U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

NUREG-1650, Revision 7
Supplement 1

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

Office of Nuclear Reactor Regulation

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

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ABSTRACT

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 eighth national report for peer review in October 2019 (NUREG-1650, Revision 7, “The United States of America Eighth National Report for the Convention on Nuclear Safety”). Supplement 1 to NUREG-1650, Revision 7, documents the answers to questions raised by contracting parties during their peer reviews of the U.S. eighth 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 licensee 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.

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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 eighth national report for peer review in October 2019, NUREG-1650, Revision 7, "The United States of America Eighth 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 7, documents the answers to questions raised by contracting parties during their peer reviews of the U.S. eighth national report.

Upon receipt of questions from contracting parties, the NRC staff categorized them according to the articles of the U.S. eighth national report that addressed the relevant material. There were no questions submitted on Part 3 of the report, which was developed by the Institute of Nuclear Power Operations, an organization that sets industry-wide performance objectives for nuclear power plant operations. Subsequently, for all other sections of the report, technical and regulatory experts at the NRC addressed questions and provided answers to the contracting parties via this report in preparation for the eighth review meeting of the CNS.

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ABBREVIATIONS AND ACRONYMS

ABWR	advanced boiling -water reactor
ac	alternating current
ACRS	Advisory Committee on Reactor Safeguards
ACMUI	Advisory Committee on the Medical Uses of Isotopes
ADAMS	Agencywide Documents Access and Management System (NRC)
ALARA	as low as reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
AP	advanced passive
APR	advanced power reactor
APR1400	Advanced Power Reactor 1400
ASME	American Society of Mechanical Engineers
ATWS	anticipated transient without scram
BDB	beyond design basis
BDBEE	beyond-design-basis external events
BWR	boiling -water reactor
CCA	cross-cutting area
CFR	*Code of Federal Regulations*
CNS	Convention on Nuclear Safety
CNSC	Canadian Nuclear Safety Commission
Co-Op	cooperative education program
CP	contracting party
DBA	design-basis accident
dc	direct current
DOE	U.S. Department of Energy
ECA	event and condition analysis
ECCS	emergency core cooling system
ELAP	extended loss of alternating current power
EOP	emergency operating procedure
EPA	U.S. Environmental Protection Agency
EU	European Union
FDA	U.S. Food and Drug Administration
FEMA	Federal Emergency Management Agency
FLEX	diverse and flexible coping strategies
FR	*Federal Register*
FTE	full-time equivalent
FY	fiscal year
GALL	generic aging lessons learned
GALL-SLR	generic aging lessons learned for subsequent license renewal
GDC	General Design Criteria
GE	General Electric

GL	generic letter
GSG	general safety guide
GSI	generic safety issue
GSR	General Safety Requirement (IAEA)
HFIS	Human Factors Information System
HOF	Human and Organizational Factors
IAB	inadvertent actuation block
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IDHEAS	integrated human event analysis system
IMC	Inspection Manual Chapter
IMS	Integrated Management System
INES	International Nuclear and Radiological Event Scale
INPO	Institute of Nuclear Power Operations
IP	inspection procedure
IRIS	Industry Reporting and Information System
IRRS	Integrated Regulatory Review Service
IRS	International Reporting System
ISFSI	independent spent fuel storage installation
ISG	interim staff guidance
ISO	International Organization for Standardization
JLD	Japan Lessons-Learned Project Directorate
LUHS	loss of normal access to the ultimate heat sink
LWR	light-water reactor
MRS	monitored retrievable storage
mSv	millisievert
MW	megawatt
MWe	megawatt electric
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NMSS	Office of Nuclear Material Safety and Safeguards
NPP	nuclear power plant
NQA	Nuclear Quality Assurance
NRC	U.S. Nuclear Regulatory Commission
NTTF	Near-Term Task Force
OIP	Office of International Programs
OSART	Operational Safety Assessment Review Team
PRA	probabilistic risk assessment
PSA	probabilistic safety assessment
PSDAR	post-shutdown decommissioning activities report
PSHA	probabilistic seismic hazard analysis
PSR	periodic safety review

PWR	pressurized -water reactor
REIRS	Radiation Exposure Information and Reporting System
RG	regulatory guide
RIDM	risk -informed decision-making
RI-ISI	Risk-Informed Inservice Inspection Service
RIS	regulatory issue summary
RMTS	risk-managed technical specifications
ROP	reactor oversight process
RPS	Reactor Program System
RS	review standard
SALTO	Safety Aspects of Long Term Operation
SAMA	severe accident mitigation alternatives
SAMG	severe accident management guideline
SAR	safety analysis report
SBO	station blackout
SEE-IN	Significant Event Evaluation and Information Network
SFP	spent fuel pool
SLR	subsequent license renewal
SMR	small modular reactor
SPRA	seismic probabilistic risk assessment
SRM	staff requirements memorandum
SRP	standard review plan
SSHAC	Senior Seismic Hazard Analysis Committee
SSC	structure, system, and component
SSG	Specific Safety Guide (IAEA)
SSR	Specific Safety Requirement (IAEA)
SWP	Strategic Workforce Planning
U.S.	United States
US-AWR	U.S. Advanced Water Reactor
U.S. APWR	U.S. Advanced Pressurized -Water Reactor
VTR	Versatile Test Reactor

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 7, "The United States of America Eighth National Report for the Convention on Nuclear Safety," issued October 2019 (hereinafter referred to as the "U.S. Eighth National Report"). 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 from all other sections of the report. 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 questions reflect the status as of February 2019, 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. Eighth 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, construction, and operation. To be consistent with the U.S. Eighth National Report, this report does not contain sections for Articles 1 through 5. In accordance with Article 1 of the CNS, the U.S. Eighth 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. Eighth 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, which may be contacted in any of the following ways:

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INTRODUCTION TO THE U.S. EIGHTH NATIONAL REPORT

This section of the U.S. 8th National Report for the CNS described the following:

- purpose and structure of the report
- summary of changes since the previous report was written in 2017
- 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.) 20
What is the design percentage of electricity produced SMR [small modular reactor] NuScale spent for in-house purposes?
Answer: Each power unit is rated at 50 megawatts electric (Mwe) gross electrical output for a total of 600 MWe gross electrical output for the 12 units. The nominal net output for all 12 units is 570 MWe. The difference (30 MWe) is for the house loads. Therefore, approximately 5 percent (30/600) is the percentage that is used for house loads with all 12 units.
Question No. 38
With respect to the tran[s]formative change area 4 [section 2.3.2.10 of the U.S. 8th National Report] “initiate a rulemaking to define high level performance-based instrumentation and control safety design principles and develop associated regulatory guidance that documents the acceptable standards that may be used to meet these principles”, Is this recommendation to initiate a rulemaking planned to be applicable to new and operating light-water reactors as well as non-light-water reactors?
Answer: In September 2019, the Commission approved the NRC staff request to withdraw SECY-18-0060, “Achieving Modern Risk-Informed Regulation,” dated May 23, 2018 (ADAMS Accession No. ML18110A187), which documented several transformative changes (such as that referenced in the question) to the NRC’s regulatory framework and approaches to better enable the safe and secure use of new technology, including advanced reactors and digital instrumentation and control. New information has superseded the basis for many of the transformative changes or recommendations in the paper and, as a result, the NRC staff has already begun certain aspects of the work described in the paper that can be pursued without seeking Commission approval. For example, the NRC staff recently completed a strategic assessment (ML19351D933), which includes a series of recommendations focused on regulatory infrastructure improvements for digital instrumentation and control that do not require rulemaking to implement. The implementation of these recommendations and other ongoing infrastructure activities will be instrumental in further increasing the efficiency and effectiveness of NRC staff’s licensing reviews of digital instrumentation and control applications for new and operating light-water reactors (LWRs) as well as non-LWRs.
Question No. 39
What actions has the U.S. NRC taken to continue to stre[n]gthen its ability to anticipate and respond to priorities based on external factors such as market forces and new technologies?
Answer: In October 2018, the NRC set in motion the Futures Assessment effort as a way to ensure that the NRC continues to effectively meet its mission in the future (i.e., 2030 and

beyond). The goal of the Futures Assessment effort is to understand the various ways the future of NRC's external environment could change, how the NRC and regulated industries could be affected, and steps the NRC could take to prepare for those changes. The Futures Assessment represents the combined input from a wide variety of stakeholders internal and external to the NRC. This input was used to develop four potential scenarios in which the NRC could operate in the future. For each of the scenarios, the assessment considers the associated challenges of aligning the NRC's resources and regulatory processes in a competitive energy market and nuclear industry in a timely fashion that does not stifle innovation. By preparing for the dynamic ways the future might unfold, the NRC can continue to evolve regulatory approaches that are practical in a dynamic nuclear future that will ensure reasonable assurance of public health and safety, promote common defense and security, and protect the environment. The findings of the Futures Assessment were documented in the report, "The Dynamic Futures for NRC Mission Areas," commonly referred to as "The Futures Report" (ML19022A178). Following the issuance of The Futures Report, the NRC staff decided the next step was to engage NRC employees and solicit feedback on how the NRC can best become a modern and risk-informed regulator. In June 2019, the entire NRC staff was invited to participate in a virtual discussion called "The Futures Jam." The information gathered from The Futures Report was used as a starting point to guide the discussion. Using real-time analytic tools, new topics were introduced to the discussion based on the flow of the conversation and identified themes. The Futures Jam had a high level of NRC staff participation from across the agency and constructive dialogue on how the NRC can become a modern and risk-informed regulator. Based on insights from The Futures Jam exercise and themes that emerged from it, NRC leadership established a framework for transforming the NRC that encompasses a broad set of activities intended to advance the agency toward the vision of being a modern and risk-informed regulator. Implementation of the transformation is organized within seven initiatives, one of which is Signposts and Markers. This initiative is developing a tool to enhance the staff's awareness of external factors pertinent to anticipating future agency workloads and adapting decision-making processes to incorporate these indicators.
Question No. 40
Good performance: It was noted that the U.S. NRC shared various lessons learned and experience regarding readiness of the regulatory body regarding transition from con[s]truction to operations.
<u>Answer</u>: Thank you for your comments and observations. We appreciate the positive feedback.
Question No. 41
Overall, good report that was both informative and well written. The report strikes a strong balance between information on existing reactor facilities, the regulatory body's readiness to regulate new technologies, experience in design certification reviews and lessons learned.
<u>Answer</u>: Thank you for your comments and observations. We appreciate the positive feedback.
Question No. 42
Well written and structured document. Safety and regulatory issues written in clear way with enough details to assess applicability for other plants of US and non-US origin. What could be useful to have been some kind of overview of operational events in Article 19. It would be

nice to see what is expected outcome of initiative to improve resilience of critical infrastructure in USA in case of NPPs [nuclear power plants], if any.
Answer: Thank you for your comments and observations. We appreciate the positive feedback. The NRC includes a summary of the most relevant safety and regulatory issues in section 2 of the U.S. CNS report. The NRC will evaluate if further information can be incorporated. For more information, the NRC public website (https://www.nrc.gov/reading-rm/doc-collections/event-status/) provides links to licensee event reports (https://lersearch.inl.gov/Entry.aspx) and reports of defects and noncompliance under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" (https://www.nrc.gov/reading-rm/doc-collections/event-status/part21/), that may have relevant operating experience information for the international community. The NRC also submits events regularly to the IAEA International Reporting System for its Operating Experience database.
Question No. 45
In the second paragraph of (i) [section 2.4.1.2 of the U.S. 8th National Report] some important examples of regulations that address BDB [beyond-design-basis] events include ATWS [anticipated transient without scram], SBO [station blackout] and loss of large areas of the plant due to fire or explosion. In (ii) [section 2.4.1.2 of the U.S. 8th National Report], it is mentioned that the NRC's regulatory requirements and guidance documents undergo systematic reviews and revisions, which are informed by international standards and guidance documents, including IAEA safety standards and recommendations. Can the USA please describe how NRC's regulatory documents and guidelines have been adapted (or are undergoing review) to take into account the release of IAEA's SSR-2/1 Rev. 1, in particular in the area of enhancing the plant's capability to withstand the conditions generated by accidents that are more severe than DBAs [design-basis accidents] by considering a more extensive set of Design Extension Conditions, both with and without core melting?
Answer: The manner in which IAEA safety standards are used to inform and guide NRC regulations and regulatory guidance varies among the NRC's technical programs. For example, the IAEA safety standards are used as reference documents to inform the development of requirements and guidance in the NRC's reactor, radiation protection, transportation, waste management, and emergency preparedness and response programs. Differences in the application of IAEA safety standards and NRC regulations largely stem from the fact that NRC regulatory infrastructure predates most IAEA safety standards. NRC requirements are also written with a greater level of detail than the IAEA safety standards. The event at Fukushima highlighted the possibility that extreme natural phenomena could challenge the prevention, mitigation, and emergency preparedness defense-in-depth layers. The NRC has strengthened U.S. nuclear power plants' resilience to beyond-design-basis events (e.g., design extension conditions) using a defense-in-depth philosophy with risk considerations, which meets the intent of the post-Fukushima principles of IAEA Specific Safety Requirement SSR-2/1, Revision 1. For example, to address the uncertainties associated with beyond-design-basis external events, the NRC issued Order EA-12-049, "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events" (the "Mitigating Strategies Order"), on March 12, 2012. This order required every U.S. commercial reactor operator to develop strategies for dealing with the long-term loss of standard safety systems. The order focused on improving plant flexibility and diversity in responding to

extreme natural phenomena, such as floods and earthquakes. The goal is to keep the reactor core cool, preserve the containment barrier that prevents or controls radiation releases, and cool the spent fuel pool for an indefinite period of time. These strategies also include, for certain plant containment types, backup power supplies for existing hydrogen mitigation systems to maintain containment functionality (i.e., pressurized-water reactor (PWR) ice condenser and boiling-water reactor (BWR) Mark III containments). At Fukushima, the lack of information on the condition of the spent fuel pools hindered decision-makers' ability to effectively prioritize emergency response actions. Therefore, the NRC also issued Order EA-12-051, "Order Modifying Licenses with Regard to Reliable Spent Fuel Pool Instrumentation" ("Spent Fuel Pool Instrumentation Order"), on March 12, 2012, which requires all U.S. nuclear power plants to install reliable water-level measurement instrumentation in their spent fuel pools to support prioritization of response activities in the event of an accident. The NRC also issued Order EA-13-109, "Order Modifying Licenses with Regard to Reliable Hardened Containment Vents Capable of Operation under Severe Accident Conditions" (ML13130A067), on June 6, 2013, which requires installation of reliable hardened wetwell vents that will assist in preventing core damage when containment heat-removal capability is lost and will also function in severe accident conditions (i.e., when core damage has occurred). In summary, the implementation of enhanced mitigation strategies and the installation of spent fuel pool instrumentation and severe-accident-capable containment venting systems are some examples of enhanced defense-in-depth protections for plants in the United States. The requirements of the Mitigating Strategies Order and the Spent Fuel Pool Instrumentation Order were later included in the NRC's regulations at 10 CFR 50.155, "Mitigation of beyond-design-basis events," which became effective in September 2019 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0155.html). The NRC also published corresponding guidance documents to support compliance with this rule. Further details about U.S. post-Fukushima activities and related documents can be found on the NRC's public website at https://www.nrc.gov/reactors/operating/ops-experience/post-fukushima-safety-enhancements.html.
Question No. 50
NRC may please elaborate on safety margin considerations for those NPPs that have already been granted 'power uprates'/'extended power uprates', when they come up for 'license renewal'/'subsequent license renewals'.
Answer: Section 14.1.3.1 of the U.S. 8th National Report describes the NRC power uprate licensing process, including the governing documents, regulatory process, recent experience, and relevant examples. In summary, because uprates affect a reactor's licensed power level, a licensee must seek NRC approval to amend its operating license to implement a power uprate. The process for requesting and approving a change to a plant's power level is governed by 10 CFR 50.90, "Amendment of license or construction permit at request of holder," through 10 CFR 50.92, "Issuance of amendment." The NRC reviews the power uprate license amendment request and documents its review in a safety evaluation. If the NRC finds the application acceptable, the NRC will issue a license amendment approving the power uprate, at which point the uprated condition becomes the current licensing basis for that nuclear power plant.

When the licensee of a nuclear power plant that has already been granted a power uprate seeks a renewed license, this is done under the License Renewal Rule in 10 CFR Part 54, “Requirements for renewal of operating licenses for nuclear power plants.” The License Renewal Rule establishes the technical and procedural requirements for renewing operating licenses and is based on two key principles:

(1) When continued into the extended period of operation, the regulatory process, which assesses and verifies safety, is adequate to ensure that the licensing basis of each currently operating plant provides an acceptable level of safety.

(2) Each plant must maintain its current licensing basis throughout the renewal term, with the addition of aging management activities.

In accordance with 10 CFR 54.21(a)(3), the licensee of a nuclear power plant that has already been granted a power uprate must demonstrate that the effects of aging on the components within the scope of license renewal will be adequately managed such that the intended functions will be maintained consistent with the current licensing basis (i.e., the power uprated condition) for the period of extended operation. Thus, during the review of any application for a renewed license, regardless of whether the plant has been granted a power uprate, the NRC does not consider additional safety margins beyond those that are already part of the licensee’s current licensing basis.

Question No. 51

The challenges encountered during ongoing subsequent license renewals appear to vary among stations, e.g., aging management of irradiated concrete structures is a challenge in Turkey Point, Units 3 and 4, whereas the same is not mentioned as challenge in other two plants. Aging management of steel components of the reactor pressure vessel is identified as challenge in Turkey Point, Units 3 and 4 and Surry, Units 1 and 2, whereas the same is not identified as challenge in Peach Bottom, Units 2 and 3.

Answer: This observation is correct in that the challenges encountered during the review of subsequent license renewal applications in the United States can vary from application to application. It is possible to encounter challenges during the review of the applications that are generically applicable; however, plant-specific challenges during the review can be the result of the plant’s unique characteristics and site design (e.g., the vintage of the nuclear power plant, the design of the system, material fabrication, etc.). In addition, plant-specific challenges can be the result of different approaches to aging management proposed by the licensee (e.g., inspection versus replacement of components, frequency of inspections, inspection technique, etc.). For the specific challenges identified, the neutron fluence levels for the reactor pressure vessel are generally lower for BWRs (e.g., Peach Bottom) and higher for PWRs (e.g., Turkey Point and Surry). Likewise, neutron fluence levels on concrete structures for the plants cited are dependent on the plant-specific design of the reactor vessel support structures.

After the issuance of the U.S. 8th National Report, the following updates of the current subsequent license renewal applications reviews have occurred:

(1) Turkey Point Nuclear Generating Units 3 and 4: The NRC issued the “Safety Evaluation Report Related to the Subsequent License Renewal of Turkey Point Generating Units 3 and 4” on July 22, 2019 (ML19191A057). The NRC issued the

subsequent renewed license for Turkey Point Units 3 and 4 on December 4, 2019 (see https://www.nrc.gov/reading-rm/doc-collections/news/2019/19-062.pdf).

(2) Peach Bottom Atomic Power Station, Units 2 and 3: The NRC issued the "Safety Evaluation Report Related to the Subsequent License Renewal of Peach Bottom Atomic Power Station, Units 2 and 3" on November 19, 2019 (ML19317E013).

(3) Surry Power Station, Units 1 and 2: The NRC issued the "Safety Evaluation Report Related to the Subsequent License Renewal of Surry Power Station, Units 1 and 2" on December 27, 2019 (ML19360A020).

Additional information about the status of the ongoing reviews of subsequent license renewal applications can be viewed at https://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-renewal.html.

Question No. 62

It is expected that all modifications that allow plant operators to identify compensatory actions needed to detect and isolate offsite power sources due to open phase conditions are to be completed by December 31, 2019. Could the USA please elaborate on the modifications identified?

Answer: In general, the proposed modifications consist of protection channels equipped with sensors, actuation relays, and tripping logic for providing automatic protection against an open phase condition. These modifications are generally installed in the vicinity of the power transformers that provide power to the station's vital busses.

The modifications will annunciate an alarm in the main control room and will have the capability to isolate the faulted power circuit. Furthermore, the modifications employ self-diagnostic features to alert the operators about the open phase isolation system failures. Specifically, the open phase isolation system modifications would generate a trouble alarm in the main control room to alert the operators that the system is not functional.

Question No. 63

Could NRC please 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 containment? Why not for other reactors, e.g. PWR's?

Answer: In SECY-11-0137, "Prioritization of Recommended Actions to Be Taken in Response to Fukushima Lessons Learned," dated October 3, 2011 (ML11272A203), the NRC staff described its proposals for immediate regulatory actions and longer-term evaluations to address the Near-Term Task Force recommendations. Among the highest-priority Tier 1 actions that the NRC staff proposed was the issuance of orders requiring reliable hardened containment vents for those licensees of BWRs with Mark I and II containment designs. Venting Mark I and II containments can help prevent the loss of and facilitate the recovery of important safety functions, such as reactor core cooling, reactor coolant inventory control, containment cooling, and containment pressure control. Further details of the NRC staff's assessment and basis for prioritization of a hardened wetwell vent for BWR Mark I and Mark II containment designs can be found in Enclosure 1, "Staff Assessment and Prioritization of Near-Term Task Force (NTTF) Recommendations," to SECY-11-0137. The NRC found that there was adequate basis to redefine the level of adequate protection of public health and safety for venting of BWR Mark I and Mark II primary containments.

The Near-Term Task Force recommended that the NRC staff evaluate the need for hardened vents for plants other than BWR Mark I or Mark II. This was prioritized as a Tier 3 item,

meaning that the evaluation could be completed later than the Tier 1 actions. The NRC completed its assessment of containment performance for other containment designs in March 2016, as described in Enclosure 1, “Closure of Tier 3 Recommendations 5.2 and 6,” to SECY-16-0041, “Closure of Fukushima Tier 3 Recommendations Related to Containment Vents, Hydrogen Control, and Enhanced Instrumentation,” issued March 31, 2016 (ML16049A079). The staff determined that there is adequate information to conclude that regulatory actions to impose further improvements to containment venting and hydrogen control are not warranted. The NRC based this finding on a conservative estimation of frequency-weighted risks to the public health and safety in comparison to the NRC’s established safety goals. The staff used insights from the evaluations and agency decisions for Mark I and Mark II containments and considered the performance of other containment designs in terms of plant response and the timing of possible failures during severe accidents. The containment responses were obtained from previous studies and more recent evaluations, such as the NUREG-1935, “State-of-the-Art Reactor Consequence Analysis Report,” and specific simulations performed for this assessment. The evaluations considered the benefits from previous regulatory actions for controlling hydrogen in Mark III and ice condenser containments and requiring mitigating strategies for beyond-design-basis external events. The NRC staff confirmed that significant margins exist between the NRC’s established safety goals and estimated plant risks that might be reduced by improvements in containment performance or hydrogen control. The staff’s conclusion that regulatory actions are not needed is supported by the evaluations of these event frequencies, plant responses, the timing of barrier failures, conditional release fractions, and the potential for plant changes to influence margins to the qualitative health objectives. NUREG-1935 is available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1935/index.html
Question No. 64
Could NRC please share some practical experiences with the new software application to generate inspection reports?
Answer: The automatic report generator function was added to RPS-Inspections in January 2019. This tool represents an important step forward in consistency, efficiency, and accountability and uses innovative methods to harness new technology to improve the antiquated way inspection reports for operating reactors have been generated by the NRC over the past 20 years or so. The automatic report generator function has allowed the NRC to (1) streamline the inspection report creation and the approval process (providing a significant resource savings for inspectors, supervisors, and administrative staff) and (2) bring additional consistency to NRC documentation of inspections. Almost all NRC operating reactor inspection reports can now be generated using the RPS-Inspections application, including all baseline (including Official Use Only – Security Related Information designated reports) and the Inspection Procedure (IP) 95001/95002, “Supplemental Inspection Reports” (ML083470431). Some of the more complex reports, such as IP 95003, “Supplemental and Reactive Inspections” (ML16050A095), are not generated using the application and are still created using the NRC’s previous methods as described in Inspection Manual Chapter (IMC) 0611, “Power Reactor Inspection Reports” (ML19317F647).
Question No. 65
The voluntary industry initiative [for open phase conditions] also addresses the installation of plant modifications (open phase isolation system) that allow plant operators to identify compensatory actions needed to detect and isolate offsite power sources due to open phase conditions. Can you describe some of those installed modifications?

Answer: In general, the proposed modifications consist of protection channels equipped with sensors, actuation relays, and tripping logic for providing automatic protection against an open phase condition. These modifications are generally installed in the vicinity of the power transformers that provide power to the station's vital busses. The modifications will annunciate an alarm in the main control room and will have the capability to isolate the faulted power circuit. Furthermore, the modifications employ self-diagnostic features to alert the operators about failures of the open phase isolation system. Specifically, the open phase isolation system modifications would generate a trouble alarm in the main control room to alert the operators that the system is not functional.
Question No. 66
Could the USA please elaborate on the background of the proposal to reduce the frequency of inspections described in SECY-18-0113?
Answer: The NRC determined that a reduction in inspection frequency would enhance program efficiency while not impacting the ability of the program to provide objective evidence that risk- or safety-significant structures, systems, and components remain capable of performing their intended safety functions consistent with their design and licensing bases. The basis for the reduced frequency is discussed in more detail in section III.3.b of the attachment to the May 24, 2018, memo titled "Proposed Transformational Changes to Nuclear Regulatory Commission Engineering Inspections" (ML18103A174).
Question No. 67
The NRC requires that power reactor license holders maintain SFP [spent fuel pool] subcriticality in accordance with 10 CFR 50.68, "Criticality Accident Requirements," General Design Criterion 62, "Prevention of Criticality in Fuel Storage and Handling," in Appendix A to 10 CFR Part 50; and other equivalent regulatory criteria. Could you describe what are other equivalent regulatory criteria?
Answer: Some plants were originally licensed under draft General Design Criteria (GDCs) from the Atomic Energy Commission. The current set of GDCs was eventually published as a regulatory requirement in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities." However, even the plants licensed before Appendix A would have been licensed with criteria essentially equivalent to GDC 62 in the area of spent fuel pool criticality. In addition, before the spent fuel pool criticality requirements in 10 CFR 50.68 went into effect in 1998, the applicable requirements for storage of large quantities of special nuclear material were captured in 10 CFR 70.24, "Criticality accident requirements." The regulation at 10 CFR 70.24 states that licensees authorized to possess and store special nuclear material in appreciable quantities are required to have a monitoring system capable of detecting inadvertent criticality. Licensees were able to obtain an exemption to this regulation based on low-density storage configurations of spent fuel in the spent fuel pool, which could be demonstrated to contain large margins to criticality. Some licensees may continue to be licensed under such exemptions. However, as the inventory of the spent fuel pool has increased over time, most licensees have updated their licenses to use high-density storage rack configurations. Compliance with the subcriticality provisions of 10 CFR 50.68 provides an alternative to the criticality monitoring system and emergency planning requirements of 10 CFR 70.24.
Question No. 71
Did NRC report on the [degradation of] baffle-former bolts findings in any of the nuclear events and incidents databases like IRS? These findings may be extremely useful to other PWR operators especially Westinghouse type.

Answer: Yes, the NRC reported the incidents that occurred in 2016 related to degradation of reactor baffle-former bolts to the IAEA International Reporting System (IRS) for Operating Experience database. (See IRS Number 8598, “Degradation of Reactor Baffle-Former Bolts.”)

Since the issuance of the U.S. 8th National Report, the NRC has completed the following activities:

(1) On August 6, 2019, the NRC published an inspection report containing additional information, “Salem Nuclear Generating Station, Units 1 and 2—Integrated Inspection Report 05000272/2019002 and 05000311/2019002 and Exercise of Enforcement Discretion” (ML19218A279).

(2) On September 18, 2019, the NRC met with Westinghouse (the meeting notice is available at ADAMS Accession No. ML19226A002) to discuss their analytical methodology for predictive evaluations of baffle-former bolt degradation and the status of the ongoing root cause analysis of the spring 2019 event at Salem Unit 1. This meeting was not open to the public due to the proprietary nature of the information shared by Westinghouse. The root cause of this event is still being investigated, as addressed in the public version of the Westinghouse presentation (ML19242B346).

The NRC will continue to monitor this situation and evaluate whether any changes are necessary to the guidance related to baffle-former bolt examination, based on this operating experience.

Question No. 79

In his report, the President of the 7th [CNS] review meeting had recommended that Contracting Parties consider the implementation of the good practices that where identified during the meeting. Could your country provide information on the actions carried out with regards to the implementation of those good practices in your country ?

Answer: The President of the 7th CNS Review Meeting recommended that the Contracting Parties consider the implementation of the four good practices that were identified during the meeting. The NRC has reviewed the good practices as follows:

(1) (Awarded to Euratom) The first topical peer review was launched in a proactive manner, even before date for transposition of the nuclear safety directive by European Union (EU) Member States.

The United States is not part of the EU; thus, it did not take part of the topical peer review process. However, the NRC conducted a gap analysis by evaluating the topical review report and its generic findings. All non-EU members participating in the Nuclear Energy Agency Committee on Nuclear Regulatory Activities developed a similar gap analysis and exchanged feedback at the June 2019 Committee meeting. The NRC assessment found that the United States is generally well aligned with the results of the topical peer review. The NRC determined that no changes in its regulatory practices are necessary. The NRC found one gap or area not addressed by the topical peer review: The peer review did not address time-limited aging analyses, which are considered of safety importance within the U.S. regulatory process.

(2) (Awarded to Euratom) The implementation of the Instrument for Nuclear Safety Co-operation Program for assisting non-EU countries.

As part of the program, the EU assists non-European countries with evolving needs. Similarly, the NRC has an international assistance program, which originated in the 1990s, that provides technical information and training to help countries develop or expand their national nuclear and radiation safety regulatory infrastructure and programs. These activities are viewed by the Commission, the larger U.S. Government, and the international community as an invaluable tool for establishing multilateral coalitions, enhancing global nuclear safety and security, and strengthening regulatory programs for nuclear power plants, research reactors, and radioactive materials. Additional information can be found in section 8.1.5 of the U.S. 8th National Report and the NRC public website at https://www.nrc.gov/about-nrc/ip/intl-assistance.html.

(3) (Awarded to Canada) The Canada Nuclear Safety Commission (CNSC) fosters openness and transparency in its regulatory process, for which it has, in particular, launched a participant funding program that gives the public, aboriginal groups, and other stakeholders the opportunity to request funding from the CNSC to participate in its regulatory process. The participants present their results directly to Commission members. Participant funds are awarded by a Board independent of the licensing and technical support branch of the regulator. The participant funding contributes to increasing safety by providing additional information to the Commission.

The NRC believes that nuclear regulation should be conducted as openly as possible. Ensuring appropriate openness explicitly recognizes the public must be informed about, and have a reasonable opportunity to participate meaningfully in, the NRC's regulatory processes. The NRC has a robust and mature public participation program. Additional information about the NRC's public participation programs and openness/transparency efforts can be found in sections 6.3.11 and 8.1.7 of the U.S. 8th National Report.

(4) (Awarded to Hungary) Extensive outreach to members of the public and to neighboring and other countries, and conduct of public hearings regarding licensing of nuclear facilities, as well as educational conferences. The extent of the outreach was well beyond that generally undertaken by other Contracting Parties. The thorough preparation for these outreach activities strengthened the licensing review.

The NRC believes that nuclear regulation should be conducted as openly as possible. Ensuring appropriate openness explicitly recognizes the public must be informed about, and have a reasonable opportunity to participate meaningfully in, the NRC's regulatory processes. The NRC uses similar practices and policies as those of our colleagues in Hungary. Additional information about the NRC's public participation programs and openness/transparency efforts can be found in sections 6.3.11 and 8.1.7 of the U.S. 8th National Report.

Question No. 87

Concerning the expected aging management needs for the 60 to 80 year operating period, does the USA intend to implement an obsolescence management program?

Answer: Managing the aging of nuclear power plants implies ensuring the availability of required safety functions throughout the life cycle of the plant, including the changes that occur over time and expected wear and tear. This requires addressing both physical aging of systems, structures, and components (SSCs), which results in degradation of their performance characteristics, and nonphysical aging of SSCs (i.e., the obsolescence of

SSCs). Obsolescence can take various forms, including technological obsolescence (lack of spare parts, technical support, suppliers, and industrial capabilities) and conceptual obsolescence (obsolescence of knowledge and compliance with current regulations, codes, and standards).

The “Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report,” Volume 1 (ML16274A389) and Volume 2 (ML16274A399), focuses on the management of physical aging for plant operation from 60 to 80 years.

The NRC has operability requirements to ensure that plants operate safely. The inability of a plant to meet those requirements due to the lack of spare parts or equipment would necessitate either some form of compensatory measures, which would be subject to NRC review, or plant shutdown. Most, if not, all plants in the United States have obsolescence management programs to prevent such occurrences.

Question No. 89

US report (Section 2.3.3.4) says that “Also in response to the request for information, all licensees completed assessments of their staffing and communication capabilities to effectively respond to multiunit and large scale emergencies.” Please elaborate what US licensee's measures to respond to multiunit and large scale emergencies are.

Answer: The NRC’s defense-in-depth strategy includes multiple layers of protection:
(1) prevention of accidents by virtue of the design, construction, and operation of a plant,
(2) mitigation features to prevent radioactive releases should an accident occur, and
(3) emergency preparedness programs.

