification, combined license or operating license application is still under NRC review.<br><br>(2) These inspections focus on the adequacy and implementation of quality-related procedures that have been established by the applicants. These are performance-based inspections in which the inspection team samples completed work performed in accordance with the applicant's quality assurance program implementation procedures. Areas such as personnel qualification and training, control of design changes, control of contractors' activities and procurement, inspections, procedure development and control, record control, corrective actions, and internal and external auditing of applicant programs and contractors' quality assurance program implementation are evaluated. |
| **Question No. 166** |
| Licensees carry out a variety of self-assessments to validate the effectiveness of their quality assurance program.<br>(1) What is the experience of the licensee with the validation of the effectiveness of the QA program?<br>(2) Are there key learnings or trends identified? |
| Answer:<br>(1) Licensees perform periodic self-assessments of the implementation of their programs in a number of functional areas such as engineering, construction, procurement, operations, maintenance, radiological protection, chemistry, and security, consistent with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. The results of |

the licensee’s audit activities are typically documented in licensee audit reports, and deficiencies are entered into the licensees’ corrective action program for further evaluation and disposition. The NRC assesses the effectiveness of licensees’ programs to find and resolve problems through a performance-based review of specific issues, during implementation of the baseline inspection program. IP 71152, “Problem Identification and Resolution (PI&R),” effective January 1, 2022 (ML21281A181), is used for this inspection, and the results are documented in NRC regional inspection reports.

(2) Under the Reactor Oversight Process (ROP), the NRC does not traditionally monitor or trend minor licensee issues; issues concerning licensees’ self-assessments would most likely be minor. Regarding the tracking of more than minor findings, the NRC can assign cross-cutting areas (CCAs) to findings. The CCAs reflect the cause of the performance deficiency. CCA P.6, “Self-Assessment,” is defined as “[t]he organization routinely conducts self-critical and objective assessments of its programs and practices” (IMC 0310 (ML19011A360)). Data on this CCA show no trends of interest. Also, the ROP has various means, through the agency’s self-assessment and operating experience programs, to monitor for any trends or lessons that may require further consideration. The NRC has not identified any significant trends or lessons in its oversight of licensee self-assessments in recent years.

## ARTICLE 14. ASSESSMENT AND VERIFICATION OF SAFETY

**Each Contracting Party shall take the appropriate steps to ensure that:**

**(i) comprehensive and systematic safety assessments are carried out before the construction and commissioning of a nuclear installation and throughout its life. Such assessments shall be well documented, subsequently updated in the light of operating experience and significant new safety information, and reviewed under the authority of the regulatory body**

**(ii) verification by analysis, surveillance, testing, and inspection is carried out to ensure that the physical state and the operation of nuclear installations continue to be in accordance with its design, applicable national safety requirements, and operational limits and conditions**

This section explains the governing documents and process for ensuring that systematic safety assessments are carried out during the life of the nuclear installation, including for power uprates and the period of extended operation. It focuses on assessments performed to maintain the licensing basis of a nuclear installation. This section explains verification of the physical state and operation of the nuclear installation by analysis, surveillance, testing, and inspection. Finally, this section addresses the Vienna Declaration on Nuclear Safety, issued February 2015.

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| **Question No. 1** |
| Wouldn't it be relevant that more information be provided concerning Severe Accidents issues, according to the recent licensing practices, on the frame of Article 14.1? |
| Answer: Article 14 of the U.S. Ninth National Report explains the governing documents and processes for ensuring that systematic safety assessments are carried out during the life of the nuclear installation, rather than specific actions (such as those implemented following the accident at Fukushima) taken by licensees during the life of the installation. Section 2.3.3.7 of the U.S. Ninth National Report describes regulatory actions taken following the accident at Fukushima. However, actions taken by licensees in response to new requirements, such as those related to severe accidents that were imposed following the accident at Fukushima, become subject to continuous oversight through the Reactor Oversight Process (ROP) and other continuous assessment processes described in section 14.1.5 of the U.S. Ninth National Report. |
| **Question No. 46** |
| A Periodic Safety Review (PSR) is regularly (typically every ten years) performed in many countries. Even if this is not necessary as a precondition for license renewal in some countries, it is a helpful tool to identify necessary safety improvements if changes in protection against external hazards (natural as well as human induced) are necessary. With that in mind, it would be appreciated if NRC could elaborate on why this safety-enhancing tool is not used in the USA. |
| Answer: The PSR objective of maintaining safety throughout the entire operating life of a plant, including the consideration of changes in external hazards, is achieved by the NRC's comprehensive set of regulations, inspections, and safety review programs. The NRC has mechanisms within its current regulatory processes to determine if changes in protection from external hazards are necessary. A recent example is the NRC's evaluation and implementation of lessons learned from the Fukushima earthquake and tsunami. Through the NRC's day-to-day focus on inspection and assessment, the reevaluation of protections |

against external hazards is performed at any time that the agency determines it is appropriate, generally based on new information on the frequency or magnitude of the external hazards.

Additionally, the NRC has a process for the ongoing assessment of natural hazard information, which systematically seeks, evaluates, and responds to new natural hazards information. If new information indicates a potential safety concern, the staff will address that concern through the appropriate regulatory programs to perform detailed assessment and identify the need for further action.

**Question No. 82**

IAEA uses the concept of practical elimination for the conditions that could lead to early or large radioactive releases.

(1) Is this concept used by the USNRC to assess the safety of a nuclear reactor and how is it translated in practice?
(2) Are there, for example, criteria for the core damage frequency or the probability of a large release?
(3) How is a large release defined?
(4) If the concept of practical elimination is not used, is there any similar or equivalent objective?

Answer:

(1) The NRC has not defined the term "practical elimination." Nonetheless, as explained below, the NRC applies similar concepts and methods in its regulatory framework and is closely following and participating in international deliberations on this topic. The NRC staff is actively engaged with designers of new and advanced reactors that are interested in using the IAEA activities regarding the concept of practical elimination of large releases in the context of Specific Safety Requirement (SSR)-2/1, Revision 1, "Safety of the Nuclear Power Plants: Design," published in 2016, for protecting the public and environment. As part of its engagement, the NRC staff is evaluating the concept of practical elimination within its regulatory framework and looking forward to the finalization of the IAEA draft guidance on this topic.

(2) The NRC's regulatory framework includes a blend of deterministic and probabilistic considerations for severe accident vulnerabilities and risk management. The NRC first stated its policy on the frequency of release of radioactive materials in its 1986 Safety Goal Policy Statement (51 FR 30028). The policy statement specified two qualitative safety goals and two quantitative health objectives (QHOs)—a prompt fatality QHO and a latent cancer fatality QHO. Through initiatives to expand the use of PRA for operating reactors, the NRC staff developed, through calculations, a large early release frequency (LERF) guideline of $10^{-5}$ per reactor year as a surrogate for the prompt fatality QHO and a core damage frequency (CDF) guideline of $10^{-4}$ per reactor year as a surrogate for the cancer fatality QHO. These metrics have been applied to various aspects of reactor operation, such as risk-informed licensing actions using RG 1.174 (ML17317A256) and RG 1.177 (ML20164A034). In addition, based on the Commission's Safety Goal Policy Statement, the NRC staff uses a large release frequency guideline of $10^{-6}$ per reactor year during licensing of new and advanced LWRs, including small modular reactors. In addition, the NRC's policies include deterministic treatment of severe accidents via containment performance objectives. These objectives include maintaining the leaktightness of the containment under severe accident conditions for 24 hours. In 2020, the NRC staff endorsed the Licensing Modernization Project approach of using frequency and consequence targets, in conjunction with a defense-in-depth evaluation, for decision-

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| making related to advanced non-LWRs (see RG 1.233 (ML20091L698)).<br><br>(3) Efforts by the NRC staff to develop guidance to implement the Commission's Safety Goal Policy Statement demonstrated that the latent cancer fatality QHO was not the more controlling objective and that, if the prompt fatality QHO is met, the latent cancer fatality risk would generally be much lower than the latent cancer fatality QHO. Recognizing that the prompt fatality QHO is more controlling, the NRC staff developed a large release definition for use as a surrogate for the prompt fatality QHO. In 1993, the staff concluded that defining a large release beyond a simple qualitative statement related to its $10^{-6}$ per reactor year release frequency (contained in the Safety Goal Policy Statement) was neither practical nor required for regulatory or design purposes. The Commission approved the staff's proposal to terminate further work on the development of a large release definition and magnitude (see SECY-13-0029, "History of the Use and Consideration of the Large Release Frequency Metric by the U.S. Nuclear Regulatory Commission," dated March 22, 2013 (ML13022A207).<br><br>(4) As noted above, the NRC staff uses the CDF and LERF surrogates for the quantitative QHOs in the Safety Goal Policy Statement for regulatory decision-making, such as in risk-informed licensing actions using RG 1.174 (ML17317A256) and RG 1.177 (ML20164A034). In addition, the Commission's Severe Accident Policy Statement includes expectations for the conditional probability of containment failure, which the NRC staff uses during reviews of new and advanced reactor applications. Applicants for new reactors under 10 CFR Part 52 are required to submit a description of the design-specific PRA and its results, as well as a description and analysis of design features for the prevention and mitigation of severe accidents for LWR designs.<br><br>In addition, to meet the requirements of the National Environmental Policy Act (NEPA), every application for a construction permit under 10 CFR Part 50 or combined license under 10 CFR Part 52 must include an environmental report that contains an evaluation of severe accident mitigation design alternatives (SAMDAs) to demonstrate that the design includes all cost-beneficial severe accident mitigation measures. This evaluation is based on the PRA for the design and a cost/benefit criterion defined in regulatory guidance NUREG/BR-0058 (ML042820192). A design certification application under 10 CFR Part 52 must also include an environmental report that evaluates SAMDAs based on the PRA for the design and the cost/benefit criterion identified above. |
| **Question No. 83** |
| Can you please explain, which are the acceptance criteria for beyond-design accidents in reactor safety assessment and licensing? |
| Answer: Beyond-design-basis accidents for LWR licensing are addressed in NUREG-0800, Standard Review Plan (SRP), Section 19.1, Revision 3, "Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," issued September 2012 (ML12193A107). For those accident sequences that are analyzed to fully understand the capability of the design, the acceptance criteria are selected to meet the relevant requirements of the NRC regulations and are derived from Commission direction and staff guidance including policy statements, SECY papers and corresponding staff requirements memorandums, and regulatory guides. SRP Section 19.1 summarizes these acceptance criteria in Section II. The section states "These acceptance criteria apply to the PRA and severe accident evaluation in general. Specific subsets of the criteria apply to individual elements of the applicant's analyses." |

| Question No. 84 |
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| Can you please explain, what is the role of deterministic and the various levels of probabilistic analysis, in safety analysis and assessment during licensing (including license renewal) of nuclear reactors? |
| Answer: The NRC staff makes complex regulatory decisions using an integrated decision-making process, which considers both deterministic and probabilistic information. Defense in depth—an approach to designing and operating nuclear facilities that prevents and mitigates accidents that release radiation or hazardous materials—is explicitly included in the integrated decision-making process. The key to achieving defense in depth is creating multiple independent and redundant layers of defense to compensate for potential human and mechanical failures so that no single layer, no matter how robust, is relied on exclusively. Defense in depth includes the use of access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures.<br><br>During agency licensing activities the NRC staff considers both qualitative, deterministic, and quantitative, probabilistic analyses as part of its integrated decision-making process to ensure the following:<br><br>(1) Decisions meet current regulations or approved exemptions.<br>(2) Decisions are consistent with the agency's defense-in-depth philosophy.<br>(3) Decisions maintain sufficient safety margins.<br>(4) Decisions undertake only small increases in risk and are consistent with the Commission's Safety Goal Policy Statement.<br>(5) Decisions utilize performance measurement strategies to monitor change.<br><br>Furthermore, while license renewal is primarily a deterministic process, probabilistic insights may be considered in the applicant's aging management programs.<br><br>For more information on the NRC's integrated decision-making program and defense-in-depth philosophy, please refer to RG 1.174, Revision 3 (ML17317A256). |

| Question No. 101 |
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| (1) With reference to Article 14, in page 161, is "forward fitting" the same as conditional approval?<br>(2) Please explain the imposition of conditions and the process of determining them. |
| Answer:<br>(1) Not always. All forward fits are conditions of approval, but not all conditions of approval are forward fits. For a condition to be a forward fit, it would have to meet the definition of "forward fitting" and be justified as such. Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," approved September 20, 2019 (ML18093B087) defines a forward fit as follows:<br><br>the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation. |

(2) The NRC can impose conditions through a licensing action currently under review or by an order. Internal guidance describes the primary processes the NRC would follow for conditioning approvals; for example, Office of Nuclear Reactor Regulation (NRR) Office Instruction (OI) LIC-101, Revision 6, “License Amendment Review Procedures,” effective August 3, 2020 (ML19248C539); NRR OI LIC-102, Revision 3, “Review of Relief Requests, Proposed Alternatives, and Requests to Use Later Code Editions and Addenda,” effective April 10, 2020 (ML18351A218); the Enforcement Policy, dated January 14, 2022 (ML21323A042), Enforcement Manual, dated February 24, 2022 (ML22056A177), and internal staff guidance for orders; and MD 8.4. The NRC would condition an approval when it deems it appropriate and necessary and typically for issues of high safety or regulatory significance. What is considered appropriate and necessary will depend on the regulatory criteria that must be met for the NRC to approve a request or issue an order. For example, to approve an amendment request, the NRC must have reasonable assurance that the change can be made without endangering public health and safety. If the proposed condition meets the backfitting or forward fitting criteria in MD 8.4, then the NRC would have to justify imposing the condition per the backfitting or forward fitting criteria. However, if the NRC’s proposed conditions of approval are not backfits or forward fits, then the agency may impose the condition without this additional justification. NRC processes strongly recommend that the agency seek the licensee’s perspective on the condition language to ensure that the wording does not cause unintended consequences because the language may have a different specific meaning at that licensee’s facility.

**Question No. 135**

(1) In the US, what kinds of modifications do the power plants licensees bring to their plants during their lifetime?
(2) What are the amounts of these various kinds of modifications?
(3) Are these power plants modifications mainly related to new requirements from the regulatory authority or to new needs from the licensees or to requests from other stakeholders?

Answer:

(1) The types of modifications made by licensees at power plants vary greatly by scope, scale, duration (i.e., temporary or permanent), and need for prior NRC approval per the requirements of 10 CFR 50.59, “Changes, tests and experiments.” An example of a large-scale modification that would likely need prior NRC approval (e.g., license amendment) may be the installation of replacement steam generators whose design may be different than those described in the licensee’s final safety analysis report. An example of a smaller scale modification that perhaps would not need NRC approval could be the replacement of an obsolete circuit card in a safety-related control system in which the new circuit card meets the quality and operational requirements as described in the final safety analysis report (i.e., like for like functionality).

(2) The amount and types of modifications vary from plant to plant depending on several factors, such as the age of the plant, equipment reliability, and licensee or NRC-imposed enhancements.

(3) Modifications are typically made on an as-needed basis because of equipment issues, obsolescence, or as part of a corrective action. Modifications may also be installed at the licensee’s discretion to support industry or owners’ group initiatives or for other reasons (life cycle issues, power uprates, long-term reliability, future needs, etc.). Less commonly,

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| modifications may be externally driven (as a result of operating experience). Even rarer, modifications may result from licensees' need to meet the NRC's specific requirements (e.g., post-Fukushima orders). |
| **Question No. 136** |
| 10 CFR 50.54 and 10 CFR 50.59 (see below) contain requirements for the processes by which, under certain conditions, licensees may make changes to their facilities and procedures as described in the final safety analysis report, as updated, without prior NRC approval.<br>(1) Are these conditions applicable to all nuclear installations or only to nuclear power plants?<br>(2) What proportion of the modifications are subject to an examination by NRC prior to be authorized or implemented?<br>(3) If possible, give examples of modifications investigated by NRC. |
| Answer:<br>(1) The regulation in 10 CFR 50.54, "Conditions of licenses," contains conditions that apply to every nuclear power reactor operating license issued under 10 CFR Part 50 (with some exceptions) and every combined license issued under 10 CFR Part 52 (with some exceptions). The regulation in 10 CFR 50.59 applies to each holder of an operating license or a combined license, including the holder of a license authorizing operation of a nuclear power reactor that has submitted the certification of permanent cessation of operations required or a reactor licensee whose license has been amended to allow possession of nuclear fuel but not operation of the facility. Various other regulations pertaining to changes or modifications to processes or programs within the materials, security, emergency preparedness, and other areas are contained in various sections of 10 CFR. For example, 10 CFR 72.44, "License conditions," and 72.48, "Changes, tests, and experiments," are similar to regulations pertaining to 10 CFR Part 50 licensees but apply to independent spent fuel storage installations.<br><br>(2) Licensees screen to determine if a modification can be made under 10 CFR 50.59 but do not report the number of modifications that were completed using the 10 CFR 50.59 process, nor does the NRC track this information. The NRC Reactor Oversight Process (ROP) requires inspection sampling (affecting ROP cornerstones and risk-informed) of permanent and temporary modifications, as well as periodic focused inspections of licensees' 10 CFR 50.59 screenings and evaluations.<br><br>(3) NRC Inspection Procedure 71111.18 (ML21040A185) provides a list of modifications by ROP cornerstone that could be inspected on a sampling basis by NRC inspectors for operating reactors. Inspection Procedure 71111.21M, "Comprehensive Engineering Team Inspection," effective January 21, 2023 (ML19084A030), calls for an NRC team of inspectors to take an indepth look at a number of modifications, as well as inspect licensee 10 CFR 50.59 screenings and evaluations. Several examples of these inspections and results can be found on the NRC's public website: https://www.nrc.gov/reactors/operating/oversight/listofrpts-body.html. |
| **Question No. 144** |
| In the USA, the license renewal process proceeds along two tracks: one for the review of safety issues and another for environmental issues.<br>(1) To what extent the environmental impact statement is revised for a licence renewal?<br>(2) According to NRC experience, what are the plant-specific environmental impacts that should be reviewed for a licence renewal? |

Answer:

(1) The NRC has issued a generic environmental impact statement (EIS) for license renewal, that evaluates the environmental impacts that are shared by all, or a distinct subclass of, NPP license renewals. In addition, a supplemental EIS, which evaluates site-specific environmental impacts that are not resolved by the NRC's generic EIS for license renewal, is developed for each license renewal. Combined, the generic and supplemental EIS documents fully evaluate the environmental impacts from operating the plant for an additional 20 years. This is described at: https://www.nrc.gov/reactors/operating/licensing/renewal/introduction/environmental.html.

