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

NUREG-1650, Rev. 6
Supplement 1

Answers to Questions from the Peer Review by Contracting Parties on the United States of America Seventh National Report for the Convention on Nuclear Safety

Office of Nuclear Reactor Regulation

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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 seventh national report for peer review in October 2016 (NUREG-1650, "The United States of America National Report for the Convention on Nuclear Safety: Seventh National Report, October 2016," Revision 6). Supplement 1 to NUREG-1650, Revision 6, documents the answers to questions raised by contracting parties during their peer reviews of the U.S. 7th 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. The International Atomic Energy Agency held the seventh review meeting of the CNS in Vienna, Austria, from March 27 through April 7, 2017.

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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 seventh national report for peer review in October 2016 (NUREG-1650, "The United States of America National Report for the Convention on Nuclear Safety: Seventh National Report, October 2016," Revision 6), which is available on the U.S. Nuclear Regulatory Commission's (NRC's) Web site at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1650/. Supplement 1 to NUREG-1650 documents the answers to questions raised by contracting parties during their peer reviews of the U.S. 7th national report.

On receiving questions from contracting parties, the NRC staff categorized them according to the article of the U.S. 7th national report that addressed the relevant material. Subsequently, technical and regulatory experts at the NRC and members of the Institute of Nuclear Power Operations answered the questions. The NRC provided these answers to the contracting parties in preparation for the seventh review meeting of the CNS, which was held at the International Atomic Energy Agency in Vienna, Austria, from March 27 through April 7, 2017.

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ABBREVIATIONS AND ACRONYMS

ABWR	advanced boiling-water reactor
ac	alternating current
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System (NRC)
ADR	alternative dispute resolution
AEA	Atomic Energy Act of 1954, as amended
ALARA	as low as reasonably achievable
ALWR	advanced light-water reactor
ANS	American Nuclear Society
ANSI	American National Standards Institute
AO	abnormal occurrence
AP	advanced passive
ASLB	Atomic Safety and Licensing Board
ASME	American Society of Mechanical Engineers
ASP	accident sequence precursor
ASR	alkali-silica reaction
BDBEE	beyond-design-basis external event
BEIR	Biological Effects of Ionizing Radiation
BRIIE	baseline risk index for initiating events
BWR	boiling-water reactor
CCF	common-cause failure
CDF	core damage frequency
CEDE	committed effective dose equivalent
CFR	*Code of Federal Regulations*
CFSI	counterfeit, fraudulent, suspect item
CNS	Convention on Nuclear Safety
COL	combined license
ConE	construction experience
CP	civil penalty
CRGR	Committee To Review Generic Requirements
CSS	Commission on Safety Standards (IAEA)
CY	calendar year
DAC	design acceptance criteria
DBA	design-basis accident
DEC	design extension condition
DG	draft regulatory guide
DHS	U.S. Department of Homeland Security
DI&C	digital instrumentation and control
DID	defense in depth
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
ECCS	emergency core cooling system
EDV	engineering design verification
EFT	event-free tool

EMDA	Expanded Materials Degradation Assessment
EME	emergency mitigation equipment
ENSREG	European Nuclear Safety Regulators Group
EOP	emergency operating procedure
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
EPU	extended power uprate
ERDS	Emergency Response Data System
ERO	emergency response organization
ESBWR	economic simplified boiling-water reactor
EU	European Union
FEMA	Federal Emergency Management Agency
FGR	Federal Guidance Report
FLEX	diverse and flexible coping strategies
FR	*Federal Register*
FSAR	final safety analysis report
FY	fiscal year
GALL	generic aging lessons learned
GDC	generic design criterion/criteria
GI	generic issue
GL	generic letter
GP	good practices
HFIS	Human Factors Information System
HFE	human factors engineering
HTGR	high-temperature gas-cooled reactor
IAEA	International Atomic Energy Agency
I&C	instrumentation and control
ICR	Institute on Conflict Resolution
ICRP	International Commission on Radiological Protection
IEEE	Institute of Electrical and Electronics Engineers
IGALL	international generic aging lessons learned
IMC	Inspection Manual chapter
IN	information notice
INES	International Nuclear Event Scale
INPO	Institute of Nuclear Power Operations
INSAG	International Nuclear Safety Advisory Group
IP	inspection procedure
IRRS	Integrated Regulatory Review Service
ISG	interim staff guidance
ISO	International Organization for Standardization
ITAAC	inspection(s), test(s), analysis (analyses), and acceptance criterion/criteria
ITP	Industry Trends Program
JLD	Japan Lessons-Learned Division
LAR	license amendment request
LER	licensee event report

LERF	large, early release frequency
LOCA	loss-of-coolant accident
LOOP	loss of offsite power
LWR	light-water reactor
MBDBE	mitigation of beyond-design-basis events
MD	management directive
MRP	Materials Reliability Program
MS	Member States
NDT	nondestructive testing
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
No.	number
NPP	nuclear power plant
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NTTF	Near-Term Task Force
NUPIC	Nuclear Utilities Procurement Issues Committee
OIG	Office of the Inspector General
OPC	open-phase condition
OSART	Operational Safety Assessment Review Team
PAG	protective action guideline
PMDA	Proactive Materials Degradation Assessment
PO&C	performance objectives and criteria
PRA	probabilistic risk assessment
PSA	probabilistic safety assessment
PSR	periodic safety review
PWR	pressurized-water reactor
PWROG	Pressurized-Water Reactor Owners Group
QA	quality assurance
QHO	quantitative/qualitative health objective
rcry	reactor-critical-year
RES	Office of Nuclear Regulatory Research
RFI	request for information
RIC	Regulatory Information Conference
RG	regulatory guide
RIS	regulatory issue summary
ROP	Reactor Oversight Process
RPV	reactor pressure vessel
RTNDT	reference temperature for nil ductility transition
RTNSS	regulatory treatment of nonsafety systems
SAFER	Strategic Alliance for FLEX Emergency Response
SAM	severe accident management
SAMA	severe accident mitigation alternative
SAMG	severe accident management guideline

SAR	safety analysis report
SAREF	SAfety REsearch Opportunities post-Fukushima
SBO	station blackout
SCPS	Safety Culture Policy Statement
SEP	Systematic Evaluation Program
SFP	spent fuel pool
SL	severity level
SLR	subsequent license renewal
SMR	small modular reactor
SOARCA	State-of-the-Art Reactor Consequence Analyses
SPAR	standardized plant analysis risk
SPU	stretch power uprate
SRM	staff requirements memorandum
SRP	Standard Review Plan
SRV	safety relief valve
SSC	structure, system, and component
SSE	safe-shutdown earthquake
STS	standard technical specification(s)
Sv	sievert
TEDE	total effective dose equivalent
TI	temporary instruction
TS	technical specification(s)
TVA	Tennessee Valley Authority
TWCF	through-wall cracking frequency
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
U.S.	United States
US APWR	U.S. Advanced Pressurized-Water Reactor
US EPR	U.S. Evolutionary Power Reactor
UT	ultrasonic testing
VDNS	Vienna Declaration on Nuclear Safety
WANO	World Association of Nuclear Operators
WBN1	Watts Bar Nuclear Plant, Unit 1
WBN2	Watts Bar Nuclear Plant, Unit 2
yr	year

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 "The United States of America for the Convention on Nuclear Safety: Seventh National Report, October 2016" (NUREG-1650, Revision 6) (hereinafter referred to as the U.S. 7th 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. Subsequently, technical and regulatory experts at the NRC and members of the Institute of Nuclear Power Operations (INPO) answered the questions. Please note that, with the exception of bracketed expansions added for some abbreviations that are not expanded in their answers, this report presents the questions exactly as they were received, without having edited them for grammar or spelling or in any other way. Also, the answers to the questions reflect the status from February 2017, which is when the United States submitted the answers to the International Atomic Energy Agency (IAEA).

This report follows the format of the U.S. 7th 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. 7th National Report, this report does not contain sections for Articles 1 through 5. In accordance with Article 1 of the CNS, the U.S. 7th 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. 7th 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 Web site (http://www.nrc.gov/reading-rm/adams.html). In addition, documents are available through the NRC's Public Document Room. One may contact the Public Document Room in any of the following ways:

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INTRODUCTION TO THE U.S. SEVENTH NATIONAL REPORT

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

- purpose and structure of the report
- summary of changes since the previous report was written in 2013
- 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 questions below on this section of the report.

Question Number (No.) 1
What is the periodicity of the “periodic confirmation of seismic and flooding hazards” as mentioned in Summary of the 7th National Report?
Answer: Near-Term Task Force (NTTF) Recommendation 2.2 suggested that the NRC initiate a rulemaking to require licensees to confirm seismic and flooding hazards every 10 years and address any new and significant information, including, if necessary, updating the design basis for structures, systems, and components (SSCs) important to safety to protect against the updated hazards. In SECY-12-0095, “Tier 3 Program Plans and 6-Month Status Update in Response to Lessons Learned from Japan’s March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami, dated July 13, 2012 (ADAMS Accession No. ML12208A208), the staff discussed other external hazards, such as those caused by meteorological effects, that should be included in the licensees’ periodic updates that the NRC would require once the agency implemented Recommendation 2.2 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0095scy.pdf). Subsequently, in SECY-15-0137, “Proposed Plans for Resolving Open Fukushima Tier 2 and 3 Recommendations,” dated November 4, 2015 (ADAMS Accession No. ML15254A006), the staff stated that the use of rulemaking to address Recommendation 2.2 was not necessary. Rather, the staff proposed to develop a method to leverage and enhance existing NRC processes and programs to ensure that information related to natural external hazards is proactively and routinely evaluated in a systematic manner. In response to the staff requirements memorandum (SRM) to SECY-15-0137, dated February 8, 2016 (ADAMS Accession No. ML16039A175), the NRC staff developed a framework that expands upon the concepts described in the SECY. The framework provides a graded approach that will allow the NRC to proactively, routinely, and systematically seek, evaluate, and respond to new information on natural hazards. Although the framework is intended to allow for ongoing assessment of new information, the staff recognizes that performance of certain activities (e.g., technical engagement activities and development of summary reports) on a defined or periodic schedule provides important institutional structure. As such, the framework paper (SECY-16-0144, “Proposed Resolution of Remaining Fukushima Tier 2 and 3 Recommendations,” dated January 13, 2017 (ADAMS Accession No. ML16286A586)) outlines the staff’s intention to develop an office instruction that will provide details on (1) the types of activities that will be performed, (2) the review approach to be used to assess new information, and (3) the periodicity of documentation of the work

under the framework. If the Commission approves the staff's proposal, the staff plans to develop the office instruction to implement the framework in 2017.
Question No. 2
We compliment the U.S. NRC for the number of regulatory documents issued on the subject of Counterfeit, Fraudulent, and Suspect Items (CFSIs). Has the U.S. NRC carried out or plan to carry out any oversight inspections on the licensee's Operations Quality Assurance Program to assess the licensee's CFSI program?
<u>Answer</u>: NRC licensees are not required to have an independent CFSI program, although they may voluntarily implement one. The NRC requires licensees to implement a quality assurance program in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The 18 criteria of Appendix B provide regulatory requirements in six broad areas directly applicable to CFSIs: (1) design control, (2) procurement document control, (3) control of purchased material, equipment, and services, (4) identification and control of material, parts, and components, (5) disposition of nonconforming materials, parts, or components, and (6) corrective action and program effectiveness reviews. At this point, the NRC has determined that a robust quality assurance program is adequate to address CFSIs. As described in Section 13.4 of the U.S. 7th national report, the NRC has one inspection procedure (IP) 71152, "Problem Identification and Resolution," that directly inspects corrective action and program effectiveness. The NRC indirectly evaluates other elements of Appendix B, based on inspection samples from other IPs.
Question No. 3
Good Practice: 1) Comprehensive national laws, regulations, standards, rules, and guides are listed in the appendix. 2) As one of the most experienced nuclear safety regulator in the world, the U.S. NRC has been participating in many IAEA, OECD/NEA, and other bilateral/multi-lateral activities to use its broad regulating experience on the NPPs (especially for LWRs) to contribute to the safety of NPPs worldwide. 3) Very comprehensive, useful, and detailed information is posted on the U.S. NRC external website to enhance its openness and transparent, as well as engagement of general public. 4) The changes to the previous National Report are summarized in a table. 5) Revision bars along the left margin of the page are added to identify changes from the previous National Report.
<u>Answer</u>: Thank you for your comments and observations. We appreciate the positive feedback.
Question No. 4
General suggestions on the National Report of USA: 1) Suggest listing all NPP safety-related legislation documentation adopted by the U.S. NRC since the 6th National Report listed in a summary table in the National Report. 2) Suggest listing major performance indicators of NPPs in 2013-2016 in a summary table. 3) Suggest listing operational events and deviations in 2013-2016 in a summary table. 4) Suggest listing past (2013-2015) and upcoming (beyond 2016) domestic and international review activities conducted/to be conducted at NPPs in the United States in a summary table. 5) Suggest listing emergency exercises conducted at NPPs in the United States in 2013-2016 in a summary table. 6) Suggest listing the Periodic Safety Review (PSR) status and planned life extension for each NPP in a summary table.

7) Suggest summarizing significant developments, if any, since the 6th National Report. 8)Suggest listing nuclear safety issues, if any, since the 6th National Report.
Answer: The United States welcomes the suggestions provided by the NRC's colleagues from Canada. The NRC provides regulatory oversight to 99 operating reactors (plus 6 units in active decommissioning and 14 reactors in SAFSTOR or deferred dismantling). Thus, upon a thorough evaluation of the recommendations, we have concluded that it is impracticable to provide this information in summary tables in the national report. The U.S. National Report currently has approximately 350 pages. Even if the NRC would attempt to summarize the information, because of the high number of reactors in the U.S. fleet, the number of pages in the U.S. report would significantly increase. This would result in an onerous peer review process. Having said this, 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 the regulatory process and have a reasonable opportunity to participate meaningfully in it. All of the suggestions referred to in the bullets above can be easily located on the NRC's public Web site, www.nrc.gov. The NRC provides links and references to its document library (ADAMS), where appropriate. ITEM 1 In the last 3 years, the NRC has issued the following rulemakings: (1) 10 CFR Part 51, "Revisions to Environmental Review for Renewal of Nuclear Power Plant Operating Licenses." This final rule was published on June 20, 2013, and became effective on June 20, 2014 (RIN 3150-AI42, Docket: NRC-2008-0608, 78 FR 37281. http://www.gpo.gov/fdsys/pkg/FR-2013-06-20/pdf/2013-14310.pdf). (2) 10 CFR Part 51, "Continued Storage of Spent Nuclear Fuel." This final rule was published on September 19, 2014, and became effective on October 20, 2014 (RIN 3150-AJ20, Docket: NRC-2012-0246, 79 FR 56238: http://www.gpo.gov/fdsys/pkg/FR-2014-09-19/pdf/2014-22215.pdf). ITEM 2 The Reactor Oversight Process (ROP) performance indicators and inspection findings for all reactors in the U.S. fleet can be found in the following links: performance indicators: https://www.nrc.gov/NRR/OVERSIGHT/ASSESS/pi_summary.html; inspection findings: https://www.nrc.gov/NRR/OVERSIGHT/ASSESS/pim_summary.html. ITEM 3 The ROP inspection findings for all reactors in the U.S. fleet and the event notification collection (for other operational events and deviations) can be found in the following links: performance indicators: https://www.nrc.gov/NRR/OVERSIGHT/ASSESS/pi_summary.html; event notifications: https://www.nrc.gov/reading-rm/doc-collections/event-status/. ITEM 4 In the last 5-years, the NRC conducted an average of 2,223 power reactor inspections per year. NRC inspection findings can be found here: https://www.nrc.gov/NRR/OVERSIGHT/ASSESS/pim_summary.html. As discussed in Section 8.1.5 of the U.S. 7th National Report, the NRC hosted an international Integrated

Regulatory Review Service (IRRS) mission in 2010 and a followup mission in 2014. The United States hosts international Operational Safety Assessment Review Team (OSART) missions every 3 years. The last OSART conducted in the United States took place in August 2014 at the Clinton Power Station, Unit 1. The followup OSART mission took place in October 2015. The Sequoyah nuclear plant in Tennessee will host an OSART in 2017.

ITEM 5
Section IV.F.2.b of Appendix E, “Emergency Planning and Preparedness for Production and Utilization Facilities,” to 10 CFR Part 50 requires that each nuclear power reactor licensee conduct an exercise of its onsite emergency plan every 2 years. Section IV.F.2.c similarly requires that the offsite emergency plans be exercised biennially. The NRC evaluates the performance of nuclear power reactor licensees in biennial exercises and documents the performance in publicly available inspection reports. The Federal Emergency Management Agency (FEMA) evaluates the performance of the offsite response organizations in graded biennial exercises and documents the performance in FEMA after-action reports. In the 4-year period between 2013 and 2016, approximately 200 graded biennial exercises would have taken place, and each would have onsite and offsite participation.

Section IV.F.2.b requires that nuclear power reactor licensees take actions to ensure that adequate emergency response capabilities are maintained between biennial exercises by conducting drills involving some of the principal functional areas of emergency response. Nuclear power reactor licensees generally conduct practice exercises annually. At some nuclear power plant sites, each designated emergency response organization (ERO) team will participate in an exercise between the graded biennial exercises. The NRC does not track or evaluate the performance of the licensee’s drills and exercises held between biennial exercises and cannot project the number of exercises.

ITEM 6
The NRC does not require licensees to perform PSRs but rather employs NRC resident inspectors for continuous safety inspection by the regulator. This process ensures that licensees perform continuous review and maintenance of safety of their facilities and their licensing bases. 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 the continuing regulatory activities of the NRC, as well as the licensee’s activities.

The U.S. 7th National Report, Section 14.1.5, “The United States and Periodic Safety Reviews,” discusses the NRC processes that substantially accomplish, on an ongoing basis, the shared objectives associated with IAEA and Western European Nuclear Regulators Association on PSR guidance.

More information on PSRs is available in the “Staff Evaluation of Periodic Safety Reviews from Other Countries” (http://www.nrc.gov/docs/ML1504/ML15043A725.html). The “Reactor License Renewal” section on page 32 of the Information Digest 2016–2017 discusses the license renewal process (http://www.nrc.gov/docs/ML1624/ML16243A018.pdf). The current status of license renewal activities and industry activities is available at http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html. The current status of subsequent license renewal activities and industry activities is available at http://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-renewal.html.

ITEM 7
Part I of the U.S. 7th National Report (ADAMS Accession No ML16293A104) discusses significant developments since the 6th National Report. The following list summarizes significant developments since the 7th National Report in August 2016:

(1) October 2016: The NRC renewed the operating licenses of LaSalle, Units 1 and 2, for an additional 20 years (ADAMS Accession No. ML16293A789).

(2) October 2016: The NRC made the CNS National Report publicly available (ADAMS Accession No. ML16301A445).