Thus, if prevention and mitigation are not successful in averting the release of radioactive materials from the plant, emergency preparedness provides additional defense in depth to protect public health and safety. The accident at Fukushima reinforced the need for effective emergency preparedness, the objective of which is to ensure the ability to use adequate measures to mitigate the consequences of a radiological emergency. The accident at Fukushima also highlighted the need to determine the number and qualifications of staff required to fill all the positions necessary to respond to a multiunit event. Finally, the accident at Fukushima illustrated a need to ensure that a plant can power the communication equipment relied upon to coordinate the event response during a prolonged station blackout. In response to the NRC’s 10 CFR 50.54(f), “Conditions of license,” request for information letter (“10 CFR 50.54(f) letter”), the Nuclear Energy Institute (NEI) developed guidance document NEI 12-01, “Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities,” Rev. 0 (ML12125A412), to assist licensees in conducting assessments of their staffing levels and communications capabilities for responding to multiunit and large-scale emergencies. The NRC staff reviewed NEI 12-01 and found this guidance to be an acceptable method for licensees to employ when responding to the 10 CFR 50.54(f) letters.

The 10 CFR 50.54(f) letter asked licensees to assess their means to power the equipment needed to communicate on site and off site during a prolonged station blackout event and to identify and implement enhancements to ensure that communications can be maintained during such an event. The letter also asked licensees to assess the staffing required to fill all necessary positions to respond to an extended loss of all alternating current (ac) power that affects all units at the site.

Licensees reviewed the site communications systems and made necessary enhancements to ensure they maintain the capability to perform critical communications, both on site and off site, during and following an event that results in an extended loss of ac power. Examples of these enhancements include purchasing additional portable communications systems (such as satellite phones, portable radio towers, etc.), portable battery chargers, and portable power generators to provide additional backup power for installed communications systems.

Licensees also verified that the minimum onsite staffing is capable of providing an initial response to a beyond-design-basis external event affecting all units at the site until augmented staff arrive to provide additional support. Licensees conducted detailed assessments of the number and composition of the response staff and made necessary enhancements to confirm that they will be able to carry out existing station blackout coping strategies and implement the mitigation strategies required by NRC Order EA-12-049 (ML12054A735) (and subsequently 10 CFR 50.155, "Mitigation of beyond-design-basis events") for prolonged station blackout events affecting all units at each site.

Improvement plans are site specific based on each licensee's review results. The NRC staff reviewed all licensees' staffing and communications assessment reports and found that all had appropriately followed the NEI 12-01 assessment criteria and guidelines. NRC inspectors performed onsite inspections of the identified enhancements.

Question No. 91

US report says in the Section 2.3.2.3 "The staff continues to work on a project to improve the process for screening inspection findings of minor safety or security significance (green findings), which make up most of the issues the NRC finds during inspections." Please elaborate what is "the improvement for screening inspection findings of minor safety or security significance" as specific as possible.

Answer: The NRC has revised IMC 0612, "Issue Screening" (ML19214A243), IMC 0612, appendix B, "Additional Issue Screening Guidance" (ML19247C384), and IMC 0612, appendix E, "Examples of Minor Issues" (ML19247C385), to improve the issue screening guidance. The staff is aware that significant resources are sometimes spent determining whether an issue is minor or more than minor. Because these issues are most often of minor or very low safety significance, they do not warrant significant effort, and the determination should be made quickly and efficiently. A working group was created to address this issue and to work on the guidance improvements. The updated guidance will help inspectors consistently apply the intended threshold to identify if an issue is minor or more than minor.

The guidance improvements include the following:

(1) new clarification guidance for each of the issue screening questions
(2) new and improved examples with consistent format and thresholds
(3) new guidance for very-low-safety-significance issue resolution—this is a new process that will be used to discontinue evaluation of an issue involving a licensing-basis question in which the issue cannot be resolved without (1) a significant level of effort and (2) an expenditure of resources the agency has chosen not to use because the issue is expected to be of very low safety significance if found to be valid

More information on the guidance changes can be found in the documents referenced in this answer.

Question No. 92

What is the installation of plant modifications (open phase isolation system) like?
Please explain the specific design and/or procedure of the said system?

Answer: In general, the proposed modifications consist of protection channels equipped with sensors, actuation relays, and tripping logic for providing automatic protection against an open phase condition. These modifications are generally installed in the vicinity of the power transformers that provide power to the station's vital busses. The modifications will annunciate an alarm in the main control room and will have the capability to isolate the faulted power circuit. Furthermore, the modifications employ self-diagnostic features to alert the operators about the open phase isolation system failures. Specifically, the open phase isolation system modifications would generate a trouble alarm in the main control room to alert the operators that the system is not functional. Upon detection of an open phase condition, alarms provided in the main control room will alert the operator to a loss-of-phase condition so the corresponding operator actions in response to such an event are taken in a timely manner. Furthermore, the open phase isolation system procedures require plant operators to troubleshoot a failure of the system.
Question No. 105
What are the criteria and technical requirements set forth in the current regulatory framework of NRC to make decisions on extension of the service life of a NPP power unit up to 20 years beyond the design life of 40 years?
Answer: The NRC acceptance criteria or standard for issuance of a renewed license for operation from 40 years to 60 years are in 10 CFR 54.29, "Standards for issuance of a renewed license." The acceptance criteria require a finding that (1) the effects of aging on the functionality of structures and components (that are in scope of license renewal and are passive and long lived) will be managed and (2) time-limited aging analyses have met requirements, such that there is reasonable assurance that plant operation will continue to be conducted in accordance with the plant's current licensing basis. For the initial license renewal, which is for plant operation from 40 to 60 years, the NRC established two fundamental safety principles during the development of 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants." First, with the exception of the detrimental effects of aging, the existing regulatory process is adequate for safe plant operations. This process includes the continued implementation of licensing and oversight activities by the NRC and ensures potential safety, security, and emergency preparedness issues are addressed when identified. Second, each plant's current licensing basis must be maintained during the renewal term. NUREG-1801, "Generic Aging Lessons Learned (GALL) Report," contains the staff's generic evaluation of existing plant programs and documents the technical basis for determining where existing programs are adequate without modification and where existing programs should be augmented for the extended period of operation from 40 to 60 years. Revision 0 of the GALL Report issued July 2001 (ML012060392, ML012060514, ML012060539, and ML012060521); Revision 1, issued September 2005 (ML052110005 and ML052110006); and Revision 2, issued December 2010 (ML103490041). All revision of NUREG-1801 are available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1801/. NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants," gives guidance to the NRC staff to review license renewal applications for the period of extended operations from 40 to 60 years. Revision 0, issued July 2001 (ML012070391 and ML012070409); Revision 1, issued September 2005 (ML052110007); and Revision 2, issued December 2010 (ML103490036). All revisions to

NUREG-1800 are available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1800/. The NRC has defined subsequent license renewal to be the period of extended operation from 60 years to 80 years. As part of the NRC procedures to determine what is needed for subsequent license renewal, the NRC reexamined the policies and principles for license renewal and determined that they remain valid and acceptable for subsequent license renewal. Therefore, the NRC acceptance criteria or standard for issuance of a renewed license for operation from 60 to 80 years is also provided in 10 CFR 54.29, which are the same as those used for license renewal from 40 to 60 years. In its review of subsequent license renewal applications, the NRC staff developed guidance documents to address the unique aging management needs for a subsequent license renewal. In July 2017, the NRC published NUREG-2191, Volumes 1 and 2, “Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report” (ML17187A031 and ML17187A204), and NUREG-2192, “Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants” (ML17188A158). These documents are also available at https://www.nrc.gov/reactors/operating/licensing/renewal/slr/guidance.html. Additional information on subsequent license renewal is available on the NRC website at http://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-renewal.html.
Question No. 107
When reading the information concerning the “subsequent license renewal” (i.e. renewal beyond 60 years) the scope of the safety evaluations to be performed for such subsequent license renewal is not very clear. For instance in § 2.3.2.9 four “technical issues related to subsequent license renewal” are mentioned. Are these the only technical issues to be dealt with in view of subsequent license renewal? Is (for instance) improvement of severe accident management (including severe accident mitigation) not one of the issues to be considered? Hence: can the scope of the safety evaluations to be performed in support of a request for subsequent license renewal be further clarified? § 2.3.3.1 mentions that “The standards for subsequent license renewal are identical to those for initial license renewal, ...”: does that mean that there is in the scope of subsequent license renewal no objective to further improve the safety level of the installation (like improvement of severe accident management)?
Answer: The NRC acceptance criteria for issuing a renewed license require a finding that the effects of aging will be managed such that there is reasonable assurance that plant operation will continue to be conducted in accordance with the plant’s current licensing basis. This process also considers the continued implementation of licensing and oversight activities by the NRC and ensures potential safety, security, and emergency preparedness issues are addressed when identified. The four technical issues identified in section 2.3.2.9 of the U.S. 8th National Report represent issues that did not, at that time, have generic resolutions but required a plant-specific resolution. Subsequent license renewal applicants must identify and propose aging management approaches to address all aging technical issues identified for the plant, in a manner analogous to that for license renewal.

As part of the initial license renewal application review (40–60 years), licensees include in the environmental report an assessment of severe accident mitigation alternatives (SAMAs). During the review of initial license renewal applications, the NRC staff performs a site-specific analysis of the SAMAs and documents its findings in a supplement to NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants." This document is available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1437/r1/index.html For the review of subsequent license renewal applications, because the staff has previously considered SAMAs, the licensee is not required to perform another SAMA analysis as part of its subsequent license renewal application in accordance with 10 CFR 51.53(c)(3)(ii)(L). However, the NRC's regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," which implement Section 102(2) of the National Environmental Policy Act of 1969, as amended, require that all applicants for license renewal submit an environmental report to the NRC and in that report identify any "new and significant information regarding the environmental impacts of license renewal of which the applicant is aware" (10 CFR 51.53(c)(3)(iv)). This includes new and significant information that could affect the environmental impacts related to postulated severe accidents or that could affect the results of a previous SAMA assessment. Accordingly, in its subsequent license renewal application environmental report, the licensee evaluates areas of new and potentially significant information that could affect the environmental impact of postulated severe accidents during the subsequent license renewal period. Additional insights on life extension can be found in the response to Question No. 105 in this report.
Question No. 109
At what stage and what changes are introduced in the regulation, operating documentation and documentation of safe operation justification of the power unit when it is finally shut down (preparation for operation without generation)?
<u>Answer</u>: NRC regulations require that all license requirements remain in effect until specific approval is provided to reduce requirements in the license, technical specifications, and program requirements. Hence, the power reactor remains within the required safety license during operations and then when during the transition to decommissioning and when in defueled decommissioning status. Changes can be made to the operating license to remove requirements no longer applicable in shutdown and defueled condition (e.g., criticality or component maintenance). Other obsoleted regulatory requirements may be removed if the licensee receives NRC approval of an exemption from the requirements (e.g., offsite emergency response, fitness for duty, or indemnification).
Question No. 111
How the equipment reliability database for probabilistic risk assessment of NPP beyond 60 years considering significant life exhaustion of this equipment is formed?
<u>Answer</u>: The NRC has defined subsequent license renewal as the period of extended operation from 60 years to 80 years. As part of the NRC procedures to determine what is needed for subsequent license renewal, the NRC reexamined the policies and principles for license renewal and determined they remain valid and acceptable for subsequent license renewal. Therefore, the NRC acceptance criteria or standards for issuance of a renewed license for operation for 60 to 80 years are also provided in 10 CFR 54.29, which are the

same as those used for license renewal from 40 to 60 years. As part of the license renewal process in the United States, which is governed by 10 CFR Part 54, the licensee is not required to update its equipment reliability database for probabilistic risk assessment for operation beyond 60 years when considering significant life exhaustion of plant equipment. Through the application of probabilistic risk assessment, the industry continuously analyzes the risk profile of the station, by considering a tremendous amount of available plant and industry data (e.g., plant configuration, available equipment, and outside influences such as weather conditions). These data reflect the ongoing operating experience practices, in which various raw data are collected and processed through Institute of Nuclear Power Operations (INPO) data analysis tools. The NRC can later assess this data for future analysis. In general, when the NRC reviews and approves risk-informed programs, the licensees must meet certain data quality requirements and the plant-specific probabilistic risk assessment models must be maintained and updated to reflect the actual plant configuration and equipment availability. Equipment failure rates and initiating event frequencies are included in these updates.
Question No. 112
(1) Could you elaborate on the research reactor VTR? (2) What are its major tasks? (3) Does of construction mean the beginning of full-scale work on commercial fast neutron reactors?
Answer: (1 and 2) The Versatile Test Reactor (VTR) is a project of the U.S. Department of Energy. Information on the design and mission of the VTR can be found at https://www.energy.gov/ne/nuclear-reactor-technologies/versatile-test-reactor. (3) The Unites States Government enacted the Nuclear Energy Innovation and Capabilities Act (Public Law No: 115-248) and the Nuclear Energy Innovation and Modernization Act (Public Law No: 115-439) to provide, among other things, the scientific and regulatory infrastructure for commercialization of advanced reactor technologies. Section 2.3.3.6 of the U.S. 8th National Report discusses the NRC's preparations to review and regulate a new generation of non-LWRs. Ultimately, the decision to request licensing of commercial advanced reactors in the United States lies with the private nuclear industry.
Question No. 113
What are the new aspects which are in focus in control and supervision of safety of the new reactor AP-1000 considering the features of safety philosophy of this reactor: high significance of the containment for a number of functions at different level of the defense-in-depth, check of performance of the passive safety systems etc.?
Answer: The NRC has not reviewed anything new that would affect the safety philosophy since approving the AP1000 design certification amendment application in 2012. However, in general, the passive nature of the design is one of the major differences from the current operating fleet of reactors. The passive design requires no operator action in response to accidents for 72 hours, and minimal active equipment is required to maintain the plant in a safe condition. According to Westinghouse (http://www.westinghousenuclear.com/new-plants/ap1000-pwr), simplification was a major design objective for the AP1000 plant. The simplified plant design includes overall safety systems, normal operating systems, the control room, construction

techniques, and instrumentation and control systems. The AP1000 plant design features include the following: • fewer safety-related valves • less safety-related piping • fewer control cables • fewer pumps • less seismic building volume	
Question No. 115	
What differences are planned in the staff schedule composition of shifts of SMR NuScale personnel as compared to NPPs with series power units?	
Answer: NuScale will have six control room operators for all 12 modules when all units are in operation. There will be three senior reactor operators and three reactor operators. How they divide the units among the six operators and what shift hours they will work has not been finalized by NuScale. A separate crew with a senior reactor operator will oversee refueling activities. Additional details about NuScale's control room staffing plans can be found in chapter 18 (ML19241A427) of the design certification application.	
Question No. 117	
What were the difficulties in licensing SMR NuScale?	
Answer: The following four examples discuss novel elements that required special evaluation to ensure safety was demonstrated: (1) The NuScale plant is designed as a fully passive plant using natural circulation during normal and post accident emergency core cooling system (ECCS) operations. NuScale safety-related systems rely on natural passive mechanisms based on fundamental physical and thermodynamic principles without the need for electrical power or pumps. There are no reactor coolant pumps for normal operation, and there are no pumps for post accident ECCS operations. Neither operator action nor electric power is required for the ECCS to be initiated and maintained. The NRC conducted extensive calculations and analyses to verify that the plant could function safely using natural circulation during both normal and post accident operations. Staff verification allowed approval of the NuScale plant, which does not need or have any Class 1E safety-related power. (2) All 12 reactors (modules) are operated from one control room with six licensed operators. To approve this departure from current regulations, the NRC conducted an extensive human factor engineering review to ensure that all 12 reactors could be operated safely by six licensed operators. Existing NRC regulations, which were developed for large LWRs, require a higher number of licensed operators per unit. (3) The ECCS system is fully passive and consists of three independent reactor vent valves and two independent reactor recirculation valves. A key subcomponent of each of the five ECCS valves is an inadvertent actuation block (IAB) valve. The IAB valve is a first-of-a-kind, safety-significant, active component integral to the NuScale ECCS. Extensive analyses had to be conducted to verify that the IAB would block inadvertent actuation of the associated ECCS valve on loss of electric power, for example, but not block ECCS actuation when needed based on reactor coolant pressure.	

(4)	NuScale does not have a typical containment building compared to existing LWR containment structures. It is a relatively small-volume steel cylinder with an upper and lower head. Conducting a containment integrated leakage rate test as specified in current regulations to measure leakage is not feasible for the NuScale containment. Consequently, the NuScale containment, which is submerged in the reactor building pool, is designed, built, and periodically inspected as a code vessel. It is initially tested for leak tightness at the factory.

Question No. 118

It is stated that to consider applicability of reviewed requirements for upcoming decommissioning of installation the Commission tasked the personnel to develop the proposed the decommissioning rule to solve such issues as … the graded approach to emergency preparedness.

Could you provide additional information on establishment of the graded approach for the transitional period and decommissioning?

<u>Answer</u>: The NRC is proposing to amend its regulations to provide an efficient regulatory framework during decommissioning using a graded approach for certain technical areas. This graded approach is commensurate with the reductions in radiological risk at four levels of decommissioning: (1) permanent cessation of operations and removal of all fuel from the reactor vessel, (2) sufficient decay of fuel in the spent fuel pool such that it would not reach ignition temperature within 10 hours under adiabatic heatup conditions, (3) transfer of all spent fuel to dry storage, and (4) removal of all fuel from the site. These levels are discussed further as follows.

Level 1—Level 1 commences after the NRC's docketing of the licensee's certifications of permanent cessation of operations and permanent removal of the fuel from the reactor vessel under 10 CFR 50.82, "Termination of license," or 10 CFR 52.110, "Termination of license." In this level, a decommissioning reactor is defueled and permanently shut down, but the spent fuel in the spent fuel pool is still susceptible to a zirconium fuel cladding fire within 10 hours under adiabatic heatup conditions if the spent fuel pool is unexpectedly drained. This configuration encompasses the period from immediately after the core is removed from the reactor to just before the decay heat of the hottest assemblies is low enough that no rapid zirconium oxidation would take place within 10 hours. The NRC anticipates licensees will remain in Level 1 for a period of at least 10 months for a BWR or 16 months for a PWR.

During this time period, an appropriate level of emergency preparedness is maintained to respond to applicable design-basis accidents and to ensure a prompt response to the low-likelihood possibility that a rapid drain down of the spent fuel pool could cause a subsequent zirconium fire and release in less than 10 hours.

Level 2—In Level 2, the reactor is defueled and permanently shut down, and spent fuel in the spent fuel pool has decayed and cooled sufficiently that it cannot heat up to clad ignition temperature within 10 hours under adiabatic conditions. In this configuration, the spent fuel can be stored long term in the spent fuel pool. The NRC anticipates that spent fuel in this decommissioning level will be stored in the pool for at least 5 years after the spent fuel is moved from the reactor vessel to the spent fuel pool. In addition, the site may possess a radioactive inventory of liquid radiological waste, radioactive reactor components, and contaminated structural materials. The radioactive inventory during this configuration may change, depending on the licensee's proposed shutdown activities and schedule.

Level 3—In Level 3, the NRC anticipates that more than 5 years have elapsed since the reactor permanently ceased operation and was defueled and that all spent nuclear fuel is in dry cask storage (e.g., an independent spent fuel storage installation (ISFSI) facility). The decision for a licensee to transfer all fuel to an ISFSI facility is based, in part, on such plant-specific factors as the timing and method of plant decommissioning, the preexistence of a licensed ISFSI, and the anticipated start of fuel shipments to a Federal high-level waste repository or a monitored retrievable storage facility. To evaluate the potential effects of alternatives considered in this analysis, the NRC assumed that the spent fuel is stored in an onsite ISFSI for 16 years before the spent fuel is transmitted to either an offsite ISFSI or a permanent geologic repository. This is based on a recently submitted decommissioning plan for transferring all the spent fuel to a U.S. Department of Energy long-term storage repository. Level 4—In Level 4, all spent nuclear fuel has been removed from the site. The site may possess a radioactive inventory of liquid radiological waste, radioactive reactor components, and contaminated structural materials. The radioactive inventory during this configuration may change, depending on the licensee's proposed decommissioning activities and schedule. There are no credible accident sequences that can result in significant offsite radiological consequences. As a result, the potential accidents that could occur during the decommissioning of a nuclear power reactor in Level 4 have negligible offsite and onsite consequences.
Questions Nos. 120, 164, and 169
[Questions 120, 164, and 169 are identical. A consolidated answer is presented below.] The NRC's new reactor program focuses on licensing reviews for small and large light-water reactors and advanced nonlight-water reactors. Most of US NPPs are LWR Types (PWR and BWR), how do you apply your existing regulations (which are dedicated for LWRs) to advanced non-LWRs?
<u>Answer</u>: The NRC's existing regulations are sufficient to license advanced non-LWRs in the near term. Many of NRC's regulations are technology neutral and can be applied to advanced non-LWRs. The NRC has several activities in progress to enhance the regulatory framework for advanced non-LWRs to facilitate more efficient and effective reviews, as discussed below. The staff has developed a vision and strategy to assure that the NRC is ready to review potential applications for non-LWR technologies effectively and efficiently. The staff described the vision and strategy in "NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," which was issued in December 2016 (ML16356A670). To achieve the goals and objectives in the NRC's vision and strategy, the NRC developed implementation action plans. The NRC issued the implementation action plans on July 12, 2017, and identified the specific activities the NRC planned to conduct in the near term, mid term and long term (ML17165A069 and ML17164A173). Near-term activities focus on strategies to license non-LWRs within the existing regulatory framework. Non-LWR criteria include the following: • In July 2013, the U.S. Department of Energy and the NRC established a joint initiative to address a key portion of the licensing framework essential to advanced reactor technologies. The initiative addresses the General Design Criteria for nuclear power

plants in Appendix A to 10 CFR Part 50, which were developed primarily for LWRs, by adapting them to the needs of advanced reactor design and licensing.

- On April 3, 2018, the NRC issued Regulatory Guide (RG) 1.232, "Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors" (ML17325A611).

- RG 1.232 gives guidance to reactor designers, applicants, and licensees of non-LWR designs on developing principal design criteria for any non-LWR. The non-LWR design criteria included in Appendices A–C to RG 1.232 are intended to give stakeholders insight into the staff's views on how the General Design Criteria could be interpreted to address non-LWR design features.

The key insights of the NEI's Licensing Modernization Project include the following:

- The objective of the Licensing Modernization Project, described in NEI-18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," is to develop technology-inclusive, risk-informed, and performance-based regulatory guidance for licensing non-LWRs under the existing regulatory requirements of 10 CFR Part 50 and 10 CFR Part 52 (ML19241A336).

- The Licensing Modernization Project outlines an approach to select licensing-basis events; classify structures, systems, and components; determine special treatments and programmatic controls; and assess the adequacy of a design in terms of providing layers of defense in depth.

- The NRC published Draft Regulatory Guide 1353, "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," in the *Federal Register* on May 3, 2019, for public comment (https://www.federalregister.gov/documents/2019/05/03/2019-09089/guidance-for-a-technology-inclusive-risk-informed-and-performance-based-methodology-to-inform-the).

- The NRC plans to issue a final regulatory guide in 2020 to endorse NEI-18-04.

Longer-term efforts include rulemaking to establish a technology-inclusive regulatory framework for advanced nuclear reactors by December 31, 2027, as required by Section 103 of the Nuclear Energy Innovation and Modernization Act, which was signed into law on January 14, 2019.

Question No. 136

According to the report, the plant's design basis appropriately considers the most severe natural phenomena at the site, with sufficient margin for the limited accuracy, quantity, and period of time in which historical data have been accumulated. How far back do the historical data go? What is the basis?

Answer: The NRC's regulations at 10 CFR Part 100, "Reactor Site Criteria," establish the siting criteria that must be satisfied in order to build a nuclear power plant. RG 4.7, Revision 3, "General Site Suitability Criteria for Nuclear Power Stations" (ML12188A053), describes an acceptable method for licensees or applicants to implement the site suitability requirements for nuclear power stations. RG 4.7 contains references to additional NRC staff

guidance that has been developed to provide information to topic-specific siting issues, such as the evaluation of severe natural phenomena at a given site. For example, NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” section 2.3.1, “Regional Climatology” (ML063600393), contains the NRC staff’s review procedures for examination of long-term weather cycles, such as 100-year return periods for extreme weather conditions such as winter precipitation, maximum wind speed, and temperatures that define a site’s meteorological characteristics. For flooding and seismic hazards, the range of data provided should be sufficient to assess the acceptability of the site and to assess the potential for those characteristics to influence the design of plant systems, structures, and components important to safety. NUREG-0800, sections 2.4.3–2.4.7 and 2.4.9, address site flooding and specific flood-producing phenomena. Sections 2.5.1–2.5.5 of NUREG-0800 describe the NRC staff’s review procedures for geologic and seismic issues. The NRC staff reviews the applicability of these and other climatological data to substantiate that they will represent site conditions during the expected period of reactor operation.
Question No. 137
According to the report, independence, multiplicity and diversity of single failures are said to be included in defense in depth. How does your country consider the multiple failures with regard to IAEA SSR-2/1?
<u>Answer</u>: In establishing a plant license, the NRC establishes the minimum equipment and plant parameters that are necessary to successfully respond to a design-basis accident. Within the license, the NRC may require redundancy (e.g., power supplies) or diversity (e.g., prime movers for pumps) as necessary means of defense in depth to ensure adequate protection of public health and safety. Since the U.S. nuclear industry is mature and composed of a manageable number of plant designs, it has been able to amass a sizeable amount of useful equipment operating experience. This information is managed through INPO as described in part 3 of the U.S. 8th National Report. The NRC maintains a robust operating experience program as described in section 19.7 of the U.S. 8th National Report. Through this program, the staff tracks equipment issues that may significantly impact plant safety. The staff coordinates some efforts with INPO and synthesizes this information with other quality assurance-related information streams like 10 CFR Part 21 reports to maintain awareness of equipment performance throughout the industry. Additionally, the NRC operating experience program considers common-cause failure information that is gathered through the NRC's inspection program and required reports under 10 CFR 50.72, “Immediate notification requirements for operating nuclear power reactors,” and 10 CFR 50.73, “Licensee event report system.” The staff uses all of these data streams to identify equipment deficiencies and a structured screening process to determine if further NRC action is required. Additional NRC actions can consist of publishing generic communications, conducting targeted inspections, or even recommending that the Commission issue orders in response to unacceptable equipment performance. Lastly, applicants seeking NRC design certification of a new reactor design are required to conduct a design probabilistic safety analysis. In practice, the probabilistic safety analysis is used to identify design vulnerabilities that includes assessment of common-cause failures and multiple independent failures using probabilistic techniques that are within the state of the practice.
Question No. 141
US national report section 2.2.2 describes “48 units have entered the period of extended operation beyond 40 years as of August 2019”. In addition, the section 2.3.2 also explains

“NRC inspection will focus on operating experience, aging management, and changes to the design basis and probabilistic risk assessment (PRA) models.” With respect to the provided information in the article in question, Korea would like to inquire the following question: (1) Please explain the regulatory body's inspection activities, as part of the reactor oversight program (ROP), to verify the effectiveness of licensee's ageing management program of the units in the extended operation. (2) In addition, please provide any lessons-learned from the ROP inspection to the units in the extended operation, focusing on aging management.
Answer: (1) Renewed license activities associated with the period of extended operation focus primarily on passive safety systems, structures, and components because most active or standby systems are routinely maintained and receive surveillance testing under the initial renewed operating licensee. In the extended period of operation, some additional license renewal inspection activities could include, but may not be limited to, observing or reviewing -examinations and monitoring efforts; walking down systems, structures, and components; assessing operating experience and lessons learned; and reviewing age-related corrective actions using risk-informed, performance-based sampling techniques. After the period of extended operation, the licensee’s aging management program would be assessed using the operating reactor assessment program. (2) Lessons learned are documented in NUREG1801, the GALL Report (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1801/).
Question No. 143
After submitting the PSDAR [post-shutdown decommissioning activities report] for going into particular decommissioning activities, which legal documents (PSDAR, operating license documents (SAR [safety analysis report]), etc.) should be amended and approved to reflect the related decommissioning equipment and systems (clean-up, decontamination, dismantling, waste treatment)? If not, is decommissioning carried out as part of the operational capability of the licensee under the operating license?
Answer: The primary rules for decommissioning a nuclear power plant are set forth in several NRC regulations, such as Subpart E of 10 CFR Part 20 and 10 CFR 50.75, 50.82, 51.53, and 51.95. Additional regulations in 10 CFR Part 50 (10 CFR 50.59, 50.36(c)(6), 50.65, 50.48(f), and 50.54(y)) are explicitly applicable to decommissioning reactors. Some regulations are no longer applicable to decommissioning reactors once they are in a permanently shut down and defueled condition. However, many operating reactor regulations continue to be applicable to decommissioning reactors. For decommissioning reactors, the types of potential accidents are fewer and the risks of radiological releases are reduced when compared to an operating reactor. Therefore, to reflect this reduction in risk, licensees of decommissioning reactors have requested certain amendments to their licenses and certain exemptions from the NRC's regulations for operating plants. These licensing actions, which were processed during the transition from operation to decommissioning, establish the long-term regulatory framework for reactors that have permanently shut down and defueled. The primary NRC regulatory guidance for decommissioning transition is provided by the following documents:

- RG 1.184, “Decommissioning of Nuclear Power Reactors,” issued October 2013 (ML13144A840)

- RG 1.185, “Standard Format and Content for Post-Shutdown Decommissioning Activities Report,” issued June 2013 (ML13140A038)

- RG 1.202, “Standard Format and Content of Decommissioning Cost Estimates for Nuclear Power Reactors,” issued February 2005 (ML050230008)

- NUREG-1713, “Standard Review Plan for Decommissioning Cost Estimates for Nuclear Power Reactors,” issued December 2004 (ML043510113)

Other documents pertinent to reactor decommissioning include the following:

- NUREG-0586, “Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities: Regarding the Decommissioning of Nuclear Power Reactors,” Supplement 1, “Regarding the Decommissioning of Nuclear Power Reactors,” Volume 1, “Main Report, Appendices A through M,” issued November 2002 (ML023470304)

- NUREG-1628, “Staff Responses to Frequently Asked Questions concerning Decommissioning of Nuclear Power Plants,” issued June 2000 (ML003726190)

- IMC 2561, “Decommissioning Power Reactor Inspection Program” (ML031270502)

All the licensees of recently permanently shut down reactors have proposed comprehensive amendments to their facilities’ technical specifications to reflect their permanently shut down and defueled status.

Most of the technical specifications for an operating power reactor specify modes of applicability that correspond to conditions of operation for the reactor or apply only when fuel is emplaced in the reactor vessel. For a permanently shut down and defueled reactor, these modes refer to conditions that are no longer possible because the reactor cannot be operated and fuel cannot be placed in the core. In such cases, technical specifications with modes of applicability can be removed from the license without affecting the safety of the facility. In addition, substantial changes are also made to the administrative controls section of the technical specifications, including changes to facility staff responsibilities, staffing organization, and staffing levels. Some program and reporting requirements only applicable to operating reactors are also deleted or modified.

In addition to decommissioning-related amendments to the operating reactor technical specifications, two narrow-in-scope license amendments to technical specifications may be requested early in the decommissioning transition process. One involves the use of the certified fuel handler. Another amendment may be needed to support irradiated fuel handling. The irradiated fuel handling amendment would remove the technical specifications limiting conditions of operation related to certain safety-related systems that are typically required for irradiated fuel handling, such as the control room habitability systems, fuel-handling building ventilation systems, actuation instrumentation, and supporting safety-related electrical systems.

All 10 CFR Part 50 reactor licenses have license conditions that the NRC has imposed on licensees whenever it was deemed appropriate and necessary, in accordance with 10 CFR 50.50, “Issuance of licenses and construction permits.” When the licensee submits the 10 CFR 50.82 letters asserting that the reactor is permanently shut down and defueled, many of the license conditions are no longer relevant and can be modified or removed from the license. Section 1 of a facility operating license should not be amended, because it documents the Commission’s findings at the time of initial licensing. Some licensees have requested amendments to the license conditions in section 2 of the reactor’s facility operating license; however, since the licensee is not authorized to operate the plant or load fuel in the vessel, many of these license conditions are not relevant even if left in place. In most circumstances, the fire protection program license condition can be removed because it ensures protections are in place to reach safe shutdown in the event of a fire. The requirements for decommissioning reactors specified in 10 CFR 50.48, “Fire protection,” require the licensee to maintain fire protection capabilities for the rest of the plant to address fire events that may have radiological consequences. Removal of the operating reactor fire protection license condition should not impact fire protection at a decommissioning reactor. The license condition related to mitigating strategies for large fires and explosions should remain for the spent fuel pool. Based on recent experience with this license condition, licensees have elected to leave the condition unchanged and implement it as appropriate for site-specific conditions. It should be noted that the NRC staff’s evaluation of the exemptions related to emergency preparedness regulations relies heavily on the licensee’s prompt implementation of the mitigating strategies license condition for the spent fuel pool. For reactors that have received renewed operating licenses, some license conditions may need modification or removal depending on site-specific conditions. See the NRC’s “Power Reactor Transition from Operations to Decommissioning: Lessons Learned Report,” issued October 2016 (ML16085A029), for examples of these licensing actions.
Question No. 145
With reference to Article 2, page 22 of the U.S national report, the NRC staff will review and evaluate the licensee’s specific request. With respect to the provided information in the article in question, Korea would like to inquire the following question: What is the NRC standard for reviewing the licensee plan for staff reduction following the application for permanent decommissioning? Based on the current standard, how many phases does staff reduction in a plant take?
<u>Answer</u>: The NRC staff would ensure that the decommissioned plant has the appropriate personnel to safely store and handle spent fuel by inspections under IMC 2561 (ML17348A400). One of the main objectives of IMC 2561 is to obtain information through direct observation and verification of licensee activities to determine whether the power reactor is being decommissioned safely; that spent fuel is safely and securely stored on site or transferred to another licensed location; and that site operations and license termination activities are in conformance with applicable regulatory requirements, the facility licensing basis, licensee commitments, and management controls. Another objective of IMC 2561 is to verify that (1) the licensee’s procedures, processes, and programs for post operational transition, decommissioning, and license termination are adequate, (2) necessary programs continue from the period of operation into decommissioning in accordance with the applicable regulatory requirements, and (3) the safety culture established during reactor operations is

maintained. These decommissioning programs are assessed by inspection of four functional areas: plant status; modifications, maintenance, and surveillances; problem identification and resolution; and radiation protection. Regarding staff reductions, staffing levels are based on the licensee's plans for decommissioning the facility. Licensees' staffing plans should be sufficient such that changes in site staffing, experience, or expertise will not result in unsafe decommissioning practices, impact spent fuel safety, or result in excessive use of the decommissioning funds.
Questions Nos. 146 and 153
[Questions 146 and 153 are identical. A consolidated answer is presented below.] (1) Are the staff's recommendations from the SECY-18-0060 to be considered altogether by the Commission? (2) Is there any way to follow-up which of the recommendations lead to an actual improvement or change in the regulatory framework and practices? (3) What are the roadmap and expectations from the staff for the transformation initiatives to become regulatory improvements at the NRC? (4) Congratulations for the [NRC's] efforts to identifying potential transformative changes to the NRC's regulatory framework, culture, and infrastructure to enhance the agency's effectiveness, efficiency, and agility in regulating new and novel technologies.
Answer: (1 and 2) SECY-18-0060, which was submitted to the Commission in May 2018, requested Commission approval of several revisions to the NRC's regulatory framework and approaches to better enable the safe and secure use of new technology, including advanced reactors and digital instrumentation and control. However, the NRC staff asked to withdraw this paper due to new information superseding the basis for many of its recommendations. The Commission approved the withdrawal request in September 2019. Additionally, the staff had already begun certain aspects of the work described in the paper that could be pursued without seeking Commission approval. For example, the Nuclear Energy Innovation and Modernization Act, which was signed into law in January 2019, requires the NRC staff to pursue several activities, including "staged licensing" for commercial advanced reactors; a risk-informed, performance-based licensing scheme for commercial advanced reactors; and a rulemaking to establish a technology-inclusive regulatory framework. The NRC staff has also made significant progress in the development of guidance to address regulatory challenges with digital instrumentation and control to ensure that digital upgrades are implemented safely. (3 and 4) In regard to the roadmap and expectations for transformation activities, the NRC has completed additional activities that focused on improving the NRC's ability to adapt when change is warranted and achieving the transformation of the agency culture to that of a modern, risk-informed regulator. Specifically, in January 2019 the NRC issued "The Dynamic Futures for NRC Mission Areas" (ML19022A178). The Futures Report describes four possible future scenarios for the NRC's mission areas, how the NRC could be affected by each future, and key takeaways that the NRC could consider preparing for any future scenario. In June 2019, the NRC staff held a "Futures Jam," a virtual discussion to which all employees were invited to discuss how the NRC can best become a modern, risk-informed regulator.