(2) Appendix B to 10 CFR Part 51 describes the environmental impacts of license renewal on each resource area that is evaluated during license renewal. Topics identified as Category 1 have been reviewed generically for initial license renewal in the generic EIS and need not be reviewed for a specific license renewal, as long as the assumptions of the generic EIS remain applicable. An update to the regulation and the generic EIS, which will fully account for subsequent license renewal, is currently being developed.

Category 2 issues require additional plant-specific review in the applicant's environmental report and EIS to assess the significance of impacts on resources.

**Question No. 150**

(1) How do licensees manage the obsolescence of structures, systems, and components (SSCs) important to safety?
(2) The maintenance of parts whose production has been stopped?
(3) Or the software maintenance?

Answer:

**NRC's Response**:

The NRC regulates SSC operability of plants and not obsolescence explicitly. Any activities a licensee may pursue to manage obsolescence are subject to the quality assurance requirements in 10 CFR Part 50, Appendix B. The requirements include control measures for the selection and review of the suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of SSCs.

**INPO's Response**:

(1) Most plants use an obsolescence program to track known obsolescence issues. These programs include identifying available replacements. For important SSCs, intentional monitoring activities are implemented to ensure that degradation is identified early and actions taken to correct.

(2) Prioritization of obsolescence issues is based on an item's importance or criticality to continued safe and reliable operation. In addition, there are industry groups and guidelines that assist plants to manage obsolescence issues, including the Nuclear Utility Obsolescence Group (NUOG) and the International NUOG.

(3) As part of life-cycle management, personnel evaluate vendor software updates and prioritize update activities. Major upgrades are tracked in system health reports or as part of long-term asset management activities.

**Question No. 152**

What safety improvements have been (or are planned to be) implemented in the spent fuel storage pools of nuclear power plants with regard to the application of the IAEA concept of practical elimination of certain accident sequences?

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| <u>Answer</u>: New LWR applicants need to address all modes of operation, including refueling operations and the movement of spent fuel, in their safety analysis. (See response to Question 82, item (1), on the NRC's current consideration of the IAEA's concept of practical elimination of large releases for new reactor designs.) Historically, several accident scenarios in spent fuel pools are of such low likelihood that they are no longer postulated, such as fires. Other events are built into the design such that no additional mitigation is needed (e.g., the loss of cooling due to an earthquake because of safety improvements in pool designs). Today, the NRC is aware of proposed new reactor spent fuel pool designs that render certain accident initiating events no longer applicable. For example, spent fuel pools designed with passive cooling systems have the potential to eliminate the need for safety-related cooling components and thus any associated initiating events that correspond to the failure of an active cooling component. |
| **Question No. 175** |
| Absent any specific reasons for withholding, information related to the review and approval of a renewal application is publicly available. Any person whose interest might be affected by a license renewal proceeding and who desires to participate as a party must file a written request for hearing and a specification of the contentions (issues) that the person seeks to have litigated. The Commission will grant the hearing request if the Commission finds that the person has standing (that is, is impacted by the license renewal) and has proposed at least one admissible contention.<br>(1) How many members of the public asked for the hearing in the time period covered by this Report?<br>(2) In how many cases was the hearing request granted by the Commission? |
| <u>Answer</u>:<br>(1) From 2017 to present, ten members (groups) of the public petitioned to intervene in the proceedings involving the subsequent license renewal (SLR) applications for Point Beach (one petitioner), North Anna (three petitioners), Turkey Point (three petitioners), Peach Bottom (one petitioner), and Oconee (two petitioners).<br><br>(2) In separate decisions, the Atomic Safety and Licensing Board denied each group's request for hearing involving the SLR applications for Point Beach, North Anna Power Station, Turkey Point Nuclear Generating, Peach Bottom, and Oconee Nuclear Station. However, on February 24, 2022, the Commission issued Memorandum and Order CLI-22-03 (ML22055A533), concerning the environmental review of the SLR applications mentioned above. In accordance with the Commission's Memorandum and Order, upon the completion of the NRC staff's site-specific environmental statements for the impacted SLR applications, a new notice of opportunity for hearing will be issued, limited to contentions based on new information in the site-specific EIS. |
| **Question No. 177** |
| What additional analyses are necessary and implemented in the process of issuing of the long-term operating licence for the plant/unit? |
| <u>Answer</u>: The license renewal process includes the following analyses of potential aging-related degradation issues, including issues that may not be adequately addressed by the existing plant safety analyses or plant maintenance frameworks:<br><br>(1) identification of the SSCs that are in the scope of license renewal in accordance with 10 CFR 54.4, "Scope"<br><br>(2) an integrated plant assessment per 10 CFR 54.21(a) which does the following: |

(a) identifies the in-scope SSCs that are subject to aging management review

(b) identifies in the aging management review those aging effects that require management for the SSCs identified in (a)

(c) demonstrates that the aging effects will be adequately managed so that the intended function(s) will be maintained consistent with the current licensing basis for the period of extended operation

(3) identification and evaluation of time-limited aging analyses (TLAAs) per 10 CFR 54.21(c)(1)

The evaluation of TLAAs in (3) involves many detailed technical analyses related to reactor pressure vessel neutron embrittlement, fatigue of safety-significant components, and other existing current licensing basis analyses which meet the definition of a TLAA in 10 CFR 54.3.

**Question No. 183**

In relation to power uprate category 2—increasing of thermal efficiency of primary and secondary circuit are probably included to be reached 7% power uprate successfully, according to Category 2 specifications, presented on page 153 of category power uprate subsection.
In relation to power uprate category 3—probably improvement of primary circuit equipment such as reactor core RCP, SGs would be required (Category 3 specifications, presented on page 153 of category power uprate subsection).

Answer: Improving thermal efficiency of the primary and secondary circuit could fall under a stretch power uprate (Category 2) or extended power uprate (Category 3) depending on the resulting increase in power output. Stretch power uprates (Category 2) do not involve replacement of major balance-of-plant system components, but may require replacement of, or changes to, supporting systems and components such as pumps or pump prime mover, pipe supports, heating and cooling system, control systems, instrumentation setpoints, etc.

Extended power uprates require significant modifications to major balance-of-plant equipment, which may include modification of reactor coolant system components, steam generator internal components, or other components in the main steam systems. Other equipment may include high-pressure turbines, condensate pumps and motors, main generators, and transformers. However, no extended power uprates have involved reactor coolant pump replacement or entire steam generator replacement.

**Question No. 184**

For what reasons the safety systems and safety system components are not included in the key technical issues?

Answer: This section refers to key technical issues that were evaluated in the “Expanded Materials Degradation Assessment” (see NUREG/CR-7153) for development of guidance for 60–80 years of operation. The NRC’s review of license renewal applications is not limited to systems and components related only to these key technical issues. All SSCs that meet the criteria in 10 CFR 54.21, “Contents of application—technical information,” are evaluated in the initial license renewal period (40–60 years) and the subsequent license renewal period (60–80 years).

The key technical issues specifically evaluated for plant operation up to 80 years were identified through engagement with the U.S. nuclear industry and the international community.

The NRC and the U.S. Department of Energy (DOE) held two international conferences, in 2008 and 2011, on reactor operations beyond 60 years. In May 2012, the NRC and the DOE also co-sponsored the Third International Conference on Nuclear Power Plant Life Management for Long-Term Operations, organized by the IAEA. In February 2013, the Nuclear Energy Institute held a forum on long-term operations and subsequent license renewal. These conferences laid out the technical issues that would need to be addressed to ensure safe operation beyond 60 years. The most significant technical issues challenging operation beyond 60 years were considered to be reactor pressure vessel embrittlement, irradiation-assisted stress-corrosion cracking of reactor internals, concrete structures and containment degradation, and electrical cable qualification and condition assessment.

**Question No. 207**

Section 14.1.5.1 states "the agency also publishes the results of operating experience analysis, research, or other appropriate analyses through generic communication documents such as bulletins, INs, RISs, and GLs. Licensee responses to these documents may also propose changes to the plant's licensing basis when appropriate." Section 6.3.10 explains that bulletins and generic letters are established instruments to request information or action to address a nuclear safety issue. Examples of communications issued during the CNS reporting period did not include any recent examples.

(1) How frequently, or under which type of circumstances, are such tools used to request specific action?

(2) How would such circumstances differ from, for example, application of the back-fitting process described in Section 14.1.5.2?

Answer:

(1) Specific actions are only requested using generic letters (GLs) and bulletins (BLs).

- GLs are used to (1) request information from and/or request specified action by the addressees regarding matters of safety, safeguards, or environmental significance, (2) request that analyses be performed and, as appropriate, submitted for staff review, (3) request that descriptions of proposed corrective actions and other information be submitted for staff review and that corrective actions be taken by a specified time; (4) request new or revised licensee commitments based on information provided in the GL, or analyses performed by each licensee and proposed corrective actions, but may not require licensee commitments, and (5) require a response from affected licensees. GLs will not request long-term actions or require actions or commitments.
- BLs are used to request licensee actions or information to address issues of safety, security, safeguards, or environmental significance that also have great urgency. BLs will not request continuing or long-term actions or require licensee actions or commitments.

For the frequency and circumstances in which the NRC issues GLs and BLs (along with other generic communications), please refer to the NRC's public website: https://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html.

(2) Backfits, if justified, must be implemented by the licensee. If the licensee does not implement the backfit, it may be imposed by an order. Generic communications cannot require actions or commitments. Rather, a license, regulation, or order can impose new requirements.

The staff uses the information provided in response to a BL or GL to determine if additional regulatory action, such as a backfit, is needed to address a safety or security concern. BLs and GLs may request specific actions of licensees, such as performing an analysis or implementing compensatory measures, when information is not readily available or to provide additional assurance while the concern is being evaluated. Specific actions requested through BLs or GLs are not mandatory; thus, BLs and GLs are not used when action by a licensee is necessary to ensure safety or security or otherwise required (e.g., by law).

A generic or plant-specific backfit would occur only if the NRC determines that the backfit is necessary or justified per 10 CFR 50.109, “Backfitting.” Any actions imposed through a backfit are mandatory.

## ARTICLE 15. RADIATION PROTECTION

**Each Contracting Party shall take the appropriate steps to ensure that, in all operational states, the radiation exposure to the workers and to the public caused by a nuclear installation shall be kept as low as reasonably achievable, and that no individual shall be exposed to radiation doses which exceed the prescribed national dose limits.**

This section summarizes the authorities and principles regarding radiation protection, the applicable regulatory framework for radiation protection, and certain measures for controlling radiation exposure to occupational workers and members of the public.

| **Question No. 52** |
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| The values of the personnel exposure rates have been provided as of 2019. Could you please provide the information as of 2021? |
| Answer: The 2021 data are still being processed, and the evaluation is not final. However, the 2020 data are available and can be found in Volume 42 of NUREG-0713, “Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities—2020 Fifty-Third Annual Report,” issued September 2022 (ML22276A269). |
| **Question No. 60** |
| “Paragraph 15.3.1 of “Control of Radiation Exposure of Occupational Workers” states that since 1980, collective doses have steadily decreased by about 10 times to the current level of about 0.59 manSv per NPP unit for 3 years. In 2019, the average collective exposure of PWR NPP was 0.27 manSv.[”]<br>(1) Could you please provide more detailed information regarding procedure for calculation of the collective dose?<br>(2) Does the collective irradiation exposure per NPP unit include:<br>• doses received during scheduled repair and maintenance works;<br>• doses received during upgrading works within the lifetime extension;<br>• doses received during operation of common-plant facilities (fresh nuclear fuel storage, spent nuclear fuel storage, radioactive waste storage, etc.);<br>• doses received during reprocessing of spent nuclear fuel and radioactive waste at NPP external facilities;<br>• doses received during works not directly related to the operation of NPP units (for example, production of isotope products);<br>• doses below the sensitivity level in conducting the personnel individual dosimetric monitoring. |
| Answer:<br>(1) Collective dose is simply the sum of the individual dose received. All worker dose that is recorded is included in the collective dose.<br><br>(2) The doses provided include all monitored activities during work at the nuclear power facility, including during repair, maintenance, and refueling, transfer of new and spent fuel at the NPP facilities. The values reported in paragraph 15.3.1 are for commercial nuclear plants and do not include dose received from activities indirectly related to the NPP facility, such as fuel fabrication, isotope production facilities, or medical exposures. Doses below the sensitivity level of personnel dosimetry would also not be included. |
| **Question No. 73** |
| In 2019, 94,237 workers at nuclear plants were monitored for radiation exposure. In 2019, the median collective dose for BWRs and PWRs was 1.01 person-Sv (101 person-rem) and |

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| 0.27 person-Sv (27 person-rem), respectively…. Of the workers that received a measurable dose in 2019, 84 percent received less than 0.0025 Sv (0.25 rem), 99.9 percent received less than 0.02 Sv (2 rem), and no worker received an excess of 0.03 Sv (3 rem).<br>Question[s]:<br>(1) What measures are established in the plants with workers who have received in 2019 more than 20 mSv (more than 94 people)?<br>(2) What has been the dose constraint per annum setting as the objective for the individual effective dose limit for exposed workers at the USA NPP? |
| Answer: The question states that in 2019, "more than 94 people" at commercial operating plants received more than 20 millisieverts (mSv). However, only four occupational workers in the United States received greater than 20 mSv.<br><br>(1) The NRC regulations that apply to question (1) are 10 CFR 20.1201, "Occupational dose limits for adults"; 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose"; and 10 CFR 20.2104, "Determination of prior occupational dose." Additionally, RG 8.7, "Instructions for Recording and Reporting Occupational Radiation Dose Data," issued May 2018 (ML17221A245), provides guidance for reporting occupational exposure information. NRC regulations state the criteria for when licensees are required to monitor occupational doses. These criteria are based on percentages of dose limits and certain exposure scenarios. If a licensee determines that an occupationally exposed individual working at its facility must be monitored, then that licensee must determine the worker's current year dose and reduce the dose the worker can receive, such that the worker would not exceed the applicable dose limit.<br><br>(2) Subpart C of 10 CFR Part 20, "Standards for Protection Against Radiation," provides the annual occupational dose limits. NRC regulations do not provide for dose constraints that are more restrictive than the occupational dose limits. Some licensees may choose to implement administrative controls; however, these are not mandated by regulation. Through oversight efforts, the NRC assesses licensees' performance in occupational exposure control and the procedures and engineering controls used by licensees to maintain occupational doses as low as is reasonably achievable (ALARA). The NRC evaluates licensees' application of industry standards and best practices, as applicable, to ensure that the licensee's approaches to maintaining ALARA are in keeping with industrywide performance. |
| **Question No. 102** |
| In page 171 [of the US CNS repot], it is stated that 38,519 workers were exposed with measurable doses. Please explain the quantitative criteria for measurable doses and the application of the recording level. |
| Answer: The minimum measurable dose of a radiation dosimeter depends on the sensitivity and resolution of the dosimeter used.<br><br>NUREG-0713 documents the histories of occupational exposures. The 38,519 workers receiving measurable dose in 2019 (provided in table 4.4b of NUREG-0713) are individuals who received measurable doses at commercial LWRs. This value is adjusted for transient workers (meaning that a worker who received measurable dose at multiple reactors is only counted once).<br><br>Based on a footnote in NUREG-0713, individuals reported with zero dose, or no detectable dose, are included in the number of individuals with no measurable exposure. Therefore, |