(3) November 2016: The NRC completed the safety review of proposed new reactors at Turkey Point in Florida (ADAMS Accession No. ML16328A267).

(4) November 2016: The NRC met performance goals and issues in the fiscal year (FY) 2016 Performance and Accountability Report (ADAMS Accession No. ML16328A268).

(5) December 2016: The NRC renewed the operating license of Grand Gulf, Unit 1, in MS (ADAMS Accession No. ML16351A118).

(6) December 2016: The NRC issued two combined licenses (COLs) for the Duke Energy Carolina William States Lee III site in South Carolina. The licenses authorize Duke to build and operate two AP1000 reactors at the site (https://www.nrc.gov/reading-rm/doc-collections/news/2016/16-075.pdf).

ITEM 8
The U.S. 7th National Report (ADAMS Accession No. ML16293A104) discusses significant safety issues since the 6th National Report. The following includes a summary of significant safety developments since the U.S. 7th National Report was issued in August 2016:

(1) October 2016: The NRC began a special inspection at Grand Gulf Nuclear Station to review circumstances surrounding several recent operational events and their corrective actions (ADAMS Accession No. ML16305A118).

(2) November 2016: The NRC began a team inspection at Pilgrim, triggered by earlier performance deficiencies (ADAMS Accession No. ML16334A222).

Question No. 5

What were the conclusions of the Fukushima Tier 3 recommendations (SECY-15-0137 and SECY-16-0041) concerning evaluations on containment vents, hydrogen control and instrumentation enhancements? What actions have been decided to be carried out at NPPs with BWR Mark I and Mark II containments? Does hardened vent mean that the system doesn't have filtering? What was the reason not to add filtering?

Answer: SECY-15-0137 (ADAMS Accession No. ML15254A006) and SECY-16-0041, "Closure of Fukushima Tier 3 Recommendations Related to Containment Vents, Hydrogen Control, and Enhanced Instrumentation," dated April 19, 2016 (ADAMS Accession No. ML16049A079), provided the NRC staff assessments related to the possible need to impose additional requirements for (1) venting capabilities for containments other than boiling-water reactor (BWR) Mark I and Mark II designs, (2) hydrogen control, and (3) severe accident instrumentation. The staff determined that potential regulatory requirements in these areas did not provide a substantial increase in the overall protection of public health and safety, which is required in the United States for the NRC to impose additional requirements on currently operating plants (i.e., as a generic or plant-specific backfit).

With respect to item (1), based on the staff's analysis, containments other than BWR Mark I and Mark II designs are expected to maintain their integrity by licensees using pre- and post-Fukushima mitigation strategies before core damage occurs. If the accident progresses to core damage, containment integrity would be maintained during a severe accident for sufficient time to allow operators to use mitigation measures defined in severe accident management guidelines (SAMGs) and, if necessary, to take protective actions such as evacuating local populations.

For item (2), the staff determined that hydrogen control is adequately addressed by the venting requirements for Mark I and Mark II containments put in place after the Fukushima accident; igniter systems previously installed in ice condenser and Mark III containments, which were enhanced after the Fukushima accident; and design margins in large dry containments.

Similarly, for item (3), the staff determined that additional instrumentation enhancements were not justified beyond those already required following the Three Mile Island accident for postaccident monitoring and included in orders for mitigating beyond-design-basis external events following the Fukushima accident. The staff's analysis also considered that SAMGs include provisions for assessing instrumentation that may be affected by severe accident conditions and, if necessary, taking alternate readings or using analytical techniques to calculate important parameters.

The NRC notes that additional requirements for severe-accident-capable hardened vents were imposed on Mark I and Mark II containments following the Fukushima accident. These systems must be able to support the operation of cooling systems that connect to the suppression pool, such as the reactor core isolation cooling system, as well as maintain the integrity of the containment following an extended loss of alternating current (ac) electrical power. The venting system is required to be seismically robust and remain functional under conditions associated with a severe accident (e.g., high temperatures, radiation levels).

The NRC staff evaluated the potential benefits of including an engineered filter to supplement the capabilities of the suppression pool or support venting without scrubbing by the pool and concluded that engineered filter systems did not provide a substantial increase in overall protection of public health and safety, as required by NRC regulations. The staff's analysis can be found in SECY-15-0085, "Evaluation of the Containment Protection and Release Reduction for Mark I and Mark II Boiling Water Reactors Rulemaking Activities," dated June 18, 2015 (ADAMS Accession No. ML15022A218).

Question No. 6

What were the conclusions of the Fukushima Tier 3 recommendations (SECY-15-0137 and SECY-16-0041) concerning evaluations on containment vents, hydrogen control and instrumentation enhancements for NPPs with other type of containment than Mark I or Mark II? In addition to considering venting system and hydrogen control, has there been any additional needs to qualify the instrumentation for the severe accident conditions?

Answer: SECY-15-0137 (ADAMS Accession No. ML15254A006) and SECY-16-0041 (ADAMS Accession No. ML16049A079) provided the NRC staff assessments related to the possible need to impose additional requirements for (1) venting capabilities for containments other than

BWR Mark I and Mark II designs, (2) hydrogen control, and (3) severe accident instrumentation.

The staff determined that potential regulatory requirements in these areas did not provide a substantial increase in the overall protection of public health and safety, which is required in the United States for the NRC to impose additional requirements on currently operating plants (i.e., a generic or plant-specific backfit). Containments other than BWR Mark I and Mark II designs are expected to maintain their integrity during a severe accident for sufficient time to allow operators to use pre- and post-Fukushima mitigation measures defined in SAMGs and to take protective actions such as evacuating local populations.

The staff determined that hydrogen control is adequately addressed by the venting requirements for Mark I and Mark II containments put in place after the Fukushima accident; igniter systems previously installed in ice condenser and Mark III containments, which were enhanced after the Fukushima accident; and design margins in large dry containments.

The staff also determined that additional instrumentation enhancements were not justified beyond those already required following the Three Mile Island accident for post-accident monitoring and included in orders for mitigating beyond-design-basis external events following the Fukushima accident. The staff's analysis also considered that SAMGs include provisions for assessing instrumentation that may be affected by severe accident conditions and, if necessary, taking alternate readings or using analytical techniques to calculate important parameters.

The NRC has not imposed additional requirements—beyond those already included in NRC regulations—for the qualification of selected instrumentation to remain functional during severe accident conditions.

Question No. 7

Staff readiness plans to transition plants from construction to operation and from operation to decommissioning seems to be good and systematic approach.

Answer: Thank you for your comment and observation. We appreciate the positive feedback.

Question No. 8

NRC describes actions taken to enhance the licensees' safety culture after the Fukushima event. NRC also reports that it places a high priority on effective and transparent communication with the public in the event of an emergency. Has NRC done any other actions to evaluate if there are concerns related to its independence, transparency and openness (which have been identified as one of the challenges by the Special Rapporteur on Fukushima)?

Answer: There are always concerns among the public about the independence of any regulatory agency, including the NRC. The NRC acknowledges these concerns and strives to maintain its commitment to being open and transparent. This includes conducting hundreds of public meetings each year so the public can observe its regulatory activities, making documents publicly available, and explaining its actions through traditional and social media.

Question No. 9

Alkali-silica reaction induced concrete degradation has been identified at Seabrook NPP. Have other licensees in the US detected similar or corresponding degradation?

Answer: To date, no other U.S. licensee has identified concrete degradation induced by an alkali-silica reaction.
Question No. 10
Summary describes the lessons learned from NRC's construction inspections, and lessons seem to be quite similar to the lessons learned in Finland in new construction projects. Could you describe how these lessons learned have impacted NRC's inspection activities or processes?
Answer: The NRC's construction inspection and oversight program is a living process. As such, the NRC inspection staff is continuously engaged in assessing and evaluating program results, capturing positive feedback, and enhancing processes as needed, in keeping with evolving new construction and licensing-basis requirements. This continuous improvement helps achieve the program's goal to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the Atomic Energy Act of 1954, as amended (AEA), and the Commission's rules and regulations. The NRC noted the following lessons learned in the U.S. 7th national report: design and configuration, supplier oversight, digital instrumentation and control (DI&C), corrective actions, and licensee responsibility. Design and Configuration Control With regard to design and configuration control, the NRC is performing focused inspections in this area. These have included engineering design verification (EDV) and design acceptance criteria (DAC) inspections. The NRC's vendor inspection staff conducts EDV inspections to verify that the design authority has (1) developed processes that allow for the complete and accurate transfer of the high-level design information and performance requirements specified in the final safety analysis report (FSAR) in a manner consistent with the requirements of Appendix B, (2) developed processes to ensure changes to the design are adequately controlled, and (3) produced detailed procedures, specifications, calculations, drawings, procurement, and construction documents that are consistent with NRC regulations, FSAR, and the NRC's safety evaluation report (if issued). EDV inspections are conducted under NRC Inspection Manual Chapter (IMC) 2507, "Vendor Inspections," and IP 37805, "Engineering Design Verification Inspections." DAC inspections are specialized inspections conducted to verify design details that are not provided at the time of design control document certification. DAC apply in three specific disciplines: DI&C design, piping design, and human factors engineering. These inspections rely on technical experts to augment the typical inspection staff and provide design insights, where possible, from the design review stage of licensing. Supplier Oversight: With regard to supplier oversight, the NRC also has a mature vendor inspection program that verifies that applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain for operating reactors and reactor design and construction through a strategic sample of vendor inspections. The vendor inspection has also been effective in identifying safety culture issues. An example was the issuance of a "chilling effect letter" (ADAMS Accession No. ML13092A077) to address safety culture issues at a major AP1000 module supplier. The NRC staff may issue a chilling effect letter for a workplace

environment where employees may be hesitant to raise safety concerns for fear of retaliation or because previously raised concerns were not adequately addressed.

A key lesson that has been incorporated into the vendor inspection program is the use of construction inspectors for vendor inspection and vice versa. This has enabled some cross-training among inspectors and provided insights from the construction environment where components are being installed and tested. The NRC's "Vendor Inspection Program Plan" (ADAMS Accession No. ML16300A273) provides details.

Digital Instrumentation and Control:
The NRC continues to find solutions for technical challenges that affect licensing and oversight of digital systems. As an example, for the AP1000 design, the staff modified the inspection approach to provide better oversight of DI&C life-cycle activities as they were being conducted in real time, enabling inspectors to observe complex design and development of DI&C systems, including software code development, hardware and software integration, and systems testing. A key lesson was the need for constant regulator-to-licensee and regulator-to-vendor communications to enable this type of real time oversight.

Corrective Actions:
Early in construction of the AP1000 units at Vogtle and V.C. Summer, the licensees were challenged with the rigor of constructing within the constraints of a COL. The NRC inspection staff identified construction issues such as concrete reinforcing steel (rebar) configuration deficiencies, module assembly (welding) deficiencies, and nonconforming steel module fabrication. The licensees undertook corrective action initiatives aimed at identifying vulnerabilities in the construction-to-licensing basis and procurement-to-licensing basis strategies and establishing mechanisms to ensure these vulnerabilities would be addressed. The construction-to-licensing basis and procurement-to-licensing basis concepts are inherent in every major construction activity and are used to establish constructability needs and licensing-basis departures. Since 2012, the NRC has noted, through corrective action program inspections, an increased level of construction-to-licensing basis and procurement-to-licensing basis awareness by the licensees and their suppliers and a corresponding decrease in construction quality deficiencies and other issues.

Licensee Responsibility:
Since the 2012 issuance of COLs for construction at Vogtle and V.C. Summer, the relationship has evolved among the licensees, design agent, and constructor and their numerous processes. The NRC recognized the licensee-design agent-constructor relationship presented some challenges to the inspection program. An early example was the use of different and discrete corrective action programs and associated document management among these organizations.

Over time, and as a key lesson learned, the NRC inspection program approach concluded that, regardless of the entities that were engaged in engineering, procurement, or construction of the facility, all activities would be treated as the responsibility of the licensee. Quality and safety issues at a vendor or design authority are addressed through inspection of the

Question No. 11

On the RPV indications in Belgium the US CNS report concludes that the ultrasonic techniques used during construction of U.S. vessels were capable of detecting quasi laminar indications, and the reporting requirements would have caused the indications to be recorded if they were present. Could it be clarified if the ultrasonic techniques used in the US had been the same as

in Belgium, and if any new NDT inspections have been performed at the US NPPs after the discovery in Belgium?
Answer: The American Society of Mechanical Engineers (ASME) Boiler & Pressure Vessel Code (Code) requires ultrasonic testing (UT) of the reactor vessel during construction. The Pressurized-Water Reactor Owners Group (PWROG) reviewed the UT performed on reactor vessel beltline ring forgings during the construction period and "determined that the inspection equipment and techniques used at the time of construction were capable of detecting quasi-laminar indications. Furthermore, the PWROG determined that the inspection recording criteria required the presence of quasi-laminar indications to be documented in nondestructive examination reports." Summaries of these assessments were documented in "Materials Reliability Program (MRP): Evaluation of the Reactor Vessel Beltline Shell Forgings of Operating U.S. PWRs (Pressurized-Water Reactors) for Quasi-Laminar Indications" (MRP-367) (ADAMS Accession No. ML14064A411). Since the discovery of this condition in Belgium, there has been no UT in the United States of the entire reactor vessel as performed during the construction period. The NRC staff interest centered on the comparison of UT performed on U.S. reactor vessels during the construction period versus UT performed with contemporary equipment and regulations, to determine if there were significant differences that would warrant additional UT inspections; a comparison to the UT techniques used on the Belgian reactor vessels was not considered to be directly relevant to making this determination and, therefore, a comparison has not been made.
Question No. 12
On page 14, a bullet list of challenges for the U.S.NRC is provided. During the last Regulatory Information Conferences (RIC) in 2015 and 2016, the NRC reported about budget cuts. Could the USA comment why the budget cuts are not seen as a challenge for the US regulator?
Answer: The NRC is committed to ensuring regulated entities are operating safely and securely in conformance with NRC requirements. Changing economic conditions in the energy market resulted in a lower workload than previously expected. The NRC took proactive steps through Project Aim to better align its resources with the newly expected workload, resulting in the identified and implemented budget cuts. The challenges listed on page 14 of the U.S. 7th National Report are the key factors the agency considered in developing its FY 2014–2018 Strategic Plan (NUREG-1614, Volume 6, ADAMS Accession No. ML14246A439). The NRC will continue to use and prioritize its budgeted resources in an effective and efficient manner to respond to any emerging challenges stemming from such factors.
Question No. 13
On page 37, the USA report on the safety evaluation of potentially existing hydrogen flakes in reactor pressure vessels produced by the same vendor as the two reactor pressure vessels of the Belgian Doel-3 and Tihange-2 units. It is stated that the NRC staff reviewed evaluations of non-destructive examination records performed by the US industry to examine the likelihood of the presence of the quasi-laminar indications in US reactor pressure vessels. What were the results of these evaluations? Could this kind of indication be excluded?
Answer: The U.S. industry, through the Electric Power Research Institute's (EPRI) MRP gathered original fabrication records and evaluated construction UT techniques, procedures, and requirements for all U.S. reactor vessels fabricated using beltline ring forgings. The industry indicated that none of the UT reports found indications of quasi-laminar indications. The NRC staff audited a sample of the nondestructive examination report packages and verified that the reviewed reports recorded no quasi-laminar indications. Based on its

assessment of the available information related to construction UT in the United States, the NRC staff agreed that the UT techniques would have detected quasi-laminar indications and, if present, indications would have been required to be recorded.

Question No. 14

On page 37, the USA report on the safety evaluation of potentially existing hydrogen flakes in reactor pressure vessels produced by the same vendor as the two reactor pressure vessels of the Belgian Doel-3 and Tihange-2 units. If present, were these indications considered acceptable according to the applicable codes and the procurement specifications for US plants?

Answer: The NRC's LIC-504 evaluation, "Technical Assessment of Potential Quasi-Laminar Indications in Reactor Pressure Vessel Forgings, dated September 8, 2015 (ADAMS Accession No. ML15282A218), states that PWROG "reviewed original ultrasonic inspection procedures to identify the equipment used. Relatively recent advances in ultrasonic testing technology have led to development of computer modelling software that facilitates sound-field mapping of complex material geometries. By processing the collected information about construction examination procedures and equipment, and by using ultrasonic modeling software, the PWROG concluded that quasi-laminar indications would have been detectable with a high level of certainty during construction examinations. They also reviewed pertinent recording and acceptance criteria and determined that quasi-laminar indications similar to those observed at Doel 3 and Tihange 2 would have been required to be recorded according to the applicable ASME Code Section III requirements as implemented in the procurement documents. The PWROG concluded the construction examinations would have detected indications much smaller than sizes that would be unacceptable (per the applicable ASME Code Section III requirements as implemented in the procurement documents) and would have required their recording. Finally, they determined that quasi-laminar indications, if they had been present and were recorded, would have been acceptable according to the construction code in effect during the time these vessels were fabricated. Furthermore, if current construction codes were applied to a new forging today and quasi-laminar indications were present in the size and numbers detected in the Belgian reactors, current codes would permit them to be accepted."

Question No. 15

The USA do not require additional ultrasonic testing to look for hydrogen flaking. This decision is based on probabilistic fracture mechanics analyses by the industry as well as structural evaluations and risk-informed evaluations by the NRC staff. Can the USA explain the first the results of the deterministic assessments? How can the integrity of the reactor pressure vessel be proven in case of pressurised thermal shocks, assuming large arrays of closely spaced flakes in the vessel wall?

Answer: In September 2013, the NRC issued Information Notice (IN) 2013-19, "Quasi-Laminar Indications in Reactor Pressure Vessel Forgings," (ADAMS Accession No. ML13242A263) to inform the U.S. industry of the quasi-laminar indications observed in the Doel 3 and Tihange 2 reactor vessel forgings. In response, the industry investigated the ultrasonic techniques used during the construction and published the findings in MRP-367 (ADAMS Accession No. ML14064A411). One objective of the report was to evaluate the structural significance of indications similar to those found in Doel 3 and Tihange 2, if they did exist in a U.S. reactor vessel. The report concluded that "the UT techniques used during construction of U.S. vessels were capable of detecting quasi-laminar indications and the reporting requirement would have caused the indications to be recorded if they were present."