Data from this Jam have been analyzed and used to inform a roadmap that will prioritize ongoing initiatives and identify initiatives that support agencywide cultural change. Specifically, based on data collected from the Jam, the NRC leadership established a framework for transforming the NRC that encompasses four focus areas: (1) managing the workforce, (2) accepting risk in decision-making, (3) generating innovative ideas to improve the ways that NRC works, and (4) adopting new technologies and approaches to data analytics. Flowing from these focus areas, the NRC identified seven initiatives that included accepting risk in decision-making, agency desired culture, career enhancement, innovation, process simplification, signposts and markers, and technology adoption. Each of these initiatives is being led by an initiative team and supported by one or more executive sponsors. The teams consist of staff from all levels, offices, and backgrounds within the NRC. Some of these initiatives leverage work that is already under way across the NRC, while others will involve new activities or programs to implement focused solutions for specific challenges. Additional initiatives are also likely to be launched as the current set are completed. The timeline for the full scope of initiative-focused work is approximately 2 years, with the understanding that the NRC will establish a culture receptive to innovation as an institutional norm.

Question No. 147

(1) How this recommendation [Section: 2.3.2.10 of the U.S. 8th National Report] combines and complements the risk-informed categorization process explained in section 2.3.2.8 (Risk-Informed Decisionmaking)?

(2) Does the SECY recommendation goes beyond the actual practice/transformation at the NRC or is it part of the same effort? / Recommendation listed as (1) reads as follows: transform the agency licensing review process by developing an agencywide process and organizational tools that expand the systematic use of qualitative and quantitative risk and safety insights, thereby, enabling the staff to scale the scope of review and level of detail needed to make a finding of reasonable assurance of adequate protection.

<u>Answer</u>:
(1 and 2) Applicants and licensees continue to innovate and pursue increased application of modern technology in nuclear plant operation, maintenance, and design. In response, the NRC is shifting its regulatory practices to accommodate this innovation. A large part of developing organizational processes and tools to expand the use of risk insights involves the knowledge management efforts for risk-informed decision-making described in section 2.3.2.8 of the U.S. 8th National Report. While the overall goal is to increase the use of risk information in all licensing actions, the NRC has focused near-term efforts on licensing actions that are submitted as formal risk-informed licensing actions. The NRC has also developed an agency internal process using risk insights to grade the level of effort to other types of licensing reviews for operating and new reactors. Whether formal risk-informed licensing actions or other types, the agency is promoting use of multidisciplinary integrated review teams, when appropriate, to coordinate and collectively manage licensing reviews with risk considerations. Consequently, the NRC has sought to optimize the review process as outlined in section 2.3.2.8 of the U.S. 8th National Report.

The review of the licensing actions to implement 10 CFR 50.69, “Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors,” serves as an example of transformational work that has already begun at the NRC. As mentioned in the

U.S. 8th National Report, 10 CFR 50.69 risk-informed categorization process allows the NRC to focus regulatory attention on issues that have the greatest potential to impact public health and safety and focuses licensee attention on the issues that have the greatest potential to impact public health and safety. This approach is very much aligned with the NRC's transformation efforts and goal to be a modern, risk-informed decision-maker. As part of future efforts, the NRC will look to apply lessons learned to improve the use of risk insights in licensing actions that are not formally submitted as risk-informed licensing actions, with the goal of enabling the staff to scale the scope of review and level of detail needed to make a finding of reasonable assurance of adequate protection.
Questions Nos. 148 and 152
[Questions 148 and 152 are identical. A consolidated answer is presented below.] For the change of paradigm towards a risk informed regulation, we agree with the importance of training the managers. How are the new methodologies applied to their offices and imposed onto the daily work of the staff? Is there any training material or activity for the staff? Being conscious of the interest posed by the industry towards a more efficient risk-informed regulation, are they allowed to contribute in any manner in the development of regulatory requirements in this matter, new regulations or methodologies (such as those affecting technical specifications, surveillance [f]requencies, etc.)? When applying the new categorization to regulatory processes, how do you measure the impact on resources or the benefit of these new approach compared to the traditional processes? Do you use any performance indicator or measurement of resources devoted to each process? A risk-informed categorization process allows the NRC to focus regulatory attention on issues that have the greatest potential to impact public health and safety and focuses licensee attention on the most risk significant equipment. The RIDM [risk-informed decision-making] Knowledge Management efforts are seeking to include the understanding of risk beyond a quantitative value to one that considers quantitative risk as one of the key principles along with defense-in-depth, safety margins, performance monitoring and regulatory compliance. Among these efforts you highlight in your report the pilot course for managers that provides perspectives on how risk and deterministic information are used together to make regulatory decisions, to review risk-informed licensing guidance and recent actions, and to illustrate risk management tools and practices at utilities. Finally, the NRC is reviewing licensing applications involving the establishment of a risk management approach for certain limiting conditions for operation contained within technical specifications and allowing licensees to apply and benefit from benefits RIDM.
<u>Answer</u>: The NRC considers the increased attention to risk-informed regulation as a natural progression in nuclear regulation. Years ago, the expertise and experience in resolving risk was not as widely held to allow risk-informed perspectives to be considered throughout the regulatory process. Therefore, the NRC included conservatism in its deliberations and applied deterministic approaches as necessary to establish the regulatory standard of adequate protection. With the Commission's direction in the 1990s and incremental projects to improve

the agency's understanding of risk information and its application to nuclear regulation, the NRC finds itself in a position to take the next step of incorporating risk information into the agency's daily work. The NRC is looking at this as a cultural shift that will take many years to fully realize and thus has yet to establish formal metrics for completion. The initial steps have already been taken as described in the report in regard to risk-informed decisionmaking. The NRC has ample training available to the staff in the areas of probabilistic safety assessment and risk-informed decision-making and has offered and will continue to offer workshops, seminars, and other forums to give staff the opportunity to practice applying risk information in a tabletop environment or discuss case studies. However, the real gains are being realized as staff are challenging themselves to more closely observe their work through a risk-informed lens. For example, through the Reactor Oversight Process (ROP) enhancement effort that is described on the NRC's public website and introduced in SECY-19-0067, "Recommendations for Enhancing the Reactor Oversight Process," dated June 28, 2019 (ML19070A036), the staff demonstrated the impact on NRC oversight efforts of a reevaluation of what the NRC does through a risk-informed perspective.

The NRC's Principles of Good Regulation include the principle of independence. The NRC will always make decisions that are free from the influence of special interests and bias. However, the agency does not function in a vacuum. The NRC greatly values external stakeholder input in all of its deliberations. Some agency processes formally require external stakeholder input, such as rulemaking or regulatory guidance development, and others demand these interactions, even if informally, if they are going to be successful. Therefore, external stakeholders, of which the U.S. nuclear industry is one, are allowed and encouraged to contribute to the development of NRC regulatory requirements.

Question No. 151

[In Section 2.3.2.10 of the U.S. 8th National Report,] recommendation listed as (1) reads as follows: transform the agency licensing review process by developing an agencywide process and organizational tools that expand the systematic use of qualitative and quantitative risk and safety insights, thereby, enabling the staff to scale the scope of review and level of detail needed to make a finding of reasonable assurance of adequate protection.

(1) How this recommendation combines and complements the risk-informed categorization process explained in section 2.3.2.8 (Risk-Informed Decisionmaking)?

(2) Does the SECY recommendation goes beyond the actual practice/transformation at the NRC or is it part of the same effort?

Answer:
(1 and 2) Applicants and licensees continue to innovate and pursue increased application of modern technology in nuclear plant operation, maintenance, and design. In response, the NRC is shifting its regulatory practices to accommodate this innovation. A large part of developing organizational processes and tools to expand the use of risk insights involves the knowledge management efforts for risk-informed decision-making described in section 2.3.2.8 of the U.S. 8th National Report. While the overall goal is to increase the use of risk information in all licensing actions, the NRC has focused near-term efforts on licensing actions that are submitted as formal risk-informed licensing actions. The NRC has also developed an agency internal process using risk insights to grade the level of effort to other types of licensing reviews for operating and new reactors. Whether formal risk-informed licensing actions or other types, the agency is promoting use of multidisciplinary integrated review teams, when appropriate, to coordinate and collectively manage licensing reviews with

risk considerations. Consequently, the NRC has sought to optimize the review process as outlined in section 2.3.2.8 of the U.S. 8th National Report.

The review of the licensing actions to implement 10 CFR 50.69 serves as an example of transformational work that has already begun at the NRC. As mentioned in the U.S. 8th National Report, the 10 CFR 50.69 risk-informed categorization process allows the NRC to focus regulatory attention on issues that have the greatest potential to impact public health and safety and focuses licensee attention on the issues that have the greatest potential to impact public health and safety. This approach is very much aligned with the NRC's transformation efforts and goal to be a modern, risk-informed decision-maker.

As part of future efforts, the NRC will look to apply lessons learned to improve the use of risk information in licensing actions that are not formally submitted as risk-informed licensing actions, with the goal of enabling the staff to scale the scope of review and level of detail needed to make a finding of reasonable assurance of adequate protection.

Question No. 155

Does the well-established regulatory process with the 4 components include the decommissioning part?

<u>Answer</u>: (Note: In responding to this question, the NRC assumes the question pertains to the four components of the life cycle of a nuclear facility: design, construction, operation, and decommissioning.)

The NRC has a well-established regulatory process that includes decommissioning in the life cycle of a nuclear facility. NRC regulations at 10 CFR 20.1406, "Minimization of contamination," require decommissioning and the minimization of contamination throughout the life cycle for all nuclear facilities. The regulations require the following:

(1) Applicants for licenses shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(2) Applicants for standard design certifications, standard design approvals, and manufacturing licenses, whose applications are submitted after August 20, 1997, shall describe in the application how facility design will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(3) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements for the radiological criteria for license termination (Subpart E of 10 CFR Part 20).

Regulatory guidance for implementing these regulations is available in RG 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning," (ML082120212) and RG 4.22, "Decommissioning Planning During Operations" (ML12158A361).

Question No. 162

"As specified in 10 CFR Part 52, the NRC can issue an early site permit to approve a site for a domestic nuclear power plant independent of an application for a combined license. Early

site permits are valid for 10 to 20 years and can be renewed for an additional 10 to 20 years. To date, the NRC has issued five early site permits and two limited work authorizations which allow the permit holder to perform limited construction activities at a site. The staff has not approved any new early site permits since the issuance of the last U.S. National Report. One early site permit application for the Clinch River Nuclear Site is currently under review. Article 18 and 19 of this report provide more detail about the 10 CFR Part 52 regulations." (1) What types of documents the applicant is to submit to obtain an early site permit? (2) What types of limited construction activities are allowed for the early site permit holder?
Answer: (1) An applicant needs to submit an application comprising administrative and financial information, a site safety analysis report, an environmental report, emergency plans, and, if applicable, departure and exemption requests. If desired, an applicant may also submit a limited work authorization. (2) Limited construction activities allowed under limited work authorizations are specified in 10 CFR 50.10(d) and include driving of piles, subsurface preparation, placement of backfill, concrete or permanent retaining walls within an excavation, and installation of the foundation, including placement of concrete.
Question No. 165
Reference section 2.3.1.8, it is stated that "All of the recent reactors transitioning to decommissioning requested amendments to their licenses and exemptions from the NRC's regulations. Most changes involve deletion of certain license conditions and technical specifications". Please share some examples of changes allowed by NRC in license conditions and technical specifications.
Answer: All of the licensees of recently permanently shut down reactors have proposed comprehensive amendments to their facilities' technical specifications to reflect their permanently shut down and defueled status. Most of the technical specifications for an operating power reactor specify modes of applicability that correspond to conditions of operation for the reactor or apply only when fuel is emplaced in the reactor vessel. For a permanently shut down and defueled reactor, these modes refer to conditions that are no longer possible because the reactor cannot be operated and fuel cannot be placed in the core. In such cases, technical specifications with modes of applicability can be removed from the license without affecting the safety of the facility. In addition, substantial changes are also made to the administrative controls section of the technical specifications, including changes to facility staff responsibilities, staffing organization, and staffing levels. Some program and reporting requirements only applicable to operating reactors are also deleted or modified. In addition to decommissioning-related amendments to the operating reactor technical specifications, two narrow-in-scope license amendments to technical specifications may be requested early in the decommissioning transition process. One involves the use of the certified fuel handler. Another amendment may be needed to support irradiated fuel handling. The irradiated fuel handling amendment would remove the technical specifications limiting conditions of operations related to certain safety-related systems that are typically required for irradiated fuel handling, such as the control room habitability systems, fuel-handling

building ventilation systems, actuation instrumentation, and supporting safety-related electrical systems. All 10 CFR Part 50 reactor licenses have license conditions that the NRC has imposed on licensees whenever it was deemed appropriate and necessary, in accordance with 10 CFR 50.50. When the licensee submits the 10 CFR 50.82 letters asserting that the reactor is permanently shut down and defueled, many of the license conditions are no longer relevant and can be modified or removed from the license. Section 1 of a facility operating license should not be amended, because it documents the Commission's findings at the time of initial licensing. Some licensees have requested amendments to the license conditions in section 2 of the reactor's facility operating license; however, since the licensee is not authorized to operate the plant or load fuel in the vessel, many of these license conditions are not relevant even if left in place. In most circumstances, the fire protection program license condition can be removed because it ensures protections are in place to reach safe shutdown in the event of a fire. The fire protection requirements for decommissioning reactors specified in 10 CFR 50.48 require the licensee to maintain fire protection capabilities for the rest of the plant to address fire events that may have radiological consequences. Removal of the operating reactor fire protection license condition should not impact fire protection at a decommissioning reactor. The license condition related to mitigating strategies for large fires and explosions should remain for the spent fuel pool. Based on recent experience with this license condition, licensees have elected to leave the condition unchanged and implement it as appropriate for site-specific conditions. It should be noted that the NRC staff's evaluation of the exemptions related to emergency preparedness regulations relies heavily on the licensee's prompt implementation of the mitigating strategies license condition for the spent fuel pool. For reactors that have received renewed operating licenses, some license conditions may need modification or removal depending on site-specific conditions. Most licensing actions processed during decommissioning transition are based on precedent. The information in table 3-3 of the "Power Reactor Transition from Operations to Decommissioning: Lessons Learned Report" (ML16085A029) provides the NRC staff a directory of the safety evaluations and other related evaluations associated with the transition licensing action. Based on lessons learned, the NRC staff is strongly encouraged to review and understand the precedent developed by the staff in these referenced evaluations when assessing any decommissioning transition activities. The NRC staff should share this table with licensees, as appropriate.
Question No. 167
USA may like to share information regarding the independent oversight of nuclear power plants by the corporate offices of the utilities.
Answer: Many nuclear power plants licensees maintain programs to assess the safety of their facilities. In addition, there are a number of nuclear groups dedicated to safety, such as the World Association of Nuclear Operators and INPO, who conduct audits and assessments. The results of these third-party audits and assessments are reviewed by the NRC in accordance with established program directions (e.g., IP 71111, "Reactor Safety-Initiating Events, Mitigating Systems, Barrier Integrity") when available but are not considered in the NRC assessment process. The information presented in these third-party audits and assessments provides valuable insights that may be used to inform independent inspection, assessment, and regulatory response to support the NRC's mission. These third-party audits and assessments are generally controlled through a memorandum of understanding with the

originating organization, which may limit the NRC's ability to share with members of the public.

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. 35
Are there any examples of research that was conducted by the Reactor Safety Research Program to address technical issues arising from design certification reviews?
Answer: The NRC's Reactor Safety Research Program conducts research to address technical issues arising from design certification reviews. The NRC staff develops models with several computer codes and performs confirmatory analyses to support the licensing of new reactors and to assess unique design aspects. For example, the NRC staff develops TRACE code input decks and runs confirmatory calculations with them for thermal-hydraulic analyses of transients and design-basis accidents. The NRC staff also develops MELCOR input decks and runs confirmatory calculations with them for source term and accident progression analyses. The staff and contractors conduct experimental research and participate in international cooperative research programs that address technical issues that are generically applicable to design certification reviews. More information and details are available in NUREG-1925, Revision 4, "Research Activities FY2018–2020," issued March 2018 (ML18071A139).
Question No. 37
In view of the six combined licenses that were terminated, is there consensus on suggested pre-licensing engagement to mitigate termination of licences in the future?
Answer: No. After the NRC issues a combined license, it is solely up to the license holder to determine if they would like to maintain or terminate the license. The decision to terminate a license is at the request of the licensee and is based on the specific business decisions of each licensee.
Question No. 49
It is mentioned that the NRC has maintained an internal Web site to provide a centralized source for accessing reactor operating experience information, including document collections, contacts, search tools, sources, and reference material. The agency's public Web site at http://www.nrc.gov/reading-rm/doc-collections/event-status/ contains all of the event reports that licensees have submitted to the NRC. May USA elaborate the information on reporting of events by licensees during construction phase and mechanism of utilizing such experience in operating facilities?

Answer: Event reporting by licensees and vendors for plants under construction occurs primarily under 10 CFR 50.55(e), which requires reporting of noncompliances related to a substantial safety hazard, defects in basic components, or a significant breakdown in any portion of the quality assurance program that could have produced a defect in a basic component (whether or not it actually did). This reporting is analogous to that of 10 CFR Part 21. The NRC posts 10 CFR 50.55(e) reports to http://www.nrc.gov/reading-rm/doc-collections/event-status under "Part 21 Reports." They can also be searched by typing "50.55(e)" in the "Search Event Reports" box on this webpage.

In addition to formal event reporting, NRC staff may become aware of construction issues via the following mechanisms:

- Licensees may request license amendments during construction to reflect constructability issues or installation deviations from certain aspects of the license that are difficult to correct.
- Licensees may request license amendments if they become aware of problems and events at similar international facilities under construction.
- Reports of NRC inspections conducted under the Construction Reactor Oversight Process can be found on the NRC public website at https://www.nrc.gov/reactors/new-reactors/oversight/crop/con-inspection-reports.html. Vendor inspection reports can be found on the NRC public website at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html.
- The NRC exchanges information with international counterparts via the inspector exchange program, the Multinational Design Evaluation Program, or other international meetings.

The NRC reviews operating experience from construction sites and operating reactors together with staff knowledgeable in both areas who can recognize relevant information. Construction operating experience that may be relevant to operating reactors includes defects in basic components that may be used at operating facilities, review of vendor quality assurance programs, oversight of contracted work on site, and nondestructive examination. The NRC incorporates these insights into general operating experience communications and recommendations for future inspections at operating reactors.

Question No. 58

Could the USA please inform about the participation of stakeholders in the NRC's rulemaking process?

Answer: The NRC invites input from members of the public during all phases of the rulemaking process and provides opportunity for stakeholders to submit written comments and attend public meetings to verbally give feedback or suggest alternate positions. All written comments on rulemakings are collected in the NRC's documents database (ADAMS) and posted to a rulemaking docket on http://www.regulations.gov/, an access portal for all Federal rulemakings. Additional information can be found in section 8.1.7 of the U.S. 8th National Report, which explains the types of tools and practices the NRC uses to reach out to stakeholders.

Question No. 60
In order to further enhance the Reactor Oversight Process stakeholders submitted feedback and identified potential improvement. Could the USA please provide information on identified improvements and recommendations and how these are considered by NRC?

Answer: Although the NRC's ROP is recognized both domestically and internationally as a highly effective oversight program for nuclear power reactors, the agency continually evaluates it for potential improvements based on oversight experience and feedback from both internal and external stakeholders. In light of the NRC's transformation initiative and the NRC's desire to be a more risk-informed and modern regulator, NRC solicited recommendations from internal and external stakeholders for ways to enhance the ROP. A significant number of recommendations were received in 2018 to make the ROP even more effective and efficient. As a result, the ROP an enhancement initiative began in October 2018 with an overall goal to be more risk informed and performance based.

The objectives for the initiative were as follows:

(1) Focus both NRC and industry attention on plant issues of higher safety significance.

(2) Improve the ROP significance determination process.

(3) Optimize the ROP baseline inspection program.

(4) Improve communications between the NRC and licensees when determining the safety significance of licensee performance deficiencies of higher significance.

All the recommendations were evaluated by a multidisciplinary team with a goal of identifying those recommendations that could be addressed in the near term (~6 months), medium term (~12 months), and longer term (more than 12 months). Near-term recommendations are documented in SECY-19-0067 (ML19070A036). Major changes requiring NRC Commission approval include the following:

- removing the four-quarter requirement for greater-than-green inspection findings to be on the assessment process Action Matrix and to revise the treatment of performance indicators accordingly

- optimizing the ROP baseline inspection program, taking into account oversight experience and licensee improved performance since 2000

- better risk-informing the emergency preparedness significance determination process by placing more oversight attention on certain standards

The NRC staff is awaiting the Commission's decision on these recommendations. NRC staff has started its review of the medium-term recommendations (2019-2020) are currently being evaluated. Highlights of these recommendations include the following:

- perform an effectiveness review of the cross-cutting issues program

- perform a comprehensive review of the problem identification and resolution inspection program

- evaluate the Inspection Program for ISFSIs

- optimize the Radiation Safety Inspection Program

These medium-term enhancement activities are expected to be completed in 2020. Other longer-term activities involve the following:

- continued enhancements to the Significance Determination Process with an emphasis on the treatment of common-cause failures and human performance assessments in the probabilistic safety assessment

- performing a holistic assessment of the Performance Indicator Program, including an overhaul of the Mitigating Systems Performance Index

- making associated ROP program changes to reflect all the activities mentioned above

Additional information can be found on the NRC's public website at https://www.nrc.gov/reactors/operating/oversight/rop-enhancement.html.

Question No. 61

The design certification for ABWR [advanced boiling water reactor] expired 2009. As stated in the [8th] National Report, NRC staff is currently reviewing the application for design certification renewal for this reactor type. In 2012 IAEA published SSR 2/1 agreed in consensus superseding NS-R-1, which was in place at the time of the design review before issuing the design certification in 1994.

(1) Could the USA please inform about how the changes and more strict design requirements for NPPs of SSR 2/1 and its update in 2016 will be considered in the design certification renewal to ensure that new reactors will be designed in accordance with the latest design requirements agreed in consensus on an international level?

(2) How will NRC ensure continuous improvement of reactor design by design certification renewals?

Answer:
(1) The NRC's regulations are consistent with, but not dependent on, IAEA guidance. Differences in the application of IAEA safety standards and NRC regulations largely stem from the fact that NRC regulatory infrastructure predates most IAEA safety standards. Design certification renewal applications—including the ABWR design certification renewal application that is currently under review by the NRC—are required to meet the regulations that were in place at the time of the original design certification, unless a backfit analysis has been conducted. An example of how the NRC has addressed and meets the intent of the post-Fukushima principles of SSR-2/1, Revision 1, for new large LWRs follows.

For new large LWR reactor designs, many NRC existing requirements and policies address traditional beyond-design-basis conditions and encompass the intent of SSR 2/1 requirements. The NRC uses goals for large release frequency based on probabilistic and deterministic containment performance that include features to mitigate severe accidents and demonstrate that the containment will survive a severe accident environment. A design probabilistic safety analysis is required and used by designers to reduce risk to a very low level. For example, severe accident prevention may be handled through improved plant

layout, greater physical separation, and better independence of power cables and electrical equipment. Plant designs have provided extended times and diverse means to cope with a station blackout and prevent core damage. New reactors are expected to have improved controls through containment design and/or mitigation of the concentrations of post accident combustible gases that could challenge the integrity of the containment. Passive plants may require additional regulatory treatment for non safety systems used to prevent or mitigate severe accidents. (2) Designs that are being reviewed for renewal must meet the regulatory requirements in 10 CFR 52.59, “Criteria for renewal.” Many of the NRC’s existing requirements and policies address traditional beyond-design-basis conditions and encompass the intent of SSR 2/1 requirements. For renewal applications, the NRC conducts an analysis and compiles a list of design changes that the agency considers to be regulatory improvements or changes that could meet the 10 CFR 52.59(b) criteria, which list other requirements the Commission may impose. Specifically, for the ABWR design certification renewal, the NRC identified 28 design changes for General Electric (GE) Hitachi to consider incorporating into its renewal application, including design changes to address Fukushima Recommendations 4.2, 7.1, and 9.3, as described in the NRC staff’s letter to GE Hitachi Nuclear Energy dated July 20, 2012 (ML12125A385).
Question No. 90
As for the "Petition for Rulemaking", were there any specific regulations which were newly established or revised? If existed, Please [explain] those concrete examples.
Answer: One of the ways the public can take part in NRC actions is to ask the agency to issue a new rule or change an existing rule. A petition for rulemaking must explain the issue and why action is needed; it also must include enough technical information to support the request. The appropriate regulatory action in response to a petition for rulemaking does not always result in a change to NRC regulations. Frequently, the outcome requested by the petitioner can be achieved under current policies or has been addressed by past decisions. In these instances, the petition is denied, and the NRC publishes an explanation for this determination. One example of a successful petition involved revising NRC requirements for emergency planning at nuclear power plants. The petition led to a new rule that allows State and local governments to include stockpiles of potassium iodide for possible use in the event of an emergency at a nuclear power plant. Another petition for rulemaking concerned fees charged to a licensee that removes uranium from drinking water at a community water system. The petition led to an NRC rule change that reduced the fee for licensed material that is a waste product from water processing and not part of a ‘‘uranium recovery’’ process whereby a licensee would profit from concentrating uranium as a source material. Issues raised by a petition for rulemaking are often considered in conjunction with a larger rulemaking project. One example is the 2019 final rule on mitigation of beyond-design-basis events at nuclear power plants discussed in section 2.3.3.4 of the U.S. 8th National Report. This rule addressed issues raised by six petitions for rulemaking that requested enhancements to emergency preparedness requirements. Each petition for rulemaking that the NRC receives, plus public comments and the NRC’s final action on the petition, is collected in a public docket. Annual compilations of those dockets are available on NRC’s website at https://www.nrc.gov/reading-rm/doc-collections/rulemaking-ruleforum/petitions-by-year.html.

Question No. 124
Could you explain the main changes regarding laws and regulations related nuclear power plant since 2016 to this day.
Answer: Section 2.3.3 of the U.S. 8th National Report summarizes the significant regulatory changes since 2016, including the NRC's final rule on mitigation of beyond-design-basis events (84 FR 39684; August 9, 2019). Other changes to NRC regulations include the issuance of a final rule certifying the Korea Hydro and Nuclear Power's (KHNP) design certification (84 FR 23439; May 22, 2019) (Note: KNHP is a wholly-owned subsidiary of the Korea Electric Power Corporation) and updates to regulations to incorporate recent editions of American Society of Mechanical Engineers (ASME) codes and standards (82 FR 32934; July 18, 2017, and 83 FR 2331; January 17, 2018). In addition, the U.S. Congress enacted two laws related to the regulation of nuclear power plants. The Nuclear Energy Innovation Capabilities Act of 2017 authorized the U.S. Department of Energy and the NRC to share technical expertise on novel reactor concepts. The Nuclear Energy Innovation and Modernization Act (January 14, 2019) requires the NRC to develop new processes for licensing nuclear reactors, including staged licensing of advanced nuclear reactors. The NRC is taking steps to implement these statutes.
Question No. 126
It is stated that: "The NRC discontinued the Industry Trends Program in 2016 because of Project Aim." Could you explain the reason of discontinuing industry Trends Program?
Answer: In 2016, the staff determined that, while the Industry Trends Program provides data that have helped validate broad industry performance trends, no regulatory action has ever resulted from its insights. The staff noted that any negative trends in industry performance that the Industry Trends Program could highlight would be self-revealing or identified through other means, such as routine licensee performance assessment, the ROP self-assessment, end-of-cycle assessment meetings, and the operating experience program. The perceived safety and regulatory benefit of the Industry Trends Program could no longer be cost justified. The staff recommended discontinuing the Industry Trends Program in 2016, and the Commission directed program termination.
Question No. 133
The decommissioning planning rule requests that when leakage of radioactive materials is detected through in-site monitoring during operation, the leakage should be prevented and the remediation should be carried out promptly or additional decommissioning funding should be secured. As contamination of the site is inevitable (subsurface, soil, groundwater, etc.) due to normal leaks (into the air, seawater), is there the quantitative limits or constraints for such leak which require remediation? If so, what is the leak condition corresponding to prompt remediation?
Answer: The decommissioning planning rule requires licensees to monitor the subsurface close to potential sources of leakage of radioactivity. If contamination is detected, the licensee is to take steps to identify and fix the leak and remediate the area or continue to monitor the leak and place additional funds in the decommissioning fund to ensure there is adequate funding to remediate the area.

Question No. 135
With reference to subsection 6.3.1, page 57 of the [8th] national report for the United States of America, the last sentence of the 2nd paragraph of subsection 6.3.1 states “Currently there are no combined license applications under review” and in the middle of the following paragraph, it is described “Two applications are currently under review.” Although they are stated in different paragraphs about two different topics, would you please add explanation for having different descriptions about combined license application.
Answer: The statement on page 57, “Currently there are no combined license applications under review,” is correct. The NRC does not have any combined license applications under review at this time. The “following paragraph” referred to in this question is describing two design certification applications that are currently under review (US-AWR and NuScale), both of which are able to be referenced by a combined license applicant if they choose to do so.
Question No. 156
Who is responsible for setting the seven screening criteria mentioned in the report?
Answer: The seven screening criteria are stipulated in NRC Management Directive 6.4, “Generic Issues Program” (ML18073A162), which outlines the major responsibilities and concepts for the day-to-day operation of the NRC’s Generic Issues Program. The NRC’s Office of Nuclear Regulatory Research is responsible for Management Directive 6.4 and its contents. Any changes to Management Directive 6.4 are proposed by the Generic Issues Program staff and concurred upon by all NRC offices, then incorporated into the next revision to the document.
Question No. 172
Section 2.3.3.4 is about implementation in the USA of lessons learned from Fukushima. NRC issued a request for information about seismic and flooding risks plus emergency arrangements in March 2012. The report states that additional evaluation of the impact of the reevaluated hazards on the sites is ongoing. Following the link included at the end of Section 2.3.3.4 to the status sheet for Operating Reactors shows that NRC has granted a deferral for the SPRA for the [Palisades] NPP until as late as Dec 31st 2022, which is more than 10 years after the March 2011 Fukushima incident and the NRC request for information. Please explain the justification for this protracted delay in implementing lessons learned from Fukushima.
Answer: The licensee for the Palisades Nuclear Plant has notified the NRC of its plans to permanently shut down on or before May 31, 2022. The licensee has requested deferral of the completion of the seismic probabilistic risk assessment (SPRA) and other actions associated with the seismic hazard reevaluations of Palisades until December 31, 2022. The NRC staff determined that deferring these actions related to the seismic hazard reevaluations poses no immediate safety concern and is acceptable. Further details about this request and the NRC staff’s approval can be found in the deferral approval letter (ML19115A413). In summary, the staff considered the following four factors in its evaluation: (1) Palisades has achieved additional defense in depth for coping with an extended loss of ac power and loss of normal access to the ultimate heat sink due to external events, including those caused by seismic and flooding events, as a result of the licensee’s compliance with NRC Orders EA-12-049 and EA-12-051. The NRC verified through

inspection that the order requirements for mitigation strategies and spent fuel pool level instrumentation have been appropriately implemented.