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| individuals who do not fall into that category are considered to have measurable doses. |
| **Question No. 103** |
| Section 15.3.2 Control of Radiation Exposure of Members of the Public (page 190) states the criteria for dose assessment: The EPA regulations in 40 CFR Part 190,… establish a regulatory standard such that the annual dose to a member of the public from exposures to radiation sources associated with the entire uranium fuel cycle does not exceed 0.25 millisievert (25 milligram) to the whole body and 0.75 millisievert (75 milligram) to the thyroid. This regulation seems to be technically useful criteria to perform dose assessment. On what grounds and logic has this conclusion been reached? |
| Answer: The U.S. Environmental Protection Agency (EPA) sets the 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," annual public dose criteria of 0.25 mSv to the whole body, 0.75 mSv to the thyroid, and 0.25 mSv to any other organ, from uranium fuel cycle operations. In "40 CFR 190 Environmental Radiation Protection Requirements for Normal Operations of Activities in the Uranium Fuel Cycle: Final Environmental Statement," Volume I, dated November 1, 1976, the EPA indicated that the rule was established with consideration of the linear nonthreshold dose-effect relationship. Volume I is available on the following website: https://www.epa.gov/sites/default/files/2015-06/documents/40cfr1904epa520-4-76-016fesufuelcyclev1_0.pdf.<br>The EPA indicated that the values were also set to protect the overall ecosystem, since there was no evidence that there is any biological species sensitive enough to warrant a greater level of protection than that adequate for humans. In establishing the values, the EPA considered, in addition to potential health effects, the available information on the effectiveness and costs of various means of reducing radioactive effluents from fuel cycle operations. The EPA believed the established values were cost effective and selected to strike a balance between the need to reduce health risks to the general population and the need for nuclear power. |
| **Question No. 114** |
| The data on releases for 2007–2019 (Table 3.6) differ by orders of magnitude depending on the year of operation and the specific power unit. Please explain the reasons for such large discrepancies in data on releases for different power units and different years of operation (power unit downtime, operating conditions, design features of filtration systems, etc.). |
| Answer: Licensees are required by 10 CFR 50.36a, "Technical specifications of effluents from nuclear power reactors," plant technical specifications, and license conditions to keep average annual releases of radioactive material in liquid and gaseous effluents and resultant doses at small percentages of the public dose limits.<br><br>Table 3.6 of the 2019 annual report summarizes activation and fission gaseous releases consisting of krypton-85, xenon-133, and xenon-135 for PWRs. These noble gas releases are primarily dependent on the following factors and may vary from site to site:<br><br>(1) Plant Operation—Reactor scrams and rapid power ascension and descension stress and fuel pins and lead to increased fuel pin leakage of noble gas into the reactor coolant system (RCS). Eventually, this noble gas has to be released.<br><br>(2) Fuel Integrity—If the fuel cladding has pinhole leaks, noble gas will be released into the RCS. The amount of gas released into the RCS is proportional to the amount of pinhole leaks. If the fuel leaks are large enough, the RCS must be degassed into the gaseous waste management system more frequently.<br><br>(3) Radioactive decay—Ideally, the noble gas release rate into the RCS is slow enough that |

the reactor system does not need frequent degassing. Thus, the noble gas will stay in the RCS longer, allowing sufficient time for radioactive decay before RCS degassing into the gaseous waste management system.

(4) Waste gas storage tank (WGST) capacity—WGSTs are typically used to store radioactive gases before release in PWRs. If frequent RCS degassing is needed, the WGSTs become full sooner, requiring more frequent releases with insufficient storage time to allow for radioactive decay. Hence, the fresh undecayed gas must be released sooner, leading to larger amounts of noble gas releases.

(5) RCS leakage into the reactor building—If the RCS itself has leakage (typically due to valve leakage) into the reactor building, then, to allow reactor building entries during power operation for maintenance, the reactor building itself will need to be degassed through periodic purges.

(6) RCS leakage through steam generators—If there are steam generator leaks, some of the noble gas in the RCS will migrate into the secondary turbine plant. The noble gas is then removed by the condensate air removal system and released via the plant vent without time for radioactive decay.

(7) Plant maintenance practices:

(a) Maintenance of RCS leakage—If plant maintenance is performed to repair valve leakage and hence stop the RCS leaks into the reactor building, there will be fewer reactor building purges and smaller amounts of noble gas released because the gas will be retained in the RCS allowing more time for radioactive decay.

(b) Fuel integrity inspection programs—Leaking fuel pins can be inspected, identified, and replaced. The inspections may also identify the cause of the leaks (e.g., grid strap vibration and abrasion on the fuel pins), which can be used to improve future fuel design.

(8) Waste gas management practices, such as dedicated effort by operations staff working with radioactive effluent staff (typically chemistry staff), can optimize waste gas management practices to allow longer holdup times before releases.

**Question No. 115**

Table 3.20 provides data on the maximum annual doses for the public from releases in comparison with the ALARA criterion.
Please explain the following:
(1) to which group of the public these data belong (residence distance, age category, etc.);
(2) for which group of organs the ALARA criterion (15 mrem) is established;
(3) what parameters of atmospheric dispersion were taken into account in calculating doses to the public (statistical weather forecast data, conservative assumptions, real data).

Answer:

(1) All members of the public are considered in determining compliance with the 15 mrem ALARA criterion, regardless of age and location in the unrestricted area. In accordance with regulatory requirements and the calculation methodologies of RG 1.109, Revision 1, “Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I,” dated October 1977 (ML003740384), the doses to members of the public are calculated for either real or

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| hypothetical individuals receiving the highest total body and organ doses. As a result, these doses are often referred to as the “maximum total body” and the “maximum organ” doses.<br><br>(2) The 15 mrem dose criterion for any organ referenced in Table 3.20 is referring to the ALARA design criteria in Appendix I, “Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion ‘As Low as is Reasonably Achievable’ for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents,” to 10 CFR Part 50. RG 1.109 describes an acceptable approach for determining compliance with the ALARA dose criteria. RG 1.109 describes the method to calculate dose to bone, liver, thyroid, kidney, lung, and gastrointestinal/lower large intestine organ pathways. Plant-specific information for how these calculations is performed is typically contained in an Offsite Dose Calculation Manual. NUREG-1301, “Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors—Generic Letter 89-01, Supplement No. 1, issued April 1991 (ML091050061), and NUREG-1302, “Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Boiling Water Reactors, Generic Letter 89-01, Supplement No. 1,” issued April 1991 (ML091050059), contain the guidance for the information presented in a plant’s Offsite Dose Calculation Manual.<br><br>(3) The atmospheric dispersion meteorological conditions assumed in the calculations are typically based on annual-average conditions. RG 1.21, Revision 3, “Measuring, Evaluating, and Reporting Radioactive Material in Liquid and Gaseous Effluents and Solid Waste,” issued September 2021 (ML21139A224), provides more specific details on performing dose calculations and meteorological assumptions. |
| **Question No. 120** |
| (1) Is exposure to radon decay products of personnel and the public monitored?<br>(2) If yes, how?<br>(3) What methods and equipment are used for this?<br>(4) With what frequency?<br>(5) Who exactly is subject to such control?<br>(6) Are dose limits set? |
| <u>Answer</u>:<br>(1) If the exposure is from naturally occurring radon, the NRC limits on occupational and public dose exclude that exposure since NRC regulations consider it part of background radiation. However, if the exposure is from radon resulting from the decay of source, byproduct, or special nuclear materials regulated by the NRC, it is treated as any other radiological hazard in accordance with the agency’s radiation protection regulations at 10 CFR Part 20.<br><br>(2) If the radon exposure is regulated by the NRC, 10 CFR 20.1101, “Radiation protection programs,” states that licensees must use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. RG 8.10, Revision 2, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable,” issued August 2016 (ML16105A136), states the philosophy and general management policies and programs that licensees should follow to meet this objective. For example, licensees must conduct surveys that are necessary to meet the regulations, they must monitor occupational exposures above certain criteria, and they must ensure that all occupational exposures remain within regulatory limits and |

ALARA and that doses to members of the public are evaluated and maintained within limits and ALARA.

For responses to questions 3 through 6, please see the information provided below. The NRC provides further guidance on compliance with 10 CFR 20.1301, “Dose limits for individual members of the public,” for radon and radon progeny to individual members of the public in Interim Staff Guidance DUWP-ISG-01, “Evaluations of Uranium Recovery Facility Surveys of Radon and Radon Progeny in Air and Demonstrations of Compliance with 10 CFR 20.1301,” issued June 2019 (ML14058A010). In addition, the following regulatory guides specific to uranium recovery facilities provide guidance on surveys, administrative practices, and bioassay methods. Regulatory Guide 8.30, Revision 1, “Health Physics Surveys in Uranium Recovery Facilities,” issued May 2002 (ML021260524), describes the health physics surveys that are acceptable to the NRC staff for protecting workers at uranium recovery facilities from radiation and the chemical toxicity of uranium while on the job. Specifically, section 2.3 of RG 8.30, Revision 1, discusses surveys for radon-222 and its progeny at these facilities. In addition, RG 8.31, “Information Relevant to Ensuring that Occupational Radiation Exposures at Uranium Recovery Facilities Will Be as Low as Is Reasonably Achievable,” issued May 2002 (ML021260630), provides guidance on design criteria and administrative practices for maintaining doses as low as is reasonably achievable in uranium recovery facilities. Further guidance for bioassay at uranium mills is provided in RG 8.22, Revision 2, “Bioassay at Uranium Mills,” issued May 2014 (ML13350A638).

Additionally, the United States recognizes the health risks involved with radon exposure, and several other Federal guidelines and requirements apply to radon exposure for domiciles and industrial environments not overseen by the NRC. For example, the U.S. Occupational Safety and Health Administration regulates workplace exposure to naturally occurring radon and the U.S. Environmental Protection Agency (EPA) provides guidance and recommendations for radon levels in homes. State programs also provide public education and technical assistance. In addition to these programs, the EPA maintains maps of radon zones (https://www.epa.gov/radon/epa-map-radon-zones-and-supplemental-information#datainfo) and anchors the National Radon Action Plan collaboration program to reduce the risk of radon in homes and buildings (http://radonleaders.org/resources/nationalradonactionplan).

**Question No. 121**

How is non-exceeding of the individual equivalent exposure dose for eye lens of personnel and the public monitored?

Answer: Regarding occupationally exposed individuals, NRC regulations at 10 CFR 20.1201 require that licensees control occupational doses to individual adults to an annual limit to the lens of the eye of 15 rem (0.15 Sv). NRC regulations at 10 CFR 20.1502 require that licensees monitor occupational exposures that are likely to exceed 10 percent of the annual limits to the lens of the eye. RG 8.34, “Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,” issued December 2021 (ML21068A160), provides guidance to licensees in meeting the monitoring criteria, advises licensees to perform prospective dose evaluations to determine the likelihood of exceeding the monitoring criteria. A prospective dose evaluation includes a review of anticipated work activities, prior monitoring results, and workplace monitoring (e.g., area monitoring). If a licensee determines, based on the prospective dose evaluation, that monitoring for the lens of the eye is required, then the licensee will apply the appropriate method, and the NRC will assess the licensee’s performance through inspection.

Regarding members of the public, exposure to the lens of the eye is not considered in the

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| NRC's public dose limits because nonstochastic impacts to the eye are not expected to occur at the dose limit established for members of the public. |
| **Question No. 122** |
| The information provided in the "Radioactive Effluents from Nuclear Power Plants" reports posted at https://www.nrc.gov/reactors/operating/ops-experience/tritium/plant-info.html shows a steady downward trend in gas releases and liquid effluents from NPP up to 99 percent for 1975–2019. This decrease ensures that public exposure is kept as low as achievable. How long did it take to implement measures that started the actual reduction of gas emissions and liquid effluents from NPPs into the environment? |
| <u>Answer</u>: Information related to measures for reducing gaseous effluent emissions from PWRs can be found in the response to question No. 114. Many of these measures, such as improving fuel performance, reducing the quantities of material in the reactor coolant system, and maintenance and operational practices, will reduce both gaseous and liquid effluents and apply to both BWRs and PWRs. However, while PWRs generally use waste gas storage tanks to delay the release of gaseous effluents, BWRs generally use charcoal delay beds, and increased efficiencies in charcoal delay beds reduce gaseous effluent releases to the environment. The efficiency of the charcoal delay beds for holding up gases before release depends on several factors, such as the quantity and the size of the beds and the temperature and moisture content of gas entering the beds (gas is normally dehumidified and temperature adjusted before the gas enters the beds to increase efficiency and operating life of the beds).<br><br>Limiting the quantities of radioactive material in the reactor coolant is one of the most significant factors in limiting the quantity of radioactive effluents released. In addition to limiting fission products in the reactor coolant, limiting activation products in the coolant will also reduce the amount of waste generated for potential release. Activation products can be limited through many methods, including reducing cobalt, to the extent practicable in the reactor core and reactor coolant system, and through zinc addition to limit corrosion and by otherwise controlling plant chemistry.<br><br>In addition, programs to control the release of radioactive material and minimize contamination of the facility and the environment under 10 CFR 20.1406, "Minimization of contamination," have contributed to lowering the liquid emissions to the environment over time. RG 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning," issued June 2008 (ML080500187), provides a method acceptable for licensees to use in the implementation of 10 CFR 20.1406.<br><br>Many of the operational improvements, such as improved fuel performance and reducing the quantities of radioactive material in the reactor coolant, resulted in a gradual reduction in effluent releases and also occupational dose over time. |
| **Question No. 128** |
| It is indicated in the report that "Appendix I requirements for ALARA are complemented by 10 CFR 20.1501, which requires, in part, that ae licensee perform surveys, including those of the subsurface, to evaluate potential radiological hazards and to demonstrate compliance with public dose limits."<br>Does U.S. NRC also perform environmental radiological monitoring activities to ensure the regulatory control over the environmental radiological surveys which are conducted by the licensees? |
| <u>Answer</u>: The NRC generally does not perform environmental monitoring. However, the agency requires licensees to monitor the discharges from their facilities and analyze nearby |

environmental samples to ensure that the impacts of plant operations are minimized. NRC inspectors review the licensee's radiological environmental monitoring program to verify that it is being implemented consistent with agency regulations and licensee requirements. NRC inspectors also verify that licensee environmental monitoring equipment is properly located, calibrated, and maintained and occasionally observe the collection and preparation of samples.

These measures ensure that any discharges are being appropriately surveyed or monitored in accordance with NRC requirements and that doses to the public living around NPPs is within regulatory limits and standards.

Separate from NRC activities, the U.S. Environmental Protection Agency monitors the environmental radiation conditions at various locations throughout the United States.

**Question No. 137**

In the report, it is indicated that the NRC evaluates compliance with the ALARA requirement on the basis of a licensee's capability to track and, if necessary, reduce exposures, rather than on whether exposures and doses represent an absolute minimum or whether the licensee used all possible methods to reduce exposures.

(1) Do operators have an obligation to rely on Best Available Techniques to respect the exposure thresholds? (If yes, please give examples)
(2) Does NRC identify further possible reductions (in the existing fleet/ in new installations?)
(3) How are arbitrages made between gaseous/ liquid/ waste releases?
(4) Does NRC set different thresholds for various radionuclides? If yes, to what extent is it a useful/effective complement?

Answer:

(1) Occupational and public dose exposure thresholds, or dose limits, are provided in 10 CFR Part 20, Subpart C, and 10 CFR Part 20, Subpart D, respectively. Beyond the dose limits, 10 CFR 20.1101(b) requires licensees to use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public ALARA. To meet the ALARA requirements, licensees are required to use reasonable practices and controls to maintain doses to the workers and to the public that are ALARA. Compliance with the ALARA requirements does not require that doses be an absolute minimum; however, licensees should be able to demonstrate that efforts have been made to achieve ALARA, considering all factors, including dose savings and costs.

(2) ALARA must be considered in the initial design and during operation. RG 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable," issued June 1978 (ML003739549), presents guidance related to ensuring that occupational exposures are ALARA. It includes guidance related to facility and equipment design features, as well as programmatic guidance for meeting ALARA. Much of the guidance related to design features is more applicable to initial facility construction.

For doses to the public, ALARA must also be considered both in the design and during operation. For effluent releases, 10 CFR Part 50, Appendix I, includes guides on design limits, which are used during initial facility licensing to assess the adequacy of design. Appendix I also provides guides for limiting conditions for operation to be used during operation.