The staff performed a high-level review of the probabilistic fracture mechanics analysis of a set of indications based on data from Doel 3 and Tihange 2, contained in the MRP-367 report. In that report, the analysis used a distribution of postulated quasi-laminar indications 10 times greater than the number observed in the Doel 3 reactor vessel forging. Further, the probabilistic failure mechanics methodology followed was consistent with that used by the NRC staff in the development of 10 CFR 50.61a, "Alternate Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events." The materials properties selected for the analysis included "the material with the highest reference temperature for nil ductility transition (RTNDT) of any material in a reactor vessel forging in the US. Results indicated the through-wall crack[ing] frequency (TWCF) was less than 1 x 10-7/reactor year, which is lower than the TWCF criteria of 1 x 10-6/reactor year that established the reference temperature screening criteria in 10 CFR 50.61a." The industry concluded that "even if quasi-laminar indications were present in a U.S. reactor vessel forging, the incremental increase in the vessel failure probability when the vessel is subjected to pressurized thermal shock loading (which is much more severe than loading during normal operation) is negligible." Based on its review of the industry analysis, the NRC staff concluded that, even if quasi-laminar indications were to exist in U.S. plants, the indications are not expected to significantly affect reactor pressure vessel integrity under normal or accident conditions.
Question No. 16
On page 38, the USA report on earlier findings of cracks in instrumentation nozzles at the South Texas Project NPP similar to those observed recently in French NPPs. Obviously, visual inspection is not sufficient to detect possible cracking. An improvement of in-service inspections by ultrasonic methods is possible. The U.S.NRC does not request ultrasonic testing of the instrumentation nozzles in all US NPPs. It would be appreciated if the U.S.NRC could explain the reasoning behind not requiring their licensees to perform such testing, even though operating experience in a domestic plant shows such cracking in the instrumentation nozzles. The U.S.NRC initiated a BPV code case to require volumetric in-service inspections of the instrument nozzles. Due to the limited number of licensees who would use the code case, the committee chose not to develop a code case. What is the position of the U.S.NRC with respect to operating experience feedback in its inspection activities?
Answer: In general, the NRC considers operating experience in performing the inspection requirements. With respect to operating experience with this issue, the NRC notes that no significant circumferential cracking in the nozzle material or degradation of the low alloy steel head material occurred before detection of the leaking nozzle. Based in part on operating experience, the NRC concluded that its current position—to rely upon visual inspections in accordance with ASME Code Case N-722-1 as conditioned by the NRC in 10 CFR 50.55a(g)(6)(ii)E—is sufficient to ensure plant safety.
Question No. 17
It would be appreciated if the USA could present the actual status of the implementation of the SFP order, mitigation strategies order and hardened vent order during the 7th review meeting. Which plants have currently not fully implemented the mitigation strategies order because they have to implement the hardened vent order in addition
Answer: As of December 2016, 84 out of 99 units are in compliance with the Mitigating Strategies Order, 97 out of 99 are in compliance with the Spent Fuel Pool Order, 5 out of 13 are in compliance with Phase 1 of the Hardened Vent Order, and none are in compliance with Phase 2 of the Hardened Vent Order.

The following plants have not yet fully complied with the Mitigating Strategies Order because carrying out that order is related to implementing Phase 1 of the Hardened Vent Order: Columbia, La Salle Units 1 and 2, Limerick Units 1 and 2, Monticello, Peach Bottom Unit 3, Quad Cities Units 1 and 2, Susquehanna Units 1 and 2, and Browns Ferry Unit 2 and 3. All other aspects of the Mitigating Strategies Order, with the exception of the required venting capabilities, were in place at these sites by the end of December 2016. Detailed information on the implementation status of these orders, along with other post-Fukushima work, will be provided to the Commission in a paper due in late January 2017.
Question No. 18
On page 53, it is reported that nine sites have screened out of any further evaluation. Could the USA explain the screening criteria for those nine sites?
Answer: Plants were screened out of further evaluation if the reevaluated hazards were bounded by their existing design-basis hazard. That is, the reevaluated ground motion response spectra were less than or equal to the values in their existing design-basis hazard for all frequencies. Because the reevaluated hazards do not exceed those for which the plant was already designed, no further evaluations of the seismic hazards under Recommendation 2.1 are necessary. Compliance with the design basis is ensured through the normal ROP.
Question No. 19
Are there any safety and security technical regulation or plan to develop such regulation for the next generation NPP, such as HTGR and Molten salt reactor? If yes, please describe the contents.
Answer: Many of the U.S. safety regulations are generally applicable to non-light-water reactors (non-LWRs). However, other safety regulations are specific only to LWRs for which the NRC would consider requests for exemptions from non-LWR applicants. With respect to the U.S. security regulations (i.e., 10 CFR Part 73 "Physical Protection of Plants and Materials"), SECY-11-0184, "Security Regulatory Framework for Certifying, Approving, and Licensing Small Modular Nuclear Reactors, dated December 29, 2011 (ADAMS Accession No. ML112991113), states the following: In the case of non-LWRs, the staff's assessment of the suitability of the current security regulatory framework was based on the limited information available on the reactor and fuel designs and operations of these technologies as described earlier in this paper. Based on this information, the staff is not currently aware of any area in which the existing security regulatory framework would not apply to non-LWRs. As specific designs mature and details are made available, the staff will continue to assess the suitability and adequacy of the security and MC&A [material control and accounting] requirements for proposed non-LWRs technologies, in order to identify any regulatory gaps and potential technical or policy issues pertaining to certifying, approving, or licensing non-LWR technologies. The NRC's "Vision and Strategy for Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," issued December 2016 (ADAMS Accession No. ML16356A670), includes near-term (0 to 5 years), midterm (5 to 10 years), and long-term (greater than 10 years) strategies for identifying and resolving regulatory gaps for non-LWRs and developing, as needed, a new non-LWR regulatory framework.

Question No. 20
American Report says about issurance of possible license renewal to operate beyond 60 years. Please elaborate the acceptance criteria for life extension beyond 60 yeras, and difference from those of 40 years.
Answer: The NRC acceptance criteria or standard for issuance of a renewed license for operation for 60 to 80 years is the same as that used for license renewal from 40 to 60 years, as provided in 10 CFR 54.29, “Standards for Issuance of a Renewed License.” For the first 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 licensing basis must be maintained during the renewal term. NUREG-1801, “Generic Aging Lessons Learned (GALL) Report,” contains the staff's generic evaluation of the 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 of 40 to 60 years. The GALL Report Revision 0, issued July 2001 (ADAMS Accession Nos. ML012060392, ML012060514, ML012060539, and ML012060521); Revision 1, issued September 2005 (ADAMS Accession Nos. ML052110005 and ML052110006); and Revision 2, issued December 2010 (ADAMS Accession No. ML103490041), are available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1801/. NUREG-1800, “Standard Review Plan [SRP] for Review of License Renewal Applications for Nuclear Power Plants,” provides guidance to the NRC staff to review license renewal applications for the period of extended operations from 40 to 60 years. SRP Revision 0, issued July 2001 (ADAMS Accession Nos. ML012070391 and ML012070409), Revision 1, issued September 2005 (ADAMS Accession No. ML052110007), and Revision 2, issued December 2010 (ADAMS Accession No. ML103490036) are available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1800/. The NRC has defined subsequent license renewal (SLR) 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 SLR, the NRC reexamined the policies and principles for license renewal and determined they remain valid and acceptable for SLR. 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, “Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR)” (ADAMS Accession Nos. ML15348A111 and ML15348A153), provides guidance for SLR applicants, contains the NRC staff’s generic evaluation of plant aging management programs, and establishes the technical basis for their adequacy. NUREG-2192, “Standard Review Plan for Review of Subsequent License Renewal Applications for Nuclear Power Plants” (SRP-SLR) (ADAMS Accession No. ML15348A265), provides guidance to NRC staff reviewers in the Office of Nuclear Reactor Regulation (NRR). These reviewers will assess the technical aspects of a plant in accordance with 10 CFR Part 54. The NRC issued the draft

GALL-SLR and SRP-SLR reports for public comment in December 2015, evaluated the public comments, and expects to publish the final documents in July 2017. Both documents are available at https://www.nrc.gov/reactors/operating/licensing/renewal/slr/guidance.html. More information on SLR is available on the NRC Web site at http://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-renewal.html.
Question No. 21
American Report shows the periodic confirmation of seismic and flooding hazards as the Tier3 recommendation after Fukushima Accident. Please elaborate the necessity of "periodic" confirmation, not "as needed confirmation".
Answer: NTTF Recommendation 2.2 suggested that the NRC initiate a rulemaking to require licensees to confirm seismic and flooding hazards every 10 years and address any new and significant information including, if necessary, updating the design basis for structures, systems, and components important to safety to protect against the updated hazards. In SECY-12-0095 (ADAMS Accession No. ML12208A208), the staff discussed other external hazards, such as those caused by meteorological effects, that should be included in the licensees' periodic updates that the NRC would require once the agency implemented Recommendation 2.2 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0095scy.pdf). Subsequently, in SECY-15-0137 (ADAMS Accession No. ML15254A006), the staff stated that the use of rulemaking to address Recommendation 2.2 was not necessary. Rather, the staff proposed to develop a method to leverage and enhance existing NRC processes and programs to ensure that information related to natural external hazards is proactively and routinely evaluated in a systematic manner. In response to the SRM to SECY-15-0137, the NRC staff developed a framework that expands upon the concepts described in SECY-15-0137. The framework provides a graded approach that will allow the NRC to proactively, routinely, and systematically seek, evaluate, and respond to new information on natural hazards. Although the framework is intended to allow for ongoing assessment of new information, it is recognized that the performance of certain activities (e.g., technical engagement activities and development of summary reports) on a defined or periodic schedule provides important institutional structure. As such, the framework paper (SECY-16-0144, ADAMS Accession No. ML16286A586) outlines the staff's intention to develop an office instruction that will provide details on (1) the types of activities that will be performed, (2) the review approach to be used to assess new information, and (3) the periodicity of documentation of the work under the framework. If the Commission approves the proposal, the staff plans to develop the office instruction to implement the framework in 2017.
Question No. 22
American Report shows the Emergency Responce Data System capability, as the Tier 3 reccomendation after Fukushima Accident. Please elaborate the measures for improvement of Emergency Responce Data System.
Answer: In SECY-15-0137 (ADAMS Accession No. ML15254A006), Enclosure 7, the staff considered several measures for improving the Emergency Response Data System (ERDS), such as requiring continuous transmission of ERDS data or expanding the ERDS data set, but ultimately concluded that changes were not warranted. As the ERDS is not the only means for the NRC to obtain information during an accident and given that the NRC does not have an

operational responsibility during an accident, the NRC concluded that changes were unlikely to represent cost-justified substantial increases in safety as required by the backfitting provisions in 10 CFR 50.109, "Backfitting." In addition, at the time of the accident, licensees were voluntarily updating the technology for transmitting ERDS information, as was discussed in NTTF Recommendation 9.4. Now, all licensees transmit data using a virtual private network. The proposed Mitigation of Beyond-Design-Basis Events (MBDBE) rulemaking would make one change to the regulations for ERDS. Specifically, the regulations would become technology neutral to reflect the use of virtual private networks rather than modems.
Question No. 23
American Report shows the expedited transfer of spent fuel to dry cask storage, as the Tier3 reccomendation after Fukushima Accident. Please elaborate the regulatory requirement for this.
Answer: The United States has no requirement for the expedited transfer of spent fuel to dry cask storage; rather, U.S. requirements are designed to ensure spent fuel safety regardless of whether it is stored in spent fuel pools or in dry storage. The accident at the Fukushima Dai-ichi nuclear facility in Japan led to questions about the safe storage of spent fuel and whether the NRC should require expedited transfer of spent fuel to dry cask storage at nuclear power plants in the United States. The NRC staff evaluated whether reactor licensees should be required to reduce the amount of spent fuel stored in their spent fuel pools. The staff concluded that the expedited transfer of spent fuel to dry cask storage would provide only a minor or limited safety benefit and that its implementation costs would not be warranted. The staff recommended to the Commission that additional studies and further regulatory analyses of this issue not be pursued and that the Tier 3 Fukushima lessons-learned activity be closed. The Commission approved the staff's recommendation. COMSECY-13-0030, "Staff Evaluation and Recommendation for Japan Lessons-Learned Tier 3 Issue on Expedited Transfer of Spent Fuel," dated November 12, 2013 (https://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/2013/2013-0030comscy.pdf), contains the staff's detailed evaluation of this issue.
Question No. 24
American Report shows the reliable hardened vents for Mark I and Mark II Containment Designs, as the Tier 1 reccomendation after Fukushima Accident. Please elaborate the regulatory requirement for the filtering at venting.
Answer: The NRC imposed additional requirements for severe-accident-capable hardened vents on Mark I and Mark II containments following the Fukushima accident. These systems must be able to support the operation of cooling systems that connect to the suppression pool, such as the reactor core isolation cooling system, as well as maintain the integrity of the containment following an extended loss of alternating current electrical power. The system is required to be seismically robust and remain functional with conditions associated with a severe accident (e.g., high temperatures, radiation levels). The analyses performed by the NRC staff and industry showed that venting through the suppression pool provided benefits in terms of limiting radiological releases and that the venting can be maintained for enough time to allow licensees to establish alternative cooling for the suppression pool. The NRC staff evaluated the potential benefits of including an engineered filter to supplement the capabilities of the suppression pool or support venting without scrubbing by the pool and concluded that engineered filter systems did not provide a substantial increase in the overall protection of

public health and safety, as required by NRC regulations. The staff's analysis can be found in SECY-15-0085 (ADAMS Accession No. ML15022A218).

Question No. 25

With reference to the summary section, page 22 of the national report, it is stated that the NRC evaluated inspection results to identify lessons learned that could be used as feedback to improve the construction inspection program, to focus future inspection activities, and to inform licensees of needed improvement areas. The report also discusses the lesson that licensees must oversee all contractors, subcontractors, and vendors when performing supplier oversight, but information related to the lessons regarding supplier oversight was not found in other parts of the report. Korea would like to point out the necessity for more detailed information in the American national report as NRC inspection activities and findings will prove to be helpful to future construction inspection programs of other countries.

Answer: The NRC's regional inspectors inspect the licensee's oversight of its suppliers as part of its baseline construction inspection program. The NRC also has a mature vendor inspection program that verifies that reactor applicants and licensees are fulfilling their regulatory obligations with respect to providing effective oversight of the supply chain. It accomplishes this through a number of activities, including performing limited scope targeted vendor inspections of vendors' quality assurance programs, establishing a strategy for vendor identification and selection that samples the effectiveness of the domestic and international supply chains for the current fleet and new reactor construction, and ensuring vendor inspectors obtain necessary knowledge and skills to perform inspections. In addition, the vendor inspection program addresses interactions with nuclear consensus standards organizations, the industry and external stakeholders, and international constituents.

A key lesson learned that has been incorporated into the vendor inspection program is the use of construction inspectors for vendor inspection and vice versa. This has enabled some cross-training among inspectors and provided insights from the construction environment where components are being installed and tested.

The Vendor inspection Program Plan (ADAMS Accession No. ML16300A273) provides details. Detailed construction inspection reports can be found at https://www.nrc.gov/reactors/new-reactors/oversight/crop/con-inspection-reports.html and vendor inspection reports can be found at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html. These reports provide more detailed information on NRC inspection activities and findings.

Question No. 26

With reference to the summary section, page 24 of the American national report, it is mentioned that EPRI-1019163 is intended for use by licensees to aid in preventing the introduction of counterfeit, fraudulent, and suspect items into nuclear facilities. With respect to the information discussed in page 24, Korea would like to inquire the following questions:

1) How do US nuclear utilities utilize EPRI inspection guideline EPRI NP-6629, Appendix C?
2) Are there any other programs in place which enable the identification of CFSI?

Answer: (1) The NRC cannot specifically address how U.S. nuclear utilities use EPRI NP-6629, "Guidelines for the Procurement and Receipt of Items for Nuclear Power Plants," 1990, Appendix C, as the NRC has not endorsed this guidance document. U.S. nuclear utilities may voluntarily implement the EPRI NP-6629 guidance for use within their facilities; however, the NRC does not have any expectations that it will be used.

(2) The primary program to enable the identification of CFSIs is a robust quality assurance program that meets the requirements of 10 CFR Part 50, Appendix B, particularly for safety-related items. Other programs to enable the identification of CFSIs include U.S. Government and industry initiatives, such as the U.S. Department of Homeland Security's National Intellectual Property Rights Coordination Center, which leverages the combined resources, skills, and authorities of the partner agencies to better combat intellectual property theft and identify and dismantle the criminal organizations that seek to profit from the manufacturing, importation, and sale of counterfeit items.

Question No. 27

With reference to page 53 of the American national report, it is described in the fourth paragraph that the US NRC issued JLD-ISG-12-05 to describe acceptable methods for conducting the integrated assessment for external flooding. This ISG describes the methodology to address human performance issues during flood hazard reassessment. With respect to the information provided in page 53, Korea would like to inquire the following questions:

Are there any other regulatory documents that address human performance issues related to post-Fukushima actions? If not, is there any technical background that limits the scope of human factors approach to only flood hazard reassessment?

Answer: The guidance for performing an integrated assessment for flooding addresses human factors. This guidance is found in Japan Lessons-Learned Division (JLD)-Interim Staff Guidance (ISG)-2016-01, "Guidance for Activities Related to Near-Term Task Force Recommendation 2.1, Flooding Hazard Reevaluation; Focused Evaluation and Integrated Assessment," dated April 15, 2016 (ADAMS Accession No. ML16090A140), which endorses Nuclear Energy Institute (NEI) 16-05, "External Flooding Integrated Assessment Guidelines," April 2016.

Furthermore, the primary guidance document for reasonably ensuring that required tasks, manual actions, and decisionmaking are feasible and may be executed within the time constraints identified in mitigating strategies, including those for potential flooding scenarios, is in Appendix E to NEI 12-06, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide," Revision 2, issued December 2015 (ADAMS Accession No. ML16005A625). The staff documented the acceptability of the guidance in NEI 12-06 in JLD-ISG-2012-01, "Compliance with Order EA-12-049, Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," Revision 1, dated January 22, 2016 (ADAMS Accession No. ML15357A163).

The process defined in Appendix E to NEI 12-06 addresses various hazards against which the mitigating strategies might be used and includes identifying tasks, describing a graded validation approach, and documenting the results.

NEI 13-02, "Industry Guidance for Compliance with Order EA-13-109," Revision 1, issued April 2015 (ADAMS Accession No. ML15113B318), describes additional guidance specific to containment venting for BWR Mark I and Mark II containments following the Fukushima accident. The staff documented the acceptability of the guidance in NEI 13-02 in JLD-ISG-2015-01 (ADAMS Accession No. ML14104A118).

In addition to the specific Fukushima-related activities, the NRC has issued guidance for the consideration of human factors engineering in licensing applications. An example is Chapter 18, “Human Factors Engineering” (ADAMS Accession No. ML13108A095), of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (Standard Review Plan). The NRC staff uses the guidance in the Standard Review Plan to review human factors engineering considerations of operating license applications, design certifications, plant modifications, and important human actions.

Question No. 28

The license renewal application for Indian Point has taken longer than projected. The cause is related with a safety issue to be considered for all the plants?