(2) For the deferral of the Palisades SPRA, the staff considered (a) the results and pertinent risk insights of previous and current evaluations of seismic risk at Palisades, (b) the additional defense-in-depth equipment and capabilities at the site, (c) the seismic design margin existing in nuclear power plants, (d) the documented ability of Palisades to cope with earthquakes larger than their design-basis earthquakes, (e) the remaining operational lifetime of Palisades, and (f) information about the seismic capacity of the spent fuel pools.

(3) Given the brief remaining operational period, there is not sufficient time to implement potential changes identified by the SPRA evaluation before permanently defueling the plant such that meaningful, further safety improvement will be achieved.

(4) If the licensee decides to continue to operate the unit beyond 2022, the licensee will need to provide the SPRA by December 31, 2022.

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. 4
"Section 186 authorizes the NRC to revoke licenses under certain circumstances (e.g., for material false statements made to the agency, for a change in conditions that would have warranted NRC refusal to grant a license on an original application, for a licensee's failure to build or operate a facility in accordance with the terms of the permit or license, or for a violation of the Atomic Energy Act or NRC regulation)." Would you describe one or two concrete examples of a construction licenses revocation with the main reasons and lessons learned?
Answer: The NRC has not issued a revocation order to a Part 50 construction permit or Part 52 combined license holder as a result of a violation of Section 186 of the Atomic Energy Act.
Question No. 17
We consider that the US NRC's use of a Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants represents a good practice that can be endorsed by other countries, as it promotes consistency and objectivity of regulatory oversight.
Answer: Thank you for your comments and observations. We appreciate the positive feedback.
Question No. 36
Does the U.S NRC verify compliance through inspection of pre-construction activities authorized under an early site permit?
Answer: The NRC defines construction activities that require a license of authorization in 10 CFR 50.10, "License required; limited work authorization." The regulation also describes what are not construction activities. However, many activities, such as land clearing and

excavating, are governed by other State and local regulations that may require permits and inspections by those authorities.
Question No. 108
This paragraph describes the process for licensing of nuclear installations. Have there been in recent years legislative or regulatory initiatives that give confidence that new nuclear power plants will have a higher safety level compared to the fleet of existing NPP? In that respective, have "new" safety objectives been defined for new installations for ensuring this higher safety level?
<u>Answer</u>: (1) The following policy statements and requirements establish the NRC's expectations about the safety of new reactors. • The Commission issued a policy statement, titled "Policy Statement on the Regulation of Advanced Reactors," (73 FR 60612) on October 14, 2008. It states that, "consistent with its legislative mandate, the Commission's policy with respect to regulating nuclear power reactors is to ensure adequate protection of the environment and public health and safety and common defense and security. Regarding advanced reactors, the Commission expects, as a minimum, at least the same degree of protection of the environment and public health and safety and the common defense and security, that is required for current-generation light-water reactors. Furthermore, the Commission expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions." • The Commission issued a policy statement, titled "Severe Reactor Accidents Regarding Future Designs and Existing Plants," (50 FR 32138) on August 8, 1985. A fundamental objective of the Commission's severe accident policy is to take all reasonable steps to reduce the chances that a severe accident involving substantial damage to the reactor core will occur and to mitigate the consequences of such an accident, should one occur. To achieve this objective, in 1989, the Commission issued regulations under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," governing applications for certification of standard designs and applications for combined licenses to require these applications to include information on the following three topics. First, the regulations in 1989 required these applications to demonstrate compliance with the technically relevant additional Three Mile Island requirements of 10 CFR 50.34(f). Second, the regulations in 1989 required applicants for design certification or a combined license to propose technical resolutions to unresolved safety issues and medium- and high-priority generic safety issues identified in the version of NUREG-0933, "Resolution of Generic Safety Issues," applicable to the application. Third, the 1989 regulations required each Part 52 application for design certification or a combined license to include a design-specific probabilistic risk assessment (PRA). In 2007, the Commission modified these provisions and added requirements for applications involving LWR designs to describe and analyze design features for the prevention and mitigation of severe accidents. In regard to PRA requirements under Part 52, the NRC in 2007 established specific requirements in 10 CFR 52.47, "Contents of applications; technical information," and 10 CFR 52.79, "Contents of applications; technical information in final safety analysis report." Under these regulations, an applicant for a design certification or a combined license, respectively, must include in its application a description of the design-specific PRA and its results. It should be noted that the

Commission confirmed in Staff Requirements Memorandum (SRM)-SECY-2015-0002, "Staff Requirements—SECY-15-0002—Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," dated September 22, 2015, that the Commission's guidance in the "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" and other Commission direction identified by staff apply to new 10 CFR Part 50 power reactor applications in a manner consistent with 10 CFR Part 52 design and license applications. The Commission has approved revision to the regulations in 10 CFR Part 50 for new power reactor applications to align more closely with requirements in 10 CFR Part 52. This rulemaking is in progress.

- On June 12, 2009 (74 FR 28,111), the Commission published requirements to consider the effects of a large, commercial airplane impact in 10 CFR 50.150, "Aircraft impact assessment." Specifically, applicants for new nuclear power reactors are required to perform a design-specific assessment of the effects of the impact of a large, commercial aircraft. The applicant is required to use realistic analyses to identify and incorporate design features and functional capabilities to show, with reduced use of operator actions, that either the reactor core remains cooled or the containment remains intact, and either spent fuel cooling or spent fuel pool integrity is maintained.

(2) Yes. See the response to item (1).

Question No. 138

In general, inspections at nuclear power plants are conducted by both site inspectors and technical inspectors (specialists) from the head office.

(1) How many regional inspectors are working at each site? Are there principles regarding the assignment (designation and rotation) of regional inspectors?

(2) Are there procedures or guides which describe site inspector's role, inspection scopes, inspection processes and the protocols related to the licensees?

(3) What is the proportion of site inspections in terms of man-year compared to the whole inspection activities conducted at NPPs in a year?

Answer:

(1) Generally, two resident inspectors are assigned to single- and dual-unit sites and three resident inspectors at triple-unit sites, with a few exceptions. The resident inspectors typically relocate to the area and may stay at the site for up to 7 years. Additional details about resident inspector policy can be found in section 11 of IMC 2515, "Light-Water Reactor Inspection Program—Operations Phase" (ML18134A170).

(2) Additional details about inspector guidelines can be found in IMC 2515, section 12 (ML18134A170). The scope of the inspection program is outlined in IMC 2515 and its appendices. For example, the scope of the baseline inspection portion of the program is defined in the inspection procedures in IMC 2515, appendix A, attachment 3 (ML18180A098). The inspection procedures available to the public are listed at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html. The Inspector Qualification Program is defined in IMC 1245, its attachments, and appendices, which can be found at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/index.html. The qualification program contains additional protocol and inspector conduct guidance.

(3) In 2018, site inspection activities made up approximately 73.9 percent of all inspection activities conducted at nuclear power plants.

Question No. 158

If an application refers to design certification, how does NRC evaluate the applicant's [knowledge] and understanding of the design, to ensure the applicant is capable to operate the reactor in a safe manner?

<u>Answer</u>: If a combined license application references a standard design, the combined license application is reviewed against the NRC's regulations, which requires the applicant to demonstrate that they have the capability and financial resources to manage a nuclear power plant. For example, the applicant provides the following information for review by the NRC:

- description of the business or occupation
- information about the organizational and management structure
- financial qualifications (for operation and decommissioning)
- foreign ownership status

The combined license applicant must also submit certain information for the NRC's review to ensure the applicant is capable of operating the reactor in a safe manner, including the following:

- Operational Programs: In chapter 13 of the application, the combined license applicant must submit a list of all operational programs required by NRC regulations. The NRC staff reviews each operational program description and the proposed implementation to ensure NRC regulations are met. A sample list of operational programs can be found in NUREG-0800, section 13.4, "Operational Programs" (ML18131A304).

- Quality Assurance Program: This comprises all planned and systemic actions that are necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Attributes of a quality assurance program include procedures, recordkeeping, inspections, corrective actions, and audits.

- Technical Specifications: These establish requirements for items such as safety limits, limiting safety system settings, limiting control settings, limiting conditions for operation, surveillance requirements, design features, and administrative controls.

Question No. 160

Page 57 [of the U.S. 8th National Report] "The NRC's reactor licensing process provides for the review and approval of changes after initial licensing. The process allows amendments to the operating license or combined license to support plant changes, changes of ownership and license transfer, exemptions and relief from NRC regulations, and increases in the reactor power level (i.e., power uprates). Articles 14, 17, and 18 of this report contain additional information". Could you please clarify when a combined license or an operating license is needed?

<u>Answer</u>: The decision to request an operating license or a combined licensee is solely up to the applicant. The NRC provides two licensing processes that can be used to obtain a license to operate a nuclear power plant. In the past, nuclear power plants were licensed under a two-step licensing process. This process required both a construction permit and an operating license. In 1989, the NRC established an alternative licensing process that essentially combines a construction permit and an operating license, with certain conditions,

into a single license. Under either process, before an applicant can build and operate a nuclear power plant, it must obtain approval from the NRC.

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. 1
It is written that Office of International Programs has responsibilities for export and import licensing. Does the OIP implement technical judgement as well as administrative matters?
Answer: The Office of International Programs (OIP) is responsible for the export and import licensing processes of the NRC, in accordance with 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material." As part of its review, the OIP staff routinely coordinates with other technical and legal offices within the NRC to ensure all relevant information is considered as part of OIP's decision-making process. This coordination includes requesting relevant input for consideration during the license review process, such as nuclear nonproliferation risk, safety and security risks of sealed sources, the status of and concerns about international safeguards, and the consistency of material and equipment with the stated end use. When a final decision is made to issue or deny a license application, this decision reflects the collective technical, legal, and administrative views of the entire NRC.
Question No. 2
Could you please explain more about how the NRC developed the SWP (Strategic Workforce Planning)? (e.g. Who were involved in? Did the NRC form an agency wide task force? How long did it take from Step (1) Set Strategic Direction to Step (5) Develop and Execute Strategies?)
Answer: The "Enhanced Strategic Workforce Planning Pilot: Lessons-Learned Report" (ML18162A051) outlines the development of the agency's enhanced Strategic Workforce Planning (SWP) process, including strengths, challenges, estimated resources, and recommended improvements. Implementation of the enhanced SWP process occurs on an annual cycle that begins in September with the development of the agency environmental scan and concludes in June with a set of strategies to address workforce needs projected over the next 5 years and beyond.

Question No. 15
In the U.S. House of Representatives, the Committee on Energy and Commerce has jurisdiction over domestic nuclear regulatory activities. Within the committee, the Subcommittee on Energy and the Subcommittee on Environment and Climate Change have responsibility for oversight of the NRC. Could you please give more information about what that oversight consist of?
<u>Answer</u>: The NRC has one primary oversight committee each in the House of Representatives and the Senate, and each of those committees has at least one subcommittee that also oversees the NRC. In addition to these committees, a number of other Congressional committees have oversight functions over some aspect of NRC activities. Congressional oversight includes the ability to summon the agency to appear at a committee or subcommittee hearing to discuss any aspect of the NRC's mission, request briefings from the NRC staff, and otherwise request information from the NRC. These oversight committees also review and analyze reports the NRC provides to Congress on various aspects of the NRC mission, and they can work to pass legislation that affects the agency and its budget.
Question No. 18
It is stated in the [U.S. 8th National] Report that except for certain classes of information, including proprietary information, security-related information, pre-decisional information, and information supplied by foreign governments that is deemed to be sensitive, the NRC makes the documentation that it uses in its decisionmaking process available in the agency's Public Document Room and on the agency's public Web site. What does the pre-decisional information include?
<u>Answer</u>: Predecisional information reflects the agency's internal deliberations on pending matters. Categories of predecisional documents that are routinely protected include, for example, draft documents, internal memoranda, and briefing materials, such as reports or other documents that summarize issues and advise superiors. The general purposes of protecting predecisional information are (1) to encourage open, frank discussions within an agency, (2) to protect against premature disclosure of proposed policies before they are actually adopted, and (3) to protect against public confusion that might result from disclosure of reasons and rationales that were not ultimately the grounds for a decision.
Question No. 33
Good performance in US NRC policy guidance directing staff to consider IAEA standards as a point of reference when drafting or revising RGs.
<u>Answer</u>: Thank you for your comments and observations. We appreciate the positive feedback.
Question No. 34
It was indicated that "in nonadjudicatory matters, such as rulemaking, the White House and executive branch officials may make their views known". Are comments and direction from the White House and executive branch officials made in a public setting?
<u>Answer</u>: This statement was intended to convey that, although the NRC is an independent regulatory agency, the President (either directly or through other executive branch officials) still has the constitutional authority to inform the Commission of his or her views on matters of policy. In an NRC rulemaking proceeding (see section 6.3.7 of the U.S. 8th National Report), the NRC solicits views from interested stakeholders on proposed regulations, and responses are docketed and made publicly available as part of the rulemaking record. There is no outright prohibition on other government officials expressing their views to the NRC outside of

this public comment process. However, when the NRC makes its final decision to issue regulations, the Administrative Procedure Act (see section 7.1 of the U.S. 8th National Report) requires that the NRC satisfactorily explain its reasoning and how its decision is supported by relevant data. Therefore, if the NRC relied on any information provided outside of the public notice-and-comment process, the NRC would generally need to disclose that information as part of the rationale for its final decision. It is common for other executive branch agencies to transparently provide comments on NRC proposed rules on the public docket. For example, the U.S. Department of Energy and the U.S. Environmental Protection Agency have publicly submitted comments in the past on regulatory matters that are of mutual interest.
Question No. 59
Could the USA please share the experience gained with the Strategic Workforce Planning (SWP) process?
<u>Answer</u>: In 2018, the NRC completed Phase II of its enhanced SWP process with 11 NRC offices. Phase II demonstrated that the enhanced SWP framework and process supports agency efforts to better forecast the amount and type of work now and in the future—and the workforce needed to perform this work. With the success of Phase II, the NRC ended the “phased” implementation of enhanced SWP and the process has become part of the agency’s normal operating procedure. Implementation begins each September and includes all offices that report to the Office of the Executive Director for Operation and several offices that report to the Commission. The outcomes of the enhanced SWP are informing the agency’s human capital management activities and are providing a greater understanding of the future workload of the NRC.
Question No. 83
(1) Could the USA clarify whether the goal of the Strategic Workforce Planning SWP of the Nuclear Regulatory Commission NRC is to develop the versatility of their employees? (2) If so, are all employees involved and how the NRC plans to anticipate their career plans and training plans?
<u>Answer</u>: (1) The objective of the enhanced SWP process is to develop strategies and action plans that enable the NRC to recruit, retain, and develop a skilled and diverse workforce with the competencies and agility to address emerging needs and workload fluctuations. While employees are not directly involved in the annual process, sharing information gathered from the enhanced SWP process benefits employees because it empowers them to make career planning and development decisions consistent with agency long-term needs. Consistent with the NRC’s Leadership Model, communicating the results of the enhanced SWP process and sharing the future direction of the agency can strengthen collaboration and empowerment among NRC employees and organizations, as well as reinforce the behaviors that build trust in agency leaders. For additional information on the Leadership Model, see the response to Question No. 82. (2) To support the SWP process, the agency began an initiative to update competencies for key positions and implement a system by which employees and supervisors can assess levels of competency for core positions. The agency now has models for the core positions that were identified in the SWP process. Moving forward, the NRC will continue to incorporate and adjust models as necessary consistent with its approach to continue SWP as a routine agency practice. The models and assessments are housed in a system that allows the

agency to track available skill sets. In the future, by using the competency model as the basis for training and qualification, the NRC will be able to improve program efficiency, and employees will be able to develop and practice the actual skills needed on the job to make them more effective immediately following qualification.
Question No. 84
(1) Does the USA conduct research on the efficiency of its communication strategy in terms of public understanding? (2) Does the USA carry out surveys and opinion polls on a regular basis, and if so, how often?
Answer: (1) While the NRC monitors media attention with a contracted clipping service that provides a daily briefing package on relevant coverage, the primary source of data on communication efforts is generated by social media monitoring. Platform analytics are augmented by social media monitoring conducted by a contractor. The monitoring allows the NRC to be informed of social media conversations of interest. The platform analytics allow the agency to determine such parameters as reach, impressions, and engagement related primary to Twitter and Facebook content. Ongoing analysis of those data steers future content. (2) The NRC surveys the public, generally related to public meetings, has a feedback mechanism on the agency website, and frequently solicits public comments on rulemakings and other pending policy matters. The agency's Office of Public Affairs does not conduct surveys or opinion polls.
Question No. 85
Could the USA specify the references of the legislation that makes provisions for adequate financial resources to enable the regulatory body to recruit and retain personnel?
Answer: Management Directive 4.2, "Administrative Control of Funds" (ML18073A128), gives procedures and practices to be followed in the agency's administrative control of funds during the implementation of the approved NRC budget. The NRC's policy is that agency systems for the administrative control of funds conform to the policies, procedures, and standards specified in this management directive, in compliance with the requirements of Office of Management and Budget Circular A-11, "Preparation, Submission, and Execution of the Budget"; the Antideficiency Act (31 U.S.C. 1341 et seq.); the Impoundment Control Act of 1974 (2 U.S.C. 681–688); the Chief Financial Officers Act of 1990 (Pub. L. 101-576); NRC appropriations acts; Government Accountability Office guidance; and the Economy Act (31 U.S.C. 1535). The NRC operates both an external recruitment program and a merit staffing program and appoints or assigns diverse employees who are well qualified to carry out the mission of the agency efficiently and effectively, without regard to political affiliation, race, color, religion, national origin, sex, marital status, age, sexual orientation, nondisqualifying physical or mental disability, or membership or nonmembership in an employee organization. The NRC conducts these activities without favoritism based on personal relationship, patronage, or other non-merit factors and with proper regard for privacy and constitutional rights. To the maximum extent practical, the NRC recruits qualified veterans and individuals who are disabled. Management Directive 10.1, "Recruitment, Appointments, and Merit Staffing" (ML18073A264), gives the operational practices and procedures applicable to recruitment, merit staffing, appointments, and general employment affecting NRC employees.

Question No. 86

(1) How did the SWP [Strategic Workforce Planning] affect the existing knowledge management system, staffing, and “training and development”?

(2) Could you give us some examples of key changes?

Answer:
(1) The NRC’s enhanced SWP process uses a data-driven approach to identify future skill gaps or surpluses by first identifying how the agency’s work will change over the next 5 years and beyond. By conducting a scan of its environment, the NRC can identify emerging areas that will require new skills and areas where the agency may experience a reduction that could result in a surplus of certain skills. Using these data, the NRC can develop strategies to recruit or retrain staff to work in a variety of areas as the NRC prepares for a range of future scenarios. This process also projects where the agency will experience attrition, allowing for proactive strategies to transfer knowledge.

(2) During the enhanced SWP process, offices and regions performed a workforce demand analysis at the division level to determine the number of people (by core position) and the competencies and proficiency levels required for accomplishing the work. Anticipated attrition can reveal expertise gaps for incorporation into short- and long-term action plans that include recruitment, retention, and training strategies. For example, many offices identified plans to continue cross-training and knowledge management activities to support and develop core capabilities, offer rotations to agency staff to build expertise in areas projected to experience a skill gap, and solicit interest in permanent reassignments from agency staff to address potential surpluses. Additionally, the NRC will continue to leverage the student summer intern and cooperative education programs to identify future permanent hires for entry-level positions.

Question No. 88

Could you please provide more details about “awards and recognition” to retain staff members?

Answer: The NRC recognizes and rewards the individual or group achievements of its employees who, in connection with or related to official employment, contribute to meeting organizational goals or improving the efficiency, effectiveness, and economy of the agency and/or the Government, or that are otherwise in the public interest. Management Directive 10.72, “Awards and Recognition” (ML18073A283), contains the program requirements and practices to award and recognize NRC employees.

The NRC uses retention incentives to retain employees who are highly or uniquely qualified or who fulfill special agency needs if it is determined that the employee is likely to leave Federal service and, as a result, the agency's ability to carry out an essential activity or function would be adversely affected. Management Directive 10.51, “Recruitment, Relocation, and Retention Incentives” (ML18165A434), gives the criteria and procedures for requesting application of the incentive pay authorities on a case-by-case basis, and for requesting exceptions to case-by-case approvals (i.e., group or “blanket” approvals).

Question No. 93

Information provided at e.g. the yearly NRC regulatory information conferences, states that the transition of NRC during the past few years and still in progress has [led] to a number of years with next to no recruitment. This has surely affected the age structure of NRC staff, but may also have impacted the possibility to maintain sufficient levels of competence in certain areas. Could you please comment on these or other challenges experienced?

Answer: One key outcome of the agency's enhanced Strategic Workforce Planning efforts was the need for the NRC to develop a pipeline of future talent to fill vacant positions anticipated due to increased attrition expected over the next 5 years. Due to the agency's declining workload and budget environment in recent years, entry-level hiring had been significantly limited, which created challenges to the NRC's long-term human capital management strategy. Not having a demographically balanced workforce with entry-level hiring put the agency at risk of not being able to accomplish its mission and meant potentially missing out on innovative ideas and opportunities those new staff might bring to its work. Accordingly, in 2018, the NRC revised the Temporary Summer Student Program as one tool to increase the pipeline of entry-level individuals for critical skill positions, and the agency received over 300 applications from interested students. In 2019, the agency continued the Temporary Summer Student Program and successfully converted 35 percent of the student hires into the NRC's Cooperative (Co-Op) Education Program. Nine of the Co-Op students are anticipated to graduate by June 2020 and are expected to fill entry-level positions. Finally, in 2020, the NRC plans to hire a cohort of 25 entry-level engineers and scientists to develop a pipeline of talent to fill future positions. To support this effort, the agency developed a new entry-level training program, the Nuclear Regulator Apprenticeship Network, which will focus on developing skills and competencies that support core positions needed to perform the work forecasted. The NRC believes this will enhance agility by preparing new employees to pursue a variety of career paths to be better prepared to respond to the agency's dynamic environment.
Question No. 97
The NRC hosted an IRRS [Integrated Regulatory Review Service] mission in October 2010 focused on the U.S. operating power reactor program, with a follow-up mission in 2014. These peer reviews are typically performed with a 10-year interval. The NR does not seem to include any information on planned future peer reviews; are there any such plans?
Answer: The NRC continues to evaluate the scope, timing, and other considerations for another peer review mission to maximize the benefits of another mission to the United States and the international community. In the meantime, the United States remains a strong supporter of the IAEA's peer review services, participating in many missions each year and supporting efforts to enhance the peer review services based on Member State experiences.
Question No. 106
Could you please elaborate on the (quality) management system of the regulatory body?
Answer: The NRC's management system is implemented through a series of internal guidance documents. These documents fall into one of five levels: (1) NRC Commission, (2) NRC policy implementation, (3) agency guidance, (4) office-specific guidance, and (5) division-, program-, or task-specific guidance. Each level represents documents with equivalent levels of authority and similar intended audiences within the NRC. The NRC uses organizational performance management, as specified in NRC Management Directive 6.9, "Performance Management," (ML18073A261) to ensure that the activities that support the agency's Strategic Plan objectives and goals are identified, communicated, given resources, and monitored. Through quarterly performance reviews, leaders regularly engage within their organization and with their partners to critically review progress toward these goals. The tool that the NRC uses in the quarterly performance reviews is called enterprise risk management, which is a systematic way to identify risks (an event or situation that may negatively affect NRC assets, activities, or operations). Once identified, each risk is assessed (what can happen, how likely is it, and what are the consequences), and internal controls are discussed. Internal controls are the agreed-on methods (for example, a working group or a procedure) by which the NRC mitigates, prevents, or prepares for the risk. Risks discussed at

quarterly performance reviews using enterprise risk management include safety and security issues, new initiatives, financial issues, workplace issues, agency reputation issues, and legal issues. The NRC's ability to achieve its goals depends on a changing mix of industry operating experience, national priorities, market forces, and availability of resources. As part of its Strategic Plan, the NRC identifies significant external factors that are beyond the control of the NRC but could have an impact on the agency's ability to achieve its mission. The NRC continuously updates its regulatory infrastructure to improve its effectiveness and efficiency. Examples include creating centers of expertise, improvements in the backfit process, Project Aim, and the most recent innovation and transformation initiatives. The NRC also has processes to assess the relevance of guidance documents, such as management directives, office instructions, and inspection procedures. The NRC's ability to proactively innovate and its commitment to continuous improvement is essential to the agency's long-term success, which has been acknowledged by external stakeholders and members of the government. Based on the 2010 IAEA IRRS mission recommendations, NRC staff developed a management systems document and as a result staff concluded that the current NRC management system generally meets the intent of the IAEA General Safety Requirements (GSR) Part 2, "Leadership and Management for Safety," and internal controls (e.g., periodic document reviews) allowing the NRC to achieve equivalent results.
Question No. 119
On page 89 it is stated that in the course of the post-mission IRRS (2014) the new proposal was made (NRC should consider the issue of development of the consolidated rulemaking and corresponding guidelines to facilitate well-ordered transition of installations from operation to decommissioning", report IAEA-NS-2014/01, "Post-mission IRRS in the USA". Could you provide additional information on how this proposal is implemented?
Answer: As documented in SECY-15-0014, "Anticipated Schedule and Estimated Resources for a Power Reactor Decommissioning Rulemaking," dated January 30, 2015 (ML15082A089), the NRC staff initiated the decommissioning rulemaking process. One objective of this potential rulemaking would be to provide a more efficient and predictable decommissioning transition process. In addition, the potential rulemaking would support the NRC's Principles of Good Regulation, including openness, clarity, and reliability. The NRC published an advance notice of proposed rulemaking in November 2015. The NRC received 161 public comment submissions, which were considered as part of the development of the regulatory basis for the proposed rule. Subsequently, the NRC staff submitted a proposed rule for Commission review and approval. Should the Commission decide to proceed with this rulemaking, the NRC staff will not provide the draft final rule to the Commission for approval until calendar year 2023, depending on the competing demands on agency decommissioning experts.
Questions Nos. 144 and 149
[Questions 144 and 149 are identical. A consolidated answer is presented below.] (1) How are members of the ACRS and ACMUI committees selected and appointed? (2) How long is their term? (3) Is the NRC directly participating at the working groups of the advisory committees, providing with the views of the NRC staff?

(4)	How do you address at the NRC the situation when a recommendation arising from the ACRS is different than the recommendation coming from the NRC staff (during a license review, for instance)?

Answer: Regarding the Advisory Committee on the Medical Uses of Isotopes (ACMUI):

(1) The members of the ACMUI are selected and appointed by the Director of the Office of Nuclear Material Safety and Safeguards (NMSS) after consultation with the Commission. A summary of the procedures for selecting new members to the ACMUI is as follows:

a. While there are 13 positions on the ACMUI, only 12 positions go through the formal solicitation and appointment process noted below. The U.S. Food and Drug Administration (FDA) representative is selected and appointed by the FDA.

b. A solicitation for nominations is formally announced through the *Federal Register* (FR). The solicitation period is approximately 60 days long.

c. At the end of the solicitation period, a screening panel may be convened. Typically, if there are fewer than five nominees, all nominees may be interviewed.

d. Following the interviews, the NMSS Director recommends a selection to the Commission. If after 10 working days there is no objection from the Commission, the selection is finalized.

e. The selectee does not become an appointed ACMUI member with full voting rights until he or she obtains an employment waiver or full security clearance.

(2) The term of an appointment to the ACMUI is 4 years, and no member may serve more than two consecutive terms (8 consecutive years), unless otherwise authorized by the Commission. The FDA representative does not have a term limit.

(3) While the NRC staff are not members of the ACMUI or ACMUI subcommittees, the ACMUI Coordinator ensures that all activities of the ACMUI are conducted in accordance with the Federal Advisory Committee Act and other applicable rules and regulations. An NRC staff member, typically from the Medical Radiation Safety Team, can be assigned as a point of contact or staff resource to any given ACMUI subcommittee. This staff resource may attend ACMUI subcommittee meetings at the request of the subcommittee and provide clarification and/or responses to questions raised by the subcommittee. The staff resource does not provide the views of the NRC staff, as these could influence the subcommittee's deliberative process.

(4) The ACMUI's independent advice as it relates to the medical use of radioactive material is factored into the NRC's decision-making process. The ACMUI comments on changes to regulations and guidance; evaluates certain nonroutine uses of radioactive material; provides technical assistance in licensing, inspection, and enforcement cases; and brings key issues to the attention of the Commission for appropriate action. In-depth reviews are generally conducted by an ACMUI subcommittee, which is formed to review and evaluate certain topics or documents. When the subcommittee has completed its review, it typically generates a report that contains the subcommittee's recommendations. A public meeting is convened with the full ACMUI to discuss and vote on the subcommittee's recommendations. The ACMUI meetings are generally open to the public (unless the topic falls under of one the categories

to warrant meeting closure) and thus provide an open forum for public participation in the review process.

Once the recommendations have been endorsed through a majority vote by the ACMUI, they are provided to the NRC staff for its consideration. The ACMUI's final recommendations are evaluated by the NRC staff and dispositioned as appropriate. After the staff has dispositioned each recommendation, a formal memorandum is sent to the ACMUI to document the staff's rationale for why a recommendation was accepted, in whole or in part, or disapproved. Additionally, during the semiannual in-person meetings of the ACMUI, the NRC staff provides an update on the status of the ACMUI's recommendations. Approximately 87 percent of the ACMUI's recommendations have been or will be fully implemented by the NRC.

Regarding the Advisory Committee on Reactor Safeguards (ACRS):

(1) The members of the ACRS, or "the Committee," are appointed by the Commission. The ACRS adopts the Commission procedures delineated in a memorandum, as outlined in ACRS bylaws, for selecting new members. The procedures are as follows:

a. The ACRS Executive Director prepares an announcement and a press release for Commission approval and a list of professional societies and technical organizations to which the documents would be sent for the solicitation of nominations. These documents indicate what specific expertise and skills are being sought for the opening. The nomination process considers, and is consistent with, the NRC's Inclusive Diversity Strategic Plan (ML22123A285).

b. A screening panel is convened to review the nominations. This panel will be composed of an Office of the General Counsel senior attorney acting as Chair, the NRC Committee Management Officer, and the ACRS Executive Director, who serves as the Secretary of the panel.

c. The screening panel reviews and rates the nominations. The panel may seek the advice of other individuals whose views may be useful to the screening panel. Specifically, the panel consults with an ethics counselor in the NRC's legal department on matters concerning potential conflicts of interest or prohibited financial holdings. The panel's report lists all the qualified candidates and ranks at least the best qualified candidates. A brief narrative identifies the criteria and rationale for the best qualified rankings.

d. The panel submits a copy of its assessment to the Committee for its independent recommendation on the nominees and submits a memorandum to the Commission. Although not specified in the Commission procedures, the screening panel and the ACRS interview the best qualified candidates, as needed.

e. The Committee submits its selection recommendations to the screening panel and/or the Commission as they see fit. The criteria used by the Committee to evaluate candidates include education and experience, demonstrated skill in nuclear safety matters, the balance of the Committee in relation to the tasks that lie ahead, availability to serve, and possible conflicts of interest.

(2) In accordance with Section 29 of the Atomic Energy Act, the term of an appointment to the Committee is 4 years. The Act does not specify a maximum number of terms.

(3) The NRC staff are not members of the ACRS working groups, but they frequently attend ACRS meetings, make presentations to the Committee and subcommittees, and provide comments, as needed. The ACRS is independent of the NRC staff and reports directly to the Commission, which appoints its members. In-depth reviews are generally done by the appropriate ACRS subcommittees (working groups). Briefings by the representatives of industry and the NRC staff are provided to both the subcommittees and the full Committee. With input from subcommittee members, subcommittee Chairs develop proposed ACRS positions. ACRS positions are developed after extensive deliberations by the full Committee. The ACRS meetings are open to public and thus provide an open forum for public participation in the review process.

(4) The ACRS is structured to provide a forum where experts representing many technical perspectives can provide independent safety advice that is considered in the Commission's decision-making process. During a licensing review, for instance, the NRC staff reviews the license application and supporting documentation. The review results are documented in a safety evaluation report. The license application and the staff's safety evaluation report are then reviewed by the ACRS. The applicant and the NRC staff appear before the ACRS, the former defending the application and the latter the safety evaluation report. When the Committee has completed its safety review, it submits a report to the Commission. At times, the ACRS issues "interim" letters to identify issues of concern and items for which additional information, discussions, and clarifications are needed. The ACRS plays an important role in the licensing process by providing an independent review of the NRC staff's determination of compliance with the applicable standards and requirements of the Atomic Energy Act and the Commission's regulations. The ACRS may identify many technical issues during its review process that are largely resolved before the Committee provides its final recommendations on the licensing action.

Questions Nos. 150 and 154

[Questions 150 and 154 are identical. A consolidated answer is presented below.]

(1) Is mentoring formalized in any way or is it just a practical arrangement during the new staff's training process?

(2) Could you please share any relevant example of mentoring experience/s within the training and development process?

(3) How are the retiring staff willing to collaborate in these type of initiatives?

Answer:
(1) The NRC encourages all employees to participate in and seek mentoring. NRC employees may discuss their career goals and aspirations with experienced NRC employees who volunteer to serve as mentors on a one-to-one basis. Additionally, a skill-based mentoring program is currently being piloted in the NRC's Office of Nuclear Material Safety and Safeguards, which provides employees an opportunity to broaden or develop specific skills and competencies needed for their job by working with fellow employees who have volunteered to share their expertise and knowledge as a skill-based mentor. Employees, or "Learners," spend time developing new skills by job shadowing, practicing new skills, receiving coaching, etc. Skill-based mentors also gain competencies by sharing their knowledge and expertise while developing leadership and coaching skills. The expected outcome is that both learners and skill-based mentors will gain proficiencies while accessing broader organizational perspectives and forming new professional relationships across

functional areas. Based on the results of the pilot, the agency will determine if the program will be expanded to other offices.