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| Since ALARA requires consideration of all factors such as cost and dose savings, new reactors should be considering the current technologies when designing their facility to meet ALARA requirements, and these design features may be incorporated into the reactor's licensing basis. During operation, while the doses received from one facility may be somewhat higher than another, based on the facility design, new reactors are not held to standards for ALARA that are different from those of the operating fleet, other than possible differences in a specific facility's licensing basis.<br><br>(3) Each release pathway is monitored. Potential liquid releases are monitored with radiation monitors to detect liquid releases or are sampled, while potential gaseous release pathways are generally monitored separately. Appendix I to 10 CFR Part 50 describes the ALARA design criteria for liquid and gaseous effluent releases. In 10 CFR Part 20, the NRC requires that the total effective dose equivalent from the licensed operation, exclusive of the dose contributions from background radiation, from all forms (i.e., liquid releases, gaseous releases, direct radiation), are within regulatory limits and ALARA.<br><br>(4) In general, NRC requirements are based on dose limits and ALARA, and not dose thresholds for specific radionuclides. However, 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," provides occupational oral ingestion and inhalation values, effluent air and water concentrations, and concentrations for releases to sewers for specific radionuclides. The criteria in Appendix B may be used in demonstrating compliance with dose limits. |
| **Question No. 146** |
| In the USA, is there a procedure in place to reduce the emission of chemical pollutants? Can you describe it? |
| Answer: Nonradiological emissions are governed by the U.S. Environmental Protection Agency, which has its own emissions reduction programs (please refer to https://www.epa.gov/haps/reducing-emissions-hazardous-air-pollutants).<br><br>Radiological releases are governed under NRC regulations, including 10 CFR 20.1406, which requires applicants for licenses to describe in their application how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste. This NRC regulation also requires licensees to conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with existing radiation protection requirements in 10 CFR Part 20. |
| **Question No. 180** |
| NRC applies an evaluation process based on performance indicators and inspection results. Performance indicators provide quantitative measurement of specific parameters of the licensee's performance against established levels/thresholds. We would like to know what these performance indicators are and how they have been established? |
| Answer: IMC 0608, "Performance Indicator Program," effective February 5, 2019 (ML19025A257), lists the performance indicators in sections 07.01 and 07.02. IMC 0308, Attachment 1, "Technical Basis for Performance Indicators," effective January 1, 2021 (ML20262H116), gives details of the technical basis for the performance indicators. |

## ARTICLE 16. EMERGENCY PREPAREDNESS

**(i) Each Contracting Party shall take the appropriate steps to ensure that there are onsite and offsite emergency plans that are routinely tested for nuclear installations, and cover the activities to be carried out in the event of an emergency.**

**(ii) For any new nuclear installation, such plans shall be prepared and tested before it [the installation] commences operation above a low power level agreed [to] by the regulatory body.**

**(iii) Each Contracting Party shall take appropriate steps to ensure that, insofar as they are likely to be affected by a radiological emergency, its own population and the competent authorities of the States in the vicinity of the nuclear installation are provided with appropriate information for emergency planning and response.**

**(iv) Contracting Parties that do not have a nuclear installation on their territory, insofar as they are likely to be affected in the event of a radiological emergency at a nuclear installation in the vicinity, shall take the appropriate steps for the preparation and testing of emergency plans for their territory that cover the activities to be carried out in the event of such an emergency.**

This section discusses emergency planning in the United States, including national response considerations, offsite emergency planning and preparedness, the emergency classification system, inspection practices, and communications activities.

| **Question No. 4** |
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| It is stated that, “the guidance document (Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,” Revision 2) was revised to integrate 35 years of lessons learned into the radiological emergency preparedness program, as well as to consolidate and clarify previous guidance”. USA may like to share key lessons learnt and corresponding changes made in the guidance document. |
| Answer: NUREG-0654, Revision 2, “Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,” issued December 2019 (ML19347D139), was developed and published in 1980 to support emergency planning rulemaking in response to the accident at Three Mile Island Nuclear Generating Station. While there have been no severe accidents in the United States in the years since the event, many technological and programmatic advances have directly impacted emergency planning and preparedness. The new and amended regulations codified in the “Enhancements to Emergency Preparedness Regulations” rulemaking (76 FR 72559; November 23, 2011), along with the development of new Federal response frameworks and programs (National Incident Management System), necessitated updating the guidance to reflect the modern emergency preparedness (EP) and response environment. A detailed list of changes and modernizations is publicly available at https://www.fema.gov/sites/default/files/2020-08/fema_NUREG-0654-REP-1-rev2-change-summary_12-2019.pdf. |
| **Question No. 34** |
| It is mentioned in the report “in March 2012, the NRC asked licensees to evaluate their current communications systems and equipment, including appropriate enhancements that |

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| would be used during an emergency event assuming that a large-scale natural event resulted in a loss of all AC power (i.e., a prolonged station blackout) and that cellular and other communications infrastructures were unavailable.” Could USNRC share additional requirements envisaged for communication systems & equipment during emergency including loss of all AC power? |
| <u>Answer</u>: In 2019, the Commission issued the final Mitigation of Beyond-Design-Basis Events rule (10 CFR 50.155). The final rule did not contain several requirements that were in the proposed rule including enhancements of staffing and communication capabilities. As a result, Nuclear Energy Institute (NEI) guidance from NEI 12-01, Revision 0, “Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities,” issued May 2012 (ML12125A412), is not endorsed for licensing purposes. However, this document provides useful information on diverse methods to meet emergency communications needs and criteria for identifying enhancements to communications systems that will ensure their availability during an extended loss of alternating current (AC) power. |
| **Question No. 35** |
| It is mentioned “During incidents with offsite consequences, DHS may assume coordination of the Federal response, while the lead Federal agency will continue to oversee the onsite response, monitor and support owner or operator activities (where applicable), provide technical support to the owner or operator if asked, serve as the principal Federal source of information about onsite conditions, and, if asked, advise the State, Tribal, and local government agencies on implementing protective actions. The lead Federal agency also will provide a hazard assessment of onsite conditions that might have significant offsite effects and ensure that onsite measures are taken to mitigate offsite consequences.” Could United States of America share information whether NRC as lead Federal agency will advise operator for taking on-site actions even if not asked for based on the outcomes of its own independent assessment? |
| <u>Answer</u>: During an incident, the NRC would inform the operator of the results of the agency’s independent assessment but would not advise the operator or recommend actions for the operator to take. In the United States, the operator is ultimately responsible for safety. The NRC, as an independent regulator, does not advise the operator on actions to take.<br><br>The NRC is empowered by Congress to intervene and direct a licensee’s response actions on site during an emergency, if the situation warrants. However, this situation is rare, and in fact, there has not been a single instance in which the NRC has instructed a licensee to deviate from its previously approved emergency response procedures. |
| **Question No. 59** |
| Are exercises on severe accident scenarios conducted at the NPP? |
| <u>Answer</u>: Yes, severe accident scenarios are included in NPP exercises. NRC regulations require licensees to vary the content of scenarios in each 8-year exercise cycle to provide the opportunity to demonstrate proficiency in the key skills necessary to respond to various accident scenarios, including severe accidents. During exercises, licensees also practice making protective action recommendations based on site-specific protective action strategies. NRC guidance for development of protective action strategies is based, in part, on analysis of severe accidents. |
| **Question No. 64** |
| The NRC staff has submitted the draft final rule package to the Commission for it its consideration as SECY-22-0001, “Final Rule: Emergency Preparedness for Small Modular reactors and Other New Technologies.” The new emergency preparedness requirements in the draft final rule and guidance adopt a consequence-oriented, risk-informed, performance-based and technology-inclusive approach. Could NRC please briefly describe, how these |

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| elements are adopted in the new regulations? For example, with regard to EPZ requirements for SMRs (a scalable approach for determining the size of EPZ). |
| Answer: The NRC employs a graded approach to EP in which the requirements adjust commensurate to the risk of the facility. In the draft performance-based approach, performance results serve as the primary basis for regulatory decisions, rather than demonstrating compliance with prescriptive criteria. Under a performance-based framework, applicants and licensees would have the flexibility to determine how to meet the established performance criteria necessary for an effective EP program. The draft performance-based framework has four basic parts: (1) the demonstration of emergency response functions through periodic drills and exercises, (2) onsite and offsite planning activities, (3) a hazard analysis of contiguous facilities, and (4) the determination and description of the boundary and physical characteristics of the plume exposure pathway emergency planning zone (EPZ) and ingestion response planning capabilities in the emergency plan. In regard to the EPZ requirements, EPZs are used to simplify protective action decision-making, when such decisions may be time constrained. Under the draft final rule, the need for a plume exposure pathway EPZ is determined through the use of two criteria. The first criterion is that the plume exposure pathway EPZ is the area within which public dose is projected to exceed 10 mSv total effective dose equivalent over 96 hours from the release of radioactive materials from the facility, considering accident likelihood and source term, timing of the accident sequence, and meteorology. The second criterion is that the plume exposure pathway EPZ is the area where predetermined, prompt protective measures are warranted. Although the size is scalable, the EPZ does not change the requirements for emergency planning; it only sets physical bounds on the planning. Detailed planning within the EPZ provides a basis for expansion of the response efforts beyond the EPZ, should it become necessary. |
| **Question No. 85** |
| (1) Can you please outline the basic components and measures within the ingestion pathway zone?<br>(2) Is this zone equal to 50 miles for all plants or it can adjusted based on specific accident analysis? |
| Answer:<br>(1) Planning within the ingestion pathway zone includes the capabilities and resources needed to prevent ingestion of contaminated food and water. Guidance for ingestion planning appears in NUREG-0654/FEMA-REP-1, Revision 2, “Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,” issued December 2019 (ML19347D139), and FEMA P-1028, “Program Manual: Radiological Emergency Preparedness,” issued December 2019. NUREG/CR-7248, “Capabilities and Practices of Offsite Response Organizations for Protective Actions in the Intermediate Phase of a Radiological Emergency Response,” issued June 2018 (ML18170A043), presents additional insights on implementing ingestion response capabilities.<br><br>(2) The 50-mile (80.47-kilometers) ingestion pathway zone applies to large LWRs licensed under 10 CFR Part 50 or 10 CFR Part 52 and is based on the technical considerations in NUREG-0396, “Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,” issued December 1978 (ML051390356). The 50 miles (80.47 km) can be adjusted based on specific accident analysis for other types of reactors. Specifically, the size of the ingestion pathway zone may be determined on a case-by-case basis for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt. |

| **Question No. 86** |
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| What is the basis for the size of the plume and ingestion pathway zones? |
| Answer: The technical basis for the 10-mile plume exposure pathway and 50-mile ingestion exposure pathway zones for large LWRs is contained in NUREG-0396. The endorsed guidance can be found in NUREG-0654/FEMA-REP-1, Revision 2. This endorsed guidance summarizes the following bases:<br><br>The size of the plume exposure pathway EPZ was based primarily on the following considerations:<br>(a) Projected doses from the traditional design-basis accidents would not exceed Federal protective action guide (PAG) levels outside the EPZ.<br>(b) Projected doses from most core melt sequences would not exceed Federal PAG levels outside the EPZ.<br>(c) For the worst core melt sequences, immediate life-threatening doses would generally not occur outside the EPZ.<br>(d) Detailed planning within 10 miles (10.09 kilimeters) would provide a substantial base for expansion of response efforts in the event this proved necessary.<br><br>The size of the ingestion exposure pathway EPZ was based on the following considerations:<br>(a) The downwind range within which contamination will generally not exceed the Federal PAGs is limited to about 50 miles (80.47 kilometers) from an NPP because of wind shifts during the release and travel periods.<br>(b) There may be conversion of atmospheric iodine to chemical forms that do not readily enter the ingestion pathway.<br>(c) Much of any particulate material in a radioactive plume would have been deposited on the ground within about 50 miles (80.47 kilometers) from the NPP.<br>(d) The likelihood of exceeding ingestion exposure pathway PAG levels at 50 miles (80.47 kilometers) is comparable to the likelihood of exceeding plume exposure pathway PAG levels at 10 miles. |
| **Question No. 104** |
| According to p.180, 10 CFR 50.47(b)(10) requires that each state consider the prophylactic use of potassium iodide (KI) as appropriate.<br>(1) Does the federal (national) government have in place the guideline on KI stockpiling and (pre)distribution procedures and the system to manage the guidelines?<br>(2) If so, which authority is in charge? |
| Answer: In the United States, the distribution of KI for the general public is the responsibility of State and local officials. For States that choose to stockpile and distribute KI, the Federal Government reviews those plans as part of the oversight process for the NRC's EP program. Specifically, the Federal Emergency Management Agency (FEMA) reviews offsite plans for commercial NPPs to ensure they are adequate and can be implemented. This includes a review of plans to stockpile and distribute KI. FEMA P-1028 contains the Federal review guidance. FEMA provides its review findings to the NRC. |

| **Question No. 105** |
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| With regard to p.180,<br>(1) in case of urgent distribution of KI, is there any guideline to include the following procedures:<br>– screening people for contraindication/precautions?<br>– checking parental consent when distributing KI to minors?<br>– managing side effects?<br><br>(2) Are these procedures different in each State? If so, please explain with some cases. |
| Answer:<br>(1) Guidelines for distribution of KI have been established by the U.S. Food and Drug Administration (FDA) and published as "Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," issued December 2001 (https://www.fda.gov/media/72510/download). Additional guidelines, based on FDA guidance, are found in section 2.2.3 of the U.S. Environmental Protection Agency's EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance," issued January 2017 (https://www.epa.gov/radiation/pag-manuals-and-resources). The guidelines include considerations for screening, distribution to minors, and side effects.<br><br>(2) States develop their own KI policies for handling distribution and direction for use during an emergency but generally follow the Federal guidance listed above. Additional information can be found in the response to questions Nos.104 and 106. |
| **Question No. 106** |
| (1) With regard to p.180, if KI is predistributed in certain states, are there documents which describe the following?<br>- Targets of KI predistribution (institution vs. resident)/guidelines for each target<br>- (In case of KI predistribution to institutions) target locations/how to manage each location<br>- (In case of KI predistribution to residents) procedures for exchanging, returning and receiving additional KI<br><br>(2) If so, how such documents are established? |
| Answer:<br>(1) Distribution varies by State. Documents that describe how State and local officials will predistribute to residents and institutions and how additional KI can be received are publicly available and typically distributed through State and local public health agencies. Much of this information is readily available online. A good summary of State programs can be found in the U.S. National Academies of Sciences, Engineering, and Medicine review, "Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident," issued in 2004 (https://nap.nationalacademies.org/catalog/10868/distribution-and-administration-of-potassium-iodide-in-the-event-of-a-nuclear-incident).<br><br>(2) States determine whether to use KI as a supplement to evacuation and sheltering in place and, if so, how they intend to predistribute KI or make it available as needed. These documents are published by the States under their own authorities, but generally follow Federal guidance published by the U.S. FDA and EPA. |
| **Question No. 107** |
| The national report (page 180) states that FEMA and NRC execute periodic radiation emergency response exercises.<br>(1) Specifically, what accident scenarios are used for exercises implemented with the states and tribal governments? |

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| (2) Please explain[:] 1. the causes of an initial emergency alert (natural disaster, terrorism, human errors, etc.) and 2. the size of the accident (requiring large scale protection measures for residents, or on-site accident response). |
| Answer:<br>(1) Exercise scenarios vary to ensure that licensees and offsite response organizations (OROs) respond to a wide spectrum of simulated emergency events. The applicable regulations driving these exercises are primarily based on Appendix E to 10 CFR Part 50. FEMA evaluates ORO performance during these exercises in accordance with NUREG-0654/FEMA-REP-1, Revision 2, and provides input to the NRC.<br><br>(2) Emergency action levels are unique to each licensee but are derived from NEI 99-01, "Development of Emergency Action Levels for Non-Passive Reactors for LWRs currently licensed" (ML12326A805). This document describes how each emergency classification level is determined. |
| **Question No. 129** |
| It is indicated in the report that the emergency action levels are used by the licensees for the emergency classification of the NPPs.<br>Does U.S. NRC have a system to monitor the safety parameters of the NPPs (emergency action levels) which are used for the emergency classification, in which the related parameters are transferred to U.S. NRC by licensees? |
| Answer: The NRC maintains the Emergency Response Data System (ERDS), which has the capability of receiving near real-time transmissions of a limited dataset of selected parameters from U.S. NPPs in the event of an emergency classified at an "Alert" or higher level (Section VI of Appendix E to 10 CFR Part 50). NUREG-1394, Revision 2, "Emergency Response Data System," issued August 2022 (ML22244A081), provides further guidelines on ERDS implementation. The NRC does not actively monitor ERDS data from licensees.<br><br>Initial emergency action levels are discussed and agreed on by the applicant or licensee and State and local governmental authorities and approved by the NRC. Thereafter, emergency action levels are reviewed annually with the State and local governments. The licensee declares emergency action levels at an NPP. |
| **Question No. 130** |
| It is indicated in the report that the protection strategy to implement the protective actions during emergencies in NPPs are mainly based on the emergency classification that is performed by licensee.<br>Does the protective strategy include the use of operational intervention levels (operational criteria) which are utilized for giving decisions about the protective actions by comparing them with the results of radiological monitoring activities which are performed during radiation emergencies? |
| Answer: Protective action strategies are informed by the U.S. Environmental Protection Agency (EPA) protective action guides (PAGs) found in the EPA PAG Manual (EPA-400/R-17/001). A PAG is the projected dose to an individual from a release of radioactive material at which a specific protective action should be taken to reduce or avoid that dose. Protective action strategies use different criteria depending on the recommended action. The PAG Manual also recommends actions that are not dependent on a PAG, such as simple methods to reduce dose by removing contaminated clothing. The PAGs for evacuation, sheltering in place, and relocation are based on the projected dose to an individual. NRC guidance leverages the PAG Manual approach and provides a tool to develop strategies for implementing evacuation and sheltering in place based on information available from plant conditions, dose projections, or field measurements obtained from |