Answer: As stated in 10 CFR 2.109(b), if a licensee submits a renewal application that is sufficient for the NRC’s review at least 5 years before expiration of the existing license, the plant can continue to operate until the application has been finally determined. The initial operating licenses for Indian Point Units 2 and 3 were to expire on September 28, 2013, and December 12, 2015, respectively. The plant operator provided a timely submittal of its renewal application, and as a result, the units are allowed to continue operating past these expiration dates and can continue operating until the NRC staff makes a final determination on the application. To ensure continued safe operation during this “timely renewal” period, the plant operator voluntarily submitted to the NRC staff (and the NRC has inspected) all applicable license renewal commitments for the units and has incorporated the NRC-approved aging management programs into their licensing bases.

The NRC staff issued NUREG-1930, “Safety Evaluation Report Related to the License Renewal of Indian Point Nuclear Generating Unit Nos. 2 and 3 (NUREG-1930),” in November 2009, as well as two supplements to this report to describe the staff’s conclusions about the Indian Point license renewal application. Renewal of the Indian Point license has been delayed because of Atomic Safety and Licensing Board (ASLB) hearings held to address contentions filed by intervenor groups. The ASLB held hearings in October, November, and December 2012 related to contentions filed for the denial of license renewal. The ASLB partial initial decision on the contentions is available at ADAMS Accession No. ML13331B465. On November 2015, the ASLB held the second set of evidentiary hearings on the remaining contentions. A timeline has been established for the submittal of supplemental testimony to the ASLB on baffle-former bolt issues and for the filing of proposed findings of fact and conclusions of law.

Currently, the NRC staff is addressing issues related to reactor vessel baffle former bolts (this safety issue is applicable to other reactors), as well as the need for the applicant to address more recent staff guidance on effective management of aging effects associated with several components, including buried piping, corrosion under insulation, coating of piping and tanks, and steam generator components.

On the environmental side, the staff is completing its review as required by the National Environmental Policy Act. The NRC issued a final supplemental environmental impact statement (FSEIS), NUREG-1439, Supplement 38, in December 2010 and issued a supplement in June 2013. The staff is preparing a second supplement to the FSEIS to address severe accident mitigating alternatives (SAMAs) on impacts from continued operation of Indian Point on aquatic resources, groundwater, and critical habitat of the Atlantic Sturgeon.

Also, the plant owner is pursuing resolution of issues related to the plant's Coastal Zone Management Act certification, Clean Water Act certification, and renewal of the plant’s State

Pollution Discharge Elimination System permit through the relevant New York State and judicial processes.

On January 9, 2017, the parties to the contentions discussed above reached a settlement agreement on the legal proceeding related to Indian Point. According to the settlement agreement, Entergy will cease operation of Indian Point Units 2 and 3 as late as April 2024 and April 2025, respectively. The settlement also lays out actions that would result in the dismissal of all remaining legal proceedings and issuance of remaining certifications from the State of New York no later than May 31, 2017. The NRC staff is monitoring these matters but is not directly involved in them.

Question No. 29

What percentage of your NPP's already have autocatalytic hydrogen recobiners installed in the containment.

Answer: The NRC revised the hydrogen control regulations in 2003, eliminating the requirements for hydrogen thermal recombiners and hydrogen purge systems in currently licensed LWRs and relaxing the requirements for hydrogen and oxygen monitoring equipment to make them commensurate with their risk significance. However, the rule retained existing requirements for ensuring a mixed atmosphere, inerting BWR Mark I and Mark II containments, and providing a hydrogen control system (igniters) capable of controlling an amount of hydrogen generated from a metal-water reaction involving 75 percent of the fuel cladding surrounding the active fuel region in BWR Mark III and pressurized-water reactor (PWR) ice condenser containments. The NRC established the technical bases for the regulations based on experience during the Three Mile Island accident, along with bounding estimates for the amount of hydrogen likely to be generated by a severe core damage accident. While some licensees may have maintained recombiners as part of their severe accident management program, the NRC does not track how many licensees have done so.

Question No. 30

What percentage of your NPP's already have a containment venting-filtration system installed.

Answer: All plants have identified a venting strategy within severe accident management programs, but only plants with Mark I and Mark II containments are required to install and maintain a severe-accident-capable hardened vent system. Engineered filter systems are not required and U.S. plants have not installed them.

As of February 6, 2017, six units were in compliance with Phase 1 of the vents order. Plants are required to be in compliance no later than June 30, 2018, for Phase 1, and June 30, 2019, for Phase 2.

Question No. 31

What criteria are used by NRC to gage licensee effort to make its plant safety status comply with para 2 of Vienna Declaration on Nuclear Safety?

Answer: The NRC's regulatory programs already achieve the principles of the Vienna Declaration on Nuclear Safety. The NRC routinely evaluates and documents licensee performance in adhering to the facilities licensing basis through ROP.

During the 2010 IAEA IRRS Mission to the NRC (IAEA-NS-IRRS-2010/02), the NRC correlated its regulatory programs with each of the 14 periodic safety review (PSR) safety factors to demonstrate how NRC programs meet the intent of these reviews. Key programs credited included the license renewal review and the operating experience and generic communication programs, among others. Programs such as ROP, operating experience, license renewal reviews, and the use of risk-informed regulation are intended to ensure that the principles of the Vienna Declaration are met and provide adequate protection of the health and safety of the public, as the AEA requires.

Under the NRC's current regulatory framework, nuclear power plants are subject to ongoing inspection, audit, and oversight throughout the life of the plant. This is achieved through regulatory programs, such as ROP and the Generic Issues Program. If the NRC receives new information showing a significant safety issue, then it acts in a timely fashion to resolve the issue at the plant(s). Examples would be the set of actions that the NRC undertook after the Fukushima accident (e.g., issuing orders to licensees, conducting inspections, requesting information from licensees, and undertaking rulemaking actions).

The ROP provides a systematic method to monitor and assess licensee performance. This is achieved through the use of indicators submitted by the licensee and the inspections by the staff (resident inspectors) assigned to each site, as well as inspectors within the regional offices. The NRC uses the ROP Action Matrix to objectively and predictably assess licensee performance and to determine the necessary regulatory response based on the results of the inspection and performance indicator data. Identified inspection findings having more than very low safety or security significance or performance indicators that cross established thresholds result in additional regulatory action by the NRC. This includes additional inspection effort, meetings with licensee management, and other regulatory actions as detailed in the ROP Action Matrix.

Question No. 32

What is total electricity generation resulting from the work at the level of the electrical capacity above the installed of all U.S. plants (and what is its per cent from potential nominal generation) in 2013-2015?

Answer: The total electricity net generation from all sectors in million kilowatt-hours is as follows:

2013: 3,903,715
2014: 3,937,003
2015: 3,930,579

The total net generation for all operating nuclear power plants in million kilowatt-hours is as follows:

2013: 789,016, which represents a capacity factor of 89.9 percent
2014: 797,166, which represents a capacity factor of 91.7 percent
2015: 797,178, which represents a capacity factor of 92.2 percent

The nuclear share of electricity net generation is as follows:

2013: 19.4 percent
2014: 19.5 percent
2015: 19.5 percent

The above information, specifically Tables 7.2a and 8.1 is from **https://www.eia.gov/totalenergy/data/monthly/**.

Information on individual plant generating capacity by year can be obtained from https://www.eia.gov/nuclear/generation/.
Question No. 33
What additional information can be given on the electrical problems with open phase conditions? Do you think it is an important international issue?
Answer: An open-phase condition (OPC) is a known phenomenon in the power industry and is recognized as having had an adverse impact on the electrical power systems of several nuclear power plants. An OPC may challenge plant safety systems. Operating experience in different countries has shown that currently installed instrumentation and protective schemes have not been adequate to detect this condition and initiate appropriate action. Both INPO and the World Association of Nuclear Operators (WANO) have communicated the operating experience to the nuclear power plant owners concerning the potential for loss of safety function of electric power systems caused by OPCs. IAEA issued Safety Report No. 91, “Impact of Open Phase Conditions on Electrical Power Systems of Nuclear Power Plants” in December 2016. The objective of the safety report is to enhance the safety of nuclear power plants by providing technical guidance to address OPC vulnerabilities in electrical systems used to start up, operate, maintain, and shut down nuclear power plants. The NRC staff issued a SECY-16-0068, “Interim Enforcement Policy for Open Phase Conditions in Electric Power Systems for Operating Reactors,” dated May 31, 2016 (ADAMS Accession No. ML15219A327), seeking Commission approval to allow interim enforcement discretion (ADAMS Accession No. ML15219A330) while licensees correct the OPC design deficiency by December 31, 2018. The Commission action is still pending. The staff issued a Temporary Instruction (TI) 2515/192, “Inspection of the Licensee’s Interim Compensatory Measures Associated with the Open Phase Condition (OPC) Design Vulnerabilities In Electric Power Systems,” November 9, 2016, for NRC inspectors to verify licensees’ implementation of interim compensatory measures until the plant modifications to correct the design deficiencies are completed. The inspections were scheduled to be completed by March 31, 2017. In addition, the NRC staff held a public meeting with NEI and licensee representatives to discuss four design solutions proposed by the industry to resolve the OPC design vulnerability issue (NRC Bulletin 2012-01) at each specific nuclear power plant site. The meeting notice and industry presentations can be found in NRC ADAMS Accession Nos. ML16340B857 and ML16340A629. The NRC has not approved or endorsed any of the proposed design solutions presented at the meeting.
Question No. 34
Could you give specific examples on how the principles of the vienna declaration have been implemented on existing nuclear power plants in the US?
Answer: NRC RESPONSE: Specific examples of how the principles of the Vienna Declaration have been implemented for existing nuclear power plants in the United States include, but are not limited to, periodic updates of the GALL Report for aging management, post-Fukushima actions taken by the NRC, and use of a generic communications process as a means for the NRC to consider new information and research to provide ongoing assurance that the licensing basis for the design and operation of each nuclear power plant provides an acceptable level of safety. A discussion of each example is provided below.

GALL Report Periodic Updates:
The NRC staff, industry, and stakeholders gain experience and develop lessons learned with each renewed license. Through use of the license renewal guidance documents, the NRC staff, industry, or stakeholders may discover areas for improvement or that warrant new guidance. The NRC staff developed a process to capture and communicate interim guidance for new insights, lessons learned, and emergent issues to create a license renewal program that progressively improves. The staff established this process in “The Interim Staff Guidance Process,” dated December 12, 2003 (ADAMS Accession No. ML023520620).

Under this process, the NRC staff, industry, or stakeholders can propose a change to certain license renewal guidance documents. The staff evaluates the issue, develops proposed ISG, issues the ISG for public comment, evaluates any comments received, and, if necessary, issues the final ISG. The ISG is then used until the staff incorporates it into the next formal license renewal guidance document revision.

The NRC captures aging-related lessons learned in the GALL Report, the agency’s primary reference document for license renewal. The NRC has revised and updated the GALL Report twice since its original issuance. In between each revision, the staff also captures, through ISG, new lessons that might affect aging management. The latest list of effective ISGs and the issues addressed are available at https://www.nrc.gov/reading-rm/doc-collections/isg/license-renewal.html.

IAEA’s “International Generic Ageing Lessons Learned (IGALL)” provides a consensus international resource for safer and more consistent international plant operation, and it opens discussion avenues for sharing international operating experience and approaches to aging management. The program develops and maintains documents and a database to provide a technical basis and practical guidance for nuclear power plants on aging management of mechanical, electrical, and instrumentation and control (I&C) components and civil structures of nuclear power plants important to safety.

IAEA developed IGALL using the U.S. GALL Report (Revision 2) as the starting point. In addition, participants to the program provided their own operating experience and aging management approaches to supplement this starting point, providing a better rounded product that has broader applicability.

NRC Post-Fukushima Actions:
The agency’s response to the accident at Fukushima Dai-ichi demonstrates the principle of implementing reasonable practicable or achievable safety improvements in a timely manner. Immediately after the accident, the NRC issued INs and bulletins and conducted inspections to determine the preparedness of U.S. plants to withstand a similar event. The agency also created NTTF to examine the event and determine the lessons that were to be applied to U.S. reactors. The staff then prioritized the NTTF recommendations to ensure that each recommendation was addressed in a timely manner commensurate with its safety significance. Currently, most plants are in compliance with the mitigating strategies and spent fuel pool (SFP) instrumentation orders. In the next few years, plants will be coming into compliance with the hardened vents order. The new regulation described in the National Report, Section 6.5, on page 78, is intended to make the requirements of the orders for mitigation strategies and enhanced SFP instrumentation discussed on that page generically applicable to currently operating and new power reactors. These requirements have been imposed on power reactor licensees with licenses issued after the orders through the use of conditions on those licenses.

By making the requirements generically applicable, the NRC expects to achieve greater regulatory consistency and a more efficient regulatory process. The new regulation also addresses the treatment of seismic and flooding hazards, which were reevaluated for currently operating power reactors to confirm the adequacy of plant design. Section 1.3.3 provides more information.

Generic Communications:
As described in the U.S. 7th National Report, Section 14.1.5.1, page 166, the generic communications process is one way for the NRC to consider new information to provide ongoing assurance that the licensing basis for the design and operation of each nuclear power plant provides an acceptable level of safety. A specific example of the NRC collecting and assessing information is Generic Letter (GL) 2016-01, “Monitoring of Neutron-Absorbing Materials in Spent Fuel Pools,” dated April 7, 2016. The NRC issued this GL for two purposes: (1) to ask that addressees submit information on, or provide references to, previously docketed information, which demonstrates that credited neutron-absorbing materials in the SFP of power reactors and the fuel storage pool, reactor pool, or other wet locations designed for the purpose of fuel storage, as applicable, for nonpower reactors, are in compliance with the licensing and design basis and with applicable regulatory requirements and that there are measures in place to maintain this compliance and (2) to collect the requested information and determine if additional regulatory action is required.

The NRC staff is reviewing the responses and will determine whether additional regulatory action is required.

The NRC commissioned additional research into the monitoring techniques in use for the neutron-absorbing materials known to experience significant degradation with time, Boraflex and phenolic resin-based neutron absorbers (i.e., Carborundum and Tetrabor). This research identified several potential concerns about the approaches used to identify or project ongoing degradation for these neutron-absorbing materials. The three technical letter reports summarizing the research findings can be found at ADAMS Accession Nos. ML12216A307, ML12254A064, and ML13141A182. The NRC continues to oversee the impact of degradation or deformation on the neutron-absorbing materials and monitoring methods currently used in the U.S. commercial nuclear power industry.

INPO RESPONSE:
The regulatory framework for existing nuclear power plants in the U.S. was constructed using a defense-in-depth philosophy, which is focused on accident prevention, accident mitigation, and emergency preparedness. In response to the accident at Fukushima Daiichi, the U.S. Nuclear Regulatory Commission issued a series of orders, information requests, and has nearly completed a broad rulemaking to further improve the ability of U.S. nuclear power plants to cope with beyond-design-basis events. These activities are focused on prevention and mitigation of severe accidents.

The NRC’s rigorous and comprehensive inspections include both an on-site resident inspection team that provides general site oversite and specialized regional inspectors carrying out topic specific and reactive inspections. In addition to those inspections, INPO performs comprehensive evaluations of plant performance on a routine basis through INPO personnel as well as industry peers from other plants with expertise in the area being reviewed. Plant maintenance in the U.S. not only complies with NRC regulations but follows the INPO guidance for work management and maintenance and factors in the critical nature of

components. Risk insights are used to determine the risk of having a system out of service for maintenance and limitations are applied commensurate with that risk. Initiatives such as single point failure vulnerability studies and modifications or other means to lessen those vulnerabilities are employed. Personnel qualifications for those providing training, operations and maintenance are tightly tracked to ensure that any work is performed properly.
Question No. 35
"A. General comments on National Report as a process of self-assessment of the implementation of the obligations of the Convention." The US report is very comprehensive and provides information covering all the topics addressed by the CNS Articles. Clear references to the regulatory framework are made. In particular the improvements following the Fukushima accident ("lessons learned") are explicitely described.
<u>Answer</u>: Thank you for your comment and observation. We appreciate the positive feedback.
Question No. 36
"B. Comments on progress made on previous Challenges and Suggestions identified at previous Review." The challenges are listed and the progress made for each challenge is discussed in the report.
<u>Answer</u>: Thank you for your comment and observation. We appreciate the positive feedback.
Question No. 37
"C. Proposals of Good Practices, Challenges, Suggestions." Candidates for GP: a) international cooperation, b) research activities, c) siting process Candidate for Challenge: Backfitting process --> does it lead to considerable improvements / plant modifications?
<u>Answer</u>: Thank you for your comment on good practices. We appreciate the positive feedback. In answer to your comment on the backfitting process, backfitting can lead to considerable (substantial) improvements in safety and security, including modifications to plant design and operation if a safety or security problem is identified. However, under the U.S. statute governing nuclear safety (AEA), safety or security improvements (including modifications to plant design and operation) needed for "adequate protection" must be implemented even if they do not represent considerable (substantial) improvements. In other words, the NRC must require changes to previously approved plant design and operations that the NRC determines are necessary for adequate protection, even if these changes do not represent "considerable improvements" to the plant's existing design and operations. Examples include the safety and security enhancements required in the aftermath of the terrorist attacks of September 11, 2001, and the Fukushima accident.
Question No. 38
With regard to the implementation of the Vienna Declaration, the first paragraph is discussed in the report and eems to be fulfilled. Regarding paragraph 2, in the US, there is no Periodic Safety Review in place (instead there are other procedures such as the reacor oversight process). It seems that comprehensive safety assessments are mainly performed in the context of power uprates and license renewals. Compared to some European NPPs there seems to be less hardware backfitting in the US (only few examples given). Paragraph 3 seems to be fulfilled. NRC participates in the development of IAEA standards and claims consistency with these standards. NRC is involved in many bilateral and international programs.
<u>Answer</u>: NRC RESPONSE: Under the NRC's current regulatory framework, nuclear power plants are subject to ongoing inspection, audit, and oversight throughout the life of the plant.

Article 14.4, “Vienna Declaration on Nuclear Safety,” of NUREG-1650 discusses this framework in detail. If the NRC receives new information showing a significant safety issue, then it acts in a timely fashion to resolve the issue at the plant(s). Examples would be the set of actions that the NRC undertook after the Fukushima accident (e.g., issuing orders to licensees, performing inspections, requesting information from licensees, and undertaking rulemaking actions).

During the 2010 IAEA IRRS to the NRC (IAEA-NS-IRRS-2010/02), the agency correlated its regulatory programs to each of the 14 PSR safety factors to demonstrate how NRC programs meet the intent of these reviews. Key programs credited included the license renewal review and the operating experience and generic communication programs, among others. Programs such as ROP, operating experience, license renewal reviews, and the use of risk-informed regulation are intended to ensure that the principles of the Vienna Declaration are met and provide adequate protection of the health and safety of the public, as the AEA requires.

INPO RESPONSE:
The benefits and costs of new and modified NRC requirements mandating “hardware” changes at operating plants that are intended to enhance reactor safety are carefully considered through the backfitting and regulatory analysis processes. These analytical tools enhance the safety of the U.S. nuclear power fleet by ensuring that industry and NRC resources are devoted to regulatory activities that will result in demonstrable safety improvements and can be justified in light of their costs. The NRC does not consider costs when imposing new or different requirements that the Commission has determined are required to ensure adequate protection of the public health and safety, or common defense and security; or that are required to redefine the level of protection that is considered adequate.