(2) The NRC has several examples, which include the following:

- The Administrative Assistants Qualification Program is designed to assist new or existing administrative assistants in fulfilling the requirements of their position. Participants are assigned a mentor to accomplish the on-the-job requirements of the program.

- The Aspiring Leaders Program is a noncompetitive NRC leadership development program open to senior staff, designed to develop their career as future supervisors. Individuals participating in the program are required to have a mentor.

- In the Senior Executive Service Candidate Development Program, candidates work with a senior executive advisor who provides advice and career mentoring.

- The Nuclear Regulator Apprenticeship Network is a development program for entry-level engineers and scientists. Mentoring will be incorporated as part of the program.

(3) The NRC has a variety of ways to engage retiring staff to transfer knowledge before they permanently leave the agency. For example, the NRC participates in the U.S. Federal government's phased retirement program (https://www.opm.gov/retirement-services/phased-retirement/), which allows retirement-eligible Federal employees to request partial retirement while continuing to work part time to ensure continuity of operations and facilitate knowledge management. Employees on phased retirement must focus a substantial portion of their time—at least 20 percent—on mentoring, training, or other knowledge management functions. The NRC's intent is to be proactive with knowledge management strategies and capture information before it is lost. One of the main goals for the NRC's Knowledge Management (KM) Program is to operationalize knowledge management and integrate it into the agency's everyday conduct of business, including mentoring (formal/informal), communities of practice, lessons-learned program, video capture, and job aids. Each office has a knowledge management plan that outlines the best approach to meet their organizational needs and desired outcomes to capture and transfer key knowledge among employees.

Question No. 170

Section 2.3.1.4 states that the NRC has reduced its total number of full time equivalent employees by 800 since 2011.

(1) How many full time equivalent employees does the NRC have now?

(2) How does NRC ensure that its current and future staffing levels are adequate?

Answer:
(1) The NRC's fiscal year (FY) 2020 budget includes funds for 2,928 full-time equivalent (FTE). As of December 7, 2019, there are 2,858 staff on board, which equates to 2,776 FTE due to various flexible work schedules.

(2) The NRC uses it is enhanced Strategic Workforce Planning process to identify appropriate staffing levels based on projected workload. In addition, agency staffing levels and workload

fluctuations are discussed in a variety of forums throughout the year to address fact-of-life changes. This includes senior leadership meetings, periodic Human Capital Council meetings, and quarterly performance management meetings. Additionally, Commission meetings focused on topics such as human capital, equal employment opportunity, and affirmative employment are held throughout the year.

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 ROP, 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. 5
The [U.S. 8th National] Report states that the NRC enforcement process involves the opportunity to participate in the "Alternative Dispute Resolution Program". In the context of this program, mediation is used. Mediation is a technique in which a neutral mediator with no decisionmaking authority helps parties to clarify issues, explore settlement options, and evaluate how best to advance their respective interests. Switzerland is interested to better understand the Alternative Dispute Resolution Program. For example, how does the NRC justify to the public that safety issues are processed using the Alternative Dispute Program? What arguments does the NRC use to convince the public, and in particular the opponents of nuclear energy, that safety issues are complex and, in part, can only be answered after intense confrontation with all the parties involved? How does the NRC justify in front of the before mentioned parties the implementation of this program with its independence of the licensee and of any other body and, that it is free from any undue pressure from interested parties (see IAEA, Safety Fundamentals No. SF-1, p. 8), respectively?
<u>Answer</u>: In 1996, though the Administrative Dispute Resolution Act, Congress directed all governmental departments and agencies to use alternative means to resolve disputes. Because of that directive, alternative dispute resolution was integrated into the NRC Enforcement Program in 2004 (Commission Policy, SECY-04-0044). The Alternative Dispute Resolution Program was expanded in 2015 (SECY-14-0077) and is now applicable to willful and discrimination cases after an investigation, as well as to traditional enforcement cases with the potential of a civil penalty. The program uses mediation to gain an understanding of each parties' interest, clarify issues, and explore innovative ways to address the underlying issues of both parties to reach a mutually agreeable settlement. Typically, a neutral expert mediator fosters reaching a mutually agreeable settlement between parties. One of the longstanding goals of the NRC's Enforcement Program is to encourage the regulated community to complete prompt and comprehensive corrective actions. As part of the Enforcement Program framework, NRC regulations require, at a minimum, that the regulated community subjected to escalated enforcement actions complete corrective actions sufficient to address the apparent cause. The Alternative Dispute Resolution Program is a tool used to achieve mutually agreeable terms that result in more broad and comprehensive actions to address the underlying complex technical and safety issues than would have been achieved under traditional enforcement approaches. Both parties enter the mediation process voluntarily and with their own set of interests, and both agree to sign confidentiality agreements, so information shared cannot be used for other purposes. Mediations are held

between the NRC and the licensee confidentially, to encourage frank discussion that is more effective in reaching settlements, and specifically to prevent undue pressure from interested parties. Also, before going into mediations, the NRC solicits input from the allegers who identified discrimination concerns about what corrective actions they would recommend. The actions resulting from enforcement alternative dispute resolution further address the NRC's interests to include both deterrence and prompt, comprehensive correction of violations, greater than the actions required by the other NRC oversight processes and enforcement tools alone e.g., the traditional enforcement process with notice of violation, civil penalty, etc.). Producing more timely and effective outcomes for both the NRC and the regulated community has shown to be more effective than the sole issuance of notices of violation and civil penalties under the traditional enforcement process. For example, under the traditional enforcement process, the regulated community are required to complete corrective actions to address the issue only at the applicable site or facility. However, under the enforcement alternative dispute resolution program, the regulated community have completed corrective actions that have applied across their multiple sites and facilities, not just the site where the violation occurred. Further, the NRC makes publicly available the results of mediations as a confirmatory order and frequently issues an associated press release to further highlight the NRC's enforcement actions.
Question No. 31
How are enforcement actions attributed to the operation of a reactor facility that has been certified fe[e]d back to the status of the design certification?
Answer: The NRC has had limited experience with design certification holders and combined licenses that reference approved design certifications. However, if operating or enforcement experience would reveal a need to amend an approved design certification, the NRC could initiate a rulemaking to revise an approved design certification.
Question No. 32
The US NRC's ability to issue an order to unlicensed vendors is a good practice to mitigate counterfeit, fraudulent or suspect goods and services.
Answer: Thank you for your comments and observations. We appreciate the positive feedback.
Question No. 94
Articles and aspects related to individual license holders, are answered by the licensee Institute of Nuclear Power Operations (INPO), an institute supporting the U.S. nuclear industry. While this provides for efficiency in a CP [contracting party] with a large number of operating nuclear reactors, there is also a risk of making the licensee input to the NR [National Report] too generic, which is also sometimes the impression. Is this a risk that has been discussed in the process of preparing the NR, and what measures have been taken to make the report sufficiently specific when it comes to relevant experience from specific licensees?
Answer: The NRC is an independent regulatory agency that ensures that the civilian use of nuclear energy and materials in the United States are conducted with proper regard for public health and safety, national security, and environmental concerns. As such, the NRC is the lead for ensuring compliance with the principles of the CNS. The NRC addresses all the articles of the CNS in Parts 1 and 2 of the U.S. 8th National Report. INPO explains how the nuclear industry maintains and improves nuclear safety in Part 3. Part 3 is considered supplementary to the NRC's discussion.

The NRC provides regulatory oversight to 99 operating reactors (not including reactors under decommissioning). Thus, it is impracticable to address the CNS principles in the U.S. 8th National Report in more detail because the number of pages would significantly increase. The NRC has carefully evaluated this matter and has concluded that a change (for example, reporting at a plant or fleet level) will result in an onerous peer review process and will significantly increase the resources needed to develop a national report of this nature. The NRC makes every effort to strike a balance and ensure that the report includes a summary of the most relevant safety and regulatory issues encountered in the current CNS cycle. This summary is included in Part 1, section 2 of the U.S. 8th National Report.

It is well recognized that the NRC has a long history of, and commitment to, openness with the public and transparency in the regulatory process. The agency's goal to ensure openness explicitly recognizes that the public must be informed about, and have a reasonable opportunity to participate meaningfully in, the regulatory process. Although the NRC is unable to address all individual or plant-specific experience in the U.S. 8th National Report, information about events, such as event reports and reports of defects and noncompliance, are available on the NRC public website at https://www.nrc.gov/reading-rm/doc-collections/event-status/. The NRC also publishes all plant inspection reports (https://www.nrc.gov/reactors/operating/oversight/listofrpts-body.html), plant performance indicators (https://www.nrc.gov/reactors/operating/oversight/pi-summary.html), and plant summaries (https://www.nrc.gov/reactors/operating/oversight/plant-by-plant-summaries.html) on its public website. Finally, the NRC regularly submits events to the IAEA International Reporting System for Operating Experience database.

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 NRC takes to fulfilling its mission. The NRC has several policy statements that describe the Commission's perspective on nuclear safety (e.g., probabilistic risk assessment 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 nuclear safety at nuclear installations.

Question No. 6
The report lists the traits of a positive safety culture the NRC has identified. Switzerland also regards these traits as important elements for describing a good safety culture. However, it is a challenge for the regulator to monitor some of these traits (e.g. leadership or respectful work enviro[n]ment) in the licensee's organization. Could you give some insights on how the NRC is monitoring these more delicate but [nevertheless] extremely effective (de-) motivators for a good safety performance of the workforce.
<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 provide a more behavior-based description of each of the safety culture traits. These attributes can be found in NUREG-2165, "Safety Culture Common Language," issued March 2014 (ML14083A200). Inspectors use these attributes within the NRC's ROP (specifically, the cross-cutting issues) to determine whether inspection findings have cross-cutting causal factors related to safety culture. The safety culture attributes are referred to as cross-cutting aspects. IMC 0310, "Aspects within the Cross Cutting Areas," gives a crosswalk between the cross-cutting aspects and safety culture traits and attributes (ML19011A360). The NRC decided not to include attributes of a "respectful work environment" within the cross-cutting issues because they appeared to be less directly related to the NRC's regulatory responsibilities. However, these attributes are indirectly included to the extent that disrespect in the workplace may negatively impact the environment for raising concerns or other safety culture traits.
Question No. 47
It is mentioned that 'there are no regulatory requirements for licensees to perform safety culture assessments routinely. However, depending on the extent of deterioration of licensee performance, the NRC has a range of options to address performance. This is carried out through enhanced reactor oversight process as part of Inspection programme. This inspection and oversight process is based on the findings of the voluntary safety culture assessment process.' Could NRC elaborate on how the safety culture inputs are obtained from the licensees where voluntary safety culture assessments have not been carried out?
<u>Answer</u>: The NRC maintains an awareness of safety culture at licensee facilities on an ongoing basis through the ROP inspections and evaluation of cross-cutting issues. The NRC can also obtain safety culture insights through the NRC's Allegation Program, such as when there are allegations of a chilled work environment. The NRC performs graded independent safety culture assessments when licensee performance deteriorates to the point that thresholds are exceeded in the ROP (refer to IP 95003 (ML15188A400)). When licensees have performed their own independent safety culture assessments, those results are

considered by the NRC inspection team. The validity of those results influences whether the NRC team expends more or less resources on their own independent assessment. If a licensee has not performed a safety culture assessment or the assessment lacks a sound methodology, then the NRC inspection team will increase their level of effort to perform an independent assessment. An NRC safety culture assessment involves performing document reviews, behavioral observations, interviews, and focus groups using the traits of a positive safety culture as a framework for deriving conclusions about the licensee's safety culture.
Question No. 48
It is said that, on significant performance decline of licensee, NRC may ask licensee to complete an independent assessment of its safety culture and with more significant performance degradation, NRC expects that the licensee will conduct a third-party independent assessment of its safety culture. Could the USA share more information on the differences between the 'independent assessment' and the 'third-party independent assessment'?
<u>Answer</u>: NUREG-2165 describes a comprehensive evaluation of the assembly of characteristics and attitudes related to all of the safety culture attributes. Individuals performing the evaluation can be qualified through experience and formal training. The difference between an independent assessment and third-party assessment is as follows: (1) An independent safety culture assessment is performed by qualified individuals who have no direct authority and have not been responsible for any of the areas being evaluated (for example, staff from another of the licensee's facilities, or corporate staff who have no direct authority or direct responsibility for the areas being evaluated). (2) A third-party safety culture assessment is performed by qualified individuals who are not members of the licensee's organization or utility operators of the plant. Also, the licensee's team liaison and support activities do not constitute team membership.
Question No. 82
Could the USA explain how the Nuclear Regulatory Commission NRC evaluates and ensures that all individuals in its staff present a good personal accountability and are in the best conditions for that?
<u>Answer</u>: Accountability is one of the safety culture traits included in the NRC's Safety Culture Policy Statement (76 FR 34773; June 14, 2011). This Safety Culture Policy Statement sets forth the Commission's expectations of licensees and certificate holders with respect to a healthy safety culture. NRC licensees and certificate holders are expected to inculcate healthy safety culture behaviors into their own organizations. Although the NRC does not directly regulate safety culture or individual safety traits, the NRC inspection program allows for dialogue with licensees and considers safety culture behaviors listed in NUREG-2165 during inspection activities through the NRC's ROP. This would allow for increased inspection in the event a licensee has degraded performance under regulated activities that include safety culture aspects in the cross-cutting areas of the ROP. Similarly, at the NRC, the agency is responsible for establishing a culture where traditional ways of doing things can be challenged and an environment where employees feel that it is "safe to speak up" is encouraged. Trust, respect, and open communication promote a positive work environment that maximizes the potential of all individual staff members and improves the agency's regulatory decision-making. Furthermore, open communication facilitates the discussion of safety issues and strengthens trust within the agency. The NRC recognizes that in a trusting organization, employees will be more willing to accept opportunities for growth

and take smart risks. To that end, the NRC expects all employees to promptly raise differing views, fairly consider the opinions of others, and demonstrate respect to their fellow employees. Additionally, the NRC periodically evaluates and provides supplemental employee resources that serve to strengthen a climate of trust and accountability and the agency's Leadership Model. The NRC's Leadership Model explicitly defines the expectation that everyone is a leader and was developed to provide a roadmap to communicate, in one place, how the NRC staff individually and collectively demonstrate leadership in fulfilling the NRC mission. Its main purpose is to better communicate the NRC's values, fundamental behaviors, key programs and processes, vision, and Principles of Good Regulation. These elements of the Leadership Model make up the NRC's culture and help the agency to achieve its mission. The Leadership Model also describes the NRC programs and activities that contribute to, implement, and allow the staff to hold each other accountable for the concepts and ideals in the Leadership Model. Additional information can be found on the NRC's public website at https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0529/.
Question No. 116
What achievements are in the study PSA-3 [probabilistic safety assessment Level 3]. What difficulties were faced when it was produced?
Answer: Since the NRC's Level 3 PRA project is still ongoing, the agency cannot provide a comprehensive assessment of achievements and lessons learned. A notable challenge to completion of the study has been the reassignment of key project personnel to other, higher-priority assignments. Another significant challenge, which is to be expected with a project of this scope (and duration), is maintaining consistency in modeling approaches and assumptions throughout the different parts of the project. To date, all of the reports prepared for the full-scope, site Level 3 PRA project are for internal use only, due to the extensive amount of information included in them that is proprietary to the reference plant. However, multiple technical reports have been completed, and work continues in key areas. Additional information on the NRC's Level 3 PRA project is available on the NRC public website at https://www.nrc.gov/about-nrc/regulatory/research/level3-pra-project.html.
Question No. 134
The NRC uses Human Factors Information System (HFIS) to support analysis of human performance or safety culture issues. (1) Is there any reason why the individual nuclear power plant's information provided in NRC HFIS web site end in 2011? (2) The NRC is updating the database to include data with a safety culture perspective. Would it be possible to give more detailed explanation on the scope and method for updating the database? For instance, is the update aimed at making the consistent categorization of CCAs [cross-cutting areas] listed in IMC 0310? Is it intended to re-use or re-analyze the existing databases in the HFIS considering safety culture aspects?
Answer: (1) Availability of resources and a change to the data coding structure resulted in a decision to no longer post reports to the HFIS after 2011. The staff continued to track and analyze human factors-related operating experience and pursued alternative approaches to gathering and analyzing the data. Analyses of the HFIS data continue to be publicly available through

specific requests submitted at https://www.nrc.gov/reactors/operating/ops-experience/human-factors.html.

(2) The staff is evaluating INPO's Industry Reporting and Information System (IRIS) as the primary source of human factors and safety culture operating experience. The NRC's Office of Nuclear Reactor Regulation has requested that the Office of Nuclear Regulatory Research examine the data display and analysis capabilities of IRIS and explore the types of analyses the NRC can conduct that best support the agency's oversight activities.

Question No. 140

As of December 2019, how many human factors specialists and safety culture assessors are working at the NRC, and in which departments (branches) are they working?

Answer: The NRC's functions concerning human and organizational factors are principally performed by personnel in the following branches.

Within the NRC's Office of Nuclear Reactor Regulation:

- The Operator Licensing and Human Factors Branch (Division of Reactor Oversight) ensures human factors engineering principles are appropriately applied to both new reactor designs and operating reactors. Staff in this branch serve as technical experts for the review of license amendment requests; development of associated rules, standards, and guidance; and the conduct of inspections and audits concerning human and organizational factors. The staff also has responsibility for establishing rules, standards, plans, and policy in the areas of training and operator licensing.

- The Reactor Assessment Branch (Division of Reactor Oversight) gives inspection support for the evaluation of the effectiveness of safety culture programs at operating nuclear power plants. Safety culture activities are matrixed throughout the NRC. Regional and headquarters inspectors coordinate to conduct safety culture inspections and to review safety culture-related events.

- The PRA Oversight Branch (Division of Risk Assessment) is responsible for conducting risk analyses, including human reliability analysis, in support of agency risk-informed decision-making, such as the NRC's significance determination process, and for improving the infrastructure and tools necessary for the agency to continue to make effective, risk-informed decisions.

Within the NRC's Office of Enforcement:

- The Concerns Resolution Branch is responsible for the NRC's safety culture program. NRC Staff responsibilities include the development of safety culture policy and outreach materials.

Within the NRC's Office of Nuclear Regulatory Research:

- The Human Factors and Reliability Branch (Division of Risk Analysis) plans, develops, and manages research programs related to human performance, personnel security, and human reliability analysis. The staff identifies and assesses potential human performance safety and security issues and provides safety perspectives on the impact of human performance on nuclear power plants and other NRC-licensed facilities and their regulated activities.

Within the NRC's Office of the Chief Human Capital Officer

- The Learning and Talent Development Branch also supports efforts to promote the NRC's internal safety culture and the analyses of the results of employee surveys and recommends effective strategies for action.

The NRC employs a multidisciplinary approach to its regulatory activities concerning human and organizational factors to bring together perspectives from both the social and physical sciences. In general, staff members possess a bachelor's degree or higher in psychology, sociology, industrial engineering, or other engineering disciplines. The staff also typically has specialized training and experience in one or more of the following areas: human factors engineering, cognitive psychology, organizational psychology, training development, plant operations, reactor systems, and human reliability analysis. Approximately 15 staff members at the NRC principally work on matters concerning human and organizational factors.

Question No. 142

The NRC has recently established a new format for inspection reports that will allow NRC inspectors to automatically generate online inspection reports.

(1) Does the software application available also for review and modification process? Are the review and modification records are tracked and managed automatically?

(2) Does the software application covers every kind of inspection reports? (e.g. baseline inspection, supplemental inspection, augmented inspection, special inspection, follow-up inspection, event investigation reports, etc.)

Answer:
(1) The software application (known as RPS-Inspections) is under continuous review and modification. All system issues and identified enhancements are tracked for resolution. The NRC has implemented an agile software development process that results in system changes and upgrades being introduced in 2-week increments. All system changes and suggested enhancements are reviewed and prioritized monthly by the RPS-Inspections Configuration Control Board. The changes and enhancements get final approval by the RPS Executive Configuration Control Board, which is controlled by the NRC's Office of the Chief Information Officer, and are scheduled for implementation. The inspection report software allows for review and modification and keeps track of all persons who edit, review, and approve the report.

(2) At this time, the software application does not cover every kind of inspection report. It does accommodate the generation of almost all of the NRC's common and frequently issued operating reactor inspection reports, including baseline inspection and some supplemental inspections (IP 95001 and IP 95002). Some of the more complex reports (supplemental inspection IP 95003 and reactive inspections) are not generated using the application and are created using the NRC's previous methods described in IMC 0611, "Power Reactor Inspection Reports" (ML17150A030). During the software design phase, it was determined that due to the unique nature and complexity of those reports (augmented inspection, special inspection, followup inspection, event investigation reports), it would be best to create them in the manner the NRC had previously been using. Also, due to the small number of these reports issued in a given year, it was not cost effective to try to get the software to handle every type of operating reactor inspection report that can be created.

Question No. 157
The text Describes key components of NRC's safety culture. The multiple ways for employees and contractors to raise mission-related concerns and differing views is interesting that are the experiences and benefits of the three-tier process for raising concerns? How often the Differing Professional Opinion Program is utilised? Do you analyse from safety culture point of view why/how this process is utilised?
Answer: The three-tier process allows the NRC to have a defined process for raising differing views at all stages of decision-making. The Open Door Policy can be used at any time for any staff member to meet with any supervisor at the agency to discuss their concern. The Non-Concurrence Process allows staff members who are involved in creating or reviewing a draft document to formally notify management of their differing view and inform the decision-making process. If requested, management provides a written response to document the rationale for the decision. The Differing Professional Opinion Program allows any staff member to raise a differing view about an established NRC technical, legal, or policy position. The process includes a review by knowledgeable experts and a written response by the decision-maker. Since the Differing Professional Opinion Program was established in 2005, 49 differing professional opinions have been accepted into the program. Feedback from two workforce surveys—the Office of Personnel Management's Federal Employee Viewpoint Survey and the NRC's Office of the Inspector General Safety Culture Climate Survey—and periodic assessments of the Non-Concurrence Process and Differing Professional Opinion Program are used to measure employee perceptions of the work environment and willingness to raise a differing view. When possible, NRC staff identifies and implements recommendations for process improvements to the Non-Concurrence Process and Differing Professional Opinion Program in an effort to continuously improve safety culture.

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. 43
Article 11 requires CPs [contracting parties] to take appropriate steps to ensure that sufficient numbers of qualified staff with appropriate education, training, etc., are available for all safety-related activities. Section 11.2 provides information on the regulatory requirements for training and qualification of staff. What are the legislative requirements and regulatory processes in place to ensure that licensees provide sufficient numbers of qualified staff to discharge their duties?
<u>Answer</u>: The NRC requires licensees to have sufficient numbers of qualified staff for safety-related activities through regulatory requirements, plant-specific licensing, and oversight activities. In 10 CFR 50.34(b)(6)(i) and 10 CFR 52.79(a)(26), the NRC requires that each application for a license to operate a nuclear power plant include information about the applicant’s organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements. The NRC reviews the application to ensure that the licensee has sufficient numbers of qualified staff for safety-related activities before the NRC issues the license. Finally, the NRC performs routine inspections to ensure that licensees maintain staffing necessary to perform safety-related activities per regulations and facility license requirements.
Question No. 69
Are there any specific provisions for making sure that financing of safety improvements to NPPs over its lifetime is available?
<u>Answer</u>: No. There are no specific regulatory provisions for ensuring availability of funds for safety improvements to nuclear power plants during operations. During operations, improvements to facilities (including safety improvements) are considered to be ongoing operational costs. While funding of operational costs does not fall within NRC oversight after initial licensing, the NRC continues to monitor the plant over its lifetime for safe and secure operation. Should safety improvements be required to meet NRC regulations or the facility license, it is the licensee’s responsibility to secure the funding for the action. Additionally, if the NRC identifies an adequate protection safety concern, it is the licensee’s responsibility to address that concern. As described in 10 CFR 50.109, “Backfitting,” facility modifications necessary to bring a facility into compliance or associated with adequate protection concerns are not required to be cost justifiable, but if there are multiple ways to resolve the concern, then cost may be a consideration in selecting a resolution approach.

Question No. 80

Construction Permit Reviews Challenge 3 The paragraph 11.1.1.1 describe conditions for construction permit "as required by 10 CFR 50.33(f)(1), applicants for construction permits must submit information that "demonstrates that the applicant possesses or has reasonable assurance of obtaining the funds necessary to cover estimated construction costs and related fuel cycle costs." Appendix C, "A Guide for the Financial Data and Related Information Required to Establish Financial Qualifications for Construction Permits and Combined Licenses," to 10 CFR Part 50 provides more specific directions for evaluating the financial qualifications of applicants."

What are the mitigation measures imposed by the US Regulatory Body to prevent the situation with the construction fail of Westinghouse Electric Co (i.e. Toshiba) during the construction of the NPP´s in Georgia (Vogtle 3 and 4) as well as in South Carolina, which led to the costs overruns?

Answer: There are no NRC regulations designed to prevent a licensee from failing to complete construction of a commercial nuclear power plant. Applicants for nuclear power plant construction permits are required by regulation to provide the information necessary to establish reasonable assurance of obtaining funding to cover estimated construction and fuel load costs. If, during the construction of a facility (and prior to initial fuel load), a licensee encounters adverse economic factors (such as cost overruns), it is a business decision on whether to continue construction and, if so, secure the necessary funding.

Question No. 132

(1) In the case of plants under permanent shutdown and decommissioning, the annual report (similar to the decommissioning funding status report) submitted to NRC should include the amount used and the amount to be used in the future. In this case, we wonder if the first estimated budget will be recalculated reflecting the amount spent, or will the original estimate remain without any change as the project proceeds?

(2) As far as we know, the U.S prepares the trust funding for decommissioning. How do you preserve the monetary value of this budget? (For instance, do you apply interest rates or put the certain amount of money additionally each year?)

Answer:
(1) Per requirements in 10 CFR 50.82(a)(8)(v), a power plant licensee that is in decommissioning is required to report the following information annually, through the end of the previous calendar year:

- the amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon

- an estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based

- any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report

- any material changes to trust agreements or financial assurance contracts

(2) For clarification, the U.S. government does not fund, prepare, or manage the decommissioning trust funds. By regulation, the NRC is responsible for ensuring licensees properly establish and fund their trust accounts per the requirements in 10 CFR 50.75, “Reporting and recordkeeping for decommissioning planning.” The NRC allows licensees to assume a 2 percent real rate of return on trust fund growth. Licensees maintain these assets separate from their own assets and outside their administrative control. Certain licensees have the ability, if they choose, to make annual contributions to their trust fund to meet the requirements of 10 CFR 50.75.
Question No. 139
The importance of managing “Human and Organizational Factors (HOF)” is increasing to ensure safe operation of nuclear power plant. Please provide detailed explanation regarding operating plants: (1) Roles of the regulator in ensuring safety management of HOF; (2) HOF under the scope of regulation (human performance program, training, fatigue management, organizational change management, etc.); (3) Departments (branches, teams, groups, etc.) of the regulatory organization responsible for HOF verification (inspection and assessment); (4) Number and qualifications of those regulators working on HOF verification/inspection/assessment.
<u>Answer</u>: (1) NRC licensees have primary responsibility for safe operation of nuclear facilities. The NRC provides assurance of nuclear power plant operational safety through a risk-informed, performance-based regulatory framework. Human and organizational factors, as they relate to plant operational safety, are addressed as an integral part of NRC’s licensing and oversight activities. Licensing activities for nuclear power plants include, but are not limited to, reviews of applications for reactor design certification and requests for operating reactor license amendments. Human and organizational factors are primarily addressed in these review activities through application of the guidance in NUREG-0800, Chapter 13, “Conduct of Operations,” and Chapter 18, “Human Factors Engineering.” The NRC’s principal means of oversight are the inspections it conducts under the ROP. Inspections, in conjunction with performance indicators, provide a means to monitor and assess licensee performance, including assessing performance relative to the cross-cutting areas of human performance and a safety-conscious work environment. The NRC also addresses human and organizational factors through its oversight activities related to the training, licensing, and requalification of operators. (2) The NRC addresses human and organizational factors, as they relate to safety, though several different regulatory requirements. Examples include the following: • control room design in 10 CFR 50.34(f)(2)(iii) • onsite minimum staffing in 10 CFR 50.54(k), (l), and (m) • operator licensing in 10 CFR Part 55, “Operators’ Licenses” • training and qualification in 10 CFR 50.120, “Training and qualification of nuclear power plant personnel” • fitness for duty in 10 CFR Part 26, “Fitness for Duty Programs”

- organization in 10 CFR 50.34(a)(6)

(3) The NRC's functions concerning human and organizational factors are principally performed by personnel in the following branches:

Within the NRC's Office of Nuclear Reactor Regulation:

- The Operator Licensing and Human Factors Branch (Division of Reactor Oversight) ensures human factors engineering principles are appropriately applied to both new reactor designs and operating reactors. Staff in this branch serve as technical experts for the review of license amendment requests; development of associated rules, standards, and guidance; and the conduct of inspections and audits concerning human and organizational factors. The staff also has responsibility for establishing rules, standards, plans, and policy in the areas of training and operator licensing.

- The Reactor Assessment Branch (Division of Reactor Oversight) gives inspection support for the evaluation of the effectiveness of safety culture programs at operating nuclear power plants. Safety culture activities are matrixed throughout the NRC. Regional and headquarters inspectors coordinate to conduct safety culture inspections and to review safety culture-related events.

- The PRA Oversight Branch (Division of Risk Assessment) is responsible for conducting risk analyses, including human reliability analysis, in support of agency risk-informed decision-making, such as the NRC's significance determination process, and for improving the infrastructure and tools necessary for the agency to continue to make effective, risk-informed decisions.

Within the NRC's Office of Enforcement:

- The Concerns Resolution Branch is responsible for the NRC's safety culture program. Staff responsibilities include the development of safety culture policy and outreach materials.

Within the NRC's Office of Nuclear Regulatory Research:

- The Human Factors and Reliability Branch (Division of Risk Analysis) plans, develops, and manages research programs related to human performance, personnel security, and human reliability analysis. The staff identifies and assesses potential human performance safety and security issues and provides safety perspectives on the impact of human performance on nuclear power plants and other NRC-licensed facilities and their regulated activities.

Within the NRC's Office of the Chief Human Capital Officer:

- The Learning and Talent Development Branch support efforts to promote the NRC's internal safety culture and the analyses of the results of employee surveys and recommends effective strategies for action.

(4) The NRC employs a multidisciplinary approach to its regulatory activities concerning human and organizational factors to bring together perspectives from both the social and

physical sciences. In general, staff members possess a bachelor’s degree or higher in psychology, sociology, industrial engineering, or other engineering disciplines. The staff also typically has specialized training and experience in one or more of the following areas: human factors engineering, cognitive psychology, organizational psychology, training development, plant operations, reactor systems, and human reliability analysis. Approximately 15 staff members at the NRC principally work on matters concerning human and organizational factors.

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 ROP and how feedback and experience in human factors is considered in the regulatory program.

Question No. 13
What is the cause of increase in a number of deviations in the area of fatigue management from 5.5 for 61 facilities in 2015 up to 211 for 54 facilities in 2017 and 253 for 58 facilities in 2018?
Answer: The value in the question for 2015 is the average number of deviations per facility, rather than the total number of deviations that are referenced for 2017 and 2018. In 2015, there was an average of 5.5 deviations per facility. In 2017, there were a total of 211 deviations from 54 facilities, resulting in an average of approximately 3.9 per facility. In 2018, the total of 253 deviations from 58 facilities resulted in an average of approximately 4.4 deviations per facility. These figures show a relatively stable level of deviations since 2015.
Question No. 130
With reference to Article 12, page 122~123 of the United States of America national report, it is stated that the events at Fukushima Dai-ichi in March 2011 highlighted the need for power reactor licensees to have strategies for responding to beyond-design-basis external events (BDBEE) affecting one or more units at a site. And the nuclear industry proposed regulatory guidance (e.g., Diverse and Flexible Mitigation Strategies (FLEX)) endorsed by the NRC, which outlines an approach for developing the mitigation strategies against beyond-design-basis external events. With respect to the information provided in the article in question, Korea would like to inquire the following questions: (1) Is there any plan to revise the current regulatory documents related to human factors (e.g., NUREG-0711) to systematically address human performance issues in the development and implementation of the BDBEE mitigation strategy? (2) Are there any regulatory documents which describe specific requirements to systematically address human performance issues in the development and implementation of the mitigation strategy against the simultaneous accidents of multiple units? (3) Does the USA have regulatory experiences dealing with the multiple simultaneous accidents? If yes, how did the USA evaluate and validate the simultaneous accidents of multiple units? (e.g., selection of power plant site, validation methods, scenarios, the scope of participants and facilities, the assumptions for the evaluation).
Answer: (1) NUREG-0711, Revision 3, “Human Factors Engineering Program Review Model,” (ML12285A131) currently includes guidance that addresses beyond-design-basis events among the plant conditions to be considered for the sampling of operational conditions in

verification and validation evaluations. The NRC does not currently plan to revise NUREG-0711 to more specifically address beyond-design-basis external events. However, the NRC has developed a human reliability assessment method and computerized tool, IDHEAS – Event and Condition Analysis (ECA), and is evaluating the ECA tool for a range of ways that licensees are using FLEX equipment and implementing FLEX strategies, including for beyond-design-basis events.

(2) The NRC's final rule at 10 CFR 50.155, "Mitigation of beyond-design-basis events," became effective September 9, 2019. Through this rulemaking, the NRC made generically applicable the requirements in NRC orders for mitigation of beyond-design-basis events and for reliable spent fuel pool instrumentation. The NRC's Mitigation Strategies Order, issued March 12, 2012, required all U.S. nuclear power plant licensees to have additional capability to mitigate beyond-design-basis external events through the implementation of strategies and guidelines that enable them to cope without their permanently installed ac electrical power sources for an indefinite period of time. This order addressed portions of the NRC's Near-Term Task Force (NTTF) recommendation 9, to require that facility emergency plans address prolonged station blackouts and multiunit events, and portions of NTTF recommendation 10, to pursue additional emergency protection topics related to multiunit events and prolonged station blackouts.