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| monitoring activities during the emergency. Public officials may need to make decisions for protection against ingestion. The PAG Manual contains guidance for developing derived reference levels to operationalize the PAGs for drinking water. |
| **Question No. 139** |
| (1) In the USA, are there a pre-distribution of potassium iodide to the public living around power plants? If yes, on which perimeter around the installations?<br>(2) How is this pre-distribution performed in practice (particularly with regard to population age or population changes/mobility)?<br>(3) How do you ensure that every inhabitant in the vicinity of nuclear installations will be reached? |
| Answer:<br>(1) The decision to predistribute KI is left to individual States. Documents that describe how states will predistribute to residents and institutions are typically publicly available and distributed through State public health agencies.<br><br>(2) A good summary of State programs for predistribution of KI can be found in the U.S. National Academies of Sciences, Engineering, and Medicine review “Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident,” issued 2004 (https://nap.nationalacademies.org/catalog/10868/distribution-and-administration-of-potassium-iodide-in-the-event-of-a-nuclear-incident).<br><br>(3) States determine whether to use KI as a supplement to evacuation and sheltering in place and if so, how they intend to predistribute KI or make it available as needed. These documents are published by the States under their own authorities, but generally follow Federal guidance for distribution and administration of KI published by the FDA and the EPA. NRC regulations do not require the use of KI, only that KI has been considered as a supplement to evacuation and sheltering in place within the plume exposure pathway EPZ. |
| **Question No. 140** |
| (1) In the USA, is potassium iodide considered as a drug?<br>(2) If yes, what is its validity period? |
| Answer:<br>(1) Yes. The FDA considers potassium iodide a drug.<br><br>(2) The shelf life (validity period) of the drug is set by the manufacturer. Recognizing the inherent stability of KI, the FDA has provided guidance for shelf-life extension beyond the manufacturer’s recommendation. |
| **Question No. 141** |
| (1) In the USA, are there local stocks of potassium iodide to be distributed in case of an emergency?<br>(2) Where are they located?<br>(3) Do you have specific provisions for very young children? |
| Answer:<br>(1) Yes, there are local stocks of potassium iodide.<br><br>(2) The stockpiles’ location and how they are stored and distributed vary by State.<br><br>(3) The FDA and EPA publish guidelines for distributing and administering KI. These contain guidance for administration to very young children, including advice on crushing tablets in food or water and liquid doses. The guidance also covers neonates and pregnant women. |

Additional information can be found at https://www.fda.gov/drugs/bioterrorism-and-drug-preparedness/radiation-emergencies and https://www.fda.gov/drugs/bioterrorism-and-drug-preparedness/frequently-asked-questions-potassium-iodide-ki.

**Question No. 142**

In 2001, the NRC amended its regulation in 10 CFR 50.47(b)(10) for emergency planning associated with potassium iodide.
(1) What are the technical criteria (environment measurement, calculated dose…) that would lead the responsible authority to order/recommend the ingestion of potassium iodide or to start a distribution?
(2) Who makes the decision?
(3) How is this decision communicated to the people concerned?
(4) Which populations are concerned by the iodide intake (is there an age limit?)
(5) What is the advice for—taking iodide (x hours before, y hours after?) If yes, how many times? On which criteria?
(6) Which formulation (chemical formula, dosage, galenic form) is chosen for stable iodine?

Answer:

(1) The EPA PAG Manual contains the guidelines for KI administration. The supplemental administration of KI begins at a PAG of 5 rem (50 mSv) projected child thyroid dose from exposure to radioiodine.

(2) In the United States, the administration of KI is the decision of State and local officials.

(3) States that choose to supplement protective actions with KI will describe in their emergency plan the various means for communicating a recommendation to emergency workers, institutionalized persons, and the public.

(4) The FDA guidelines for administration of KI consider the following age groups: Infants (birth through 1 month); Children (1 month through 3 years); Children (over 3 years through 12 years); Adolescents (12 through 18 years); Pregnant women; Adults (over 18 through 40 years); and Adults (over 40 years).

(5) The EPA PAG Manual notes that KI is most effective if taken before exposure. FDA guidelines note that KI is effective for approximately 24 hours and may be dosed daily, if needed. Table 2-1 and table 2-2 of the 2017 EPA PAG Manual contain the specific KI dosage and criteria for recommended use.

(6) The FDA and EPA offer guidelines for use of KI in tablet and liquid (oral solution) form depending on age.

**Question No. 143**

In the USA, the Reactor Oversight Process includes drill evaluation and exercice evaluation.
(1) Are there complemen[t]ary exercices to the biennal exercise[e]?
(2) How often do NRC staff observe these types of drills or exercices?
(3) How do NRC take into account organizational and human factors in the crisis organisation of the licensee?

Answer:

(1) Yes, 10 CFR 50.47, “Emergency plans,” and 10 CFR Part 50, Appendix E, paragraph IV.F.2.b, require in part that, in addition to biennial exercises, licensees take actions necessary to ensure that adequate emergency response capabilities are maintained during the interval between biennial exercises by conducting drills. These drills

must include at least one exercise involving a combination of some of the principal functional areas of the licensee’s onsite emergency response capabilities. The NRC also has additional exercises related to communications, medical response, and other areas that can be performed in parallel with the biennial exercises or at other times as determined to be necessary by the licensee, OROs, or both.

(2) Regional EP inspectors observe full participation exercises once every 2 years. Site resident inspectors observe a minimum of one EP drill and some combination of two additional drills or training evolutions.

(3) The NRC accounts for organizational and human factors in the crisis organization of licensees in the Reactor Oversight Process (ROP). The ROP consists of three key strategic performance areas: reactor safety, radiation safety, and safeguards. Within the strategic performance area are seven cornerstones that reflect the essential safety aspects of facility operation. These seven cornerstones include initiating events, mitigating systems, barrier integrity, emergency preparedness, public radiation safety, occupational radiation safety, and physical protection. Certain elements of licensee performance can impact more than one cornerstone and are termed “cross-cutting areas” (CCAs). CCAs are defined as the fundamental performance characteristics that extend across all of the ROP cornerstones of safety. These areas are human performance, problem identification and resolution, and safety-conscious work environment (SCWE). Organizational and human factors in the crisis organization are covered under human performance and or SCWE. In addition, initial approval of a licensee’s emergency plan includes consideration of organizational and human factors issues when the NRC makes its reasonable assurance determination.

**Question No. 147**

Based on feedback from the Fukushima accident, what actions are implemented regarding the management and reporting of key parameters (such as temperature, water level...) from research reactors that would be inaccessible after an extreme hazard?

Answer: The Fukushima diverse and flexible coping strategies (FLEX) apply only to power reactors, and there are no new or additional requirements for nonpower production or utilization facilities to monitor or implement additional actions or measures outside of previously established responses during emergency events. Any changes facilities may have made in response to the Fukushima event would have been entirely voluntary.

The NRC staff evaluated 31 licensed research and test reactors (RTRs) licensed by the agency to assess the applicability of lessons learned from the Fukushima Dai-ichi nuclear accident to these facilities. The NRC staff assessed two categories of RTRs based on the licensed thermal power level of each facility. Category 1 consisted of the 26 research reactors licensed to operate at power levels lower than 2 MWt. Category 2 comprised the remaining five NRC-licensed RTRs licensed to operate at 2 MWt or higher. The NRC staff’s assessment concluded that all of the Category 1 and the two lowest powered Category 2 research reactors were highly resilient to the loss of electrical power, active decay heat removal systems, and heat sink. These 28 research reactors generate minimal decay heat, which can be adequately removed via air cooling to prevent fuel cladding failure. In contrast, the three largest Category 2 RTRs rely on the availability of water for adequate decay heat removal. For this reason, the NRC staff performed an additional assessment of these three facilities to determine the resilience of their primary coolant systems to a beyond-design-basis seismic event. For the 20 MWt test reactor, the NRC staff also assessed the resilience of emergency power, active decay heat removal systems, and coolant makeup systems for flooding and beyond-design-basis seismic events. The results of the NRC staff’s assessment revealed that the existing design bases for NRC-licensed RTRs adequately protect against fuel cladding failures and the release of radioactive material during a beyond-design-basis external event. For more detailed information refer to the following:

- “Assessment of Lessons Learned from the Fukushima Dai-ichi Nuclear Accident to Research and Test Reactors in the United States,” issued November 2017 (ML17312B044)
- SECY-15-0081, “Staff Evaluation of Applicability of Lessons Learned from the Fukushima Dai-Ichi Accident to Facilities Other Than Operating Power Reactors,” dated June 9, 2015 (ML15050A066) (the evaluation of RTRs starts on page 81 of the attachment)
- SECY-17-0016, “Status of Implementation of Lessons Learned from Japan’s March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami,” Enclosure 2, “Status Update on Other than Tier 1 Activities,” dated January 30, 2017 (ML16356A047), which documents the resolution of the three high-powered RTRs

**Question No. 208**

Section 16 of the report focuses mainly on the role of the NRC. We suggest the roles and responsibilities of other stakeholders (other federal departments, state and local governments etc.) in EM be elaborated and the interoperability be discussed.

Answer: The Nuclear Radiological Incident Annex (NRIA) to the Response and Recovery Federal Interagency Operational Plans (available at: https://www.fema.gov/pdf/emergency/nrf/nrf_nuclearradiologicalincidentannex.pdf) details the roles and responsibilities of Federal departments and agencies in responding to nuclear and radiological incidents. It is important to note that Federal interagency partners respond to support State, local, Tribal, and Territorial governments’ response efforts. The NRIA does the following:

(1) describes the process and organizational constructs that Federal departments and agencies will use to support State, local, Tribal, and territorial governments in responding to nuclear or radiological incidents

(2) identifies how Federal interagency partners will respond, coordinate national response to nuclear or radiological incidents, and provide recovery support under Federal authorities

(3) provides information specific and unique to Federal nuclear or radiological incident response and recovery processes, assets, resources, and teams

Thank you for your recommendation; the NRC will consider including the above reference in the next CNS report.

**Question No. 209**

Does the US consider any other factors when making protective action decisions other than the nuclear specific indicators (i.e. psych[o]social impacts, impacts on vulnerable populations)?

Answer: NRC guidance for developing protective action strategies considers external factors such as adverse weather, impediments to evacuation, and hostile action. Protective action strategies are also informed by an evacuation time estimate (ETE), which is updated at least after each decennial census. ETEs collect and provide site-specific information on evacuation logistics for transit-dependent populations and vulnerable populations in special facilities (e.g., hospitals and prisons), and schools, among other site-specific considerations. ETEs are used to develop evacuation plans and to guide the choice of protective action during an emergency.

NPP operators are required to make protective action recommendations based on predetermined protective action strategies developed in collaboration with offsite authorities. Offsite authorities make protective action decisions for the public based on the protective action recommendations provided by the NPP and their independent analyses. These decisions are guided by the predetermined strategies and PAGs.

A PAG is the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. The EPA PAG Manual provides recommended PAGs to guide the choice of protective action (https://www.epa.gov/radiation/pag-manuals-and-resources). The EPA evaluated dose consequences to several age groups across many scenarios and has determined that basing evacuation, sheltering in place, and relocation dose projections on an adult is appropriate for all age groups. However, there are guidelines for different PAGs for different subpopulations for KI, food, and water. These PAGs reflect differences in radiosensitivity, primarily due to age.

The technical basis for the EPA PAGs is to prevent acute effects, reduce the risk of chronic effects, balance protection with other important factors, and ensure that actions result in more benefit than harm. However, PAGs are not meant to be used as strict numeric criteria, but rather as guidelines to be considered in the context of incident-specific factors. This gives decision-makers flexibility to consider other factors. For example, during the COVID-19 public health emergency in the United States, two States adjusted their PAG levels for evacuation and recommended actions for facilities with vulnerable populations (i.e., hospitals and nursing homes) after considering the risk of COVID-19 transmission at reception centers (A. Leek and J. Semanczik. “Compensatory considerations for radiological emergency response and public protective actions during the COVID-19 pandemic.” *Health Phys*. 122(2):333–340; 2022).

## ARTICLE 17. SITING

**Each Contracting Party shall take the appropriate steps to ensure that appropriate procedures are established and implemented for**

**(i) evaluating all relevant site-related factors that are likely to affect the safety of a nuclear installation for its projected lifetime**

**(ii) evaluating the likely safety impact of a proposed nuclear installation on individuals, society, and the environment**

**(iii) re-evaluating, as necessary, all relevant factors referred to in subparagraphs (i) and (ii) so as to ensure the continued safety acceptability of the nuclear installation**

**(iv) consulting Contracting Parties in the vicinity of a proposed nuclear installation, insofar as they are likely to be affected by that installation and, upon request, providing the necessary information to such Contracting Parties, in order to enable them to evaluate and make their own assessment of the likely safety impact on their own territory of the nuclear installation**

This section explains the responsibilities of the U.S. NRC for siting, which include site safety, environmental protection, and emergency preparedness. This section discusses the regulations applying to site safety and their implementation, emphasizing regulations applying to seismic, geological, hydrological, meteorological, and radiological assessments. It explains environmental protection and reevaluation of site-related factors. It also addresses the Vienna Declaration on Nuclear Safety, issued in February 2015. Article 16 of this report discusses emergency preparedness and international arrangements, which would apply to contracting parties in obligation (iv) above. Finally, no changes to the current NRC practices associated with siting were identified as part of the NRC's Fukushima lessons-learned initiatives.

| **Question No. 15** |
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| It's stated that "In 2012, a new seismic source model was completed for the central and eastern United States, which built on previous seismic source models."<br>Question: Is it necessary to re-analyze the safety based on the new model, for the unconstructed nuclear facilities that were licensed before 2012? |
| Answer: The NRC does not consider it necessary to reanalyze the safety of unconstructed nuclear facilities that were licensed before 2012. However, should a previously considered site move forward with plans for construction or operation of a new nuclear facility, it may be necessary to reanalyze seismic hazards using the updated seismic source model to meet the regulatory requirements for construction and operation of the new facility. Additionally, the NRC is currently reviewing operating nuclear reactor sites to consider the effect of the updated seismic source and ground motion models, as well as updated site response approaches based on the agency's understanding of seismic hazards and associated risks for individual locations. |
| **Question No. 30** |
| It is proposed to give a complete list of external impacts of natural and technogenic origin, which are considered in the site selection indicating the potential hazard degree. |
| Answer: The NRC does not provide an exhaustive list of all potential external impacts to be considered by individual applicants or licensees because of the various site-specific factors. The NRC does not have rigid exclusion criteria for site selection, and applicants may select sites |

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| with known hazards provided the applicant can meet all regulatory requirements despite the known hazards. Comprehensive characterization of potential external hazards supports reasonable assurance of adequate protection. A licensee would need to adequately characterize the hazard and its potential effects on the site and, if needed based on the potential effects and risks, demonstrate adequate mitigation of the hazards. |
| **Question No. 36** |
| It is mentioned "A design has an acceptably low level of seismic risk if the design-specific seismic capacity of the plant can withstand at least 1.67 times the ground motion acceleration of the design-basis safe shutdown earthquake." Could USA clarify the basis for the value of 1.67 wrt [with respect] to acceptably low level of risk for a design? |
| Answer: NUREG/CR-6926, "Evaluation of the Seismic Design Criteria in ASCE/SEI Standard 43-05 for Application to Nuclear Power Plants," issued March 2007 (available at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr6926/index.html), provides some background on the basis for the value of 1.67, which originates from SRM-SECY-93-087, "SECY-93-087—Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated July 21, 1993 (ML003708056). Specifically—<br><br>> …the Commission approved the use of a PRA-based seismic margins analysis which considers sequence-level HCLPFs [high confidence of low probability of failure] and fragilities for all sequences leading to CDF up to approximately 1.67 times the SSE [safe shutdown earthquake]. The staff anticipated that fully developed seismic PRAs will be performed for new NPP designs, and sufficient margin shown in the plant level HCLPF will effectively identify any seismic significant contributors to risk and capture potential design-specific seismic vulnerabilities. |
| **Question No. 61** |
| (1) How many early site permits and combined licenses were issued by NRC in accordance with the Law 10 CFR, part 52 for the period from 2019 to 2022 and how many is planned to be issued in 2023?<br>(2) If it is possible to provide the information in tabular form (year, site name and reactor plant thermal capacity, expected commissioning dates). |
| Answer:<br>(1) No combined licensees have been issued since 2019. One early site permit (Clinch River Nuclear Site) was issued since 2019. No combined licensees or early site permits are planned to be issued in 2023. Additional information can be found in section 2.3.3.8 of the U.S. Ninth National Report.<br><br>(2) There is only one data point:<br><br>• Year: 2019<br>• Site Name: Clinch River<br>• Capacity: not applicable to an early site permit<br>• Expected Commissioning Date: not applicable to an early site permit |
| **Question No. 87** |
| (1) How is the design-basis safe shutdown earthquake selected?<br>(2) Are there requirements for the recurrence period? |
| Answer: The requirement to determine the SSE ground motion appears in 10 CFR 100.23, "Geologic and seismic siting criteria." The regulation states, "the Safe Shutdown Earthquake Ground Motion for the site is characterized by both horizontal and vertical free-field ground |

motion response spectra at the free ground surface.” A probabilistic seismic hazard analysis must be performed to assess inherent uncertainties. Additionally, 10 CFR Part 50, Appendix S, “Earthquake Engineering Criteria for Nuclear Power Plants,” paragraph IV(a)(1), defines the minimum SSE ground motion for design. RG 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,” issued March 2007 (ML070310619), provides additional details on the performance of a probabilistic seismic hazard analysis to determine the ground motion response spectrum or SSE for the site, including guidance on the minimum return period ground motion amplitude.