The US industry continuously strives to operate and maintain the plants in an excellent and not solely a compliant manner. Through INPO guidance documents and routine evaluations, the industry sets higher than regulatory required standards and is evaluated to those standards by INPO and industry peers. US plant personnel strive to meet those INPO excellence targets through incorporation of them in procedures and practices. US plant leadership ensures through internal and external review boards and other management review meetings that these industry excellence targets are discussed and actions are taken to address any gaps.

Question No. 39

Principle 1
1.1 How do you define ‘a new nuclear power plant’?
For example: do you consider a power plant to cease being a ‘new nuclear power plant’ once operation begins?

Answer: The NRC does not have a specific regulatory definition for a “new nuclear power plant.” At the NRC, the use of the term “new” can apply in multiple contexts. For example, “new” can be viewed as a new technology and may include large, light-water, small modular, and non-light-water designs. More frequently at the NRC, a “new nuclear power plant” refers to a potential new plant that will go through the initial license application process described under 10 CFR Part 50 or 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The application for a new nuclear power plant may reference either an approved technology or a technology yet to be approved by the NRC. The label of “new” would generally be removed from reference once all of the licensing reviews are complete and a unit enters operation.

With respect to advanced reactors, the NRC's Advanced Reactor Policy Statement defines advanced reactors as follows:

> 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 (LWRs). 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 classification of an advanced reactor does not change once operation begins.

Within the context of the Vienna Declaration on Nuclear Safety, the NRC considers a "new nuclear power plant" as a reactor that is licensed by using a reactor design and technology approved after the effective date of the Declaration. Reactors licensed using designs approved by the NRC before the effective date of the Declaration would not be considered "new nuclear power plants."

More information on the NRC's licensing process is in Articles 17 and 18 of the U.S. 7th National Report, which discuss how the United States meets the principles of the Vienna Declaration on Nuclear Safety.

Question No. 40

Prevention
1.2 How does your national requirements and regulations incorporate appropriate technical criteria and standards to address the objective of preventing accidents in the commissioning and operation of new nuclear power plants?
For example: can you describe the basic design objectives and the measures you have in place to ensure the robustness and independence of defense in depth measures? Consider for instance inclusion of implementation of Regulatory requirements for:

• Robustness of DiD and independency of the levels of DiD;
• Design Extension Conditions (DEC);
• practical elimination of high pressure core melt scenarios;
• achieving a very low core melt frequency;
• protecting digital safety equipment against Common Cause Failure (CCF).
• External events analysis

<u>Answer</u>: NRC RESPONSE:

Robustness of Defense in Depth
The defense-in-depth (DID) philosophy, as applied in regulatory practice, is a fundamental element of the NRC's safety philosophy that employs successive compensatory measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The DID philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating DID into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges. The NRC does not impose the DID philosophy on applicants and licensees through an explicit requirement in its regulations. Rather, it embodies the philosophy

in its regulatory requirements, associated guidance, and regulatory programs. At U.S. nuclear power plants, DID includes, for example, the use of access controls, physical barriers, redundancy, independence and diversity of key safety functions, safety margins, detection, surveillance and inspection, and emergency response measures to achieve its purpose. The robustness of DID in U.S. plants is reflected in their exemplary safety performance over the past 50 years.

For nuclear power plants, DID can be viewed in terms of successive layers providing protection to the public and the environment. For purposes of this discussion, these layers are broadly characterized as (1) robust plant design to survive hazards and minimize challenges that could result in an event occurring, (2) prevention of a severe accident (core damage) should an event occur, (3) containment of the source term should a severe accident occur, and (4) protection of the public from any releases of radioactive material (e.g., through siting in low population areas and the ability to shelter or evacuate people, if necessary).

Major factors that are considered in determining that the plant design, construction, maintenance, and operation are consistent with the DID philosophy include (1) preserving a reasonable balance among the layers of defense, (2) preserving adequate capability of design features without an overreliance on programmatic activities as compensatory measures, (3) preserving system redundancy, independence, and diversity commensurate with the expected frequency and consequences of challenges to the system, including consideration of uncertainty, (4) preserving adequate defense against potential common-cause failures (CCFs), (5) maintaining multiple fission product barriers, (6) preserving sufficient defense against human errors, and (7) continuing to meet the intent of the plant's design criteria. (Regulatory Guide (RG) 1.174, Revision 2, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," issued May 2011 (ADAMS Accession No. ML100910006)).

In 1994, the Commission published the policy statement, "Regulation of Advance Nuclear Power Plants." The Commission stated in its policy that advanced design attributes include designs that minimize the potential for severe accidents and their consequences by providing sufficient inherent safety, reliability, redundancy, diversity, and independence in safety systems, and that designs incorporate DID philosophy by maintaining multiple barriers against radiation release and by reducing the potential for and consequences of severe accidents.

Prevention of Accidents

Prevention or preclusion of accidents is normally considered the first layer of DID. It is sought through conservative design and high quality and standards in construction and operation. The NRC governs this through a number of regulations and programs, including but not limited to, general design criteria (GDC) for the design of SSCs, provided in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50; quality assurance requirements in Appendix B to 10 CFR Part 50; industry codes and standards imposed through regulation or endorsed for use by the NRC and its programs for inspecting design, construction and operational activities; and enforcing compliance with its regulations. The GDC govern the design of multiple fission product barriers, protection and reactivity control systems, fluid systems, containment design, and fuel and radioactivity control. GDC 1, "Quality Standards and Records," of Appendix A to 10 CFR Part 50, and its implementing regulatory requirements specified in Appendix B to 10 CFR Part 50, establish quality assurance requirements for all activities affecting functions of the SSCs considered important to safety. Many codes and standards developed by ASME, the Institute of Electrical and Electronics Engineers (IEEE), and by the NRC itself are incorporated in 10 CFR Part 50 of the Commission's regulations by reference (10 CFR 50.55a, "Codes and Standards").

Design Extension Conditions

Since the accident at Three Mile Island in 1979, the NRC has implemented requirements for the prevention and mitigation of accidents not included in the original design bases for LWRs. Several important examples of this include anticipated transients with scram, which are addressed in 10 CFR 50.62, "Requirements for Reduction of Risk from Anticipated Transients Without Scram (ATWS)"; station blackout, which is addressed in 10 CFR 50.63, "Loss of All Alternating Current Power"; and loss of large areas of the plant due to fires and explosions, which is addressed in 10 CFR 50.54(h)(h)(2) and Order EA-12-049, "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events," issued to NRC licensees on March 12, 2012. New plants are also required to meet analysis and design requirements provided in 10 CFR 50.150, "Aircraft Impact Assessment," which are aimed at protecting key barriers against release or radioactivity (i.e., fuel, reactor vessel, and containment) from the effects of an impact of a large commercial aircraft on the plant.

In 1985, the Commission published the policy statement, "Severe Reactor Accidents Regarding Future Designs and Existing Plants." This statement describes the policy that the Commission intended to use to resolve safety issues related to reactor accidents more severe than design-basis accidents. The main purposes of this policy statement are to (1) clarify the procedures and requirements for licensing a new nuclear plant, (2) reexamine the need for the generic rulemaking proceeding contemplated in the TMI Action Plan commitment on degraded core accidents, currently referred to as severe nuclear reactor accidents, (3) avoid unnecessary delays of plants now under construction, (4) close out, for now, severe accident issues for existing plants without imposing further backfits unless this can be justified by new safety information, and (5) achieve improved stability and predictability of reactor regulation in a manner that would merit improved public confidence in its regulatory decisionmaking.

The NRC requires applicants for design certification of new plants under 10 CFR 52.47, "Contents of Applications; Technical Information," to perform a probabilistic risk assessment (PRA) for their proposed design. The PRA is not limited to modeling and analyzing design-basis accidents; the PRA models and analyzes all potential severe accidents contributing to core damage and radionuclide releases.

Practical Elimination of High-Pressure Core Melt Scenarios

The goal of "practically eliminating" severe accidents in new plants is addressed through incorporation of design features for the prevention and mitigation of severe accidents. Indeed, NRC regulations in 10 CFR 52.47(a)(23) require applicants for design certification under 10 CFR Part 52 to provide, in their application, a description and analysis of design features for the prevention and mitigation of severe accidents (e.g., challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass). The NRC's position specific to high-pressure core melt ejection scenarios is stated in the SRM to SECY-93-087, "Policy, Technical and Licensing Issues Pertaining to Advanced and Evolutionary Light Water Reactor (ALWR) Designs," dated July 21, 1993 (ADAMS Accession No. ML003708056). The NRC's position is that evolutionary and passive LWR designs should provide a reliable depressurization system and reactor cavity design features to decrease the amount of ejected core debris that reaches upper containment.

Achieving a Very Low Core Melt Frequency
NRC regulations do not include limits on core damage frequency (CDF) that new plants must meet. However, the NRC does require holders of a COL issued under 10 CFR Part 52 to perform a PRA for their proposed designs in accordance with requirements in 10 CFR 50.71, “Maintenance of Records, Making of Reports.” This regulation states the following:

> (h)(1) No later than the scheduled date for initial loading of fuel, each holder of a combined license under subpart C of 10 CFR part 52 shall develop a level 1 and a level 2 probabilistic risk assessment (PRA). The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel.
>
> (2) Each holder of a combined license shall maintain and upgrade the PRA required by paragraph (h)(1) of this section. The upgraded PRA must cover initiating events and modes of operation contained in NRC-endorsed consensus standards on PRA in effect one year prior to each required upgrade. The PRA must be upgraded every four years until the permanent cessation of operations under § 52.110(a) of this chapter.
>
> (3) Each holder of a combined license shall, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (h)(1) of this section to cover all modes and all initiating events.

Regulations in 10 CFR 52.47(a)(27) require applicants to submit a description of the design-specific PRA and its results. The NRC expects applicants to use the PRA to do the following:

- Identify and address potential design features and plant operational vulnerabilities; for example, vulnerabilities in which a small number of failures could lead to core damage, containment failure, or large releases (i.e., assumed individual or CCFs could drive the plant risk to unacceptable levels with respect to the Commission’s goals).

- Reduce or eliminate the significant risk contributors of existing operating plants applicable to the new design by introducing appropriate features and requirements.

- Select among alternative features, operational strategies, and design options.

- Demonstrate that the risk associated with the design compares favorably to the Commission’s goals of less than $1x10^{-4}$ per year (/yr) for CDF and less than $1x10^{-6}$/yr for large early release frequency (LERF).

The NRC has established safety goals in the form of quantitative health objectives (QHOs), (Commission Policy Statement on Safety Goals). These QHOs include $5x10^{-7}$ for prompt fatalities and $2x10^{-}6$ for latent fatalities. The NRC has established risk metric acceptance guidelines for CDF of $1x10^{-4}$ and LERF of $1x10^{-5}$, based on the Commission QHOs of latent and early fatalities, respectively. (U.S. NRC “Safety Goals for the Operations of Nuclear Power Plants; Policy Statement,” *Federal Register* (FR), Vol. 51, No. 149, pp. 28044–28049, August 4, 1986 (republished with corrections, Vol. 51, No. 169, pp. 30028–30023, August 21, 1986 (ADAMS Accession No. ML051580404), and RG 1.174, Revision 2 (ADAMS Accession No. ML100910006).

In addition, 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," establishes these requirements. The intent of this regulation is for the licensee to provide reasonable assurance that the SSCs are capable of fulfilling their intended functions; when their performance does not meet the intended goals, appropriate corrective actions are taken. This regulation applies to safety-related SSCs that are relied upon to remain functional during and following design-basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure; they are applicable to nonsafety-related SSCs that are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (EOPs), when their failure could prevent safety-related SSCs from fulfilling their safety-related function, or when their failure could cause a reactor scram or actuation of a safety-related system. This regulation helps ensure that the reliability of SSCs is sufficiently high to achieve a very low CDF.

Protecting Digital Safety Equipment Against Common Cause Failure
The NRC does not have specific requirements for protecting digital safety equipment against CCF. However, it has established the following position on defense against CCFs in DI&C systems in advanced and evolutionary plant designs:

(1) The applicant should assess the DID and diversity of the proposed I&C system to demonstrate that vulnerabilities to CCFs have been adequately addressed.

(2) In performing the assessment, the vendor or applicant should analyze each postulated CCF for each event that is evaluated in the accident analysis section of the safety analysis report (SAR) using best estimate methods. The vendor or applicant should demonstrate adequate diversity within the design for each of these events.

(3) If a postulated common-mode failure could disable a safety function, then a diverse means, with a documented basis that the diverse means is unlikely to be subject to the same common-mode failure, should be required to perform either the same function or a different function that is vulnerable to CCF or a different function that provides adequate protection. The diverse or different function may be performed by a nonsafety system if the system is of sufficient quality to perform the necessary function under the associated event conditions.

(4) A set of displays and controls located in the main control room should be provided for manual, system-level actuation of critical safety functions and for monitoring parameters that support the safety functions. The displays and controls should be independent and diverse from the computer-based safety system identified in items 1 and 3 above.

Full details of this position appear in NUREG-0800, Branch Technical Position 7-19, "Guidance for Evaluation of Defense-in-Depth and Diversity in Digital Computer-Based Instrumentation and Control Systems," issued March 2007 (ADAMS Accession No. ML070550072).

The NRC is currently considering addressing CCFs in certain digital equipment through rulemaking, in part by requiring that new plant designs comply with provisions of an IEEE standard on DI&C. The agency has provided information on its approach in a preliminary document, "Integrated Action Plan to Modernize Digital Instrumentation and Controls Regulatory Infrastructure," dated March 24, 2016 (ADAMS Accession No. ML16075A466). The NRC requested public comment on this preliminary document on March 30, 2016 (81 FR 17740).

External Event Analysis
The NRC states its position on external event analysis for new plants in the SRM related to SECY-93-087 (ADAMS Accession No. ML003708056) as follows:

(1) PRA insights will be used to support a margins-type assessment of seismic events.

(2) A safety margin of 1.67 times the design-basis safe shutdown earthquake (SSE) is acceptable for a margin-type assessment of seismic events.

ALWR vendors should perform bounding analyses of site-specific external events likely to be a challenge to the plant (such as river flooding, storm surge, tsunami, volcanism, high winds, and hurricanes). When a site is chosen, its characteristics should be compared to those assumed in the bounding analyses to ensure that the site is enveloped. If the site is enveloped, the COL applicant need not perform further PRA evaluations for these external events. The COL applicant should perform site-specific PRA evaluations to address any site-specific hazards for which a bounding analysis was not performed or which are not enveloped by the bounding analyses to ensure that no vulnerabilities caused by siting exist.

The NRC has issued DC/COL-ISG-028, the ISG for determining the technical adequacy of the PRA for the design certification and COL applications. This ISG covers seismic, high winds, external floods, and other external events.

After the accident at Fukushima Dai-ichi, the NRC issued a request for information, which asked, in part, that plants reevaluate their seismic and flooding hazards using present-day guidance and methods. All plants have responded to this request. For those plants where hazards are not bounded by their design basis, additional evaluations are being performed to determine how the plant would respond to the reevaluated hazard. The NRC will use the results of these additional assessments to determine if further safety enhancements are needed, beyond those associated with the actions discussed above. Section 1.3.3 gives more information.

NTTF Recommendation 2.2 suggested that the NRC initiate a rulemaking to require licensees to confirm seismic and flooding hazards every 10 years and address any new and significant information, including, if necessary, updating the design basis for SSCs important to safety to protect against the updated hazards. In SECY-12-0095 (ADAMS Accession No. ML12208A208), the staff discussed other external hazards, such as those caused by meteorological effects, that should be included in the licensees' periodic updates that the NRC would require once the agency implemented Recommendation 2.2.

Subsequently, in SECY-15-0137 (ADAMS Accession No. ML15254A006), the staff stated that the use of rulemaking to address Recommendation 2.2 was not necessary. Rather, the staff proposed to develop a method to leverage and enhance existing NRC processes and programs to ensure that information related to natural external hazards is proactively and routinely evaluated in a systematic manner. In response to the SRM to SECY-15-0137

(ADAMS Accession No. ML16039A175), dated February 8, 2016, the NRC staff developed a framework that expands upon the concepts described in SECY-15-0137. The framework provides a graded approach that will allow the NRC to proactively, routinely, and systematically seek, evaluate, and respond to new information on natural hazards. Although the framework is intended to allow for an ongoing assessment of new information, it is recognized that performance of certain activities (e.g., technical engagement activities and the development of summary reports) on a defined or periodic schedule provides important institutional structure. As such, the framework paper (ADAMS Accession No. ML16286A586) outlines the staff's intention to develop an office instruction that will provide details on (1) the types of activities that will be performed, (2) the review approach to be used to assess new information, and (3) the periodicity of documentation of the work under the framework. If the Commission approves the proposal, the staff plans to develop the office instruction to implement the framework in 2017. INPO RESPONSE: NRC regulations require that an application for a new plant must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. Regulations contain General Design Criteria that establish minimum requirements for the principal design criteria, covering a broad range of topics including accident prevention, defense-in-depth, and protection against natural phenomena.
Question No. 41
Mitigation 1.3 How do your national requirements and regulations incorporate appropriate technical criteria and standards to address the objective of mitigating against possible releases of radionuclides causing long-term offsite contamination and avoiding early radioactive releases or radioactive releases large enough to require long-term protective measures and actions. For example: can you describe the measures you have in place to protect against severe accidents and your accident management arrangements - how do you protect staff during accident management? Consider for instance inclusion of implementation of Regulatory requirements for: • Engineered systems to protect the containment; • engineered systems to cool the molten core; • severe accident management, protection of staff during the accident. • Provision and resilience of Emergency Mitigation Equipment (EME)
Answer: NRC RESPONSE: As described in Section 18.1 of the U.S. 7th National Report, Appendix A to 10 CFR Part 50 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appa.html) embodies the DID philosophy. GDC cover multiple fission product barriers, protection and reactivity control systems, fluid systems, containment design, and fuel and radioactivity control. The following address these more specifically: • GDC 2, "Design Bases for Protection against Natural Phenomena," requires that the plant's design basis reflect appropriate consideration of severe natural phenomena, including the effects of normal and accident conditions.

- GDC 16, "Containment Design," and GDC 50, "Containment Design Basis" require that the plant's design basis ensure that the containment design conditions important to safety are not exceeded for as long as postulated accident conditions require.

- GDC 35, "Emergency Core Cooling," requires that the plant's design basis include a system to provide abundant emergency core cooling.

- 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors," provides more detailed system requirements (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0046.html).

- 10 CFR 50.54(hh) requires plants to 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 caused by explosions or fire (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0054.html).

- 10 CFR Part 50, Appendix E, Section IV, "Content of Emergency Plans," requires the plant to have the means to determine the magnitude, and continually assess the impact, of the release of radioactive materials from all reactor core and spent fuel pool sources on site (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appe.html).