The NRC gives implementation guidance for 10 CFR 50.155, in part, in RG 1.226, "Flexible Mitigation Strategies for Beyond-Design-Basis Events" (ML19058A012). This regulatory guide endorses, with clarifications, the methods and procedures promulgated by the Nuclear Energy Institute (NEI) in technical document NEI 12-06, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide," Revision 4, issued December 2016, as a process the NRC considers acceptable for meeting, in part, the regulations at 10 CFR 50.155. NEI 12-06, Revision 4, includes guidance in appendix E, "Validation Guidance," that describes a process that may be used by licensees to reasonably assure required tasks, manual actions, and decisions for FLEX strategies are feasible and may be executed within identified time constraints.

(3) The NRC has regulatory experience dealing with serious degradation and equipment failures affecting multiple units simultaneously, such as the following examples:

- The 5.8 magnitude earthquake at the North Anna Power Station in 2011. This was a design-basis earthquake affecting both units that exceeded the ground motion for some levels for which the plant was originally licensed, although no core damage resulted.

- The Browns Ferry Nuclear Plant fire in 1975. This was a more severe event that caused significant damage to approximately 1,600 electrical cables that control Units 1 and 2. Unit 1 lost all the emergency core cooling systems and the ability to monitor power from the control room. However, there was no core damage due to actions taken by the operators.

- A loss of offsite power during mid-loop operations event in the Vogtle Electric Generating Plant in 1990. Both units were affected, with Unit 2 stabilizing in a safe shutdown condition, but Unit 1 remained in a high-risk situation because the unit was in a mid-loop condition, with an open containment and ongoing maintenance activities, that substantially increased the risk.

All of these events resulted in the agency revising its requirements or guidance to address either design weaknesses, such as (a) adequate train separation and the evaluation of fire hazards that resulted in the creation of 10 CFR Part 50, Appendix R, "Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979" (in the case of Browns Ferry), (b) updating the NRC's seismic hazard data and models and methods for analyzing earthquake hazards (in the case of the North Anna earthquake), and (c) recognizing the need to create shutdown risk guidance for licensees who may be in high-risk situations, such as mid-loop conditions (in the case of Vogtle).

Typically, when such an event occurs, the NRC conducts an agencywide review of the event, develops lessons learned for both the agency and industry, reviews the adequacy of existing requirements and guidance, including changes to inspection programs and procedures, and develops risk profiles and insights to prioritize generic actions in accordance with its risk significance. To share the information in a timely fashion in such instances, the NRC may issue applicable generic communications, such as a generic letter, bulletin, or regulatory issue summary, when the agency requires a response from the industry, as well as any applicable information notices. The NRC's Office of Nuclear Regulatory Research may undertake longer-term studies to review the event to determine if additional agency action may be warranted.

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. 81
(1) Could the USA precise procedures and guidance to manage detection of non-conforming, counterfeit, suspect or fraudulent items received from suppliers before they are installed in the plant? (2) Could the USA precise the inspection program focusing on preventing and detecting the incorporation of non-conforming, counterfeit, suspicious and fraudulent items?
<u>Answer</u>: (1) Appendix B, “Quality Assurance Criteria for Nuclear Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50 is the fundamental regulation that establishes the requirements for quality at an NRC licensee’s nuclear facility. Specific regulatory requirements related to activities to deter and/or prevent the infiltration of a counterfeit, fraudulent, or suspect item into an NRC licensed facility exist in two of the criteria: Criterion VII, “Control of Purchased Material, Equipment, and Services”; and Criterion X, “Inspection.” Licensees contractually impose Appendix B to 10 CFR Part 50 on suppliers for activities affecting safety-related plant equipment. Under Appendix B, licensees are required to verify the adequate implementation of its suppliers’ quality assurance program through periodic audits and continuous evaluation of the items or services supplied. In addition to ensuring a robust quality assurance program, the licensees perform receipt inspections, preinstallation acceptance testing, and postinstallation testing of supplied items or services. (2) The NRC’s vendor and resident inspection programs are detailed in IMC 2507, “Vendor Inspections,” and IMC 2515, “Light-Water Reactor Inspection Program—Operations Phase,” respectively. The application of these NRC inspection programs ensures that vendors and licensees adequately implement their Appendix B quality programs. As discussed above, licensees periodically audit and continuously evaluate vendors. Additionally, licensees conduct a number of activities to ensure an item will perform satisfactorily in service prior to reliance on the item. Although the NRC inspection program does not have a specific focus on counterfeit, suspicious, and fraudulent items, the implementation of the Appendix B quality assurance program and NRC/licensee oversight ensure there is a robust process to mitigate the introduction of counterfeit, suspicious, and fraudulent items into the procurement chain.
Question No. 99
Section 13.4 states: “NRC inspectors look for cases in which a licensee may have missed generic implications of specific problems and for the risk significance of combinations of problems that individually may not have significance. They do not inspect other aspects of quality assurance program implementation in the baseline inspection program but may do so through supplemental inspections.” In which case the supplemental inspections are carried out?

Answer: Supplemental inspections consist of Inspection Procedures 95001, 95002, and 95003, which must be carried out by inspectors only when a licensee's performance has declined sufficiently for the licensee to be moved across the Action Matrix, as described in IMC 0305, "Operating Reactor Assessment Program" (ML102730571). Licensee movement across the Action Matrix is triggered by performance indicators crossing significance thresholds or by greater-than-green inspection findings as determined in accordance with IMC 0609, "Significance Determination Process" (ML18187A187). Unlike the ROP baseline inspection program, which conducts risk-informed, performance-based inspection samples intended to be indicative of licensee performance, supplemental inspections become increasingly diagnostic of the root and contributing causes, extent of cause, extent of condition, and licensee corrective actions to prevent recurrence of significant licensee performance issues associated with declining licensee performance. Supplemental inspections expand in breadth, depth, and rigor as licensees progress across the Action Matrix from lower to higher column numbers.
Question No. 101
Section 13.2.3 states: "The NRC has reviewed options for adopting more widely accepted international quality standards, such as International Organization for Standardization Standard 9001, 2000 Edition, "Quality management systems – Requirements" by considering how international standards compare with the existing framework in Appendix B to 10 CFR Part 50. Based on this review, the NRC concluded that supplemental quality requirements would be needed when implementing Standard 9001 within the existing regulatory framework." Was the similar work done when ISO 9001-2015 was implemented?
Answer: The NRC staff has not conducted a similar comparison of Appendix B to 10 CFR Part 50 with subsequent revisions of International Organization for Standardization (ISO) 9001, as U.S. licensees have not asked the NRC to conduct such a review. NRC licensees have requested and received reviews on revisions to the ASME NQA-1 standard, which the NRC endorsed in RG 1.28, "Quality Assurance Program Criteria (Design and Construction)" (ML17207A293). The comparison of ISO 9001 to Appendix B can be found in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," dated July 9, 2003 (ML031490421).
Question No. 102
What is the frequency of inspections of how contractors fulfill the quality assurance programs?
Answer: Appendix B to 10 CFR Part 50 is contractually imposed through purchase orders by licensees on vendors for safety-related items or services. This regulation requires the development and implementation of a quality assurance program to be applied to the design, fabrication, construction, and testing of structures, systems, and components. Licensees are required to meet the criteria in Appendix B. Under Appendix B, licensees are required to verify the adequate implementation of safety-related vendors' quality assurance programs through periodic audits and continuous evaluation of the items or services supplied. As stated in RG 1.28, licensees should audit vendors, at a minimum, on a triennial basis. The audit frequency is adjusted based on the results of an annual evaluation of the objective evidence that activities affecting quality are being satisfactorily accomplished.

Question No. 110
National reports of other countries provide information about implementation status of the Integrated Management System (IMS) in organizations that operate nuclear facilities. Recommendations for this system were laid down in the IAEA Safety Guide GS-G-3.1. The USA Report does not contain information on the implementation of IMS. What is the situation with IMS implementation in the nuclear power sector of the USA?
Answer: The NRC endorsed American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.2-2012, “Managerial, Administrative and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants,” in RG 1.33, Revision 3, “Quality Assurance Program Requirements (Operation),” issued in June 2013 (ML13109A458). In RG 1.33, the NRC staff noted that the regulatory guide incorporates administrative and quality assurance controls for the operational phase that are consistent with the basic safety principles in IAEA GS-R-3, “The Management System for Facilities and Activities” (which was superseded by GSR Part 2). Further, RG 1.33 is therefore, is consistent with the basic principles in IAEA Safety Guide GS-G-3.1, “Application of the Management System for Facilities and Activities.” However, RG 1.33, Revision 3, did not elaborate on the similarities.
Question No. 131
In the United States national report, Article 13, page 130, it is stated that “The NRC has reviewed options for adopting more widely accepted international quality standards, such as International Organization for Standardization Standard 9001, 2000 Edition, “Quality management systems – Requirements” by considering how international standards compare with the existing framework in Appendix B to 10 CFR Part 50. Based on this review, the NRC concluded that supplemental quality requirements would be needed when implementing Standard 9001 within the existing regulatory framework.” Please provide your review result for adopting more widely accepted international quality standards. If not possible, please explain the differences with ASME NQA-1 Part IV Subpart 4.1 (Guides on Use and Comparison of NQA-1 with other Quality requirements).
Answer: The result of the NRC’s review of ISO 9001-2000 is publicly available in SECY-03-0117 (ML031490421). The document outlines the comparison of ISO 9001-2000 and Appendix B to 10 CFR Part 50.
Question No. 161
“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 Appendix B to 10 CFR Part 50, as required by procurement contracts with applicants and licensees, and to verify that the quality assurance program provides controls for reporting of defects and noncompliance in accordance with 10 CFR Part 21, “Reporting of Defects and Noncompliance.” IMC 2507, “Vendor Inspections,” dated May 16, 2018 (ML13247A725), provides guidance for these inspections.” Could you please clarify who inspects the vendors: the NRC itself or NRC interacts with vendors through the licensee?
Answer: The NRC staff directly inspects vendors of safety-related components. Staff in the Quality Assurance and Vendor Inspection Branch, which is housed under the NRC’s Office of Reactor Regulation, Division of Reactor Oversight, performs vendor inspection activities for the NRC. The vendor inspection reports are available on the NRC’s public website at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html.
Question No. 166
Reference section 13.2.3, NRC has mentioned ISO 9001 standard 2000 edition as an example for comparison of more widely accepted international quality standards with

framework in Appendix B to 10 CFR Part 50. Please share examples of supplemental quality requirements that would be included in the Appendix B as result of this comparison.
<u>Answer</u>: The results of the NRC's review of ISO 9001-2000 are publicly available in SECY-03--0117 (ML031490421). The document compares ISO 9001-2000 and Appendix B to 10 CFR Part 50. ISO 9001 and Appendix B are similar in format and text; however, they are substantially different in their implementation. Appendix B requirements are amplified and defined through consensus standards that licensees and Appendix B suppliers have committed to implement. Many licensees and suppliers have committed to follow the guidance of NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications." The NRC endorsed NQA-1-1983 and some subsequent editions in RG 1.28. No other comparison of subsequent editions of the ISO standard to Appendix B have been requested or completed by the NRC staff.

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.

Question No. 10
In [Article] 14.1.5.1 the scope of license renewal is mentioned. To what degree is an update of the enveloping spectrum of accidents (initiating events) of the safety analysis report performed by the licensee for the renewal of the license?
Answer: As part of the license renewal process in the United States, which is governed by 10 CFR Part 54, the licensee is not required to update the enveloping spectrum of accidents (initiating events) in its safety analysis report. As described below, plants in the United States are required to maintain an updated spectrum of accidents under the licensee’s current license. In developing the License Renewal Rule (10 CFR Part 54) in 1995, the Commission concluded that issues material to the renewal of a nuclear power plant operating license are limited to those issues that are uniquely relevant to protecting public health and safety and preserving the common defense and security during the period of extended operation. As such, the license renewal process focuses on managing the adverse effects of aging on passive and long-lived systems, structures, and components rather than identifying all aging mechanisms. The License Renewal Rule ensures that important systems, structures, and components will continue to perform their intended function during the period of extended operation. Other issues not unique to the period of extended operation would, by definition, be relevant to the safety and security of the public during current plant operation and are, therefore, addressed during the current plant operating period. The NRC manages these issues by implementing the ROP, generic communications, and the Generic Issues Program. Updates to the enveloping spectrum of accidents (initiating events) of the safety analysis report are not unique to the period of extended operation and would be addressed as part of the regular regulatory processes.

Question No. 11
The respective Code of Federal Regulations (CFR) under which licensees may change without prior NRC approval specific portions of their licensing basis, emergency plan or to the facility or procedures and conduct tests or experiments is mentioned. In what stage of the process and to what extend is the NRC informed about these changes?
<u>Answer</u>: For changes to the licensing basis that a licensee has determined do not require prior approval or notification, the licensee must submit a summary of the changes to the NRC within the timeframe defined in the applicable regulation. For example, the regulation at 10 CFR 50.54(q)(5) requires licensees to submit a report of changes made to an emergency plan without prior approval to the NRC within 30 days after the change is put into effect. In addition, the NRC's regulations require licensees to maintain records of the changes made, which are subject to NRC inspection.
Question No. 12
(1) To what degree are backfitting and safety analyses requested for non-NPP nuclear facilities, like research reactors and intermediate storage facilities for radioactive waste? (2) How and to what degree are the IAEA Specific Safety Guides SSG-20 “Safety Assessment for Research Reactors and Preparation of the Analysis Report“ and SSG-24 “Safety in the Utilization and Modification of Research Reactors“ considered by the NRC?
<u>Answer</u>: (1) The NRC's backfitting provisions for reactors are in 10 CFR 50.109. The regulatory basis for 10 CFR 50.109 was expressed solely in terms of nuclear power reactors. The NRC has not applied 10 CFR 50.109 to research reactors, testing facilities, and other nonpower facilities licensed under 10 CFR Part 50. In a 2012 final rule concerning nonpower reactors, the NRC stated, “The NRC has determined that the backfit provisions in 10 CFR 50.109 do not apply to test, research, or training reactors because the rulemaking record for § 50.109 indicates that the Commission intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record” (77 FR 27561; May 11, 2012). While 10 CFR 50.109 may not apply to these facilities, the NRC still has the authority to modify a research reactor, testing facility, or other nonpower facility license when warranted to ensure adequate protection of the public health and safety. The NRC’s backfitting provisions for independent spent fuel storage installations (ISFSIs) and monitored retrievable storage installations (MRSs) are in 10 CFR 72.62, “Backfitting.” Backfitting of an ISFSI or MRS will be required when necessary to ensure adequate protection of occupational or public health and safety, to bring an ISFSI or MRS into compliance with its license or the rules or orders of the Commission to bring an ISFSI or MRS into conformance with written commitments by a licensee. Backfitting may be required if the action would result in a cost justified, substantial increase in overall protection of occupational or public health and safety. (2) The NRC published NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors,” Parts 1 and 2, to help applicants for nonpower reactors prepare license applications for NRC review and to establish a standard review plan for the NRC staff to evaluate these applications. NUREG-1537 provides an acceptable methodology for demonstrating compliance with the NRC’s regulations for nonpower reactors. Applicants may use other guidance and analysis methodologies to develop applications for NRC review, including the IAEA Specific Safety Guides SSG-20, “Safety

Assessment for Research Reactors and Preparation of the Safety Analysis Report," and SSG-24, "Safety in the Utilization and Modification of Research Reactors." The NRC staff considers an application prepared using the IAEA guidance documents on a case-by-case basis and confirms that the application meets all applicable NRC regulatory requirements. The NRC staff contributed to the IAEA's international effort to develop the Code of Conduct on the Safety of Research Reactors (Code of Conduct) and participated in the periodic meetings, reporting on its self-assessment of the level of application of the various aspects of the Code of Conduct. The IAEA Code of Conduct constitutes an important development in strengthening the international nuclear safety arrangements for civil research reactors. The NRC staff supported the application of the Code of Conduct, and the NRC's self-assessment found the NRC conducts the regulation of nonpower reactors in harmony with the recommendations of the Code of Conduct. NUREG-1537 can be found on the NRC public website at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1537/index.html
Question No. 14
(1) How are safety assessments of nuclear facilities (NPP and non-NPP) done that are in the state of decommissioning? What activities are carried out by NRC? (2) What activities are carried out by NRC? (3) How far are there differences made between the different states of decommissioning, e.g. when fuel is still in the reactor core, is still on the site of the facility or when the fuel has left the site of the facility?
Answer: (1) Safety assessments and inspections continue when the facilities shut down and enter decommissioning. When transitioning to decommissioning, the licensee may submit requests for relief from requirements that are no longer needed to maintain the safety of the facility. (2) The NRC oversees decommissioning of nuclear reactors through inspections that emphasize radiological controls, management, procedure compliance, spent fuel pool operations, and the safety review program. Many activities that occur during decommissioning are very routine and occur frequently in operating plants. These include decontamination of surfaces and components, surveys for radioactive contamination, waste packaging and disposal, and other activities. Additional information can be found on the NRC public website at https://www.nrc.gov/waste/decommissioning/oversight.html. (3) Licensing and safety requirements change as the facility is defueled and the fuel is placed in dry storage. Changes can be made to the operating license to remove requirements no longer applicable in the progressive decommissioning states (shut down, defueled, fuel offsite), such as requirements related to criticality or component maintenance. Other obsoleted regulatory requirements may be removed if the licensee receives NRC approval of an exemption from the requirements (e.g., offsite emergency response, fitness for duty, or indemnification).
Question No. 30
Could a licensee propose a change resulting in a potential decrease in defence-in-depth provisions without prior receipt of a licence amendment?
Answer: Licensees are required to evaluate changes to their facility, as described in the final safety analysis report, per the criteria in 10 CFR 50.59, "Changes, tests and experiments." If

the decrease in defense in depth will require a change to the licensee's technical specifications or if it meets other criteria included in 10 CFR 50.59, then the licensee would have to obtain NRC approval before making the change. In addition, the licensee must evaluate its proposed change against other relevant regulatory requirements to ensure that the facility continues to comply with all of the applicable NRC regulations as described in the facility's license.
Question No. 70
Could You provide more information on the acceptance criteria for the extended power uprates?
Answer: For review of extended power uprate and stretch power uprate applications, the NRC staff uses Review Standard (RS)-001, "Review Standard for Extended Power Uprates" (https://www.nrc.gov/reactors/operating/licensing/power-uprates/rs-001-rev-0-dec2003.pdf). This document establishes standardized review guidance and acceptance criteria for the NRC's reviews of those applications. In addition, RS-001 provides detailed references to various NRC documents containing information related to the specific areas of review. To guide its review of measurement uncertainty recapture power uprates, the NRC staff uses Regulatory Issue Summary (RIS) 2002-03, "Guidance on the Content of Measurement Uncertainty Recapture Power Uprate Applications," dated January 31, 2002 (https://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2002/ri02003.html). Attachment 1 to RIS 2002-03, "Guidance on the Content of Measurement Uncertainty Recapture Power Uprate Applications," describes the scope of information and level of detail necessary for the NRC staff's review of measurement uncertainty recapture power uprate applications.
Question No. 95
Have any international peer reviews been performed of the ageing management programmes of operating nuclear reactors, e.g., making use of the IAEA SALTO review service (Safety Aspects of Long Term Operation)?
Answer: The IAEA Safety Aspects of Long Term Operation (SALTO) peer reviews focus on assessing the strategy and key elements related to the safe long-term operation of nuclear power plants. The evaluation of the ageing management programs of operating nuclear reactors is based on the IAEA's safety standards and guidance documents. As an IAEA Member State, the United States has not requested the IAEA to provide a SALTO peer review. However, the United States has supported SALTO missions to Mexico, South Africa, Armenia, Brazil, China, Argentina, and Sweden. The summaries of all the SALTO missions are available on the IAEA website at https://www.iaea.org/services/review-missions/calendar?type=3169&year%5Bvalue%5D%5Byear%5D=&location=All&status=All. Similar IAEA missions, in particular IAEA Operational Safety Review Team (OSART) missions, have been performed at 10 U.S. plants since 1987, with recent missions at Sequoyah Nuclear Plant (August 2017), Clinton Power Station (August 2014), Seabrook Station (June 2011), Arkansas Nuclear One (July 2008), and Brunswick Steam Electric Plant (May 2005). The NRC understands that the Sequoyah OSART mission included the long-term operation module that includes aging management. An OSART mission is provisionally scheduled for September 2020 at Wolf Creek Generating Station.
Question No. 100

(1)	On what power units the applications are being prepared (sent) for service life extension beyond 60 years?
(2)	What additional criteria and technical requirements will be established in the current regulatory framework of NRC to make a decision on life extension of a NPP power unit after 60 years of operation?

Answer:

(1) As of January 2020, the NRC is reviewing two applications for subsequent license renewal for Peach Bottom Atomic Power Station, Units 2 and 3, and Surry Power Station, Units 1 and 2. In December 2019, the NRC completed its review of the first subsequent license renewal application for Turkey Point Nuclear Generating Units 3 and 4 and issued an 80-year operating license. The NRC has also received two letters of intent for additional subsequent license renewal applications between 2021 and 2022. Additional information on the status of the application reviews is available on the NRC public website at https://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-renewal.html.

(2) The NRC has defined subsequent license renewal to be the period of extended operation from 60 years to 80 years. As part of the NRC procedures to determine what is needed for subsequent license renewal, the NRC reexamined the policies and principles for license renewal and determined that they remain valid and acceptable for subsequent license renewal. Therefore, the NRC acceptance criteria or standard for issuance of a renewed license for operation for 60 to 80 years, as stated in 10 CFR 54.29, are the same as those used for license renewal from 40 to 60 years.

NUREG-2191 (ML17187A031 and ML17187A204) provides guidance for subsequent license renewal applicants, contains the NRC staff's generic evaluation of plant aging management programs, and establishes the technical basis for their adequacy. NUREG-2192 (ML17188A158) provides guidance to NRC staff reviewers, who will assess the technical aspects of a plant in accordance with 10 CFR Part 54. Both documents are available on the NRC public website at https://www.nrc.gov/reactors/operating/licensing/renewal/slr/guidance.html.

Question No. 103

There are several references to risk-informed process throughout the document but no reference to RI-ISI [Risk-Informed Inservice Inspection Service] acc. to ASME [Section] XI App. [Appendix] R. Has it been utilized in license renewal processes within US nuclear fleet?

Answer: NRC regulations at 10 CFR 50.55a, "Codes and standards," govern the inservice inspection requirements of ASME Boiler and Pressure Vessel Code (ASME Code), Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components." Regulations at 10 CFR 50.55a impose additional conditions and augmentations of inservice inspection requirements specified in ASME Code, Section XI.

One such condition is identified in 10 CFR 50.55a(b)(2)(xxix), which states that nonmandatory appendix R, "Risk-Informed Inspection Requirements for Piping," of ASME Code, Section XI, 2005 Addenda through the latest edition and addenda incorporated by reference in paragraph (a)(1)(ii) of this section, may not be implemented without prior NRC authorization of the proposed alternative in accordance with 10 CFR 50.55a(z).

Licensees may use relief requests to seek NRC approval to use nonmandatory appendix R in accordance with 10 CFR 50.55a(z) but must demonstrate that either the proposed alternative would provide an acceptable level of quality and safety, or compliance with the specified requirements in 10 CFR 50.55a would result in hardship or unusual difficulty without a compensating increase in the level of quality and safety.

There have been two recent instances in which licensees in the United States have cited guidance from ASME Code, Section XI, nonmandatory appendix R, in their proposed alternatives submitted in accordance with 10 CFR 50.55a(z)(1) (ML17325B215 and ML17303B183). The NRC's safety evaluations for these proposed alternatives are documented in ADAMS Accession Nos. ML18192C183 and ML18186A588, respectively.

Question No. 104

When a license is renewed for e.g. 20 years, are there any additional requirements to the ISI program or is it identical to the first 40 years program?

<u>Answer</u>: NRC regulations at 10 CFR 50.55a govern the inservice inspection requirements of ASME Code, Section XI. The rules of Section XI require a mandatory program of examinations, testing, and inspections to demonstrate adequate safety and to manage deterioration and aging effects. The NRC's regulations at 10 CFR 50.55a impose additional conditions and augmentations of inservice inspection requirements specified in ASME Code, Section XI.

The ASME Code, Section XI, inservice inspection program has been shown to be effective in managing aging effects. In certain cases, based on the recommendations in the GALL Report, a licensee can decide to augment its ASME inservice inspection program during the review of its application for a renewed license. However, this is a voluntary decision made by the licensee; the NRC imposes no additional requirements beyond those in 10 CFR 50.55a on a licensee when a license is renewed for an additional 20 years.

Licensees are required to use the latest edition of ASME Code and Section XI and Addenda incorporated by reference in 10 CFR 50.55a for the Inservice Inspection Service (ISI). This requirement applies to initial 120-month inspection interval and during successive 120-month inspection intervals for plant operation under the original 40-year license, as well as under a renewed or subsequently renewed operating license.

Question No. 125

In contrast to the seventh National Report, part of content required by SRM-SECY-14-0016 are missed here. Do the missed parts not need to be implemented? Is there any other consideration?

<u>Answer</u>: In SRM-SECY-14-0016, "Staff Requirements—SECY-14-0016—Ongoing Staff Activities to Assess Regulatory Considerations for Power Reactor Subsequent License Renewal," dated August 29, 204, the Commission directed the staff to do the following:

(1) Continue to update the license renewal guidance and address emerging technical issues and operating experience.

(2) Address Option 2 and Option 3 as presented in SECY-14-0016 through alternative vehicles (e.g., issuance of generic communications, voluntary industry initiatives, or updates to the Generic Aging Lessons Learned Report). Option 2 recommended minor editorial changes to 10 CFR Part 54 to add alternate fracture toughness requirements and clarify how existing recordkeeping requirements apply to newly identified systems, structures, and components. Option 3, which includes Option 2, recommended an expansion in scope of 10 CFR Part 54 to include equipment associated with 10 CFR 50.54(hh)(2) and added a provision to address timely renewal

so that a licensee must implement aging-management activities before the expiration of its current license.

(3) Submit an information paper to the Commission reporting on the progress of the implementation of the inspection enhancements described in the ROP enhancement project related to aging management and the Inspection Procedure Operating Experience Update Process.

(4) Keep the Commission informed of the staff's progress in resolving technical issues and the staff's readiness to accept an application and any further need for regulatory process changes, rulemaking, or research related to subsequent license renewal.

(5) Emphasize in communications with industry the need to strive for satisfactory resolution of these issues before the NRC begins a review of any subsequent license renewal application.

To address items (1) and (2), the staff published the following guidance documents in July 2017 to support the staff's readiness to receive and evaluate the acceptability of a subsequent license renewal (SLR) application:

- NUREG-2191, "Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report: Final Report," Volumes 1 and 2 (ML17187A031 and ML17187A204, respectively)

- NUREG-2192, "Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants: Final Report" (SRP-SLR) (ML17188A158)

The GALL-SLR report gives guidance on the content of SLR applications and identifies acceptable methods to manage aging effects for nuclear plant operations from 60 to 80 years of operation. The SRP-SLR provides guidance to the staff reviewers performing safety reviews of SLR applications.

To address item (3), the NRC integrated aging management inspection and guidance into four inspection procedures (IPs):

(1) IP 71111.04, "Equipment Alignment," was updated to include an inspection requirement to observe whether there is indication of age-related degradation on systems, structures, and components. The IP included inspection guidance to consider whether the observed degradation has been entered in the licensee's corrective action program at the appropriate threshold and ensure the degradation is being appropriately managed in accordance with an aging management program, if one exists for the degraded structure or component.

(2) IP 71111.08, "Inservice Inspection Activities," was updated to remind inspectors that equivalent inspections performed to fulfill a license renewal activity may be credited as a sample under this IP.

(3) IP 71111.17T, "Evaluations of Changes, Tests, and Experiments," was updated to remind inspectors that changes to equipment may lead to a review of the updated final safety analysis report supplement for aging management.

(4) IP 71003, “Post-Approval Site Inspection for License Renewal,” was updated to include an additional one-time inspection phase that would occur 5–10 years into the period of extended operation to verify that the licensee is managing aging effects in accordance with the aging management programs described in the updated final safety analysis report. This inspection phase is intended to review the effectiveness of the licensee’s aging management programs to ensure systems, structures, and components have maintained their ability to perform their intended function.

Inspection procedures are available on the NRC public website at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html

To address item (4), the staff briefed the Commission on April 26, 2017 (ML17118A300). As described in the Commission meeting, the staff has cooperated with the U.S. Department of Energy and the Electric Power Research Institute to address four key technical issues: (1) reactor pressure vessel neutron embrittlement at high fluence, (2) irradiation-assisted stress-corrosion cracking of reactor internals and primary system components, (3) concrete and containment degradation, and (4) electrical cable qualification and condition assessment.

To address item (5), the staff engaged extensively with industry and other external stakeholders to incorporate appropriate guidance on these issues in the documents mentioned above. The staff continues to perform long-term confirmatory research that will provide additional generic information that will make reviews more effective and efficient as additional licensees submit SLR applications.

Question No. 171

Section 14.1.5 states that some other countries carry out periodic safety reviews (PSR) including an assessment of plant design and operation against current safety standards. Section 14.1.5 further asserts that the NRC Licence renewal and subsequent licence renewal processes are considered equally adequate and acceptable to a periodic safety review.
In a PSR the NPP safety analysis report, much of which may be based on quite old analysis, is revisited to see if it meets current safety standards. Why are the NRC licence renewal processes considered equally adequate and acceptable to a PSR when a review of the NPP safety analysis report is absent from the list of requirements for licence renewal shown in Section 14.1.4.1?

Answer: The NRC does not require licensees to perform periodic safety reviews. Instead, it has established processes to ensure that licensees perform continuous review and maintenance of the safety of their facilities and their licensing bases, including updates to the final safety analysis report. The licensing basis for nuclear power plants is established on issuance of the license and evolves throughout the term of the operating license because of continuing NRC regulatory activities and the activities of the licensee. For active systems, structures, and components, licensees implement quality assurance program requirements (in accordance with Appendix B to 10 CFR Part 50) and the Maintenance Rule at 10 CFR 50.65, “Requirements for monitoring the effectiveness of maintenance at nuclear power plants.” Licensees are also required to perform assessments of modifications under 10 CFR 50.59 and submit license amendments under 10 CFR 50.90.

In addition, the NRC evaluates licensee operating experience; information from inspections, audits, and investigations; and regulatory research. As necessary, the NRC requires changes to the licensing basis through the release of new or revised regulations, the issuance of orders modifying licenses, and the acceptance of licensee commitments to modify nuclear power plant designs and procedures (e.g., in response to licensee events or generic communications). In such cases, the NRC follows established processes that ensure that the appropriate NRC actions (e.g., rulemaking, the hearing process, and backfit analysis) are taken with full consideration of the safety significance of the issue and with opportunity for stakeholder involvement. Finally, the NRC requires implementation of aging management programs for passive components as part of licensees' preparation and the NRC's review of license renewal and SLR applications.

An IAEA Integrated Regulatory Review Service (IRRS) mission in 2010 reached the following conclusion:

> Although the NRC utilizes an alternate approach to meet the PSR [Periodic Safety Review] safety factors, NRC should incorporate lessons learned from Periodic Safety Reviews performed in other countries as an input to the NRC's assessment processes.

After the IAEA IRRS mission, the staff conducted limited-scope review of a sample of the periodic safety reviews performed in other countries for potential insights to be assessed by the NRC's regulatory processes. The staff found that the U.S. nuclear regulatory approach would be sufficient for detecting and correcting the types of plant-specific issues documented in the periodic safety review summary reports if they were to occur in U.S. plants. The report summarizing the staff's evaluation of periodic safety reviews from other countries is available at ADAMS Accession No. ML15043A725.

Question No. 173

There are many references in the report to 'Licensing Basis' and it is clearly a key concept in terms of US nuclear regulation. For example in 14.1 it is stated 'Once a license is issued for a nuclear plant, the licensee must operate the plant in conformance with its license and its licensing basis. The licensing basis evolves throughout the term of the license because of the continuing regulatory activities of the NRC, as well as the activities of the licensee.'

(1) Please provide a definition of 'Licensing Basis'.

(2) More specifically, does Licensing Basis include the NPP safety analysis report, 'as updated'?

Answer:
(1) In general terms, the licensing basis is the collection of documents or technical criteria that provides the basis upon which the NRC issues a license to construct or operate a nuclear facility. Although the term "licensing basis" is widely used throughout 10 CFR Part 50, the regulation does not specifically define it, nor does the regulatory guidance related to Part 50. For the purpose of license renewal, the NRC's regulations at 10 CFR 54.3, "Definitions," define, in part, a facility's current licensing basis as, "the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect."

(2) Yes. The safety analysis report, as updated, is considered part of a facility's licensing basis.

Question No. 174

Section 14.1.2.1 states 'A licensee is to operate its facility in accordance with the license and as described in its final safety analysis report, as updated.'