**Question No. 108**

In the United States national report, Article 17.2.2 states that “In addition, the distance to a population center of more than about 25,00 residents must be at least 1.3 times the distance from the reactor to the outer boundary of the low population zones”.

(1) Is there the definition of “a population center” in practice? Please explain whether the population center means a single town or a certain region with a higher population density than the surrounding regions.

(2) If possible, please present or explain some examples of determining the population center in the United States.

Answer:

(1) “Population center” means an urbanized area of high population density. It could be a town, city, region, cluster, etc. The NRC considers the proximity to population centers along with other factors when reviewing potential sites for NPPs. For NPPs licensed to date, the NRC considered not only the distance to a population center but also the overall population density, which under NRC guidance should be less than 500 persons per square mile (193 persons per square kilometer) from the plant. These guidelines for population density complement the consideration of the nearest specific population center. When considering the distance to the border of a population center of more than about 25,000 residents, the NRC uses an increase in population density and not political boundaries to define the border. Refer to the following guidance regarding distance to a population center:

- SRP Section 2.1.3, Revision 3 “Population Distribution,” issued March 2007 (ML070550028)
- Regulatory Guide 4.7, “General Site Suitability Criteria for Nuclear Power Stations,” issued March 2014 (ML12188A053)

(2) For examples, see the following:

- Sections 2.1.3.4 and 2.1.3.5 of the “Vogtle Early Site Permit Application,” Revision 5, Part 2, “Site Safety Analysis Report,” Chapter 2, “Site Characteristics,” Section 2.1, “Geography and Demography,” issued December 2008 (ML091540847).

  The low population zone (LPZ) for the Vogtle Electric Generating Plant (VEGP), Units 3 and 4, is the same as the LPZ for the existing VEGP units and consists of the area falling within a 2-mile radius. The nearest population center to the VEGP site with more than 25,000 residents is Augusta, Georgia, with a 2000 population of 195,182. Augusta is approximately 26 miles (41.84 kilometers) north-northwest of the VEGP site.

- Section 2.1.3.5 of the “PSEG Site ESP Application,” Part 2, “Site Safety Analysis Report,” Revision 4, Chapter 2, “Site Characteristics and Site Parameters,” Section 2.0, Appendix 2AA, issued June 2015 (ML15169A282), for a discussion of the population centers located within 50 miles (80.47 kilometers) of the PSEG site.

- Section 2.1.3.5 of the Clinch River ESP application, Part 02, “Site Safety Analysis Report” (Revision 2), Chapter 02, “Site Characteristics,” Section 02.01, “Geography and Demography,” issued January 2019 (ML19030A282).

  The population center distances from the site’s center point to the nearest boundaries of the Knoxville and Cleveland, Tennessee, urban areas are approximately 4.8 miles (7.72 kilometers) (southeast) and 45 miles (72.42 kilometers) (south-southwest), respectively. These distances are greater than one and one-third times the distance from the site center point to the boundary of the LPZ.

**Question No. 1109**

According to Article 17.2.2 of the national report and 10 CFR Part 100, population centers with more than 25,000 residents are considered for evaluating the population center distance. Is there any technical background or reason for the number of 25,000 residents?

Answer: “Population center distance” is defined in 10 CFR 100.3 as “the distance from the reactor to the nearest boundary of a densely populated center containing more than about 25,000 residents.” This term was defined early in the development of commercial nuclear power in the United States and was based on considerations such as the potential difficulty in implementing protective actions in larger cities.

Note that the “25,000” number was developed when 10 CFR Part 100 was first issued in 1962, well before the emergency preparedness rule was issued in 1980. The following references are provided for further historical context:

- NUREG-0478, “Metropolitan Siting—A Historical Perspective,” issued October 1978 (ML12187A192)
- David Okrent’s document titled “On the History of the Evolution of Light Water Reactor Safety in the United States” (ML090630275).

  Page 2-54 (PDF page 132): “The reactor should be located sufficiently distance [distant] from cities (metropolitan areas) of above 10,000 to 25,000 population so that no inhabitant receives more than 300 rems in the extremely improbably [improbable] accident defined by a complete failure of all confinement barriers and a source strength equal to most of the fission product inventory.”

  Page 2-420 (PDF page 501): “Letter of 12/13/60, refers to using reactors of proven design. This letter refers to limiting the number of people killed to less than a catastrophic number. The reactor should be sited such that if the incredible accident occurs with no safeguards, people in a city > 15-25,000 people should not receive> 300 Rem.”

  Page 2-483 (PDF page 565): “The population standards contain the additional requirement that no ‘population center larger than 25,000 persons may be closer to the reactor than one and one-third times the distance from the reactor to the outer boundary of the low population zone.’ If that requirement is not met, however, a proposed reactor does not necessarily have to be relocated nor an existing one abandoned. Instead, a smaller low population zone may be selected so long as the plant has the capability, or can be redesigned, to limit further the potential radiation dosages that could be encountered at the boundary of that zone.”

- 10 CFR Part 100 definitions and Statements of Consideration (SOC) (27 FR 3509). The SOC states the following:

> These [reactor site] criteria are based upon a weighing of factors characteristic of conditions in the United States and may not represent the most appropriate procedure nor optimum emphasis on the various interdependent factors involved in selection of sites for reactors in other countries where national needs, resources, policies and other factors may be greatly different.

- Definitions from 10 CFR 100.3:

> *Low population zone* means the area immediately surrounding the exclusion area which contains residents, the total number and density of which are such that there is a reasonable probability that appropriate protective measures could be taken in their behalf in the event of a serious accident. These guides do not specify a permissible population density or total population within this zone because the situation may vary from case to case. Whether a specific number of people can, for example, be evacuated from a specific area, or instructed to take shelter, on a timely basis will depend on many factors such as location, number and size of highways, scope and extent of advance planning, and actual distribution of residents within the area.
>
> *Population center distance* means the distance from the reactor to the nearest boundary of a densely populated center containing more than about 25,000 residents.

- SOC (27 FR 3509), concerning population center distance:

> One basic objective of the criteria is to assure that the cumulative exposure dose to large numbers of people as a consequence of any nuclear accident should be low in comparison with what might be considered reasonable for total population dose. Further, since accidents of greater potential hazard than those commonly postulated as representing an upper limit are conceivable, although highly improbable, it was considered desirable to provide for protection against excessive exposure doses of people in large centers, where effective protective measures might not be feasible. Neither of these objectives were readily achievable by a single criterion. Hence, the population center distance was added as a site requirement when it was found for several projects evaluated that the specifications thereof would approximately fulfill the desired objectives and reflect a more accurate guide to current siting practices.

Note: For further guidance in developing the exclusion area, the LPZ, and the population center distance, see Technical Information Document (TID) 14844, "Calculation of Distance Factors for Power and Test Reactor Sites," dated March 23,1962 (ML021720780), which contains a procedural method and a sample calculation that result in distances roughly reflecting current siting practices of the Commission. The calculations described in TID 14844 may be used as a point of departure for consideration of particular site requirements resulting from evaluation of the characteristics of a particular reactor, its purpose, and method of operation.

**Question No. 127**

It is mentioned that "… the distance to a population center of more than about 25,000 residents must be at least 1.3 times the distance from the reactor to the outer boundary of the "low population zone.” Could you please give further explanation on the technical background of the distance and population criteria?

Answer: See answer to previous question No. 109.

**Question No. 167**

Regarding Probable Maximum Precipitation at Nuclear Power Plants in the United States of America the NRC published in September 2021 the NUREG/KM-0015.
(1) Are there already values for PMP developed according to NUREG/KM-0015?
(2) How do they compare to the previous values?

Answer: The report NUREG/KM-0015, “Considerations for Estimating Site-Specific Probable Maximum Precipitation at Nuclear Power Plants in the United States of America,” issued September 2021 (ML21245A418), captures knowledge gained with a focus on methodology as part of the recent flood hazard reevaluation efforts following the accident at Fukushima Dai-ichi. The report focuses on procedures such as storm selection, reconstruction, and transposition; dewpoint; moisture maximization; terrain adjustments; and spatial and temporal distributions. The NRC sent a request to all operating plants to submit revised flood hazard analyses. Some of the licensees developed site-specific probable maximum precipitation (PMP) as their input for the basinwide riverine and stream flooding, as well as local intense precipitation flooding hydrologic models. The NRC reviewed each on a case-by-case basis. NRC guidance generally references PMP estimates for the United States based on hydrometeorological reports (HMRs) prepared by the National Weather Service (NWS) of the National Oceanic and Atmospheric Administration (NOAA). The HMRs have regional coverages. NOAA is engaged in activities aimed at updating the HMRs and has the mandate as the Federal agency responsible for HMRs.

The PMP is defined in the HMR documents as “theoretically, the greatest depth of precipitation for a given duration that is physically possible over a given storm area at a particular geographical location at a certain time of the year.” The most recent HMR was published by NWS/NOAA for California in 1998, whereas most of the reports date back to the 1970s and 1980s. NUREG/KM-0015 does not provide a summary of PMP values nor a specific methodology. The specific reviews from which the knowledge was developed are not sufficiently representative to make general comparisons with NOAA’s HMR values.

**Question No. 168**

Regarding Probable Maximum Precipitation at Nuclear Power Plants in the United States of America the NRC published in September 2021 the NUREG/KM-0015. This document also identifies key considerations in developing and reviewing these estimates that may be used during flooding analyses. How did the NRC consider the possible change in Probable Maximum Precipitation due to climate change?

Answer: The key considerations presented in NUREG/KM-0015 generally focus on the methodology and specific techniques to be used in developing and reviewing potential future site-specific PMP studies. These include storm selection, storm construction, storm transposition, moisture maximization, terrain adjustment, and spatial and temporal distributions of PMP. Section 10 of the U.S. Ninth National Report discusses the potential effects of long-term climatic change within the context of PMP estimates. NUREG/KM-0015 is not intended to serve as a guidance document nor does it invalidate any prior guidance documents or prior studies.

**Question No. 179**

(1) Is there a statutory obligation on licensees, when a plant’s license is renewed, to conduct such a reassessment for the site or is this only done at the express request of the national nuclear regulatory agency?

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| (2) What additional measures have been implemented or are envisaged to be implemented at nuclear power plant sites in the country as a result of such reassessments? |
| Answer:<br>(1) The NRC regulations allow for the renewal of NPPs for up to an additional 20 years beyond the initial licensing period depending on the outcome of an assessment to determine whether the reactor can continue to operate safely and whether the protection of the environment can be ensured during the 20-year period of extended operation. In accordance with 10 CFR Part 54 and 10 CFR Part 51, licensees must submit a license renewal application to the NRC. The NRC's review of a license renewal application consists of a safety and environmental review. The NRC regulations covering these reviews are found in 10 CFR Part 54 and 10 CFR Part 51, respectively. The results of the staff's safety review are documented in a publicly available safety evaluation report. The safety review determines if the applicant has adequately demonstrated that the effects of aging will not have adverse impacts on the nuclear facility's operation. The environmental review evaluates the potential environmental impacts from continued operation and is documented in a site-specific supplemental environmental impact statement. The environmental review determines whether the adverse environmental impacts of license renewal are great enough to deny the option of license renewal for energy-planning decision-makers. Environmental reviews for license renewals can be found in the library of completed site-specific supplemental environmental impact statements: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1437/index.html.<br><br>(2) The NRC's statutory mission is to protect public health and safety from the effects of radiation from nuclear reactors, materials, and waste facilities. The NRC cannot impose mitigation measures that are not related to public health and safety from radiological hazards or common defense and security. However, these limitations on the NRC's authority do not foreclose or restrict the ability of other regulatory authorities to take such actions as they deem necessary to ensure compliance with applicable orders, consent agreements, or other regulatory requirements or lawful statutory jurisdiction. |
| **Question No. 194** |
| In the "Beyond-Design-Basis Events" principle, could the NRC comment on the concept of Design Extension Conditions present in other regulatory frameworks and how this is addressed in this principle, or another one. |
| Answer: While the NRC does not use the term "design extension conditions" (DEC) in its regulatory infrastructure, it has long considered beyond-design-basis events as part of its regulatory decision-making, as demonstrated by the following regulations:<br><br>• combustible gas control per 10 CFR 50.44<br>• anticipated transient without scram per 10 CFR 50.62<br>• station blackout per 10 CFR 50.63<br>• effects on the facility of a large commercial aircraft impact per 10 CFR 50.150<br>• mitigation of beyond-design-basis external events from natural phenomena and mitigation of extensive damage associated with loss of large areas of the plant due to explosions or fire per 10 CFR 50.155<br><br>All U.S. operating reactors have severe accident management guidelines (SAMGs) as part of the NRC's post-Fukushima actions that they will continue to update as a post-Fukushima commitment. Through the agency's Reactor Oversight Process, NRC inspectors can check that |

the SAMGs are maintained to reflect the plant as-built, modified, and operated. New LWR certified designs also have associated SAMGs. Further, for mitigation of beyond-design-basis external events per 10 CFR 50.155, licensees are required to develop strategies and guidelines for beyond-design-basis external events and extensive damage mitigation guidelines, protect equipment from the effects of natural phenomena with sufficient capacity and capability to mitigate beyond-design-basis external events, and train the personnel who perform activities related to beyond-design-basis external events and extensive damage mitigation. RG 1.226 identifies methods and procedures that the NRC staff considers acceptable for nuclear power reactor applicants and licensees to demonstrate compliance with 10 CFR 50.155.

The NRC staff is actively engaged with designers of new and advanced reactors that are interested in using the IAEA activities related to the concept of DEC from SSR-2/1, Revision 1, "Safety of the Nuclear Power Plants: Design," published in 2016, for protecting the public and environment. As part of its engagement, the NRC staff is evaluating the concept of DEC within its regulatory framework. As explained above, the NRC applies similar concepts and methods in its regulatory system. As noted in response to question No. 82, the NRC is looking forward to finalization of the IAEA guidance on practical elimination for new reactors. This pending IAEA guidance also addresses DECs for new reactors.