Additionally, as described in Section 1.3.1 of the U.S. 7th National Report, the NRC has taken a number of actions in response to the Fukushima accident to ensure nuclear power plant operators' preparedness to respond to and mitigate the consequences of beyond-design-basis events. On March 12, 2012, the NRC issued the first regulatory requirements, in the form of orders, for the operating reactors, based on lessons learned from the accident. Specifically, they require nuclear power plants to implement safety enhancements related to (1) having mitigation strategies to respond to beyond-design-basis external events, (2) ensuring severe-accident-capable reliable hardened containment vents for BWRs with Mark I and Mark II containment designs, and (3) enhancing SFP instrumentation. Section 19.4 of the U.S. 7th National Report describes how the NRC has entered the rulemaking process to codify these orders. On December 15, 2016, the staff sent SECY-16-0142: "Draft Final Rule—Mitigation of Beyond-Design-Basis Events" (ADAMS Accession No. ML16301A005), to the Commission for approval.

Section A.9 of Appendix E to 10 CFR Part 50 addresses onshift staffing for personnel assigned emergency plan implementation functions, which requires nuclear power reactor licensees in the United States to perform a detailed analysis to confirm the adequacy of the staffing. The regulatory guidance for this analysis is in NSIR/DPR-ISG-01, "Interim Staff Guidance – Emergency Planning for Nuclear Power Plants," dated November 20. 20011 (ADAMS Accession No. ML113010523), supported by the industry guidance document NEI 10-05, "Assessment of On-Shift Emergency Response Organizations Staffing and Capabilities," issued June 2011 (ADAMS Accession No. ML111751698). Additionally, NEI 12-06 (ADAMS Accession No. ML15244B006) provides guidance for the protection, maintenance, and testing of equipment used to mitigate beyond-design-basis events, including provisions for spare equipment, to ensure the availability of the equipment necessary to execute the mitigating strategies. The guidance applies to equipment stored on site, as well as offsite equipment stored at the National SAFER Centers.

The NRC issued a request for information on the related subject of staffing for the beyond-design-basis event mitigation strategies by letter dated March 12, 2012, under 10 CFR 50.54(f). NEI 12-01, “Guideline for Assessing Beyond Design Basis Accident Response Staffing and Communications Capabilities” (ADAMS Accession No. ML12125A412), which the NRC endorsed in a letter dated May 15, 2012 (ADAMS Accession No. ML12131A043), contains the guidance for performing the analysis requested in that letter. The staff discussed the suitability of the guidance in NEI 12-01 for use in staffing for the MBDBE rulemaking in Draft Regulatory Guide (DG)-1319, “Integrated Response Capabilities for Beyond-Design-Basis Events,” issued November 2016 (ADAMS Accession No. ML14265A070), which the NRC expects to issue as RG 1.228 in conjunction with the final MBDBE Rule.

In addition to the guidance for staffing analyses for emergency plan implementation, the NRC has endorsed guidance to validate the licensees’ strategies and guidelines under the MBDBE Rule. That guidance is in Appendix E to NEI 12-06, Revision 2 (ADAMS Accession No. ML16005A625), which the NRC endorsed in JLD-ISG-2012-01, Revision 1 (ADAMS Accession No. ML15357A163).

INPO RESPONSE:
The U.S. industry’s compliance with NRC regulations and guidance is inspected by the NRC. In addition, INPO performs evaluations in engineering, maintenance and operational areas to provide a higher level of excellence in addressing these areas. The plant performs routine preventive maintenance on these systems and if deficiencies are found they are entered into the plant corrective action system for timely resolution. Additionally, to support effective risk management, PRA models are maintained which allow any out of service/unavailable equipment to be factored into the overall risk profile for the plant.

At each U.S. nuclear power plant, personnel are trained on a recurring basis to apply existing procedures and guidance to handle design basis and beyond design basis events. Severe accident mitigation guidance is supported through augmented trained utility personnel in emergency response. During an event, protection of site staff would be achieved through assessment, pre-activity briefings, special exposure permissions by trained management, and the use of potassium iodide. All emergency equipment, and their associated implementing procedures, is maintained and tested periodically.

After Fukushima, the US implemented additional measures, one of which is to ensure extra equipment is available at two off site warehouse locations to all plants. This additional equipment would be allocated during an event through a pre-arranged protocol, with timelines and logistics for delivery. Both the offsite warehouse and plant personnel are trained on the process for requesting, dispatching, receiving, and installing this equipment. To ensure that it will function upon arrival at the site, the equipment also follows a strict maintenance protocol.

Question No. 42

Principle 2
2.1 How do your national requirements and regulations address the application of the principles and safety objectives of the Vienna Declaration to existing NPPs?

Answer: NRC RESPONSE: Under the NRC's current regulatory framework, nuclear power plants are subject to ongoing inspection, audit, and oversight throughout the life of the plant. Detailed discussion of this framework appears in Article 14, "Assessment and Verification of Safety," of NUREG-1650. If the NRC receives new information showing a significant safety issue, then it acts in a timely fashion to resolve the issue at the plant(s). Examples would be the set of actions that the NRC undertook after the Fukushima accident (e.g., issuing orders to licensees, performing inspections, requesting information from licensees, and undertaking rulemaking actions). During the 2010 IAEA IRRS to the NRC (IAEA-NS-IRRS-2010/02), the NRC correlated its regulatory programs with each of the 14 PSR factors to demonstrate how NRC programs meet the intent of the reviews. Key programs credited included the license renewal review and the operating experience and generic communication programs, among others. Programs such as ROP, operating experience, license renewal reviews, and the use of risk-informed regulation, are intended to ensure that the principles of the Vienna Declaration are met and provide adequate protection of the health and safety of the public, as required by the AEA. New and existing nuclear power plants in the United States must meet safety, security, technical, and financial qualification requirements as outlined in NRC regulations (10 CFR Chapter I, including 10 CFR Parts 20, 50, 52, 30, 40, 70, 73, and 100, as well as 10 CFR Part 21, "Reporting of Defects and Noncompliance"; and 10 CFR Part 55, "Operators' Licenses"). These NRC requirements govern the design, siting, construction, and operation of nuclear power plants. Failure by the licensee to meet these requirements can result in regulatory action. INPO RESPONSE: At U.S. nuclear power plants, safety objectives are addressed through strict adherence to plant procedures requiring availability and operability of safety equipment, qualified training of personnel to ensure an understanding of the procedures and basis for the safety systems, PRA models that continuously evaluate the plant risk profile during maintenance in which equipment may be unavailable, limiting timeframes for out of service equipment, and a robust corrective action program that identifies to all site personnel equipment and procedural issues and evaluates and ensures implementation of corrective actions. Additionally, nuclear oversight plant personnel exist at each site, who, independent of the line organizations, perform audits and assessments in areas impacting safety and quality on a routine basis. Off-site knowledgeable industry personnel, who serve on safety review boards for the plant, also perform independent reviews of areas affecting safety and quality.
Question No. 43
2.2 Do your national requirements and regulatory framework require the performance of periodic comprehensive and systematic safety assessments of existing NPPs – if so, against what criteria/benchmarks are these assessments completed and how do you ensure the findings of such assessments are implemented?
Answer: NRC RESPONSE: Yes. Some countries use the PSRs as the main process for conducting comprehensive and systematic safety assessments. Sometimes these reviews are used to support the decisionmaking process for long-term operation or license renewal. Other countries use routine comprehensive safety assessment programs concerned with specific safety issues, significant events, and changes in safety standards and practices as they arise. These programs, if applied with appropriate scope, frequency, depth, and rigor, achieve the same review standards (RSs) and objectives as a PSR. Alternative processes, such as the

NRC's ROP and the license renewal process, are considered equally adequate and acceptable. Under the NRC's current regulatory framework, nuclear power plants are subject to ongoing inspection, audit, and oversight throughout the life of the plant. During the 2010 IAEA IRRS, (IAEA-NS-IRRS 2010/02), the NRC correlated its regulatory programs to every single one of the 14 PSR safety factors to clearly demonstrate that the NRC programs robustly meet the intent of the PSR. Key programs credited included the license renewal review and the operating experience and generic communication programs, among others (for additional details, refer to ARM IRRS Module 11a). The IRRS team concluded that "the NRC has in place a number of programmes (the analysis of the operating experience, the Reactor Oversight Process, the generic upgrades and regulatory changes, the use of risk informed regulation and the license renewal rule) that are intended to ensure that the goals of the periodic safety review are met and that provide adequate protection to the health and safety of the public, as required by the Atomic Energy Act." Section 14.1.5 of the U.S. 7th National Report contains further discussion. The NRC's Inspection Manual is at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/. INPO RESPONSE: The U.S. nuclear industry focuses on safety daily through a multitude of programs and processes. For example, the U.S. nuclear industry, through line-independent nuclear oversight personnel, provides quality audits of safety equipment and procedures. Acceptance criteria for audits are proceduralized and ensure equipment and programs meet regulatory requirements. In addition, the U.S. industry maintains plant-specific PRA models are maintained and updated to reflect the actual plant configuration and equipment availability. These PRA models also take into account external factors such as weather, in determining the overall risk of the station. The risk profile informs and limits activities based on predetermined limits for risk. INPO and other industry guidance drive the acceptable limits, which are also developed to ensure that they drive performance that is well within NRC requirements.
Question No. 44
2.3 Do your national requirements and regulations require reasonably practicable/achievable safety improvements to be implemented in a timely manner – if so, against what risk/engineering objective or limit are these judged and can you give practical examples?
Answer: NRC RESPONSE: The U.S. national requirements mandate that, at a minimum, reasonable assurance (no undue risk) of adequate protection be provided with respect to public health and safety and the common defense and security without regard to cost. The NRC's licensing process ensures that this U.S. national requirement is met with respect to initial licensing, amendments of licenses, renewals of licenses, and decommissioning of a facility followed by termination of the license. The NRC may issue orders to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or take such other action as may be proper. Examples would be the issuance of three orders following the Fukushima accident. The three orders addressed hardened containment venting, mitigating strategies for beyond-design-basis external events, and SFP instrumentation. Problem identification and resolution is largely governed by 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action," and it focuses on correcting conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances for those systems, subsystems, and components subject to 10 CFR Part 50, Appendix B. As the NRC identifies the need for safety improvements, it establishes and

imposes deadlines for licensee implementation. Conditions need to be corrected in a manner commensurate with safety or security significance not to exceed one operating cycle unless justified by licensee senior management. An example would be the post-Fukushima requirements for certain designs to implement various safety improvements by specific time periods contained in the order.

The staff uses NRR Office Instruction LIC-504, Revision 4, "Integrated Risk-Informed Decision-Making Process for Emergent Issues," dated May 30, 2014 (ADAMS Accession No. ML14035A143), to outline the process by which the staff and managers evaluate and communicate risk-informed decisions and thereby improve NRC's efficiency and effectiveness. Also, the backfitting process is the process by which the NRC decides whether to issue new or revised requirements or staff positions to licensees of nuclear power reactor facilities. Backfitting is expected to occur and is an inherent part of the regulatory process. However, it is to be done only after formal, systematic review to ensure that changes are properly justified and suitably defined. Two NRC rules, 10 CFR 50.109 and 10 CFR 50.54(f), contain requirements for proper justification of backfits and information requests. NUREG-1409, "Backfitting Guidelines," issued July 1990 (ADAMS Accession No. ML032230247) contains the NRC's guidelines.

INPO RESPONSE:
Safety improvements are driven through NRC required deadlines and through INPO and NEI industry initiatives to ensure that the industry addresses any industry wide safety improvements in a timely and appropriate manner. A recent example involved the industry's voluntarily initiative to develop a program to address underground piping integrity. All U.S. utilities committed to certain actions within a designated timeframe to address concerns that arose from the NRC and public stakeholders. In response to the NRC's post-Fukushima orders, the U.S. industry devised a strategy that involved adding additional equipment and procedures at all stations and in two centralized shared off-site warehouse locations. That plan included detailed timeframes, to ensure compliance with NRC mandated schedules . US plant leadership recognizes the need to get ahead of safety issues and does a good job of working together with the support of NEI for coordination and INPO for guidance to identify and drive industry led safety improvements.

Question No. 45

Principle 3
How do your national requirements and regulations take into account the relevant IAEA Safety Standards throughout the life-time of a Nuclear Power Plant.

Answer: NRC RESPONSE: The NRC's regulatory requirements and guidance documents undergo systematic reviews and revisions, which are informed by international standards and guidance documents, as needed. Built into the process for updating NRC guidance is an examination of applicable technical-basis information, including related guidance available in domestic and international consensus standards, IAEA nuclear safety standards and recommendations, and other relevant documents. The NRC's RGs, for example, routinely cite or reference relevant IAEA safety standards and guides that address similar technical content and note that the IAEA Safety Standards present international good practices to help users striving to achieve high levels of safety. The NRC's RGs state that they are consistent with the basic safety principles in the cited IAEA documents.

NRC senior managers serve as the U.S. delegates to each of the five safety standards committees under the aegis of the IAEA Commission on Safety Standards (CSS). This participation helps harmonize NRC requirements and guidance with international standards and guidance. The NRC staff supports the functions of these committees by participating, reviewing, and commenting on the content of draft IAEA documents and approval of final documents through the CSS.

NRC's regulatory decisionmaking for licensing reviews that concern nuclear power plant safety is largely guided by NUREG-0800. The NRC developed and maintains this Standard Review Plan through a formal process that involves review and careful consideration of the applicable technical-basis information. Technical bases for these guidelines are existing standards and guidelines, engineering handbooks and texts, basic literature, industry experience, and original research. As a result, these guidance documents integrate guidelines from consensus standards, including international standards; address gaps or deficiencies in available standards by drawing on other technical-basis sources; and present the guidelines and criteria in a form that can be readily applied to the NRC staff reviewer's tasks. The effect is that the staff applies the guidance of many international standards to its regulatory decisionmaking, through its use of these review guidelines.

Revised regulatory requirements may be imposed on operating nuclear power plants if warranted by significant safety concerns. As part of ROP, the NRC has established processes to ensure that licensees perform continuous review and maintenance of safety of their facilities and their licensing bases. 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 the continuing regulatory activities of the NRC, as well as the activities of the licensee. As such, licensees are required to perform actions such as the following to continually maintain their licensing bases:

- Implement quality-assurance program requirements that control the procurement of materials and services and implementation of changes to facilities, processes, and procedures (Appendix B to 10 CFR Part 50). These requirements apply through the term of the license and the extended term (i.e., the term of the renewed license).

- Implement the Maintenance Rule (10 CFR 50.65) for active components. This controls the maintenance and oversight of active components through the term of the license and the extended term.

- Review plant changes in accordance with 10 CFR 50.59, "Changes, Tests and Experiments."

- For each nuclear power plant, implement performance- and condition-monitoring activities such as inservice testing, inservice inspection, technical specification surveillance tests, and postmaintenance operability.

- Develop and submit license amendments in accordance with 10 CFR 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit."

- Develop and submit license renewal applications in accordance with 10 CFR Part 54. License renewal applicants are required to complete an integrated plant assessment and evaluate time-limited aging analyses. An integrated plant assessment identifies and lists structures and components subject to an aging management review. These include passive structures and components that perform their intended function without moving parts or without a change in configuration or properties. Examples of these components include the reactor vessel, steam generators, piping, component supports, and seismic Category I structures.

The U.S. 7th National Report, Articles 8.1.5 and 14.1, contain more information.

INPO RESPONSE:
The U.S. industry takes into account safety standards for the life of the operation of the unit.

Question No. 46

General question
What issues have you faced or expect to face in applying the Vienna Declaration principles and objectives to your existing fleet or new build of Nuclear Power Plants

Answer: The United States considers that the principles of the Vienna Declaration on Nuclear Safety have been addressed by the Articles of the CNS since its inception. The Vienna Declaration did not establish new concepts or guidance; rather, the Declaration represents a recommitment to certain Articles of the CNS, which were already in place. As of today, the United States has not faced (and it is not expecting to face in the near future) significant hurdles in implementing the objectives of the CNS, including the principles reinforced in the Vienna Declaration. The NRC provides more information on the general safety and regulatory challenges identified by the United States in the 7th National Report, Section 1.3.

Question No. 47

Some current and expected future challenges include:
…
- changes in the demographics, experience, and knowledge of the workforce
…
Ukraine also face challenges associated with maintenance of experience and knowledge of regulatory body staff. Could you share approaches to the solution of these issues?

Answer: The NRC is a knowledge-centric agency that relies on its staff to make the sound regulatory decisions needed to accomplish the agency's mission. Until about the 2005–2006 timeframe, the agency had enjoyed a relatively stable workforce and climate of slowly evolving technologies. This allowed for meeting performance goals by using an informal approach to knowledge management and to account for the typical hiring and retirement cycles. Beginning in the early 2000s, and for several years, NRC leadership had been concerned with the changing demographics, experience levels, and knowledge of the workforce. The NRC, like the rest of the Federal Government, faced a "retirement tsunami," where a significant percentage of the workforce was or would be eligible for retirement within 5 years. Given a changing environment, the agency determined it had to institute a systematic approach to knowledge management that could support the faster rate of knowledge collection, transfer, and use needed to accommodate increased staff retirements, midcareer staff turnovers, the addition of new staff, and the broader scope of knowledge needed to expand the agency's knowledge base to support new technologies and reactor designs.

It became increasingly important to integrate knowledge management into the agency's business processes and technology, rather than approaching knowledge management as an additional or ancillary requirement outside the normal scope of work. This fundamental change in perspective required top-down support from senior managers in the form of clear expectations, adequate resources, and rewards for desired behaviors and results.

To ensure successful implementation, the NRC appointed a very senior leader to serve as the agency knowledge management champion for overall leadership, direction, and integration of the knowledge management program. Each Office Director and Regional Administrator names a senior manager who leads the development and implementation of knowledge management activities within his or her organization. A steering group of office and regional managers provides cross-communication and integration of knowledge management initiatives. Each Office Director and Regional Administrator also appoints a senior staff knowledge management lead who assists in implementing specific knowledge management initiatives. The Office of the Chief Human Capital Officer provides program support, coordination, and evaluation.

The offices and regions are tasked with identifying occupational priorities of the NRC staff and critical bodies of knowledge where knowledge management is most needed in their organizations. Occupational priorities are those positions where the office or region is most likely to lose significant relevant knowledge in the near term. Critical bodies of knowledge are technical and administrative areas of expertise where knowledge management techniques are most needed to avoid losing significant mission-critical knowledge. The occupational priorities and critical bodies of knowledge identified by inputs from the offices and regions are compiled into a consolidated list to inform and direct the agency's knowledge management efforts.