Article 2 of the Vienna Declaration requires that comprehensive and systematic safety assessments be carried out regularly on existing NPP throughout their lifetime. An up to date NPP safety analysis report is needed to allow a valid safety assessment since comparisons must be made between the actual NPP plant state and that set out in the safety analysis report. What processes are in place to ensure that individual NPP's safety analysis reports are: • reviewed regularly, comprehensively and systematically; • updated as necessary; and • positively confirmed to be valid and appropriate by the NPP operator?
Answer: The NRC's regulations at 10 CFR 50.71, "Maintenance of records, making of reports," require licensees to periodically update their safety analysis reports to reflect changes made to the facility as described in the safety analysis report. This includes both changes that were approved by the NRC (e.g., through a license amendment request) and those changes where the licensee, using one of the change-control processes described in the regulations, has determined that prior approval was not necessary. The regulations at 10 CFR 50.71(e)(4) require, in part, that licensees give the NRC revisions to their safety analysis reports within 6 months after each refueling outage, at a frequency not to exceed every 24 months. In addition, safety analysis reports are subject to inspection through the NRC's oversight process, both on an ongoing and periodic basis. For example, the NRC periodically conducts design-basis assurance inspections at facilities. As a part of these inspections, inspectors will evaluate whether the safety analysis report has been appropriately updated to reflect the permanent plant modifications within the scope of that particular inspection.

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. 57
As stated in the National Report the requirements for radiation protection in 10 CFR Part 20 are dated from 1991 and implement ICRP Recommendations No. 60. 2007 ICRP published a new recommendation No. 103, which is also the basis for IAEA GSR Part 3 published 2014. It is acknowledged, that the principle of regulatory stability is important, but one update of a regulation within approximately 30 years seems to be reasonable and acceptable. Could the USA please inform whether NRC has performed a benchmark auf 10 CFR Part 20 against ICRP 103? Does NRC intent to initiate an update of the requirements in 10 CFR Part 20 to align with ICRP 103 and IAEA GSR Part 3?
Answer: In general, the NRC introduces changes to its regulatory structure when necessary to maintain adequate protection of the health and safety of the public within the United States. Taken alone, the age of a regulatory requirement or guidance does not factor into the NRC's decision-making on whether or not to pursue changes. When considering the NRC's regulations in 10 CFR Part 20, "Standards for Protection against Radiation," it is true that the last major change to that regulation was published in 1991. However, since then, the NRC has made several changes to the regulation to address issues within its regulated community. For example, with one update in 1999, the NRC introduced changes to respiratory protection requirements and, with another in 2011, the NRC introduced requirements associated with nuclear power plant decommissioning. The NRC has considered the International Commission on Radiological Protection (ICRP) 2007 recommendations as described in ICRP Publication 103 as well as the ICRP's position on noncancer effects of radiation, in particular its new recommended dose limit to the lens of the eye, which was eventually described in ICRP Publication 118. The NRC staff described its consideration of the ICRP's recent recommendations in SECY-12-0064, "Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance," dated April 25, 2012 (ML121020108), and in the other relevant documents referenced in that SECY. The staff conducted several roundtable discussions throughout the United States, held multiple public meetings, and solicited external stakeholder feedback about potential changes to the NRC's radiation protection regulatory framework. At the direction of the Commission, the staff ensured that views from the multitude of NRC stakeholders were considered. In the end, the staff determined that there was sufficient scientific basis to initiate the process to update the NRC's radiation protection rules. As reflected in the staff requirements memorandum to SECY-12-0064 (ML12352A133), the Commission agreed in part with the staff's recommendations and directed the staff to pursue further study and development of the regulatory basis for updating the rules. However, as part of the NRC's prioritization efforts that culminated in the development of SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-baselining of Agency Activities," dated January 31, 2016 (ML16028A189), the NRC

suspended activities associated with this rulemaking. The low priority of this rulemaking was in recognition of the staff's position, as stated in SECY-12-0064, that the NRC's radiation protection framework provides adequate protection of the health and safety of the public within the United States. The staff acknowledges the differences between the ICRP's recent recommendations and the NRC's framework. However, the staff does not believe that these differences are of sufficient magnitude to necessitate urgent rulemaking. Instead, the staff will continue its normal processes of interacting with external stakeholders and organizations, domestically and internationally, with the aim of identifying information that may challenge the staff's finding of the adequacy of the current radiation protection regulations. Additionally, a licensee may request an exemption from a section of 10 CFR Part 20 and use equivalent quantities calculated using new internal dosimetry models, as described in ICRP Publication 68; see SRM-SECY-99-077, "Staff Requirements—SECY-99-077—To Request Commission Approval to Grant Exemptions from Portions of 10 CFR Part 20," dated April 21, 1999 (https://www.nrc.gov/reading-rm/doc-collections/commission/srm/1999/1999-077srm.pdf). It should also be noted that the annual dose to workers (total effective dose equivalent and lens dose equivalent) from 2008 through 2018 was less than 20 millisievert (mSv) for 99.8–99.9 percent of monitored workers, thus suggesting that the current 10 CFR Part 20 regulations are adequately protective of worker exposure.
Question No. 74
ICRP No. 103 recommends the limit on the equivalent dose for the lens of the eye 20 mSv in a single year or 100 mSv in any five consecutive years subject to a maximum dose of 50 mSv in a single year, do you plan to decrese your current limit for eye lens (150 mSv in a single year)?
<u>Answer</u>: In general, the NRC introduces changes to its regulatory structure when necessary to maintain adequate protection of the health and safety of the public within the United States. Taken alone, the age of a regulatory requirement or guidance does not factor into the NRC's decision-making on whether or not to pursue changes. When considering the NRC's radiation protection regulations in 10 CFR Part 20, it is true that the last major change to that regulation was published in 1991. However, since then, the NRC has made several changes to the regulation to address issues within its regulated community. For example, with one update in 1999, the NRC introduced changes to respiratory protection requirements and, with another in 2011, the NRC introduced requirements associated with nuclear power plant decommissioning. The NRC has considered the ICRP's 2007 recommendations as described in ICRP Publication 103 as well as the ICRP's position on noncancer effects of radiation, in particular its new recommended dose limit to the lens of the eye, which was eventually described in ICRP Publication 118. The NRC staff described its consideration of the ICRP's recent recommendations in SECY-12-0064 (ML121020108), and in the other relevant documents referenced in that SECY. The staff conducted several roundtable discussions throughout the United States, held multiple public meetings, and solicited external stakeholder feedback about potential changes to the NRC's radiation protection regulatory framework. At the direction of the Commission, the staff ensured that views from the multitude of NRC stakeholders were considered. In the end, the staff determined that there was sufficient scientific basis to initiate the process to update the NRC's radiation protection rules. As reflected in the staff requirements memorandum to SECY-12-0064, the Commission agreed in part with the staff's recommendations and directed the staff to pursue further study and development of the regulatory basis for updating the rules. However, as part of the NRC's prioritization efforts that culminated in the development of SECY-16-0009 (ML16028A189), the NRC suspended activities associated with this rulemaking. The low priority of this

rulemaking was in recognition of the staff's position, as stated in SECY-12-0064, that the NRC's radiation protection framework provides adequate protection of the health and safety of the public within the United States. The staff acknowledges the differences between the ICRP's recent recommendations and the NRC's framework. However, the staff does not believe that these differences are of sufficient magnitude as to necessitate urgent rulemaking. Instead, the staff will continue its normal processes of interacting with external stakeholders and organizations, domestically and internationally, with the aim of identifying information that may challenge the staff's finding of the adequacy of the current radiation protection regulations. Additionally, a licensee may request an exemption from a section of 10 CFR Part 20 and use equivalent quantities calculated using new internal dosimetry models, as described in ICRP Publication 68; see SRM-SECY-99-077 (https://www.nrc.gov/reading-rm/doc-collections/commission/srm/1999/1999-077srm.pdf). It should also be noted that the annual dose to workers (total effective dose equivalent and lens dose equivalent) from 2008 through 2018 was less than 20 mSv for 99.8–99.9 percent of monitored workers, thus suggesting that the current 10 CFR Part 20 regulations are adequately protective of worker exposure.
Question No. 75
Is there a database of exposed workers and their doses (national register of doses)?
Answer: The NRC maintains a database called the Radiation Exposure Information and Reporting System (REIRS) for radiation workers. The REIRS database contains dose information from certain types of licensees that are required to report to the NRC per 10 CFR 20.2206, "Reports of individual monitoring." Further information on REIRS is available at https://www.reirs.com or by searching "REIRS" on the NRC public website. Additionally, the NRC publishes an annual summary of occupational exposures in the United States through the NUREG-0713, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities," series (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0713/).
Question No. 76
Are pregnant and breastfeeding exposed workers protected with lower dose limits?
Answer: NRC regulations provide for a lower dose equivalent limit for the duration of a pregnancy to protect a developing embryo/fetus, not the pregnant woman. The NRC defines dose to the embryo/fetus as the sum of the deep dose equivalent to the declared pregnant woman and the dose equivalent resulting from any radionuclides in the embryo/fetus and/or the pregnant woman. The fact that the lower limits are applied to the pregnant woman is the result of the impracticability of measuring dose to an embryo/fetus directly. Once born, the child would be protected as a member of the public in terms of dose limits and the mother, if she is an occupationally exposed individual, would be subject to the applicable occupational dose limits based on her age (minor or adult), regardless of whether she is breastfeeding.
Question No. 77
How often do exposed workers have to undergo preventive medical examinations?
Answer: There is no NRC regulation that requires medical examinations based solely on occupational radiation exposure.
Question No. 78
Are exposed workers categorized?
Answer: NRC occupational exposure regulations distinguish between adult workers, minors (i.e., those less than 18 years of age), and dose equivalent to an embryo/fetus during a pregnancy. The annual occupational dose limits for minors are 10 percent of the dose limits for adult workers, and the dose equivalent limit to an embryo/fetus is 5 mSv for an entire pregnancy. The NRC defines dose to the embryo/fetus as the sum of the deep dose

equivalent to the declared pregnant woman and the dose equivalent resulting from any radionuclides in the embryo/fetus and/or the pregnant woman.

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. 56
The General Safety Guide No. GSG-11, 'Arrangements for the Termination of a Nuclear or Radiological Emergency' of the IAEA deals with a transition phase until the end of the emergency. Is such a phase considered in the planning of American emergency management and if so, which sectors are all taken into account?
Answer: Emergency planning in the United States considers multiple phases of an emergency. The U.S. Environmental Protection Agency (EPA) Protective Action Guide Manual (EPA 400/R-17/001) contains planning guidance for early (hours to days), intermediate (weeks to months), and late phase (months to years) actions, including specific guidance for transitioning between phases. Guidance in the joint NRC/Federal Emergency Management Agency document, NUREG-0654, Revision 2 (also known as NUREG-0654/FEMA-REP-1), "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants: Final Report," issued December 2019 (ML19347D139), also describes a post-plume phase. Nuclear plant licensees and State, local, and Tribal government organizations consider the transition between phases in their emergency plans, including criteria for terminating the emergency and initiating recovery actions as described in NUREG-0654/FEMA-REP-1.
Question No. 72
What are dose limits for emergency workers in case of a nuclear or radiological emergency?
Answer: The NRC gives dose limits for occupational workers in 10 CFR Part 20 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/). It is the NRC's position that the dose limits for normal operation should remain the primary guidelines in emergencies. However, in some incidents, doses above the annual occupational dose limits may be

unavoidable. Guidelines for emergency workers are in the EPA Protective Action Guide Manual (EPA 400/R-17/001). The emergency response planning regulations in 10 CFR 50.47(b)(11) require licensees to meet the following standard: “Means for controlling radiological exposures, in an emergency, are established for emergency workers. The means for controlling radiological exposures shall include exposure guidelines consistent with EPA Emergency Worker and Lifesaving Activity Protective Action Guides.”
Question No. 73
What is the emergency response plan or management system for solving non-nuclear radiological emergency situations involving orphan sources of ionizing radiation or contaminated materials in scrap yards?
Answer: The U.S. framework to address the general issue of orphan sources is twofold: the primary goal is to prevent orphan sources, and the secondary goal is to respond. A robust system to address the issue of orphan sources is first to ensure a robust regulatory framework to prevent orphan sources. Then, secondarily, ensure a safety net structure exists to address orphan sources. This framework addresses all sources, including those found at scrap yards or other recycling collection or processing facilities. In addition, many of these scrap/recycling facilities have incorporated radiation detection screening as part of their handling processes, including detectors at facility entrances and at points along the handling process (e.g., material conveyor belts, material handling claws). This maximizes the facility’s ability to detect the source before mechanical or thermal processing that could result in breach of the source and contamination of the facility.
Question No. 96
Communication with neighboring states and international agreements. Please explain on the emergency response after receipt of notification from another state or information from the IAEA on actual or potential trans-national emergency which may affect the given state.
Answer: Upon notification of an event, an NRC Headquarters operations officer would notify NRC management. For emergency events, such notification would be immediate. NRC management would then direct the NRC response the same as is done for emergency events occurring inside the United States. As an example, during the Fukushima event, the NRC entered monitoring mode, which means the event was monitored from the NRC Headquarters Operations Center (24 hours a day, 7 days a week) by NRC emergency response personnel.
Question No. 98
Please explain on specific measures ensuring the emergency preparedness and response in case of multi-unit accident at a nuclear power plant site in case of an extreme external peril (tornado, strong winds etc.).
Answer: The accident at Fukushima highlighted the complexity of emergency response when multiple reactors on the same site are affected at the same time and electrical power is unavailable. After this event, the NRC asked U.S. nuclear power plant operators (1) to assess how many emergency staff would be needed to respond to a large accident that may affect multiple reactors at a site and (2) to change their emergency plans, as necessary. The NRC also asked the plant operators to ensure that they could power the communications equipment necessary to respond effectively to such an accident. This included power for response team radios, cellular telephones, and satellite telephones. Based on the insights from these evaluations, licensees purchased additional equipment and modified their emergency response procedures. The NRC reviewed these enhancements and performed inspections to verify the implementation.

Question No. 123
It is stated that: “All licensees submitted the requested communications and staffing assessments, and the NRC responded to document the staff’s reviews by July 2013 and March 2017, respectively.” Please indicate the overall results of the review. Is there any improvement action developed by the review?
Answer: Licensees verified that the minimum onsite staffing was capable of providing an initial response to a beyond-design-basis external event until augmented staff arrived to provide additional support. Licensees also reviewed the site communications systems. The majority have committed to purchasing additional portable communications systems and portable power generators to provide additional backup power for installed communications systems and portable battery chargers. Improvement plans are site specific based on each licensee’s review results; plans vary from site to site, with licensees committing to provide for adequate staffing and communications.
Question No. 129
With reference to Article 16.1.3, page 164 of the American national report, it is stated that the Commission directed that SAMGs [severe accident management guidelines] continue to be implemented voluntarily rather than being imposed as an NRC requirement. With respect to the provided information in the article in question, Korea would like to inquire the following questions: (1) Recently, the importance of severe accident management has increased. Is there particular reason why NRC still leaves SAMGs to be voluntarily implemented? (2) After general emergency declaration, who has the authority of the ultimate decision making on severe accident management and emergency preparedness?
Answer: (1) During the rulemaking process for mitigation of beyond-design-basis events, the NRC considered including SAMGs as a regulatory requirement. While SAMGs provide defense-in-depth benefits associated with their use after the onset of core damage, the available risk information indicates that SAMGs have only a small safety benefit (see the NRC staff regulatory analysis in SECY-15-0065, Enclosure 3; ML15049A201). The Commission determined that the additional defense in depth that would be gained from making the SAMGs a regulatory requirement rather than a voluntary initiative did not provide sufficient basis to support this provision in the rule, either as a question of adequate protection or as a cost-justified, substantial safety enhancement in accordance with 10 CFR 50.109, the Backfit Rule. However, the Commission noted that it is appropriate for the industry to continue implementing the SAMGs as a voluntary initiative and directed the NRC staff to update the ROP to explicitly provide periodic oversight of industry’s implementation of the SAMGs. The Nuclear Energy Institute (NEI) submitted a letter dated October 26, 2015 (ML15335A442), describing the industry initiative to update and maintain the SAMGs. Specifically, each licensee will perform timely updates of their site-specific SAMGs based on revisions to generic severe accident technical guidelines. Every operating plant licensee has submitted a docketed, site-specific regulatory commitment to the NRC. These commitments ensure maintenance of SAMG strategies, integration with emergency operating procedures and other guideline sets, timely incorporation of owners’ group revisions, and establishment of configuration controls.

The regulatory commitment process is described in NEI 99-04, "Guidelines for Managing NRC Commitments," which the NRC has reviewed and found acceptable. Docketed commitments ensure that licensee voluntary initiatives are well documented and transparent to the public. While a voluntary industry initiative is not directly enforceable, the NRC can provide oversight to verify implementation. As such, licensee failure to meet a formal commitment could be the basis for a notice of deviation, and any associated finding would be captured by the ROP. In a letter to NEI dated February 23, 2016 (ML16032A029), the staff outlined its approach for making changes to the ROP regarding SAMG oversight. The staff engaged NEI and other stakeholders to identify the near-term and long-term changes to the ROP consistent with the licensees' near-term and long-term SAMG commitments. In November 2016, the staff revised IP 71111.18, "Plant Modifications" (ML16306A185), to provide oversight of the initial inclusion of SAMGs within the plant configuration management processes to ensure that the SAMGs reflect changes to the facility over time. In November 2018, the staff published a revision to IP 71111.18 (ML18176A157) to provide oversight of the site-specific incorporation of SAMG guidance revisions by generic owner's groups. (2) Licensees are responsible for implementing their emergency plans during an emergency and for maintaining the plans at all times. This responsibility does not depend on the classification level (e.g., general emergency) of the event.
Question No. 159
"The NRC and FEMA coordinate their evaluation of periodic emergency response exercises and require all operating nuclear power plant sites to conduct an exercise every 2 years, as outlined in Section IV.F.2.b of Appendix E to 10 CFR Part 50. These mandatory full-participation exercises are integrated efforts by the licensee and State, Tribal, and local radiological emergency response organizations that play a role the licensee's radiological emergency plan." Is the operator required to conduct emergency response exercises together with exercises on response to security events to check the consistency between the emergency response plan (safety) and contingency plan (security)?
Answer: Yes. In accordance with paragraph IV.F.2.c(4) of Appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to 10 CFR Part 50 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appe.html#4_appe), a licensee is required to conduct a hostile action exercise of its onsite emergency plan in each 8-year exercise cycle. Additionally, as required in Appendix E, paragraph IV.F.2.d., each State should fully participate in a hostile action exercise at least once every 8-year cycle. Drill and exercise scenarios must include a wide spectrum of radiological releases and events, including hostile action, as required by Appendix E, paragraph IV.F.2.i. Hostile action and security events are addressed in many planning areas, and security-based events are intended to demonstrate simultaneous implementation of emergency and security plans.
Question No. 163
Reference section 16.1.4, US may like to share the extent of actual public evacuation demonstrated during integrated emergency exercises at nuclear power plants.
Answer: In the United States, actual public evacuations are not typically demonstrated during integrated emergency exercises. However, large-scale urban evacuations are common in the United States, and the NRC has performed extensive studies on evacuations. See the findings that evacuations are successful whether pre-planned or ad hoc in NUREG/CR-6864, "Identification and Analysis of Factors Affecting Emergency Evacuations," issued January 2005 (https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr6864/), and NUREG/CR-6981, "Assessment of Emergency Response Planning and Implementation for

Large Scale Evacuations," issued October 2008 (https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr6981/).

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, which was 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. 8
Are high/low air temperatures as well as high/low water temperatures considered as potential initiating events in the safety evaluation of the NPP?
Answer: No. There are no high/low air/water temperature initiating events in U.S. plant safety evaluations. However, these parameters are typically included in a plant's technical specifications and/or updated final safety analysis reports and are monitored to ensure safety functions are preserved.
Question No. 9
In Chapter 17.2.2 it is stated that RG 1.59, "Design Basis Floods for Nuclear Power Plants" Revision 2 is dated from August 1977. Is it foreseen that this RG will be updated and that more probabilistic methods will also be an acceptable approach?
Answer: RG 1.59, Revision 2, "Design Basis Floods for Nuclear Power Plants," was issued in August 1977 and establishes the NRC's position for acceptable approaches to be used in the estimation of design-basis flood for nuclear power plants. The guide is in the process of being updated. The update, which will be applicable to new reactors only, is expected to include the following:

• references on new flood hazard data and online databases • references on new data and databases for characterizing watersheds • information on new and improved analytical methods for both inland and coastal flooding hazards • information from interim staff guidance (ISG) developed for the flood hazard reassessments being conducted by licensees in response to the NRC's 10 CFR 50.54(f) request for additional information issued on March 11, 2012 (ML12053A340) A technical basis document for the revision of RG 1.59 has been published as NUREG/CR-7046, "Design-Basis Flood Estimation for Site Characterization at Nuclear Power Plant Sites," issued in November 2011 (ML11321A195). Interim staff guidance documents have also been published and will be included in the revision: • JLD ISG 2012-06, "Guidance for Performing a Tsunami, Surge, or Seiche Hazard Assessment" (ML12314A412) • JLD ISG 2013-01, "Guidance for Assessment of Flooding Hazards Due to Dam Failure" (ML13057A863) Currently, there is limited discussion in RG 1.59 about probabilistic approaches for such topics as, for example, joint probability method for storm surge and probabilistic seismic hazard assessment for seismic dam failure scenarios. The staff expects that probabilistic methods will be included in future revisions.
Question No. 16
In section 17.4 it is stated that operating nuclear power plants are not reevaluated periodically for site-related factors and that if there is a significant change in any hazard to an already licensed nuclear plant, then the NRC will determine whether a backfit action is necessary. Please, explain how a significant change in any hazard, including seismic, would be identified without periodic reevaluation of the hazards.
<u>Answer</u>: The NRC has a Process for the Ongoing Assessment of Natural Hazards Information. The NRC implemented this process to systematically identify new natural hazards information (e.g., new data, models, and methods) as it becomes available and assess its potential risk significance to nuclear power plant sites in a timely manner. This process ensures the timely identification and assessment of new information and facilitates a methodical assessment of the cumulative effect of new data, models, and methods that accrue over time. The framework that the NRC uses to assess new natural hazards information is based on three primary components: (1) knowledge base activities, (2) active technical engagement and coordination with external counterparts (including other Federal agencies, industry, academia, international regulators, and other technical and scientific organizations), and (3) assessment activities that involve the aggregation and evaluation of the significance of new natural hazards information. Further, if the NRC staff determines that the new hazards information has a potentially significant effect on plant safety, it will refer the issue to appropriate NRC regulatory programs (e.g., the NRC Generic Issues Program) for detailed assessment and further action.

Question No. 19

Reactor of Generations I and II BWR and PWR have two channels of emergency core cooling that contradicts to Requirement 25 "Single failure criterion" (paras. 5.39, 5.40, safety requirements SSR-2/1 IAEA). Severe accidents at NPPs Three Mile Island 2 and Fukushima Daiichi demonstrated incapability of this scheme to ensure cooling of the core of reactors BWR и[and] PWR in combined external and internal impacts on the NPP sites.

In the report of the IAEA Director General "Fukushima Daiichi NPP Accident" it is noted that the initial design solutions did not ensure similar safety margins for extreme external phenomena leading to flooding such as tsunami and earthquakes and it is recommended in assessing hazardous natural phenomena to account a probability of a combination of simultaneously or sequentially going events and their combined impact to the NPP. In assessing hazardous natural phenomena, it should be considered their impacts on several power units placed on the NPP site.

(1) Have then recommendations of above said IAEA Report been implemented at the USA's NPPs located on the Pacific, Atlantic coasts, in the Gulf of Mexico (in total 20 NPPs) where such combined external phenomena are possible (like in Japan happen on March 11, 2011) and were the emergency core cooling systems of reactors modernized to prevent their common cause failure?

(2) The new revision of the IAEA Standard GSR-3 (rev.1) "Site Evaluation for Nuclear Installations" requires conduct of evaluations of aircraft crashes in the nuclear plant siting region:

"3.44. The potential for aircraft crashes on the site shall be assessed with account taken, to the extent practicable, of characteristics of future air traffic and aircraft.

3.47. If the assessment indicates that the hazards are unacceptable and if no practicable solutions are available, then the site shall be deemed unsuitable".

Given the heavy air traffic over many NPP sites in the USA and terrorist act of September 11, 2001 in New York and the state of Pennsylvania with the use of four heavy aircrafts, would you specify whether the post-Fukushima stress tests were carried out as initiated by the IAEA and EU to evaluate probability of aircraft crashes of heavy aircrafts (more than 140 tons) on the NPP sites in the USA and danger of consequences of such aviation accident?

(3) Given the climate changes on the planet and recommendations of the IAEA and EU regarding conduct of the post-Fukushima stress tests to evaluate danger of extreme weather conditions impact on the NPP sites, whether the revaluation was done of extreme weather conditions impacts on NPP sites in the USA?

<u>Answer</u>: (1) Licensees were not required to modify their emergency core cooling systems as a result of the lessons learned from the events at Fukushima. Rather, to maintain key safety functions, the NRC's Mitigation Strategies Order required every U.S. commercial reactor operator to develop strategies for dealing with the long-term loss of standard safety systems. Instead of speculating on which events (or combination of events) might happen, the NRC order focused on improving plant flexibility and diversity in responding to extreme natural phenomena, such as severe flooding and earthquakes. The goal is to keep the reactor core cool, preserve the containment barrier that prevents or controls radiation releases, and cool

the spent fuel pool, all for an indefinite period of time. Plants with multiple reactors must be able to implement these measures at all reactors simultaneously. Each plant developed the required strategies and installed new emergency response equipment, stored on site and protected from natural hazards. Sufficient amounts of this equipment (with spares as needed) are located at each site to address emergency response at all reactors simultaneously. NRC inspectors have verified that the strategies and necessary equipment are in place at all U.S. nuclear power plants. Additional equipment and resources are also stored and maintained at two National Response Centers (five sets of equipment at each center), ready to be deployed to a plant during an emergency. Each center is capable of deploying the equipment to any U.S. site within 24 hours.

The requirements of the Mitigation Strategies Order were included in the NRC's regulations at 10 CFR 50.155, which became effective in September 2019. Further details about U.S. post-Fukushima activities and related documents can be found on the NRC's public website at https://www.nrc.gov/reactors/operating/ops-experience/post-fukushima-safety-enhancements.html.

(2) For U.S. operating power reactors, the NRC assessed and addressed aircraft impacts following the events on September 11, 2001. Section B.5.b of NRC Order EA-02-026, "Order Modifying Licenses," issued on February 25, 2002, required licensees to develop specific guidance and strategies to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities using existing or readily available resources (equipment and personnel) that can be effectively implemented under the circumstances associated with loss of large areas of the plant due to explosions or fire (from any cause). By letter dated November 28, 2011 (ML111220447), the NRC partially rescinded Order EA-02-026. Subsequently, the NRC added requirements similar to those of section B.5.b of EA-02-026 to the NRC's regulations at 10 CFR 50.54(hh). For operating power reactors, 10 CFR 50.54(hh)(1) requires licensees to develop, implement, and maintain procedures that describe how the licensee will address potential aircraft threats. In 10 CFR 50.54(hh)(2), the NRC requires licensees to develop guidance and strategies for addressing the loss of large areas of the plant due to explosions or fires from a beyond-design-basis event.

One of the earliest actions the NRC took as a result of the accident at Fukushima was to inspect every U.S. operating power reactor site (Temporary Instruction 2515/183, dated March 23, 2011; ML11077A007). The intent of the inspection was to conduct a high-level look at the nuclear industry's preparedness for events that may exceed the design basis for a plant and to assess each licensee's capability to mitigate conditions that result from beyond-design-basis events. This capability included the types of threats specified in NRC Order EA-02-026, section B.5.b, and in 10 CFR 50.54(hh). The NRC provided an individual inspection report for each site. A summary of the observations from those inspections can be found in ADAMS Accession No. ML11325A020.

Additionally, in May 2011, the NRC issued Bulletin 2011-01, "Mitigating Strategies" (ML111250360), requesting licensees to provide (1) a comprehensive verification of their compliance with the regulatory requirements of 10 CFR 50.54(hh)(2) and (2) information associated with the licensee's mitigation strategies under that section. In 10 CFR 50.54(hh)(2), the NRC stated, in part: "Each licensee shall develop and implement guidance and strategies intended to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities under the circumstances associated with loss of large areas of the plant due to explosions or fire."

The requirements of 10 CFR 50.54(hh)(2) were relocated to 10 CFR 50.155(b)(2) when the Mitigation of Beyond-Design-Basis Events Rule was finalized. This change became effective in September 2019. For new applicants, 10 CFR 50.150 requires a design-specific aircraft impact assessment. (3) As described in section 2.3.3.4 of the U.S. 8th National Report, the NRC staff issued a 10 CFR 50.54(f) request for information letter in March 2012 (ML12053A340), in part to request licensees to confirm appropriate levels of reevaluated, beyond-design-basis seismic and flooding events and to allow the NRC staff to assess individual plant responses and determine if additional regulatory actions were needed. Licensees of operating power reactor sites in the United States were asked to reevaluate all appropriate external flooding sources and seismic information using present-day regulatory guidance and methodologies. The licensees used current techniques, software, and methods consistent with present-day standard engineering practices to develop the reevaluated flood and seismic hazards. Extreme weather conditions were included in these assessments where appropriate. The reevaluated hazard information is used to determine the impact on the site, identify potential vulnerabilities, and identify appropriate actions to address these vulnerabilities. The NRC evaluates the licensees' information to consider any additional regulatory actions. Nearly all of these evaluations have been completed. The few remaining evaluations are expected to be completed in 2020. In addition to the reevaluated hazard requests, the NRC has enhanced its existing processes to ensure that the NRC staff proactively and routinely aggregates and assesses new natural hazard information. The framework of this process includes a "Natural Hazards Information Digest "(knowledge base), active technical engagement and coordination with internal and external partners (including international regulators), and ongoing assessment activities. Potentially risk-significant issues that are identified will be referred to the appropriate regulatory program offices.
Question No. 28
What factors are prohibiting for placing a NPP on the studied site?
<u>Answer</u>: The NRC does not have geologic, seismic, hydrologic, or meteorological exclusionary criteria in the regulations related to siting a proposed nuclear power plant. Rather, structures, systems, and components must be designed to withstand the effects of the most severe natural phenomena that have been historically reported for the proposed site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated. Various regulatory guidance documents implement these regulations and recommend, but do not require, the application of more detailed criteria. In addition, guidance to staff in chapter 2 of the Standard Review Plan (NUREG-0800) allows an applicant flexibility in proposing alternate approaches to specific regulatory guidance as long as the applicable regulations are met. NUREG-0800 can be found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/.
Question No. 146
Please give the full list of external impacts of natural and man-induced origin with showing the degree of hazard which is considered in the site selection.
<u>Answer</u>: Chapter 2, "Site Characteristics and Site Parameters," of the NRC's Standard Review Plan (NUREG-0800) discusses hazards of natural and human-induced origins and how the NRC staff reviews an applicant's information to ensure the hazards have been

adequately addressed to assess potential impacts at a proposed site. For natural hazards, the NRC requires that structures, systems, and components important to safety be designed to withstand effects of the most severe natural phenomena historically reported for the proposed site and surrounding area, and with sufficient margin for the limited accuracy and quantity of the historical data as well as the time period those data cover. Potential natural and human-induced hazards determined from detailed information for a proposed site are collected by an applicant and evaluated by NRC staff when the site has been selected. Various regulatory guidance documents implement the NRC's regulatory requirements and recommend, but do not require, application of specific approaches for assessing the impacts of potential natural and human-induced hazards. Guidance to the staff in chapter 2 of NUREG-0800 allows an applicant flexibility in proposing alternate approaches to specific regulatory guidance as long as the applicable regulatory requirements are met.
Question No. 54
According to the National Report a re-evaluation of site parameters will only be requested in case of incidents/accidents happened. How does NRC ensure, that new insights or changed site conditions (e.g. new seismic studies, climate change, etc.) became aware to the license holder to initiate further analysis if corrective actions may be necessary?
Answer: The NRC has an internal Process for the Ongoing Assessment of Natural Hazards Information. This process was implemented to systematically identify new natural hazards information (e.g., new data, models, and methods) as it becomes available and to assess its potential risk significance to nuclear power plant sites in a timely manner. This process ensures the timely identification and assessment of new information and facilitates a methodical assessment of the cumulative effect of new data, models, and methods that accrue over time. The framework the NRC uses to assess new natural hazards information is based on three primary components: (1) knowledge base activities, (2) active technical engagement and coordination with external counterparts (including other Federal agencies, industry, academia, international regulators, and other technical and scientific organizations), and (3) assessment activities that involve the aggregation and evaluation of the significance of new natural hazards information. Further, if the NRC staff determines that the new hazards information has a potentially significant effect on plant safety, it will refer the issue to appropriate NRC regulatory programs (e.g., the NRC Generic Issues Program) for detailed assessment and further action.
Question No. 127
(1) Are there requirements for groundwater monitoring for uncontrolled release of radionuclide during operation of NPPs? (2) If a groundwater monitoring program is in place, does the regulatory body inspect the program? (3) How is the groundwater monitoring program operated with regard to decommissioning of NPP? And what are the regulatory requirements and how is inspection of the regulatory body being done?
Answer: (1) There are regulatory and monitoring requirements for protection against radiation resulting from the release of radionuclides into groundwater and surface water. Two types of releases are of concern for a nuclear power plant: normal releases resulting from daily operations and abnormal releases due to unexpected or unforeseen circumstances that result in accidental release. Each nuclear power plant licensee is required to submit two annual reports that describe the radioactive effluents discharged from the site and the effects of those discharges (if any) on the environment. The reports describe effluent concentrations, which are

compared to the legal effluent concentration limits. The concentration limits are tied to the acceptable dose limits.

Applicable NRC regulatory requirements include the following:

- In 10 CFR 20.1406(a), the NRC requires that applicants for licenses other than early site permits and manufacturing licenses under 10 CFR Part 52 describe in the application how facility design and procedures for operation will minimize contamination of the facility and the environment to the extent practicable, facilitate eventual decommissioning, and minimize generation of radioactive waste to the extent practicable.

- In 10 CFR 20.1406(b), the NRC requires that applicants for standard design certifications, standard design approvals, and manufacturing licenses under 10 CFR Part 52 describe in the application how facility design will minimize, to the extent practicable, contamination of the facility and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, generation of radioactive waste.