## ARTICLE 18. DESIGN AND CONSTRUCTION

**Each Contracting Party shall take the appropriate steps to ensure that:**

**(i) the design and construction of a nuclear installation provides for several reliable levels and methods of protection (defense in depth) against the release of radioactive materials, with a view to preventing the occurrence of accidents and to mitigating their radiological consequences should they occur**

**(ii) the technologies incorporated in the design and construction of a nuclear installation are proven by experience or qualified by testing or analysis**

**(iii) the design of a nuclear installation allows for reliable, stable, and easily manageable operation, with specific consideration of human factors and the man-machine interface**

This section explains the defense-in-depth philosophy and how it is embodied in the general design criteria of U.S. regulations. It explains how applicants meet the defense-in-depth goals and how the NRC reviews applications and conducts inspections before issuing licenses to ensure that this philosophy is implemented in practice. Next, this section discusses measures for ensuring that the applications of technologies are proven by experience or qualified by testing or analysis. This section discusses requirements for reliable, stable, and easily manageable operation, specifically considering human factors and the human-machine interface.

| **Question No. 5** |
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| It is mentioned that NRC has developed inspection program for NPP that incorporated Inspection, Test, Analysis, and Acceptance Criteria (ITAAC) along with lessons learned from inspection programs used for previous era (1970-1980)". USA may like to share major improvements made in new inspection program. |
| <u>Answer</u>:<br>The NRC describes its Construction Reactor Oversight Process (cROP) in Inspection Manual Chapter (IMC) 2506, "Construction Reactor Oversight Process General Guidance and Basis Document," dated November 25, 2020 (ML20310A259). Appendix B-2 to that IMC describes the development history, including its application of lessons learned from NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants: A Report to Congress," issued May 1984 (ML063000293).<br><br>The IMC describes how the NRC developed the cROP based on the one-step licensing process (10 CFR Part 52), which incorporates the concept of ITAAC. The ITAAC process allowed the NRC to preplan inspections and focus on observing the most risk-significant work. The process has been effective in identifying and resolving issues that the licensee can remedy through its corrective actions program.<br><br>In continuing with the practice of continuous improvement, the NRC formed a working group to capture the lessons learned from the construction of Vogtle, and the abandoned Virgil C. Summer Nuclear Station project (ML21160A031). The lessons-learned initiative collects the experiences from staff into an internal database and includes reaching out to external stakeholders through public meetings to gather input. These sources will form the basis for recommendations that the NRC plans to include in a report. |

| Question No. 37 |
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| The section states “Therefore, periodic Type A containment testing is not required, reducing refueling outage time. Based on the fabrication methodology and continued Inservice inspections, NuScale requested and received an exemption from Appendix J to 10 CFR Part 50. The containment structure of light water reactors are also constructed and inspected as per the applicable ASME code. And, these containments are 100-percent inspectable, both from inside and outside, as specificities for NuScale containment structure.” USNRC is requested to share the considerations while accepting NuScale proposal for exemption from periodic type A containment testing? |
| Answer: The NRC staff provided details of its considerations in accepting the NuScale request for exemption from periodic Type A containment testing in Section 6.2.6.4, “Technical Evaluation for Exemption Request No. 7,” of the final safety evaluation report for the NuScale standard plant design, issued July 2020 (ML20205L406).<br><br>The NRC staff acceptance of the exemption from the requirement to perform an integrated leak rate (or Type A) test and the requirement to provide design capability for integrated leak rate testing as stipulated in 10 CFR Part 50, Appendix A, GDC 52, “Capability for containment leakage rate testing,” for the NuScale design is based, to a large extent, on the following considerations:<br><br>• The NuScale containment vessel (CNV) is designed as an ASME Code, Section III, “Rules for Construction of Nuclear Power Plant Components,” Class 1, pressure vessel, whose leakage, because of vessel design or fabrication flaws, would be identified during the structural integrity test required by the ASME Code. This is a hydrostatic leakage test at CNV design pressure, with no visible leakage as an acceptance criterion.<br>• The NuScale CNV is 100 percent inspectable, both inside and outside, so that aging-related flaws leading to potential leakage can be observed. ASME Code, Section XI, “Inservice Inspection of Nuclear Power Plant Components,” requires 100 percent vessel inspection every 10 years.<br>• At each refueling, the CNV and several of its bolted flange penetrations are opened and reclosed. NuScale has committed to inspecting the flanges, flange bolts, and flange gaskets for each opened penetration, including the main closure flange.<br>• NuScale will perform a preservice design pressure test to confirm the low-leakage design of the CNV.<br>• The containment leakage test program includes preoperational and periodic containment local leak rate testing requirements for CNV Inservice Inspection of Nuclear Power Plant Components flanged openings (Type B) and CNV piping penetrations (Type C). Successful Type B and Type C leakage rate tests are required at each refueling. NuScale stated that its CNV design, in combination with the results from Type B and Type C tests, is sufficiently representative of accident conditions to provide confidence that the technical specification leak rate, La, would not be exceeded. In accordance with Appendix J, “Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors,” to 10 CFR Part 50, the sum of Types B and C leakages must remain less than 0.6 the maximum allowable containment leakage rate denoted La, a conservative acceptance criterion that will be demonstrated at each refueling. Based on the additional considerations above, NuScale concluded that all contributors to potential CNV leakage could be identified and detected by local leak rate testing and other means and that Type A testing is not necessary. |

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| The NRC staff has reasonable assurance that the NuScale CNV design, with its inservice inspections, ASME Code design, and preservice design pressure test, combined with periodic Type B and Type C tests, is acceptable to show that the allowable leakage rate allowed in the technical specifications would not be exceeded. |
| **Question No. 53** |
| Has the reliability of new technologies used for design and development of new innovative small modular reactor of NuScale been proven in accordance with the requirements of 10 CFR 50.43? |
| Answer: Because NuScale applied for a design certification, compliance with 10 CFR 50.43(e) is required before issuance of the design certificate. All new technologies associated with the NuScale design were sufficiently demonstrated through one of the means provided in 10 CFR 50.43(e). |
| **Question No. 67** |
| It was mentioned, that successful use of the design-specific review standards and the lessons learned in evaluating NuScale instrumentation and control design formed a basis for developing the design review guide. Can NRC please give some examples of lessons learned in evaluating the NuScale instrumentation and control and how these supported the development of the design review guide? |
| Answer: The traditional NRC review guidance in NUREG-0800 (Standard Review Plan) is based on review of individual instrumentation and control (I&C) safety and control systems, whereas new reactors, such as NuScale, employ I&C systems that predominantly consist of a single platform for safety functions and a single platform for nonsafety functions. Further, modern I&C systems can have several interconnections, dependencies, and commonalities that traditional analog systems do not have. Thus, the overall I&C architecture and the individual I&C systems need to be appropriately designed to prevent fault propagations affecting one or more trains of plant equipment.<br><br>The design-specific review standard (DSRS) (ML15355A295) provides guidance for applicants to address potential hazards in high-integrated digital I&C architecture. The guidance in the DSRS also reflects the four fundamental I&C design principles—independence, redundancy, predictive and repeatable, and diversity and defense in depth—plus the design concept of simplicity. It has an improved format that minimizes duplication and is simpler, more risk informed, and more safety focused. The primary objectives for the DSRS were to (1) improve the safety focus of the staff review by ensuring that a license application has sufficient licensing-basis details to clearly demonstrate that the I&C systems meet the applicable regulations and address fundamental I&C design principles, (2) improve the efficiency of the review by eliminating unnecessary information from being docketed and reviewed, and (3) improve guidance to avoid unnecessary or repeated requests for additional information.<br><br>The demonstrated advantage of the DSRS was the review of fundamental design principles once for all systems, rather than repeated evaluation of these concepts and compliance system by system without consideration of the system's safety significance.<br><br>The applicant found the DSRS useful in preapplication interactions with the staff. The use of DSRS for the staff review of the NuScale I&C systems was a huge success, which facilitated the completion of the NuScale I&C review earlier than most other areas of the application with no significant challenges. |

The Design Review Guide (DRG) (ML20238B936) is a technology-neutral evolution of the DSRS. So, it reflects the safety-focused approach from the DSRS, including the four fundamental I&C design principles. Also, the staff's lessons learned from their reviews of NuScale (ML21050A431) and the Advanced Power Reactor 1400 (APR1400) (ML13059A239) were considered in the development of the DRG. Examples of lessons learned that were incorporated in the DRG were for the guidance to be (1) technology neutral (i.e., applicable to new, operating, and licensed reactor designs), (2) focused on risk importance and safety significance, (3) providing quantitative and/or qualitative means for demonstrating reasonable assurance of safety, and (4) acknowledging the "Trust and Verify" Principle of Good Regulation. The DRG also provides clear division of responsibilities among internal NRC staff (licensing, safety, security, programmatic processes, construction oversight, and operations).

**Question No. 68**

It was mentioned, that NuScale has received exemption from pressurized containment leakage testing. The NuScale's metallic containment vessel is proposed be fabricated and certified as an ASME Code Class 1 leak-tight pressure vessel. The containment vessel remains certified as a leaktight as long as periodic Inservice inspections are conducted. In general, were there many justified exemptions, comparable to this one, in NuScale's Design Certification review?

<u>Answer</u>: NuScale submitted, and the NRC approved, 17 exemption requests, which are provided in the Design Certification Application, Part 7, "Exemptions," issued July 2020 (ML20224A521), with an introduction, justification for the request, regulatory basis, and conclusion. The staff recognized that the application of certain regulations to the NuScale small modular reactor design would not serve the underlying purpose of the rule from which exemption is being sought or would not be necessary to achieve the underlying purpose of the rule. The staff evaluated these exemptions as outlined in table 1.14 of the staff's final safety evaluation report, issued July 2020 (ML20204A986).

**Question No. 78**

The discussion on NuScale design focused solely on containment.

(1) Is containment the only feature introduced in NuScale design that is deemed as needed to be proved?
(2) Could USA provide more information on NRC's verification of other novel features that needed to be verified via test facilities like normal operation without pumps.

<u>Answer</u>: No, containment is not the only feature introduced in the NuScale design that needs to have its performance validated. For example, the NuScale safety analysis primarily used its proprietary NRELAP5 system thermal-hydraulic code to perform the transient and accident analyses. NuScale used a scaled test facility called NIST-1 to gather realistic test data to validate the NRELAP5 computer code predictive capabilities. NuScale "Design Certification (DC) Final Safety Evaluation Report," section 15.0.2, issued August 2020 (ML20023A318), summarizes the staff review of transient and accident analysis methodology and computer codes used for non-loss-of-coolant accident (non-LOCA), LOCA, and post-LOCA long-term cooling evaluations, and includes references to the detailed staff reviews documented in the associated topical report safety evaluations.

The NuScale DC application reactor design includes a first-of-a-kind emergency core cooling system (ECCS) valve system that initiates natural circulation cooling of the reactor core in the event of a plant transient. The NRC regulations in 10 CFR 50.43(e) require that an applicant demonstrate the safety features of a new reactor design that uses simplified, inherent, passive, or other innovative means to accomplish safety functions. The NRC staff evaluated the design demonstration testing conducted by NuScale to satisfy 10 CFR 50.43(e) for the

ECCS valve system by reviewing the ECCS valve system design, performing audits of the ECCS valve system design documentation, and observing testing of the prototype ECCS valve system by the valve manufacturer. (Please refer to the final safety evaluation report, section 3.9.6.4.6.1).

Additionally, the staff requires an initial test program to demonstrate the performance of systems and features that must function to maintain the plant in a safe condition in the event of malfunctions or accidents. For example, preoperational tests of the ECCS are included in the NuScale initial test program to verify that the as-constructed system functions as credited in the safety analysis. Design Certification Application (DCA) Part 2, Tier 2, table 14.2-47, describes a first-of-a-kind performance test of the integral ECCS for the first NuScale power module, and DCA Part 2, Tier 2, table 14.2-63, describes ECCS valve testing for all NuScale power modules. The staff considers these tests as essential to demonstrating initial operability at a component level and of the system as a whole.

The NuScale DCA and the staff's safety evaluation report can be found on the NRC's public website: https://www.nrc.gov/reactors/new-reactors/smr/licensing-activities/nuscale.html.

**Question No. 110**

Page 197 [of the U.S. national report] describes the defense-in-depth. It is desirable for safety that a higher level of independence between the stages of the defense-in-depth is ensured. Are there regulatory requirements to ensure independence between defense-in-depth stages in the U.S.?

Answer: Section 18.1 of the U.S. Ninth National Report (as opposed to page 197 of the report) explains in significant detail how the defense-in-depth philosophy is followed in regulatory practice, governing documents, and regulatory process for designing, constructing, and operating an NPP. It also discusses relevant experience and examples at the NRC. Section 18.1.4 of the U.S. Ninth National Report provides additional information with respect to how the NRC's strong commitment to the defense-in-depth philosophy manifested in some NRC experiences.

The regulatory requirements to ensure independence between defense-in-depth stages are integrated into various Commission documents. For example, the NRC's emphasis on the independence between the stages of defense in depth as it should apply to digital I&C is documented in section 18 of SRM-SECY-93-087 (ML003708056). Another example of the NRC's emphasis on the independence between the stages of defense in depth as it should apply in the fire protection program is explicitly stated in section II.A of Appendix R to 10 CFR 50, "Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979," to 10 CFR 50.48.

**Question No. 160**

In the summary sections 2.3.1.6, 2.3.3.2, the US national report mentions design vulnerabilities associated with open (loss of) phase conditions in offsite power systems at most operating nuclear plants in the US. This condition, if occurs, may adversely affect safety system performance. For plants that are susceptible to open phase conditions, the licensees have completed plant modifications (installing an open phase isolation system).
Would you please describe in more details the open phase isolation system? It could perhaps be considered and shared as a good practice.

Answer: Most licensees consider the full details of the open phase isolation systems and the modifications performed as proprietary information. However, the NRC's public website provides more history and links to public documents including the NRC staff response to the Nuclear Energy Institute's proposed open phase isolation system. The staff response

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| includes functional criteria for an open phase isolation system. The NRC's public website also references the branch technical position on open-phase conditions (https://www.nrc.gov/reactors/operating/ops-experience/open-phase-electric-systems.html).<br><br>In March 2023, the NRC issued a *Federal Register* Notice stating that the licensees have completed necessary actions to detect, isolate, or both any open phase conditions in the offsite power systems (notice is available at https://www.federalregister.gov/documents/2023/03/06/2023-04501/nrc-bulletin-2012-01-design-vulnerability-in-electric-power-system). The notice will provide references (ADAMS accession numbers) to the various closure letters issued to licensees concerning Bulletin 2012-01, "Design Vulnerability in Electric Power System," dated July 27, 2012 (ML12074A115). The closure letters will contain references to various inspection reports or various licensing actions taken by the NRC, which in turn will briefly describe actions and design modifications performed by various licensees. |
| **Question No. 169** |
| (1) What is the maximum distance from a NPP to the nearest (of the two) national response center?<br>(2) Within what timeframe can the equipment be delivered to the NPPs in case of an accident? |
| Answer:<br>(1) The maximum straight-line distance between an operating NPP and one of the two National Response Centers is approximately 1,200 miles (1,931 kilometers). Either center is capable of responding to any plant in the United States within the required timeframe.<br><br>(2) Equipment stored at the National Response Centers can be brought to any U.S. NPP within 24 hours via ground or air transportation. Before delivery of backup equipment from the National Response Centers, core and spent fuel cooling and containment integrity are maintained with installed plant equipment that is protected from natural hazards, as well as backup portable equipment stored on site. |
| **Question No. 176** |
| The NRC established and formed various groups and offices to work on licensing, inspection and regulatory questions concerning Vogtle Units 3 and 4. Could you give a rough estimation how many full time employed staff have worked on activities related to Vogtle Units 3 and 4 in the time period covered by this Report? |
| Answer: Since 2019, 45 full-time NRC employees worked directly on inspection, ITAAC, and licensing of Vogtle, Units 3 and 4. The breakdown includes 25 inspectors and 8 management and supporting staff in the regional office and 12 licensing and ITAAC staff at headquarters. Some of the early lessons learned from the project have highlighted the advantages of having dedicated organizations for the project.<br><br>The NRC also created a Vogtle Readiness Group (VRG) to identify and resolve any licensing, inspection, or regulatory challenges or gaps that could impact the schedule for completion of the Vogtle construction project. The VRG provides high-level assessments, coordination, oversight, and management direction of NRC activities associated with the licensing, inspection, testing, and operation of Vogtle, Units 3 and 4. The VRG has been an effective way to maintain awareness, focus, and support across the various NRC offices that support the NRC's safety mission. The charter for the VRG is available on the NRC's public website: https://www.nrc.gov/reactors/new-reactors/large-lwr/col-holder/vog/vogtle-readiness-group.html. |

## ARTICLE 19. OPERATION

**Each Contracting Party shall take appropriate steps to ensure that:**

**(i) the initial authorization to operate a nuclear installation is based upon an appropriate safety analysis and a commissioning program demonstrating that the installation, as constructed, is consistent with design and safety requirements**

**(ii) operational limits and conditions derived from the safety analysis, tests, and operational experience are defined and revised as necessary for identifying safe boundaries for operation**

**(iii) operation, maintenance, inspection, and testing of a nuclear installation are conducted in accordance with approved procedures**

**(iv) procedures are established for responding to anticipated operational occurrences and to accidents**

**(v) necessary engineering and technical support in all safety related fields is available throughout the lifetime of a nuclear installation**

**(vi) incidents significant to safety are reported in a timely manner by the holder of the relevant license to the regulatory body**

**(vii) programs to collect and analyze operating experience are established, the results obtained, and the conclusions drawn are acted upon and that existing mechanisms are used to share important experience with international bodies and with other operating organizations and regulatory bodies**

**(viii) the generation of radioactive waste resulting from the operation of a nuclear installation is kept to the minimum practicable for the process concerned, both in activity and in volume, and any necessary treatment and storage of spent fuel and waste directly related to the operation and on the same site as that of the nuclear installation take into consideration conditioning and disposal**

The NRC relies on regulations in 10 CFR and internally developed associated programs in granting the initial authorization to operate a commercial nuclear facility and in monitoring its safe operation throughout its service life. This section describes the most significant regulations and programs corresponding to each obligation of Article 19.

| **Question No. 16** |
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| It's stated that "To date, a majority of the operating commercial nuclear plants has converted their technical specifications to the improved standard technical specifications."<br><br>Question:<br>(1) Are the improved standard technical specifications applicable to all the operating commercial nuclear plants?<br>(2) If so, why are there still a few nuclear power plants that have not yet used the improved standard technical specification? |

Answer:

(1) Yes, the improved Standard Technical Specifications (STS) are applicable to all operating commercial nuclear plants.