The staff developed a set of knowledge management standard practices and techniques from which the offices and regions can select the tools best suiting their individual needs. Standard practices and techniques include mentoring, formal training and qualification programs, policies and procedures, RGs, SRPs, job aids, best practices, and information technology and information management solutions. A number of offices and regions developed their own knowledge management initiatives. The NRC's knowledge management program integrates these and other initiatives across the agency to ensure that the staff has a common set of tools to effectively and efficiently do their jobs.

Beginning in June 2014, the NRC embarked on Project Aim 2020, which sought to ensure that the NRC is using its resources effectively and efficiently. The Project Aim 2020 report entitled, "Achieving Exemplary Nuclear Regulation in the 21st Century," issued by the Executive Director for Operations and the Chief Financial Officer on January 31, 2015, provided concrete and specific projections of the workload for the agency 5 years out and developed recommendations to prepare the NRC to excel long into the future.

The project developed a forecast, along with the framework and recommendations, to enhance the NRC's ability to plan and execute its mission while adapting in a timely, effective, and efficient manner to a dynamic environment. The project recommended, among other things, a plan for right sizing (i.e., mapping the current workforce to the projected future state of the agency workforce and workload needs).

To assist with right sizing, the NRC developed a strategic workforce plan to ensure the agency is positioned to have the right number of people with the right competencies at the right time. Strategic workforce planning takes a long-term view of the organization's staffing needs and how those needs may change, based on internal and external factors. It allows management to plan for current and future staffing decisions based on organizational mission, strategic direction and objectives, budgetary resources, and a set of desired workforce skills and competencies.

To date, the NRC has accomplished the following Project Aim 2020 deliverables:

- defined and implemented a workforce planning process across the agency
- identified and defined the functional work and occupations of the current agency workforce (e.g., materials inspections, reactor inspections, rulemaking) and the occupations and positions that support the work (e.g., reactor systems engineers, security specialists)
- developed a future-state agency workforce and staffing plan (e.g., percent of technical vs. corporate staff, diversity, staff to supervisor ratios, grade structure, entry level, and recruitment plans)
- compared the current to future agency workforce to identify staff overages and gaps
- identified critical, at-risk positions and competencies
- developed an action plan and strategies to alleviate staff overages and gaps
- identified best practices and lessons learned to continuously monitor and revise the agency workforce planning process.

Question No. 48

The summary states that the NRC had concerns regarding the adequacy of licensees' current Spent Fuel Pool (SFP) neutron-absorbing materials monitoring. It also states, "the NRC has issued three technical letter reports discussing some of the methods that license holders use to monitor the degradation of neutron-absorbing materials, the uncertainties in the methodologies employed to monitor the performance, and the degradation mechanisms." Please summarize whether there were any particular concerns for any of the materials reviewed by the NRC?

Answer: The NRC issued GL 2016-01, "Monitoring of Neutron-Absorbing Materials in Spent Fuel Pools," on April 7, 2016 (ADAMS Accession No. ML16097A169), which summarizes the NRC concerns with respect to neutron-absorbing materials. Boraflex was the first neutron-absorbing material to exhibit significant degradation, as documented in IN 1987-43, IN 1993-70, " Degradation of Boraflex Neutron Absorber Coupons," dated September 10, 1993; IN 1995-38, " Degradation of Boraflex Neutron Absorber in Spent Fuel Storage Racks," dated September 8, 1995; and GL 1996-04, "Boraflex Degradation in Spent Fuel Pool Storage Racks," dated June 26, 1996. The NRC staff has also documented concerns about monitoring and mitigating Boraflex degradation in IN 2012-13, "Boraflex Degradation Surveillance Programs and Corrective Actions in the Spent Fuel Pool," dated August 10, 2012. Several license holders identified instances of degradation or deformation of Carborundum and Boral® neutron-absorbing materials in SFPs, such as that documented in IN 1983-29, "Fuel Binding Caused by Fuel Rack Deformation," dated May 6, 1983; and IN 2009-26, "Degradation of Neutron-Absorbing Materials in the Spent Fuel Pool," dated October 28, 2009. Unidentified and unmitigated degradation of these materials may challenge the subcriticality margin of the SFP (for commercial nuclear power plants) and other wet fuel storage locations (for research and test reactors), as required by the existing regulations. The existing regulatory criteria for the subcriticality margin are designed to prevent an inadvertent criticality event. If local conditions in the SFP are such that criticality is achieved, the local heat generation is likely to increase from power generation through fission. Such an event could challenge the ability of the credited SFP SSCs to maintain adequate cooling of the fuel.

Based on the operating experience discussed above, the NRC commissioned additional research into the monitoring techniques in use for the neutron-absorbing materials known to experience significant degradation with time, Boraflex and phenolic resin-based neutron absorbers (i.e., Carborundum and Tetrabor). This research identified several potential concerns about the approaches used to identify and project ongoing degradation for these neutron-absorbing materials. The three technical letter reports summarizing the research findings can be found at ADAMS Accession Nos. ML12216A307, ML12254A064, and ML13141A182. The NRC continues to oversee the impact of degradation or deformation on the neutron-absorbing materials and monitoring methods currently used in the U.S. commercial nuclear power industry.

Question No. 49

The summary describes the Southern Exposure 2015 “Whole Community” Emergency Preparedness Exercise as the first nuclear plant exercise to include long-term recovery elements that focused on housing, agriculture, and economic impact from a catastrophic radiological event. Please provide more details regarding this exercise. What were the challenges? Lesson learned ? Scenarios during the 5 day exercise? What program was used for the simulation of the “time jumps”? How accurate is the simulation and what assumptions were made?

Answer: Challenges to preparing for and conducting the Southern Exposure 2015 exercise included developing appropriate objectives and scope or level of participation for all stakeholders, ensuring a common understanding of the roles and responsibilities for the multiple Federal authorities involved in responding to and recovering from an accident of this nature, and the need for more time to discuss and consider recovery actions.

The U.S. 7th National Report, Section 1.3.3, enumerates both the major NRC lessons learned and the major interagency lessons learned from the Southern Exposure 2015 exercise.

The Southern Exposure 2015 exercise used one technical scenario, consisting of an accident at a nuclear power plant that resulted in offsite radiological consequences, which carried through all timelines and phases. Simulation of offsite data and the technical situation at the nuclear power plant did not continue after initial phases of the exercise. Simulated data and measurements were then extrapolated for the 14-day, 6-month, and 18-month timeframes. After the initial release and offsite deposition, extrapolated data assumed a normal or expected decay of radionuclides.

Question No. 50

The report states “In 2013 and 2014, five power reactor units permanently ceased operation (i.e., Kewaunee; Crystal River, Unit 3; San Onofre, Units 2 and 3; and Vermont Yankee). These were the first reactors to permanently cease operations since 1998 - a span of nearly 15 years without a power reactor permanently shutting down.” And this number will increase in few years. Please describe any lesson learned to improve the regulatory oversight of the transition from operation to decommissioning beyond the new rule making?

Answer: Both the operating and decommissioning inspection program guidance for the oversight of plants transitioning from operating to permanently shut down required substantive revisions because the programs were not fully maintained and updated as changes were made to the regulatory and oversight framework over the years. As a result, the NRC staff has revised its IPs to enhance oversight at sites where licensees have announced their intention, and are preparing, to transition to a permanently shutdown and defueled condition. Of note, the NRC staff has developed new inspection guidance to supplement the ROP to focus inspection activities on programs and equipment important to reactor safety during decommissioning activities. Furthermore, the NRC staff has revised or developed decommissioning IPs to be current with changes to the regulatory framework for a decommissioning facility. The NRC staff described additional lessons learned in the "Power Reactor Transition from Operations to Decommissioning Lessons Learned Report," issued October 2016 (ADAMS Accession No. ML16085A029).

Question No. 51

The report states "In 2016, the scope of the PWR materials review visit is being expanded to take an even broader look at materials degradation and will include flow accelerated corrosion programs and buried pipe and tank integrity." So, 1) Summarize the methodology used to assess the buried pipes system? 2) What were the key conclusions from this program?

Answer: Buried piping and tanks are assessed by (1) direct visual examination of the external surface of the components or the coating condition, if the components are coated, (2) backfill conditions (i.e., absence of deleterious materials), and (3) if cathodically protected, annual cathodic protection surveys and monitoring of the availability of the rectifiers. Alternatives to direct visual inspection include monitoring leakage from fire water systems, internal wall thickness measurements, and periodic pressure tests. The number of direct visual examinations is based on the effectiveness of the cathodic protection system, coatings, backfill, and soil conditions (e.g., resistivity, corrosion accelerating bacteria, pH, moisture, chlorides, sulfates, redox potential).

The industry, in conjunction with NEI, initiated a buried and underground piping and tanks initiative. This initiative resulted in (1) identification of all buried and underground piping and tanks with safety or environment risk significance at each site, (2) development of program and procedures to manage the components, (3) prioritization of inspection locations, (4) initial set of inspections, and (5) development of long-term management plans. The NRC staff conducted inspections to determine whether each plant was complying with the initiative and the milestone schedule. With few exceptions, the industry met all schedules and all milestones were met. The NRC staff reviewed the results of inspections during license renewal audits and used them to adjust the recommended number of direct visual examinations in the GALL Report.

The staff's final position on an acceptable aging management program for buried piping and tanks for the license renewal operating period from 40 to 60 years is in LR-ISG-2015-01, "Changes to Buried and Underground Piping and Tank Recommendations," dated January 28, 2016 (ADAMS Accession No. ML15308A018).

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, programs for public participation, and lessons learned from Fukushima, and it addresses the Vienna Declaration on Nuclear Safety, issued in 2015.

The NRC posts the major results of assessments on the agency's public Web site at http://www.nrc.gov.

Question No. 52
prevention of accidents and by mitigating releases in the event of an accident, the risk of offsite contamination is rendered acceptable low…". Can the Contracting Party elaborate on how environmental protection is maintained as NPPs age?
Answer: Licensees must meet NRC requirements for the entire duration of the original license, any license renewal period, and decommissioning. Therefore, licensees maintain environmental protection, in terms of occupational exposures and offsite contamination, during the entire period of operation until decommissioning is completed, by complying with the regulations designed to prevent accidents and mitigate adverse consequences in a manner that effectively minimizes the potential for unintended releases of radioactive material.
Question No. 53
Regarding the Reactor Oversight Process (ROP), it is stated that "the [NRC] staff recognizes the value of continuous improvement and has actively sought to improve various key program areas through the solicitations of internal and external stakeholder feedback, lessons learned studies, and broader enhancement initiatives". As RPO is also used as a communication tool (e.g. on the NRC's website), could the USA give some details about the feedback provided by external stakeholder (public in general, NGO…)? Does RPO meet its objective as a communication tool?
Answer: The NRC considers public involvement in, and information about, its activities to be a cornerstone of strong, fair regulation of the nuclear industry. The NRC recognizes the public's interests in the proper regulation of nuclear activities and provides opportunities for citizens and other stakeholders to be heard. For that reason, consistent with the NRC approach to open government, the agency is committed to providing opportunities for the public to participate meaningfully in the NRC's decisionmaking process.

Though the purpose of the ROP is not primarily that of a communications tool, public input is considered in making improvements to it. Various means exist for the public to provide input and feedback. Such means include but are not limited to (1) public meetings, such as ROP public meetings, where ROP matters are openly discussed, (2) public feedback on draft documents made available for comment, and (3) general public inquiries via various types of correspondence. More information on public involvement is at https://www.nrc.gov/public-involve.html.
Question No. 54
With respect to the lessons learned from the identification of cracking in a bottom mounted instrument nozzle at a French NPP, it is stated that the after an NRC request, “the ASME Code committee considered developing a code case, but found only a limited number of licensees would consider using the code case. Therefore, the committee elected not to develop a code case. Licensees who want to perform volumetric inspections in lieu of visual inspections can do so using the NRC’s relief request process.” Does that mean that NRC would not be able to enforce the implementation of such technical inspections without the agreement of the ASME Code committee? In other words, is the agreement of the ASME Code committee mandatory to impose the implementation of this type of controls?
Answer: No, it is not mandatory that the NRC have the agreement of the ASME Code committee to impose this type of control. However, the NRC is directed to work with consensus expert bodies or organizations to develop efficient and effective regulations. It is the policy of the NRC to (1) involve all interested stakeholders in the NRC’s regulatory development processes, (2) participate in the development of consensus standards that support the NRC’s mission, and (3) use consensus standards developed by voluntary consensus standards bodies consistent with the provisions of the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113). The NRC also takes into account (e.g., evaluates, integrates) standards development through multilateral international organizations, such as IAEA. NRC Management Directive (MD) 6.5, NRC Participation in the Development and Use of Consensus Standards,” dated October 28, 2016 (ADAMS Accession No. ML16193A497), contains further details. With regard to bottom-mounted instrument nozzles, the NRC concluded, based on its review of operating experience, that its current position to rely upon visual inspections in accordance with ASME Code Case N-722-1, as conditioned by the NRC in 10 CFR 50.55a(g)(6)(ii)E, is sufficient to ensure plant safety.
Question No. 55
On page 78, it is stated that the goal of the Vienna Declaration to avoid large and early releases are met through the prevention of accidents and by mitigating releases in the event of an accident. Indeed, this is the objective of the defence-in-depth concept. It would be appreciated if the USA could explain in more detail the requirements for the safety demonstration and the associated assessment criteria for judging whether the risk is acceptably low in order to demonstrate that large and early releases are avoided. As this is a radiological goal, do the USA have radiological objectives if an off-site contamination is considered as inacceptable?
Answer: Licensees of U.S. nuclear power plants may request risk-informed changes to their licensing basis. The NRC evaluates the risk assessment as well as the extent to which the proposed change affects DID and safety margins. RG 1.174 contains the guidance for such

risk-informed change requests. Any risk increases must be small and consistent with the Commission's Safety Goal Policy Statement. DID and safety margins must remain adequate following the change. This helps ensure that risk, including large, early releases, are kept acceptably low. New reactors in the United States are licensed under 10 CFR Part 52. These licensees are required by regulation to have a PRA and must submit the results from that PRA during initial licensing. These PRA models must be maintained and updated over the life of the reactor. Although a reactor accident capable of a large release of radioactive material is not expected during the life of the plant, the NRC requires reactor licensees to establish emergency plans that implement the U.S. Environmental Protection Agency (EPA) protective action guidelines (PAGs) to mitigate radiological effects in the unlikely event of such an occurrence. EPA has established dose-based PAGs (PAG Manual at http://www.epa.gov/rpdweb00/rert/pags.html) for the relocation and reentry of members of the public during the intermediate phases of a radiological incident or accident. In addition, in February 2009, the U.S. Department of Energy (DOE) published its "Preliminary Report on Operational Guidelines Developed for Use in Emergency Preparedness and Response to a Radiological Dispersal Device Incident" (DOE/HS-0001; ANL/EVS/TM/09-1, at http://www.evs.anl.gov/resrad/documents/ogt_manual_doe_hs_0001_2_24_2009c.pdf). These operational guidelines provide stay times and concentrations for several different sets of assumptions about the exposure and can be used to calculate doses to members of the public. INPO RESPONSE: Through the application of PRA, the industry continuously analyzes the risk profile of the station. This risk profile takes into account plant configuration, available equipment and outside influences such as weather conditions. Therefore, everyday risk is continuously being monitored by the station to pre-determined limits that are deemed acceptable. In addition, the US plants follow strict adherence to technical specifications, which ensure that defense in depth is employed through limiting allowed outage time of equipment and defining requirements for operability. Through the use of both the technical specifications and PRA in day to day operations and work control practices, the plant is maintained in a manner that maintains a high degree of safety. The basis for the PRAs performed is to ensure that core damage frequency and large early release frequency is maintained below a very low acceptance limit. Additionally emergency preparedness procedures coordinated with state and local authorities and practiced and evaluated on a routine basis, ensure that in the unlikely case of a radiological release above the very low prescribed regulatory thresholds, that the public is protected through implementation of actions such as sheltering, evacuation and distribution of potassium iodide.
Question No. 56
One Fukushima-related issue is the implementation of filtered containment venting systems in BWRs with Mark I and Mark II containments. How is the objective of the Vienna Declaration to avoid large releases ensured for those reactors not yet having implemented a filtered containment system? As this is considered as a long-term action resulting from the NTTF, what is the current mitigation strategy for those plants in case of a severe accident?
Answer: NRC RESPONSE: All plants are required by the Mitigating Strategies Order (ADAMS Accession No. ML12054A735) to have strategies to maintain core and SFP cooling and preserve the containment. Protecting those key safety features is expected to prevent large releases. Furthermore, SAMGs provide additional mitigation capabilities, should fuel damage

occur. The guidelines are intended to stop the progression of fuel damage and to limit releases to the environment. The NRC includes additional information on the implementation of lessons from the Fukushima accident in Sections 1.3.1 and 1.3.3 of the U.S. 7th National Report.

INPO RESPONSE:
Procedures and practices exist and personnel are trained in them that will protect public health and safety in a Fukushima type event. These practices include many redundant and diverse cooling methods. Even in the event that all installed cooling systems were to fail, new portable power and water systems will cool the reactor core and protect spent fuel in storage pools at the facility. These new systems, part of a new diverse and flexible safety strategy (FLEX), also include additional pre-staged pumps, generators and other equipment at other US nuclear plants and two regional response centers..

In the extremely unlikely event that an accident progresses to the point of the fuel melting through the reactor vessel onto the containment floor, it is imperative that water be injected into containment to cool the fuel debris on the floor. Ensuring core cooling this way has the added benefit of "filtering" radioactive material inside the containment building. The water in containment would work the same way that it would in an external filter. Thus, keeping damaged fuel cool through the injection of water, with its inherent filtering capability. Therefore, the US industry employs methods to provide reliable cooling of the fuel debris by injecting water into containment and filtering the radioactive material from the vent gases with water inside the containment building. Since the 1980s, the U.S. industry has proceduralized these strategies within the Severe Accident Management Guidelines (SAMGs). The U.S. industry has recently updated these strategies and the NRC is modifying its inspection programs to ensure proper oversight.

Question No. 57

Fukushima Lessons Learned: The report does not describe any site-specific technical and administrative measures taken into account after the Fukushima accident for any of the US NPPs. It would be preferable to have more information about that. A description of site-specific technical details of measures taken into account after Fukushima would be useful for other Contracting Parties, which also operate American nuclear technology in their countries. Section 1.3.1 only provides general information.

Answer: The U.S. plants all implemented similar technical and administrative measures, as appropriate for their particular reactor designs. All measures were consistent with the general information given in Sections 1.3.1 and 1.3.3. These included developing mitigating strategies for beyond-design-basis events, enhancing SFP instrumentation, and reevaluating seismic and flooding hazards. For plant-specific information, please see the NRC's public Web site (https://www.nrc.gov/reactors/operating/ops-experience/japan-dashboard/japan-plants.html). In particular, each plant's Final Integrated Plan for the Mitigating Strategies Order may be of interest.