- In 10 CFR 20.1406(c), the NRC requires that licensees, to the extent practicable, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 10 CFR Part 20, Subpart B, "Radiation Protection Programs," and radiological criteria for license termination in Subpart E, "Radiological Criteria for License Termination."

- In 10 CFR 20.1501, "General," the NRC requires that licensees perform surveys of areas, including the subsurface, that are reasonable to evaluate magnitude and extent of concentrations or quantities of residual radioactivity and to determine the potential radiological hazards of the radiation levels and residual radioactivity detected.

- General Design Criterion 64, "Monitoring Radioactivity Releases," of Appendix A to 10 CFR Part 50 requires that a means be provided for monitoring, among other things, the facility environs for radioactivity that may be released from normal operations, including anticipated operational occurrences, and from postulated accidents.

(2) Yes. The NRC has resident inspectors who perform inspections as part of their daily work and also perform targeted inspections when there is a reason to do so. For example, if there is evidence of an abnormal release in the monitored groundwater wells, then the resident inspector will perform an inspection, evaluate the licensee's response, and document any findings or issues with the licensee's program.

(3) As explained above, some regulatory requirements addressing minimization of contamination are aimed at maintaining a reasonably low level of contamination that would aid in the decommissioning phase. As part of the licensing review process and through regular updates to the safety analysis report, the nuclear power plant licensee is expected to provide for NRC staff review information related to possible pathways for surface water and groundwater transport mechanisms of radionuclides to help identify exposure pathways. At the time of decommissioning, radionuclides retained on site must be dispositioned in accordance with guidance in NUREG-1757, Volume 2, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria: Final Report"

(ML20273A010). The groundwater monitoring program gives insights on the pathways and possible hotspots that require additional consideration.

The NRC has established the Radiological Environmental Monitoring Program, which licensees rely on to satisfy the requirements of General Design Criterion 64. The licensee is required to implement the program in accordance with its technical specifications and/or offsite dose calculation manual. The program is based on the as low as is reasonably achievable (ALARA) requirements in 10 CFR Part 50. The design objectives upon which the Radiological Environmental Monitoring Program is based are in 10 CFR 50.34a, “Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors.” The program requirements also include biennial inspections, which have four objectives:

(1) Verify that the program quantifies the impact of radioactive effluent releases to the environment and sufficiently validates the integrity of the radioactive gaseous and liquid effluent release programs.

(2) Verify that the program is implemented consistently with the licensee’s technical specifications and/or offsite dose calculation manual and to validate that the radioactive effluent release program meets the design objectives in 10 CFR Part 50, 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.”

(3) Insure that the program monitors noneffluent exposure pathways (e.g., onsite spills or leaks, exposures from direct and scattered (skyshine) radiation from plant facilities and components); is based on sound principles and assumptions; and validates that doses to members of the public are within the dose limits of 10 CFR Part 20 and 40 CFR Part 190, “Environmental Radiation Protection Standards for Nuclear Power Operations,” as applicable.

(4) Verify that the licensee continues to implement the voluntary industry Groundwater Protection Initiative.

Question No. 128

(1) For facilities that have lower heat output than commercial nuclear power plant, such as nuclear cycle facilities (refining, converting, processing, spent fuel processing) and research reactor, will the safety review be subject to the same safety requirements as commercial nuclear power plant?

(2) If a graded approach is applied, is there quantitative criteria and relevant reference document?

Answer:
(1) The safety reviews for nuclear fuel cycle facilities and research reactors are not subject to the same regulatory requirements as commercial nuclear power plants.

The safety requirements for nuclear fuel cycle facilities, including plutonium processing or fuel fabrication plants and uranium enrichment facilities, are in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” which establishes procedures and criteria for the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material. The NRC conducts its safety reviews of fuel cycle facilities primarily using the guidance in NUREG-1520, Revision 2, “Standard Review Plan for Fuel Cycle Facilities License Applications,” issued June 2015 (ML15176A258).

Section 104 of the Atomic Energy Act requires the NRC to impose only such minimum amount of regulation on research reactors and testing facilities as will permit the Commission to fulfill its obligations under the Act. The NRC implements this requirement through the licensing processes and technical safety requirements applicable to research reactors and testing facilities in its regulations at 10 CFR Part 50. The NRC published NUREG-1537, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors,” Parts 1 and 2, to assist applicants for nonpower reactors prepare license applications for NRC review and to establish a standard review plan for NRC staff evaluating these applications. This guidance provides an acceptable methodology for demonstrating compliance with the NRC’s regulations for nonpower reactors.

(2) For fuel cycle facilities, a graded approach is applied to the licensing of facilities that possess greater than a critical mass of special nuclear material. Additional accident safety requirements for these facilities are in 10 CFR Part 70, Subpart H, “Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material.” Subpart H identifies risk-informed performance requirements and requires applicants and existing licensees to conduct an integrated safety analysis and submit an integrated safety analysis summary, as well as other information. NUREG-1520, Revision 2, provides guidance for conducting reviews of fuel cycle facilities.

The NRC uses a graded approach in its regulation of research reactors and testing facilities by applying additional regulatory processes and technical requirements to facilities with greater risk of radiological consequences to members of the public. This approach considers several attributes of the facility design and operation, including the type of reactor, the power level of the reactor, the quantity and form of the special nuclear material possessed by the reactor, and the reactor activities. For example, the regulations at 10 CFR 50.2, “Definitions,” define a testing facility as a reactor for research and development that is authorized to operate at a power level greater than 10 megawatts (MW), or greater than 1 MW for other specific design and operational characteristics. These facilities are subject to additional regulatory requirements and processes compared to research reactors with lower licensed power levels, such as the siting and accident dose criteria in 10 CFR Part 100, an independent review by the Advisory Committee on Reactor Safeguards, and a mandatory hearing before the issuance of a license. The guidance in NUREG-1537 gives additional information on the NRC’s graded approach to reviewing applications for the licensing of nonpower 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. 7
In chapter 18.1.4 it is stated regarding experience and implementation of defense-in-depth measures as response to the Fukushima Dai-ichi accident that “the NRC issued requests for information asking licensees to reevaluate their seismic and flooding hazards. The information obtained helped the NRC consider the protection levels for those events and determine whether additional regulatory action was needed”. In this regard, Switzerland would like to learn of the main results of the requests for information, e.g. the number of NPP sites with adequate/appropriate design against the reevaluated seismic and flooding hazards, the measures that were or will be taken in order to increase the protection levels of the plants with inadequate protection levels. (1) Which seismic hazard analysis methods (SSHAC level) were applied? (2) Were there any measures required regarding protection against tsunamis for coastal NPP sites?
Answer: The NRC staff issued a 10 CFR 50.54(f) request for information letter in March 2012 (ML12053A340) with two main goals: (1) Confirm appropriate levels of reevaluated, beyond-design-basis seismic and flooding events assumed for each plant (and their ability to protect against them). (2) Allow the NRC staff to assess individual plant responses and determine if any additional regulatory actions were needed at a particular site.

As a result of the assessments performed in response to the request, several nuclear power plant owners modified the protection of certain plant structures, systems, and components, or they identified alternative strategies to maintain the safety of the reactors in the event of a reevaluated beyond-design-basis flooding or seismic event. (Examples of site modifications can be found on the NRC's public website as noted below.)

Seismic Events: The evaluations performed by the licensees and reviewed by the NRC staff confirmed that most of the nuclear power plants have inherent structural capacity, meaning that adequate safety margins exist for the reevaluated seismic events. Approximately 30 percent of sites pursued modifications to address potential vulnerabilities and enhance existing capabilities. Examples of such modifications include enhanced anchorage for safety-related equipment, alternate means for safety-related functions, additional operator actions to address relay chatter issues, adequate clearance around equipment (such as fire sprinklers), and enhanced FLEX strategies. The NRC's regulations and guidance point U.S. nuclear power plant licensees to probabilistic seismic hazard analysis (PSHA) as the favored assessment process. "The Probabilistic Seismic Hazard Analysis: Background Information" (ML14140A648) provides background information on the PSHA methods used for this effort. As specified in Enclosure 1 to the 10 CFR 50.54(f) letter, licensees for plants in the central and eastern United States used previously developed and endorsed SSHAC level 3 seismic source models and ground motion models. The licensees for the three western United States plants developed site-specific SSHAC level 3 models. The NRC provides specific recommendations for SSHAC levels in NUREG-2213, "Updated Implementation Guidelines for SSHAC Hazard Studies," issued October 2018 (ML18282A082).

Flooding: The evaluations confirmed that over 90 percent of the sites already had existing flooding protection strategies that met or exceeded the reevaluated flooding hazards calculated using present-day guidance and methods. A small subset of sites made additional safety enhancements and/or credited defense-in-depth strategies such as FLEX in order to address potential vulnerabilities from the reevaluated flooding hazard, consistent with the guidance in Nuclear Energy Institute guidance document NEI 16-05 (ML16165A176). Examples of modifications to address these potential vulnerabilities include crediting advance warning time triggers to implement site actions, installing additional flooding protection barriers, relocating permanently installed equipment, and improving drainage conditions at the site. All sites evaluated the impact of tsunami hazards, as appropriate, using present-day guidance and methods. Only a limited number of sites (approximately 5 percent) were determined to have exceedances above the site's current design basis. For these sites, the modifications and guidance described above are representative of the changes made at the site. No additional measures were required for protection against tsunamis at coastal sites.

In general, based on the reviews that the NRC staff has completed as of December 1, 2019, the U.S. nuclear sites have adequate response strategies for protection against the reevaluated seismic and flooding hazards. The NRC staff expects to complete its remaining reviews of the 10 CFR 50.54(f) assessments by the end of 2020.

The NRC summarized the agency's conclusions and path forward for the remaining work in letters dated July 3, 2019 (ML19140A307), for seismic events, and August 20, 2019

(ML19067A247), for flooding. The NRC public website has additional details of the existing flooding and seismic defenses at U.S. nuclear power plants: https://www.nrc.gov/reactors/operating/ops-experience/post-fukushima-safety-enhancements/flooding-and-seismic-defense.html
Question No. 22
According to the report, "A common-cause failure attributable to software errors was not possible in analog systems. This possible failure mode may be addressed using diversity and defense-in-depth in the application of digital instrumentation and control systems." (1) Please explain how these principles are applied in new NPP designs. (2) What forms/types of diversity are used?
Answer: (1) For new nuclear power plant designs, an applicant performs and submits a diversity and defense-in-depth assessment to demonstrate that vulnerabilities of the digital instrumentation and control systems to common-cause failures have been adequately addressed. For each design-basis event, this assessment analyzes potential common-cause failures due to latent software defects that could disable a safety function credited in the safety accident analysis. The assessment results inform the applicant's design decisions to determine how to address these failures, including identifying an existing diverse means or adding a diverse means to perform the safety function or a different function. (2) The NRC staff has approved applications with many design solutions, and in some cases, multiple design solutions, to address common-cause failures in digital instrumentation and control systems. Applicants have credited (a) manual operator action, (b) the existing instrumentation and control system, (c) diverse actuation systems, or (d) diversity within the digital instrumentation and control system or component. The applicant must show that the credited diverse means are not subject to the same postulated common-cause failure that disabled the safety function.
Question No. 29
The phrase "nuclear plants that leverage the defense-in-depth philosophy in the design of the plant can gain some flexibility in operations and maintenance" is misleading. Conservative design contributes to level 1 of defence-in-depth along with operation and maintenance of SSC in accordance with the safety case, as is indicated in NEA-7248. Implementation of the defence-in-depth concept in one area does not promote relaxation of requirements in others. Defence-in-depth is a comprehensive consideration of the consecutive levels of protection.
Answer: The NRC agrees that implementation of a defense-in-depth philosophy in one area does not promote relaxation of requirements in other areas of plant operation and design and that a defense-in-depth philosophy is characterized by varying layers of defense. The NRC regrets that the statement in the question was misunderstood but affirms the statement is consistent with the NRC's application of the defense-in-depth philosophy. As an example, if in the design stage a licensee includes redundancy in a pump system, then during the operation of that system perhaps the licensee can avail itself of increased flexibility in maintenance periods (e.g., online maintenance). Because of the redundancy within the system, this flexibility would be justified because the system might be able to satisfy limiting conditions for operation even with certain components out of service.

Question No. 44
It is mentioned in the 2nd paragraph of section 18.1.4 that the station blackout conditions experienced at the Fukushima Dai-ichi NPP exceeded the conditions and time period of a station blackout in 10 CFR 50.63. Did this fact result in revisions to 10 CFR 50.63 or to the requirements related to station blackout for the design of new NPPs?
Answer: The NRC did not revise 10 CFR 50.63, “Loss of all alternating current power,” as a result of the lessons learned from the events at Fukushima Dai-ichi. Instead, the NRC took the approach to add an additional layer of defense in depth by requiring the development of mitigating strategies for responding to beyond-design-basis external events. One of the primary lessons learned from the accident at Fukushima was the significance of the challenge presented by a loss of safety-related systems following a beyond-design-basis external event. In the case of Fukushima, the extended loss of alternating current power (ELAP) condition caused by the tsunami led to loss of core cooling and a significant challenge to containment. To address these challenges, the NRC issued the Mitigation Strategies Order, EA-12-049 (ML12054A735), which required operating power reactor licensees, construction permit holders, and combined license holders to define and deploy mitigation strategies (FLEX strategies) that will enhance their ability to cope with an ELAP with concurrent loss of normal access to the ultimate heat sink (LUHS) (for nuclear power plants with passive reactor designs, a loss of normal access to the normal heat sink). FLEX strategies are designed to be used regardless of the cause. For a simultaneous ELAP and LUHS, the FLEX strategies identify actions to establish an indefinite coping capability during which key safety functions are maintained. FLEX strategies consist of three phases: (1) initially cope by relying on plant equipment, (2) augment or transition from plant equipment to onsite FLEX equipment and consumables to maintain or restore key functions, and (3) obtain additional capability and redundancy from offsite resources to maintain the key functions indefinitely. The first step in developing FLEX strategies was a plant-specific assessment to establish a baseline coping capability. All U.S. plants have a coping capability for station blackout conditions under 10 CFR 50.63. While initial actions following the event may focus on restoration of ac power to essential loads, procedural guidance assures a timely decision is made on whether or not the event has resulted in a station blackout condition that is an ELAP. This is an important decision to ensure that the actions to maintain or restore key safety functions are taken consistent with the timelines required for the successful implementation of the FLEX strategies for the initial response phase. Procedure guidance also specifies actions needed to assure equipment functionality can be maintained in an ELAP or can be performed without ac power. Procedures also ensure direct current (dc) loads are stripped down as soon as possible to the minimum plant equipment necessary and one set of instrument channels for required indications for the purpose of conserving dc power. The requirements of the Mitigating Strategies Order were added to the NRC’s regulations in 10 CFR 50.155, which became effective in September 2019 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0155.html). All new nuclear power plant applicants must meet the requirements of this regulation when an operating license is issued (or the Commission makes a finding that the acceptance criteria in the combined license are met per 10 CFR 52.103(g)).

Question No. 55
In the National Report it is stated, that “leverage the defense-in-depth philosophy in the design of the plant can gain some flexibility in operations and maintenance”. To allow maintenance, in-service inspections or corrective actions during operation is usually justified by a high degree of redundancy (n+2). Time frames for maintenance, in-service inspections or repair are usually defined by insights from probabilistic safety analysis. IAEA SSR 2/1 Rev. 1 states in para. 4.10 that “(T)the design shall take due account of the fact that the existence of multiple levels of defence is not a basis for continued operation in the absence of one level of defence”. Could the USA please elaborate on how the above mentioned requirement of SSR 2/1 Rev.1 are met?
<u>Answer</u>: The question brings up both design and operational aspects of regulation. From a design perspective and IAEA SSR 2/1 standpoint, NRC regulations require that plants include redundancy and diversity in certain capabilities and systems that are necessary for safe operation of the plant. In this way, there is defense in depth with conservatism in how plants are designed and constructed to enable safe operation. Defense in depth in the plant design is demonstrated in the associated safety analysis report and other supporting documents. For conduct of plant operations, operability of safety-related systems and components that are necessary for the continued operation of a U.S. plant are described in the plant-specific license that includes plant technical specifications per 10 CFR 50.36, “Technical specifications.” The technical specifications define limits and conditions for normal operation, consistent with expectations of SSR 2/2 and associated IAEA safety standards such as NS-G-2.2, “Operational Limits and Conditions and Operating Procedures for Nuclear Power Plants.” Limiting conditions for operation represent the lowest functional capability or performance levels of equipment required for the safe operation of the facility. During plant operations, certain systems or capabilities may experience failures or require periodic maintenance. For these temporary absences of certain capabilities or systems, limiting conditions for operation and associated times for plant actions are provided (consistent with SSR 2/2 and NS-G-2.2). Therefore, a possible outcome when a plant cannot meet a limiting condition for operation is that the plant would have to shut down until the deficiency is remedied. These specified times were established using deterministic judgement for each plant at initial plant licensing. In the late 1990s, the NRC required, per 10 CFR 50.65(a)(4), that licensees manage risk when equipment is out of service for maintenance because insights from probabilistic safety analyses revealed some plant temporary configurations have elevated risk but were still in compliance with the technical specifications. In more recent times, the NRC has authorized certain plants to adopt risk-managed technical specifications to allow for greater operational flexibility. For example, the program for risk-informed completion times to restore operability of safety systems allows for greater outage times than traditional technical specifications times. These risk-informed approaches reflect insights from probabilistic safety analyses, defense-in-depth considerations, and safety margins to allow for only small changes in risk.
Question No. 168
In the Report paragraph entitled “18.2 Technologies Proven by Experience or Qualified by Testing or Analysis” it is stated that: “the NRC requires that new technologies are demonstrated to be proven”. No information is given on general regulatory requirements in this area. (1) What is the status of implementation of the proven technologies in older operational U.S. NPPs?

(2)	What are the NRC requirements regarding qualification of the NPP equipment?
(3)	How was the original equipment of the U.S. NPPs qualified for its use so that it could be considered sufficiently proven for use in nuclear installations?

Answer:

(1) In 2007, the NRC revised its regulations at 10 CFR 50.43, “Additional standards and provisions affecting class 103 licenses and certifications for commercial power,” to require applicants for a nuclear power plant license or design certification whose designs differ significantly from those designs that were licensed before 1997 or that use simplified, inherent, passive, or other innovative means to accomplish their safety functions to demonstrate the performance of new technologies through analysis, appropriate test programs, experience, or a combination of all three. This requirement applies to new applications. All currently operating nuclear power plants were licensed to the requirements in place at the time of licensing. For design changes requiring a license amendment, licensees must provide sufficient justification, which could include test results, operating experience, etc., for the NRC staff to conclude with reasonable assurance that the proposed change will satisfy the applicable regulatory requirements. As the NRC identifies generic safety issues that warrant actions by or information from licensees, the NRC issues appropriate generic communications such as bulletins or generic letters that identify the issue and requested action or information. The NRC also has the authority to issue orders to licensees, such as was done for the post-Fukushima actions.

(2) Criterion III, “Design Control,” of Appendix B to 10 CFR Part 50 requires licensees, in part, to have design control measures that provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. In addition, the NRC staff has issued many regulatory guides that address equipment qualification, which identify acceptable approaches and consensus standards that satisfy the NRC’s regulations. For example, RG 1.9, “Application and Testing of Safety-Related Diesel Generators in Nuclear Power Plants,” (ML070380553) describes an acceptable method to ensure that emergency diesel generators are selected with sufficient capacity, are qualified, and have the necessary reliability and availability for design-basis events.

(3) Licensees are required to have design control measures that provide for verifying or checking the adequacy of design. The NRC staff reviewed each licensee’s quality assurance and initial test programs during the nuclear power plant licensing and performs inspections of these programs after a license is issued.

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. 3
"In August 2013, the U.S. Court of Appeals for the District of Columbia Circuit ordered NRC to continue with the licensing process for DOE's [U.S. Department of Energy's] Yucca Mountain construction authorization application, until Congress directs otherwise or there are no appropriated funds remaining. After the Court's decision, the NRC completed the safety evaluation report for Yucca Mountain. In addition, the NRC developed a supplement to DOE's environmental impact statement to address ground water impacts previously identified by the NRC staff as requiring additional analysis." What kind of water analysis was required by the NRC?

Answer: Under the Nuclear Waste Policy Act, the NRC is to adopt the U.S. Department of Energy's (DOE's) environmental impact statements to the extent practicable. The NRC staff determined that it was practicable to adopt DOE's environmental impact statements in September 2008 but noted the need to supplement DOE's assessment of the effects of groundwater on the Yucca Mountain aquifer beyond the site boundary. The NRC evaluated the flow of groundwater and the potential for releases of contaminants beyond the site boundary and into Death Valley (56 kilometers (35 miles) from the site).

The NRC's supplement to DOE's environmental impact statements describes the affected environment and assesses the potential environmental impacts of contaminant releases from the proposed repository that could be transported through the volcanic-alluvial aquifer in Fortymile Wash and the Amargosa Desert, and to the Furnace Creek/Middle Basin area of Death Valley. The supplement evaluated the potential radiological and nonradiological impacts—over a 1 million-year period—on the aquifer environment, soils, ecology, and public health, as well as the potential for disproportionate impacts on minority or low-income populations. The NRC staff found that each of the potential direct, indirect, and cumulative impacts on the resources evaluated in the supplement would be small.

Question No. 21

According to the report, the NRC "… approved … technical specifications program allowing licensees an option to determine the appropriate out-of-service times for equipment, based in part on the risk profile of the overall plant configuration." How have the US NPPs used this permission in practice? Please provide some examples of changing out-of-service time.

Answer: The "Risk-Informed Completion Time Program" allows a select number of required action completion times in a licensee's technical specifications to be extended, provided risk is assessed and managed within a configuration risk management program, when the limiting conditions for operations are not met. The program methodology is based on industry guidance document NEI 06-09, Revision 0-A, "Risk-Informed Technical Specifications Initiative 4b, Risk-Managed Technical Specifications (RMTS) Guidelines," issued November 2006 (ML122860402). For risk-informed completion time calculations, the configuration-specific risk is determined and the time to reach an integrated core damage probability of 10^{-5}, or an integrated large early release probability of 10^{-6}, is calculated. The risk-informed completion time is limited to a deterministic maximum of 30 days. In addition to the integrated risk limits for calculating the risk-informed completion time, the methodology also imposes a restriction that prohibits voluntary entry into a plant configuration that exceeds a risk level equivalent to 10^{3}/year core damage frequency, or 10^{4}/year large early release frequency. Only the completion time is changed by this methodology. The following are examples applying this methodology.

(1) A licensee used the "Risk-Informed Completion Time Program" to extend the completion time from 72 hours for one required offsite circuit to 30 days for planned maintenance. The technical specification required action, and completion time was exited after 6 days.

(2) A licensee used the "Risk-Informed Completion Time Program" to extend the completion time from 48 hours to 30 days for an emergent inoperability of the reactor protective system instrumentation. The technical specification required action, and completion time was exited after 16 days.

(3) A licensee used the "Risk-Informed Completion Time Program" to extend the completion time from 2 hours to 30 days for an emergent inoperability of an inverter,

which resulted in the inoperability of its associated alternating current bus. The technical specification required action, and completion time was exited after 4 days.
Question No. 23
According to the report, “The NRC and the nuclear industry have developed risk-informed improvements to technical specifications. Recently, the NRC approved a technical specification program allowing licensees to determine the appropriate surveillance test intervals based in part on risk information.” How have the US NPPs used this permission in practice? Please provide some examples of changing intervals.
Answer: The technical specifications program relocates most periodic surveillance requirement frequencies in a licensee’s technical specifications to a licensee-controlled program referred to as the Surveillance Frequency Control Program. The Surveillance Frequency Control Program does not include surveillance frequencies that are event driven, controlled by an existing program (e.g., the inservice testing program), or are condition based (e.g., battery degradation, age, and capacity). The program methodology is based on industry guidance document NEI 04-10, Revision 1, “Risk-Informed Technical Specifications Initiative 5b, Risk-Informed Method for Control of Surveillance Frequencies,” issued April 2007 (ML071360456). The methodology provides a risk-informed process to support a plant expert panel assessment of proposed changes to surveillance frequencies, assuring appropriate consideration of risk insights and other deterministic factors that may impact surveillance frequencies, along with appropriate performance monitoring of changes and documentation requirements. Only the surveillance frequency is changed by this methodology; the surveillance test requirements (test methods) themselves remain in the technical specifications. The following are examples of applying this methodology. • When above the preset power level of the rod worth minimizer, all withdrawn control rods not required to have their directional control valves disarmed electrically or hydraulically shall be demonstrated operable by moving each control rod at least one notch at least once per 7 days. A licensee used the Surveillance Frequency Control Program to extend this surveillance test from 7 days to 31 days. Typically, this surveillance requirement takes over 5 hours to move each of the 185 control rods one notch and usually involves between two and four reactor operators to perform. The licensee extended this surveillance frequency to reduce the potential for a reactivity management event and human error. • Each standby gas treatment subsystem and reactor enclosure recirculation subsystem shall be demonstrated operable at least once per 31 days by initiating, from the control room, flow through the high-efficiency particulate air filters and charcoal absorbers and verifying that the subsystem operates with the heaters operable. A licensee used the Surveillance Frequency Control Program to extend these surveillance tests from 31 days to 92 days. The 31-day surveillance test frequencies result in running the standby gas treatment system multiple times per month, which introduces wear on system components; challenges the operators because these tests are personnel intensive; and requires shutting down the normal ventilation system, which elevates room temperatures. When a high-temperature condition exists, the surveillance test is aborted until normal operating temperatures are restored, resulting in additional fan stops and starts. The licensee extended these surveillance frequencies to reduce the operator challenges by permitting this test to be scheduled out of the summer months.

• Each emergency core cooling system actuation instrumentation channel for the 4.16 kilovolt emergency bus undervoltage/degraded voltage relay shall be demonstrated operable by the performance of a channel functional test at least once per 31 days. A licensee used the Surveillance Frequency Control Program to extend this surveillance test from 31 days to 92 days. The degraded bus relays are normally energized and perform an overlapping design function to detect degraded line voltage and auto-transfer to the alternate 4 kilovolt source. The licensee extended this surveillance frequency because performance of this monthly test requires application of test jacks into live circuits and carries with it the potential to trip the bus; additionally, frequent testing can promote accelerated wear and aging that could promote premature failure.
Question No. 24
Are the external support organizations involved in screening of information about external and internal operating experience?
Answer: All licensees committed to review internal and external operating experience as part of the response to action items in the Three Mile Island Action Plan. In NRC Generic Letter (GL) 82-04, "Use of INPO SEE-IN Program," dated March 9, 1982, the NRC endorsed the operating experience screening program established by an external organization, the Institute of Nuclear Power Operations (INPO), for review of external operating experience. Industry screening of operating experience both by INPO and by licensees is separate from and independent of NRC screening of operating experience. The NRC and INPO have a memorandum of agreement where operating experience staff in each organization exchange information and reports on reactor events regularly and meet face-to-face at least once per year. GL-82-04 can be found on the NRC public website at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1982/gl82004.html.
Question No. 25
How the risk-oriented approach is used in drafting corrective measures for accounting of the operating experience?
Answer: NRC screening of operating experience uses risk as one of the criteria for determining the level of NRC response needed for identified issues. Quantitative risk information is developed from calculated increases in core damage frequency or core damage probability. Issues with higher risk are more likely to receive in-depth evaluation of potential generic applicability. Corrective actions for individual issues are the responsibility of the affected licensees, but the NRC will review potential regulatory actions on a broader scale if a risk-significant issue has the potential to occur at more sites. These actions could include industry communications, targeted inspection samples, or changes to regulatory guidance or the regulations themselves.
Question No. 26
Is the safety significance evaluation of the event and its consequence carried out during investigation of NPP events (including quantitative assessment of PSA)?
Answer: Section 19.6 of the U.S. 8th National Report describes the incident reporting system for events at U.S. nuclear facilities. For significant operational events, the NRC uses IMC 0309, "Reactive Inspection Decision Base for Reactors," (ML111801157) as the guide for conducting event investigations (also referred to as "reactive inspections"). Additional guidance on event investigation can be found in Management Directive 8.3, "NRC Incident Investigation Program" (ML18073A200). For events at power reactors, the NRC either conducts inspections under the ROP as described in IMC 2515 or reactive inspections as described in IMC 0309. When an event occurs at a U.S. nuclear power plant, the NRC initially gathers information on the event using IP 71153, "Follow Up of Events and Notices of

Enforcement Discretion," (ML18122A142) and then conducts a deterministic assessment and, when applicable, a preliminary risk assessment to determine the conditional core damage probability. The NRC uses this information, along with the criteria in IMC 0309, to determine if a reactive inspection is required. For more significant events, the formal significance of the event is determined as part of the event investigation. However, most event investigations in the United States are in response to lower significance events. In these cases, the reactive inspection/event investigation typically is charged with gathering the facts associated with the event (e.g., timeline, actions taken by operator), evaluating causal factors, and determining performance deficiencies that may have contributed to the event. Subsequently, the significance of any associated performance deficiencies, probabilistic or deterministic, is determined using the significance determination process described in IMC 0609. The IMCs and IPs can be found on the NRC's public website at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/ and https://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/, respectively.
Question No. 27
The Report provides information about the procedure of the use of NPP operating experience. Do the operating organization and regulatory body apply any criteria, performance assessment indicators of this activity (the use of operating experience)?
<u>Answer</u>: The NRC uses no performance indicators for assessing the licensee's use of operating experience. A licensee's use of operating experience is currently evaluated under the ROP baseline inspection program, specifically, the problem identification and resolution inspections. This information is in NRC IP 71152, "Problem Identification and Resolution," (ML21281A181).
Question No. 52
According to the National Report NEI has initiated a petition for rulemaking to change the reporting requirements of 10 CFR 50.72. Could the USA please share its view of this proposal. In particular, as the National Report describes in detail the advantages of the analysis of non-emergency events and its role for international event reporting systems?
<u>Answer</u>: This is a petition for rulemaking currently under staff evaluation. Therefore, it would be premature for the NRC to comment on the initiative until an official agency response is prepared.
Question No. 53
According to the National Report operating procedures, emergency operating procedures, severe accident management guidelines and FLEX strategies are in place in NPPs. For new NPP designs it is expected, that the design includes engineered safety features to cope with postulated core melt accidents. Could the USA please comment whether this lead to an extension of the EOPs [emergency operating procedures] for such plants to provide guidance to the operators to timely activate such engineered safety features (e.g. flooding reactor cavity for in-vessel retention)?
<u>Answer</u>: Generally, the scope of the emergency operating procedures does not include the guidance for mitigating severe accidents. The Severe Accident Management Guidelines (SAMGs) contain guidance for mitigating severe accidents. The emergency operating procedures do contain criteria for the operators to decide whether to transition to the SAMGs from the emergency operating procedures during an event at a nuclear power plant.
Question No. 68
Please clarify whether USA requires the licensee to have procedure or process to deal with low level events and near misses.

Answer: Licensees are required by regulations in Appendix B to 10 CFR Part 50 to correct conditions adverse to quality and prevent recurrence of significant conditions adverse to quality. To meet this requirement, licensees maintain a corrective action program to prioritize the evaluation and resolution of identified issues. Licensee participation in the Reactor Oversight Process, which is voluntary, assumes that licensees maintain a corrective action program that is able to effectively detect, correct, and prevent problems with the potential to impact reactor safety and security. NRC inspection of each licensee's corrective action program occurs under the baseline inspection program using IP 71152 to verify the continuing adequacy of the program.
Question No. 114
What are projected dates of construction completion of Yucca Mountain repository?
Answer: The United States currently has no facility for spent fuel disposal. An application for a construction authorization for a geologic repository at Yucca Mountain, Nevada, for the disposal for spent fuel and high-level waste was filed before NRC by the U.S. Department of Energy (DOE) in 2008; however, the adjudication on the application is suspended. In its license application for Yucca Mountain, DOE estimated that it would be ready to receive and emplace waste approximately 5½ years after a construction authorization was granted, and that it would take approximately 50 years to complete the emplacement of all the waste (i.e., 63,000 metric tons of commercial spent nuclear fuel and 7,000 metric tons of DOE high-level waste and spent nuclear fuel).
Question No. 121
It is stated that: “Early site permits are valid for 10 to 20 years and can be renewed for an additional 10 to 20 years.” What are the main considerations when determining 10 to 20 years for the validity period of early site permits?
Answer: It is up to the applicant to propose the duration of the early site permit in its application, which is usually based on the applicant’s specific business decisions. During its review of the early site permit application, the NRC confirms that the analyses properly assess the corresponding duration.
Question No. 122
It is stated that: “In addition, the NRC participates in international event reporting systems. The NRC reviews each reported 10 CFR 50.72 reactor-related event and assigns a rating of 1 through 7 or below scale on the International Nuclear and Radiological Event Scale. The agency submits events with a rating of 2 or higher to the IAEA nuclear events Web-based system for public posting.” (1) Do the operators indicate the INES [International Nuclear and Radiological Event Scale] level of the event when they submit the event report to NRC? (2) Is the final rating of the INES level subject to the judgment of the NRC?
Answer: (1) Licensees report events to the NRC in accordance with regulations, but they do not classify such events by INES level. (2) The NRC reviews each licensee report submitted under 10 CFR 50.72 and determines the equivalent INES level per IAEA’s guidelines. The NRC then submits to the IAEA events rated level 2 (incident) or higher.

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This report is an update to NUREG-1650, Revision 7, 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 eighth national report for peer review in October 2019 as NUREG-1650, Revision 7, “The United States of America National Report for the Convention on Nuclear Safety: Eighth National Report, October 2019.” Supplement 1 to NUREG-1650, Revision 7, documents the answers to questions raised by contracting parties during their peer reviews of the United States’ eighth 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 licensee holder, priority 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.

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