(2) In its "Final Policy Statement on Technical Specification Improvements for Nuclear Power Reactors" published in the *Federal Register* on July 22, 1993 (58 FR 39132), the Commission encouraged NPP licensees to implement a voluntary program to update their technical specifications (TS) to be consistent with the improved STS. The policy statement also indicated that the Commission would entertain requests to adopt portions of the improved STS. Since adoption of the improved STS is voluntary, nuclear plant licensees who have not chosen to fully adopt the improved STS have done so based on their individual business considerations. However, licensees who have not adopted the entire improved STS have typically adopted portions of the STS. For instance, all licensees have adopted various portions of the Section 3.0, "Use and Application Rules."

**Question No. 111**

Section 19.2 (page 208) of the national report states that the extension of inspection cycles and time for out-of-service are determined based on risk information to ensure operational flexibility.

(1) Are there process and criteria for the NRC to make risk-informed decisions?

(2) Are there any other items on which the NRC makes risk-informed decisions, other than the extension of inspection cycles and timing of out-of-service for components?

Answer:

(1) The NRC has a strong regulatory framework for risk-informed decisions with a number of regulatory guides dedicated to risk-informed decisions. RG 1.174, Revision 3 (ML17317A256), is the main regulatory guide used for risk-informed changes to the licensing basis for operating reactors. This regulatory guide describes five key principles of regulatory decision-making which include, in addition to meeting the risk metrics, the need to be consistent with the defense-in-depth philosophy, maintain sufficient safety margins, and ensure appropriate performance monitoring. RG 1.177 (ML20164A034) is a similar guide, explicitly dedicated to risk-informed changes to the TS. Additionally, RG 1.200, Revision 3, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," issued December 2020 (ML20238B871), provides a set of requirements and independent review criteria for the PRA. It is the key regulatory guide that establishes the technical acceptability of the licensee's PRA used in risk-informed decision-making.

(2) The NRC has a longstanding commitment to increase the use of PRA in a manner that complements its deterministic approach and has continuously improved how it uses risk insights to make better informed decisions in meeting its important safety and security mission. The NRC uses risk-informed decisions in all aspects, including plant licensing, as well as inspection and oversight. Refer to sections 2.3.1.8, 2.3.1.10, 2.3.2.7, and 10.2 of the U.S. Ninth National Report for additional descriptions of recent risk-informed initiatives at the NRC. Recent examples include advances in risk-informed operational programs for operating reactors such as risk-informed categorization and treatment of SSCs under 10 CFR 50.69 (described in section 2.3.1.8 of the U.S. Ninth National Report) and risk-informed TS completion times (described in sections 2.3.1.8 and 2.3.2.7 of the U.S. Ninth National Report).

Another example is the Reactor Oversight Process (ROP), as described in Section 6.3.2 of the U.S. Ninth National Report. The ROP, described in NUREG-1649, Revision 6, "Reactor Oversight Process," issued July 2016 (ML16214A274), is the NRC's program to inspect, measure, and assess operating commercial NPP licensees' safety and security and to predictably respond to declining performance. The program provides an objective, risk-informed approach to NPP oversight. The ROP includes risk-informed thresholds to measure performance through performance indicators and to assess the significance of inspection findings. A risk-informed baseline inspection program establishes the minimum regulatory interaction for all licensees. The significance determination process, also part of the ROP, is a risk-informed approach used to evaluate the significance of inspection findings.

The NRC has been implementing the Be RiskSMART framework to apply risk insights more broadly in decision-making, enabling better focus on those items of greatest importance. For example, the NRC is applying Be RiskSMART to better risk-inform its response to emergent operating reactor events, licensing reviews, and oversight efforts. Refer to section 2.3.2.7 of the U.S. Ninth National Report for an overview.

Another example of risk-informed decision-making at the NRC is described in the internal procedure LIC-504, Revision 4, "Integrated Risk-Informed Decision-Making Process for Emergent Issues," effective June 2, 2014 (ML14035A143), which provides guidance to the staff on how risk information can be used to determine regulatory responses to emerging issues (discussed in section 10.2 of the U.S. Ninth National Report). The LIC-504 analysis process has two steps that can result in four different scenarios: (1) determining whether to take prompt regulatory action, such as issuing an order to shut down the unit(s) or take compensatory measures at the site where the concern is identified, (2) determining whether it is necessary to take prompt regulatory action for other operating NPPs (i.e., if a generic concern exists), such as issuing shutdown orders or ordering compensatory measures, (3) developing risk-informed options to resolve the issue at the unit or site where the concern is identified, and (4) developing risk-informed options to resolve the issue at other potentially affected units, as appropriate.

**Question No. 112**

Please share the following Information on the web site "Operating Experience Hub."
(1) Objectives of the system
(2) Operating organization and dedicated human resources
(3) Scope of accessible users

Answer:

(1) This system provides a single portal for users to access the services and dashboards created for operating experience. This is helpful for users who are unfamiliar with all the tools available for use. The operating experience group's goal is to systematically collect, communicate, and evaluate operating experience and apply the lessons learned.

(2) No specific resources are dedicated to the site. Different staff members across the Office of Nuclear Reactor Regulation maintain the various tools as part of their duties. The NRC's Office of the Chief Information Officer supports the information technology infrastructure. Any changes to the site are agreed on by the operating experience group.

(3) There is no sensitive information on the Operating Experience Hub, so all NRC users can generally access the dashboards there. In cases where access may need to be limited, the NRC controls the permissions of dashboards based on certain user groups or individual users.

| Question No. 123 |
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| How open is information in the Operating Experience Hub, who can access it, are there any restrictions in be presented there provided? |
| Answer: The site is available for all internal NRC staff. The data do not require any further restriction aside from internal use only. In cases where access may need to be limited, the agency is able to control the permissions of dashboards based on certain user groups or individual users. |
| **Question No. 124** |
| What measures are used at radwaste management facilities to reduce their generation? |
| Answer: The NRC promulgated its regulation on waste minimization in 10 CFR 20.1406. In this context, license, approval, and certification applicants are asked to minimize contamination and radioactive waste generation over the total life cycle of a facility, from initial facility layout and design through procedures for operation and concluding with final decontamination and dismantling at the time of decommissioning. RG 4.21 provides details about reducing waste generation and contamination during operation and decommissioning of licensed NRC facilities.<br><br>In addition, the NRC routinely conducts inspection and monitoring to minimize any releases to environmental media, particularly subsurface ground water. The NRC Inspection Procedure (IP) 71124, "Radiation Safety—Public and Occupational," effective January 1, 2010 (ML092190586), provides NRC IPs for power reactors. Several procedures, including IP 71124.01, "Radiological Hazard Assessment and Exposure Controls," IP 71124.06, "Radioactive Gaseous and Liquid Effluent Treatment," and IP 71124.07, "Radiological Environmental Monitoring Program," include inspection items related to minimizing contamination of radioactive material.<br><br>On May 1, 2012, the NRC issued a policy statement (ML15023A098) to emphasize the desirability of reducing waste volume to conserve disposal capacity and reduce overall disposal costs. NRC licensees, as a practical matter, take steps to reduce the volume of radioactive waste because of the cost of disposal at licensed commercial burial sites. Licensees use process control to help reduce the amount of waste generated. Common means of volume reduction are compaction and incineration. The NRC states requirements for treatment or disposal by incineration in 10 CFR 20.2004, "Treatment or disposal by incineration." Licensees may seek Commission approval for treatment or disposal of other licensed materials by incineration pursuant to 10 CFR 20.2002, "Method for obtaining approval of proposed disposal procedures." This provision in the NRC's regulations allows for other disposal methods, different from those already defined in the regulations, provided that doses are maintained ALARA and within the regulatory dose limits in 10 CFR Part 20. The NRC volume reduction policy can be found at https://www.federalregister.gov/documents/2012/05/01/2012-10433/low-level-radioactive-waste-management-and-volume-reduction. |
| **Question No. 125** |
| The section on spent nuclear fuel provides information on the consolidated interim storage facility in Lea County, NM. The fuel from which NPPs is planned to be stored there, are there any restrictions on fuel types that can be placed there? |
| Answer: As of January 2023, the application for the consolidated interim storage facility (CISF) in Lea County, New Mexico, is still under NRC review. If the CISF application is approved, it will allow for a commercial business decision (not a Federal Government requirement) to ship spent fuel to the facility, which could accept only the fuel/canister designs approved on the license. |

| **Question No. 126** |
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| How is the integrity of spent fuel monitored during its storage in on-site dry storage facilities, and is there a procedure and experience for the return fuel unloading into reactor spent fuel pools? |
| Answer: The NRC's regulations provide robust inspection and monitoring procedures for identifying conditions that could undermine safety. Depending on the cask design, the integrity of dry cask storage equipment is verified by inspection of the cask cooling system (e.g., sufficient number of cooling vents open) and radiological surveys. Additionally, the NRC's regulatory guidance assists licensees in meeting the requirements. The regulations at 10 CFR 72.44(c)(1)(3) require that a licensee provide the surveillance requirements for inspecting and monitoring stored waste and for maintaining the integrity of required systems and components of a storage facility in its TS. The regulations at 10 CFR 72.122, "Overall Requirements," item (h)(4) require that licensees be capable of monitoring spent fuel to identify concerns and take corrective actions as necessary to maintain safe storage conditions.<br><br>The NRC continues to evaluate aging management programs and to monitor dry cask storage in order to update its service-life assumptions and to identify and address circumstances that could require repackaging of spent fuel earlier than anticipated. If the repackaging of spent nuclear fuel becomes necessary, the regulations in 10 CFR 72.236, "Specific requirements for spent fuel storage cask approval and fabrication,***" item*** (h) require that spent fuel storage systems be compatible with wet or dry spent fuel loading and unloading facilities. If a storage canister needs to be opened, the licensee must keep radioactive material confined, maintain the fuel in an arrangement that does not cause a nuclear chain reaction, and shield the workers and the public from radiation. After a lengthy dry cask storage period, additional evaluation of the spent fuel storage pad and dry cask container integrity may be necessary |
| **Question No. 131** |
| It is mentioned in the report that the NRC issued a new regulation, 10 CFR 50.155, to require licensees to develop, implement, and maintain strategies and guidelines to mitigate beyond-design-basis external events. Please provide information on whether Technical Specifications (for example in the category of surveillance requirements, design features and / or administrative controls) have been required and developed also for the plant equipment (permanently installed, portable and mobile equipment) credited in the response to such events. |
| Answer: The NRC has not required new TS to be implemented for equipment relied on to meet 10 CFR 50.155. In 10 CFR 50.36, "Technical specifications," the NRC identifies the criteria for including items in TS. To date, no equipment relied on to meet the 10 CFR 50.155 regulation has been identified as requiring technical specifications in accordance with 10 CFR 50.36.<br><br>However, permanently installed systems for initial response to beyond-design-basis external events, such as those systems to maintain core cooling and containment integrity, have existing TS requirements because they are systems that are part of the primary success path to mitigate design-basis accidents, and as such, require TS per 10 CFR 50.36. These TS have not changed because of the 10 CFR 50.155 rulemaking. |
| **Question No. 145** |
| (1) Have NRC, INPO or licensees already taken into account the French feedback on stress corrosion discovered on safety injection circuits of pressurised water reactors (IRS number 9063)? If yes, how? |

| (2) Have specific inspections been carried out? |
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| Answer:<br>**NRC's Response**:<br>(1) The NRC coordinated with its counterparts at the French regulatory authority (ASN) to obtain relevant information and to understand the regulatory path forward. With that information, the NRC evaluated the information for applicability to the U.S. fleet, performed an initial safety assessment, and communicated its understanding to agency stakeholders, including the NRC Advisory Committee on Reactor Safeguards.<br><br>In addition, the NRC is closely following the industry response being led by the Electric Power Research Institute and the Pressurized-Water Reactor Owners' Group, which has developed a focus group to study the issue and recommend any industry action. This focus group is in the process of developing a safety and applicability assessment. The first will assess the potential safety impact of French operational experience on the U.S. industry by determining the likelihood and consequence of similar cracking in the U.S. fleet. The second will assess the applicability of the operational experience to the U.S. industry by considering the root cause provided by the French licensee and assessing whether those conditions are applicable or possible in U.S. reactors. Both of those reports will be complete before April 2023. Any further decision on industry actions will occur after those reports are finalized.<br><br>For the U.S. fleet, these welds are susceptible to thermal fatigue and are part of an augmented risk-informed inservice inspection program, in which inspections are done on a 10-year frequency. Even though these programs are focused on finding thermal fatigue cracks, the American Society of Mechanical Engineers Code, Section XI, Appendix VIII, program used in these inspections is capable of finding stress-corrosion cracking due to its performance demonstration qualification.<br><br>(2) In response to this operational experience, no additional inspections have been carried out in the U.S. fleet. However, as part of the industry effort described above, prior inspections have been revisited to determine if any indications were found and if those indications may be from stress-corrosion cracking. At this point in the effort, no stress-corrosion cracking has been identified in these welds in U.S. reactors.<br><br>**INPO's Response**:<br>(1) Yes, an industry focus group was established to track the operating experience, collaborate on information needs, and identify actions for the U.S. fleet.<br><br>Ongoing actions include the following:<br><br>• Evaluation of U.S. fleet inspection coverage and U.S. ultrasonic testing methods<br>• Evaluation of U.S. fleet affected materials (304 and 316 stainless steels), environment (chemistry for safety injection and residual heat removal), and stress states<br><br>(2) The industry focus group reviewed the inspection results for the most recent 10-year interval. This included the elbow welds for both large- and small-diameter safety injection piping, large residual heat removal piping, and pressurizer spray piping. There were no reportable indications. |
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| NRC FORM 335 (12-2010) NRCMD 3.7 — U.S. NUCLEAR REGULATORY COMMISSION<br>**BIBLIOGRAPHIC DATA SHEET**<br>*(See instructions on the reverse)* | 1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)<br>**NUREG-1650, Revision 8 Supplement 1** |
|---|---|
| 2. TITLE AND SUBTITLE<br>**Answers To Questions From The Peer Review By Contracting Parties On The United States Of America Ninth National Report For The Convention On Nuclear Safety** | 3. DATE REPORT PUBLISHED<br>MONTH: **February** YEAR: **2024**<br>4. FIN OR GRANT NUMBER |
| 5. AUTHOR(S)<br>U.S. Nuclear Regulatory Commission<br>Institute of Nuclear Power Operations (INPO) | 6. TYPE OF REPORT<br>Technical<br>7. PERIOD COVERED (Inclusive Dates)<br>Aug 2019–Aug 2022 |

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above", if contractor, provide NRC Division, Office or Region, U. S. Nuclear Regulatory Commission, and mailing address.)

Same as above

10. SUPPLEMENTARY NOTES

This report is an update to NUREG-1650, Revision 8, Supplement 1.

11. ABSTRACT (200 words or less)

The Convention on Nuclear Safety (CNS) was adopted in June 1994 and entered into force in October 1996. The objectives of the CNS are to achieve and maintain a high level of nuclear safety worldwide. Contracting parties to the Convention have four obligations: submit a national report for peer review, review the national reports of other contracting parties, respond to questions and comments submitted by the contracting parties, and participate in the organizational and review meetings. The United States published its ninth national report for peer review in August 2022 as NUREG-1650, Revision 8, “The United States of America National Report for the Convention on Nuclear Safety: Ninth National Report.” Supplement 1 to NUREG-1650, Revision 8, documents the answers to questions raised by contracting parties during their peer reviews of the United States’ ninth CNS national report. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations; legislative and regulatory framework; regulatory body; responsibility of the license holder; priority given to safety, financial, and human resources; human factors; quality assurance; assessment and verification of safety; radiation protection; emergency preparedness; siting; design and construction; operation; implementation of the lessons learned from the Fukushima accident; and the principles of the Vienna Declaration.

| 12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.) | 13. AVAILABILITY STATEMENT<br>unlimited<br>14. SECURITY CLASSIFICATION<br>*(This Page)* unclassified<br>*(This Report)* unclassified<br>15. NUMBER OF PAGES<br>16. PRICE |
|---|---|

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

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NUREG-1650
Revision 8
Supplement 1

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February 2024