Question No. 58

"The NRC recognizes that the effective use of operating experience is important for the agency's safety mission. Under the current NRC Strategic Plan, the agency is committed to using lessons learned from domestic and international operating experience and other sources as part of its effort to achieve the goal of safety. As a result, the NRC's emphasis on the effective use of operating experience remains strong."

Do you use the Operating Experience Program for low level events, too? Do the companies share those events with each other?

Answer: The operating experience group reviews low-level issues and events reported in event notifications and licensee event reports (LERs) reported to the NRC in accordance with 10 CFR 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors,” and 10 CFR 50.73, “Licensee Event Report System,” respectively, and records of these reviews are maintained on an internal database. In addition, the database contains information on selected events of interest at U.S. plants that plant inspectors review during daily phone calls with the regions and the operating experience group. These events generally do not rise to a level requiring reporting to the NRC but are tracked for future trending and analysis in case similar events with higher safety significance occur in the future. Individual licensees share operating experience with each other through INPO, as described in NRC GL 82-04, “Use of INPO See-In [Significant Event Evaluation and Information Network] Program,” dated March 9, 1982. INPO changed the SEE-IN acronym to “Operating Experience and Construction Experience Program” in 2010, but the functions of the program remain essentially the same. This program serves as a central collection and screening point for reviewing and communicating operating experience across the industry. This includes both low-level events and events that may rise to a higher significance. INPO establishes guidance and thresholds for licensee reporting of event and equipment failure information. All licensees have access to INPO’s event and equipment failure databases, and they review records from other sites for plant-specific applicability. INPO reviews all database records and will issue more detailed reports for events that meet its screening thresholds.
Question No. 59
With reference to article 6.4, page 78 of the American national report, it is stated that "Because NRC requirements protect public health and safety through prevention of accidents and by mitigating releases in the event of an accident, the risk of offsite contamination is rendered low as an indirect benefit, rather than as a direct performance goal" and it is stated in article 18.6 that "Because NRC requirements protect public health and safety through prevention of accidents and by mitigating release in the event of an accident, including severe, beyond design-basis accidents, the risk of offsite contamination is rendered acceptably low". With respect to offsite contamination, Korea would like to inquire the following questions: 1) What meaning does "the risk of offsite contamination" have in comparison with the risk of fatality in the Safety Goal Policy Statement? 2) Are there any actual examples of accident analysis or assessment that confirm low risk of offsite contamination (e.g., the release fraction of radioactive isotopes related to long-term offsite contamination, release frequency)? 3) Have safety goals been revised to consider the risk of offsite contamination as a direct performance goal?
Answer: The NRC regulatory framework requires that plants be designed with multiple independent and redundant safety systems. Plants must also be designed with multiple barriers, including a reactor containment to prevent a radioactive release, and be designed with systems that would mitigate any potential releases. These features provide a DID approach that reduces the probability of reactor accidents and precludes a large release. To further minimize the risk of an accident, nuclear power plant operators are required to be highly trained and skilled personnel who undergo continual training and testing. This layered approach has been successful in ensuring that plants are designed and operated safely in the United States. While there have been a small number of incidents at nuclear facilities, because of these regulatory requirements, none of them have resulted in a large release to the public or the environment.

In addition to the safety features of a nuclear power plant, the NRC requires licensees to establish emergency preparedness plans to assure that protective measures can be taken to protect the public. In the unlikely event of an emergency, these plans will guide the response, including assessing the consequences of the event, promptly notifying the public, and determining protective measures that should be taken to protect the public. These emergency plans require close cooperation between nuclear power plant owners, government agencies, State and local officials, and first responders. As part of the NRC requirements, periodic emergency plan drills are conducted to test the licensee's ability to effectively implement emergency plans. This regulatory requirement provides added assurance that, if an accident were to occur that released radiological material, effective plans are in place to protect the public. Through these mechanisms, the public is protected in the event of a release and any potential releases would be mitigated so, while it is not directly measured nor has it been made a performance goal, the environment is protected by this DID philosophy in conjunction with the emergency preparedness plans. Therefore, if the risk of releases caused by severe accidents is kept sufficiently small, the risk of land contamination is also kept low. There is no link between the risk of a fatality in the Commission's Safety Goal Policy Statement and the risk of land contamination. The NRC has initiated several studies that realistically assess the accident progression, radiological releases, and offsite consequences of postulated severe reactor accidents. The latest study is the State-of-the-Art Reactor Consequence Analyses (SOARCA) (ADAMS Accession No. ML12332A057). SOARCA's main findings fall into three basic areas: how a reactor accident progresses, how existing systems and emergency measures can affect an accident's outcome, and how an accident would affect public health. The project found that existing resources and procedures can stop an accident, slow it down, or reduce its impact before it can affect public health. Even if accidents proceed uncontrolled, they take much longer to happen and release much less radioactive material than earlier analyses suggested. With these insights, the study concluded that, under the accidents analyzed, there would be essentially zero immediate deaths and only a very, very small increase in the risk of long-term cancer deaths. Because the current safety goals indirectly protect the environment from the risk of offsite contamination and meets the intent of protecting the environment, the NRC does not plan to revise them to explicitly include the risk of offsite contamination.
Question No. 60
Can you please give a real example of NRC actions meant to facilitate the activities of a particular licensee using risk-informed approach acceptable for NRC when the licensee needs to extend the lifetime of its nuclear facility?
Answer: The Commission's regulations (10 CFR Part 51) require that license renewal applicants consider alternatives to mitigate severe accidents if the NRC staff has not previously evaluated SAMAs for the applicant's plant. Severe accidents are those that could result in substantial damage to the reactor core. The NRC staff reviews and evaluates SAMAs to ensure that changes that could improve severe accident safety performance are identified and evaluated. The evaluation of SAMAs is a four-step process. The first step is to characterize overall plant risk and the leading contributors to the risk using plant-specific PRAs. The PRA identifies the

different contributors to system failures and human errors that would be required for an accident to progress either to core damage or to containment failure.

The second step is to identify potential improvements that could reduce the risk. Information from the PRA, such as dominant accident sequences, equipment failures, and operator actions is used to identify plant improvements that would have the greatest impact in reducing risk. This process also considered improvements identified in other NRC and industry studies, as well as SAMA analyses for other plants.

The third step is to quantify the risk-reduction potential and the implementation cost for each of the improvements. The risk reduction is typically estimated using a conservative analysis that generally overestimates the risk-reduction potential by assuming that the plant improvement is highly effective in eliminating the accident sequence that the improvement is intended to address. Implementation costs are generally underestimated by neglecting certain cost factors, such as maintenance costs or surveillance costs, associated with the plant modification. Overestimating the risk-reduction potential and underestimating the implementation costs in this step make it more likely that a potentially useful safety improvement would be retained for further consideration in the final step.

The risk-reduction potentials and the implementation cost estimates are used in the final step, which is to determine whether implementation of any of the improvements is justified. In making this determination, the NRC staff looks at three factors: (1) whether the improvement is cost beneficial; in other words, whether the estimated benefit is greater than the estimate of the implementation cost of the SAMAs, (2) whether the improvement provides a significant reduction in total risk; in other words, whether it eliminates a sequence or containment failure mode that contributes to a large fraction of plant risk, and (3) whether the risk reduction is associated with aging effects during the period of extended operation, which would be an improvement implemented as part of the license renewal process.

The outcome of the SAMA analysis is a list of plant improvements that meet the criteria of being cost beneficial, providing a significant reduction in total risk, and being associated with aging effects during the period of extended operation. In some cases, however, the review leads to a determination that there are no specific SAMA candidates that are cost beneficial. This may be the case where there is a low residual level of risk and where the applicant has, in fact, already implemented many plant improvements. In other cases, a SAMA that is potentially cost beneficial may not relate to adequately managing the effects of aging during the period of extended operation. Such SAMAs need not be implemented as part of the license renewal under 10 CFR Part 54.

Question No. 61

What are specific features of aging management in case of second subsequent licence renewal, and what significant issues have made the NRC plan to issue by mid-2017 "Generic Aging Lessons Learned (GALL) Report" and "Standard Review Plan" for operations beyond 60 years?

Answer: In the last several years, there has been a consensus that the following significant aging management and technical issues provide assurance of safe operation of nuclear power plants for operation from 60 to 80 years:

- neutron embrittlement of the reactor pressure vessel

- stress-corrosion cracking and other types of degradation of reactor pressure vessel internals concrete and containment degradation, and

- electrical cable qualification and condition monitoring

The NRC works with the nuclear industry to implement the technical resolutions of these issues into the license renewal process. The NRC is also collaborating on research activities with both domestic industry organizations (i.e., EPRI, NEI, and DOE research centers, such as Oak Ridge National Laboratory and Pacific Northwest National Laboratory), and international partners.

The NRC developed the GALL-SLR Report (NUREG-2191) and SRP-SLR (NUREG-2192), using the GALL Report (NUREG-1801, Revision 2) and the SRP (NUREG-1800, Revision 2) as the basis, with consideration of the following:

- expected aging differences for increased operating time from 60 to 80 years
- new plant operating experience since GALL Revision 2
- gaps identified in current guidance
- improvements in efficiency and effectiveness of applications and NRC reviews
- corrections to GALL Revision 2 and SRP Revision 2
- ISGs incorporated since GALL Revision 2

The current status of subsequent license renewal activities is available at http://www.nrc.gov/reactors/operating/licensing/renewal/subsequent-license-renewal.html.

Question No. 62

Para 1.2.2 gives a list of nuclear units that had their licenses renewed in the reported period. Could you please give information about major activities carried out at each operating nuclear unit to justify service life of equipment, perform refurbishment and enhance safety.

Answer: The NRC reviews the license renewal application for compliance with the requirements of 10 CFR Part 54. When an applicant submits a license renewal application to the NRC, the applicant must demonstrate that it will manage the effects of aging in such a way that it will maintain the intended functions of “passive” and “long-lived” SSCs (e.g., the reactor vessel and steam generators), as identified in 10 CFR 54.4, “Scope,” during the period of extended operation. The NRC has developed the GALL Report (NUREG-1801) SRP (NUREG-1800) as documents to guide the staff’s review of license renewal applications. The GALL Report contains numerous aging management programs to age-manage passive SSCs.

The NRC documents the results of the review of the license renewal application in a safety evaluation report. On the basis of its evaluation of the license renewal application, the NRC staff ensures that (1) actions have been identified and have been or will be taken with respect to managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified as requiring an aging management review under 10 CFR 54.21(a)(1), and (2) actions have been identified and have been or will be taken with respect to time-limited aging analyses that have been identified as requiring review under 10 CFR 54.21(c).

The plant license renewal safety evaluation reports and the current status of license renewal reviews are available at: http://www.nrc.gov/reactors/operating/licensing/renewal/applications.html.
Question No. 63
The section discusses policy of encouraging employees to report safety issues. What is this encouragement and how is it pursued?
Answer: Regulated Communities: The NRC expects licensees to establish and maintain a “safety-conscious work environment” that encourages employees to raise safety concerns to their management, free of any fear of reprisal for doing so. Such a work environment is critical to a licensee’s ability to safely carry out its responsibilities. The NRC provides further guidance in its Policy Statement, “Freedom of Employees in the Nuclear Industry To Raise Safety Concerns Without Fear of Retaliation” (61 FR 24336, May 14, 1996), and Regulatory Issue Summary-05-18, “Guidance for Establishing and Maintaining a Safety Conscious Work Environment,” dated August 25, 2005. Licensees must post or otherwise make available to workers a copy of NRC regulations, licenses, and operating procedures that apply to their work. They must also post all NRC-issued notices of violations involving radiological working conditions and proposed imposition of civil penalties and orders. Further, licensees are required by law to post NRC Form 3, “Notice to Employees,” that describes protected activities and encourages employees to take concerns to their supervisors but also explains how workers can report allegations of licensee violations directly to the NRC. Licensees must post NRC Form 3 at prominent locations at the workplace to permit workers to view it easily. The sections titled “Introduction” and “A Worker’s Role in Nuclear Safety” of NUREG/BR-0240, “Reporting Safety Concerns to the NRC,” Revision 6, issued May 2012 (ADAMS Accession No. ML12146A003), give additional details. Regulator: Creating an environment that encourages all NRC employees and contractors to raise concerns and differing views promptly, without fear of reprisal, is a key component of the NRC’s safety culture. The free and open exchange of views or ideas conducted in a nonthreatening environment provides the ideal forum where concerns and alternative views can be considered and addressed in an efficient and timely manner that improves decisionmaking and supports the agency’s safety and security mission. The NRC’s commitment to the free and open discussion of professional views is illustrated by the provision of multiple ways for employees and contractors to raise mission-related concerns and differing views. Although all NRC employees and contractors are expected to discuss their views and concerns with their immediate supervisors on a regular, ongoing basis, there are times when informal discussions are not sufficient to resolve issues. The NRC uses a multitiered approach for addressing concerns and differing views, including MD 10.160, “Open Door Policy,” dated October 26, 2015; MD 10.158, “NRC Non-Concurrence Process,” dated March 14, 2014; and MD 10.159, “NRC Differing Professional Opinion Program,” dated August 11, 2015. These directives provide increasing levels of formality to air differences: the broad Open Door Policy is the least formal and does not require documentation, the Non-Concurrence Process requires documentation and is part of “business-as-usual,” and the Differing Professional Opinion Program is the most formal and provides a high level of agency review. The NRC believes that the existence of multiple channels for expressing disagreement helps create a positive environment for raising concerns by reducing barriers to expressing

differing opinions. The Non-Concurrence Process and Differing Professional Opinion Program also support the openness value, in that, when the process is complete, an employee can ask to make the records public. Volume 10 of the NRC MDs is at https://www.nrc.gov/reading-rm/doc-collections/management-directives/volumes/vol-10.html.
Question No. 64
The section states that the NRC has concluded that the licensee provided reasonable assurance that, with the current condition, the shield building at Davis-Besse will perform its safety function, including withstanding earthquakes and tornadoes. How was it validated that the shield building found to have traits of laminar cracking will withstand external impacts?
Answer: The licensee developed root cause analyses, technical reports, and calculations that evaluated the extent of laminar cracking and its effects on the shield building structural integrity, based on the results of impulse response test mapping and core bore analyses, as well as large-scale tests of the effect of laminar cracking on rebar splice (bond) capacity. The licensee's calculations evaluated the design-basis earthquake, tornado wind and differential pressure, and tornado-generated missile loads. These calculations conservatively incorporated the shield building cracking into the structural evaluations. In addition, the licensee developed a program to monitor potential future changes in condition. The licensee's calculations confirmed that the building stresses remained within acceptable limits specified in the original design and licensing bases. The NRC publishes the results of the staff's inspection of the licensee's actions to address the issue and demonstrate the operability of the containment system in the agency inspection reports (ADAMS Accession Nos. ML12173A023, ML12276A342, ML14132A259, ML15148A489, and ML12128A443).
Question No. 65
What methodology is used to calculate Baseline Risk Index for Initiating Events (BRIIE)?
Answer: The Baseline Risk Index for Initiating Events (BRIIE) was an enhancement to the Industry Trends Program (ITP) in the Initiating Events Cornerstone of Safety of the NRC's ROP, designed to provide short-term trending of risk-significant changes on individual initiating events (NUREG/CR-6932, "Baseline Risk Index for Initiating Events," issued June 2007, (https://www.nrc.gov/docs/ML0720/ML072080252.pdf)). Input for this indicator was derived from LERs. The last BRIIE index was SECY-16-0044, "Fiscal Year 2015 Results of the Industry Trends Program for Operating Power Reactors," dated April 5, 2016 (https://www.nrc.gov/docs/ML1605/ML16050A462.pdf). In response to the initiative to rebaseline NRC's scope of work, the agency eliminated the ITP (line item 36, Enclosure 1, "Rebaselining Recommendations," to SECY-16-0009, "Recommendations Resulting from the Integrated Prioritization and Re-Baselining of Agency Activities," dated February 9, 2016 (https://www.nrc.gov/docs/ML1602/ML16028A212.pdf)). As such, the NRC no longer calculates or tracks BRIIE. As discussed in NUREG/CR-6932, BRIIE did the following: • included 9 BWR and 10 PWR initiating event categories, which collectively represented approximately 60 percent of estimated CDF risk from internal events occurring during at-power operation • provided performance-based prediction limits (actual yearly numbers of events) for each initiating event (listed below) that, if reached or exceeded, indicated potential degradation of industry performance

- assembled the individual initiating event current performance along with Birnbaum importance measures into an integrated risk measure, approximating CDF, that could be used to assess the risk significance of changes in BWR and PWR plant performance in response to initiating events

- addressed only internal event CDF, and so did not include external events or LERF

- calculated each BRIIE category as an average of events per reactor critical year

To enhance the ITP coverage of the Initiating Events Cornerstone of Safety, a three-step BRIIE process was created. The first step identified key initiating events based upon results obtained from the standardized plant analysis risk (SPAR) models. The risk-significant initiating events chosen (applicable to both BWR and PWR plant types unless otherwise noted) were (1) general transients, (2) loss of condenser heat sink, (3) loss of main feedwater, (4) loss of offsite power (LOOP), (5) loss of vital ac bus, (6) loss of vital direct current bus, (7) stuck-open primary coolant safety relief valve (SRV), (8) loss of instrument air, (9) very small loss-of-coolant accident (LOCA), and (10) steam generator tube rupture (PWR only). These events could be monitored because they occur with some frequency. Each initiating event was assigned a corresponding performance indicator, typically unplanned scrams, which would be reported in LERs.

The second step developed performance-based prediction limits for the individual initiating events. These were known as the BRIIE Tier 1 prediction limits. The prediction limits were performance based and represented the 95th percentile of each initiating event's current year distribution as derived from a prior baseline period experiencing relatively stable occurrence rates. The current year's distribution was obtained via a Bayes' update.

To guide the determination of the baseline period, the following characteristics were necessary:

- The baseline period must be representative of current industry performance.

- The baseline period should be long enough to give a good estimate of frequency and not be strongly influenced by random variation.

- The baseline period should be limited in length to ensure that the true frequency is approximately constant but must be at least 4 years.

When such a period and its associated statistical model had been established, the prediction limit threshold should not have changed from one year to the next unless a clear change had been noted in the actual industry performance relative to that indicator. Such a change would need to be both noticeable and persistent. Thus, data from a single year would not be sufficient to change a model and its prediction limit.

Initiating event frequency distributions were generated assuming there was plant-to-plant variation across the industry. A frequency distribution was first established using the baseline period, as is typically done in parameter estimation, using Bayes' Theorem. Then, a new, current year's initiating event frequency distribution was derived, again from a Bayes' update

process but this time informed partially by the baseline period statistical information (the mean value) and also by use of a constrained non-informative prior distribution designed to highlight current-year plant group information in the resultant posterior distribution. The 95th percentile of this distribution, taken with the reactor operating years covered, created a prediction for each initiating event (i.e., it will predict future performance, subject only to random fluctuations in the data). Random fluctuations should only exceed this value about 5 percent of the time based on current conditions. However, if those conditions should degrade, then the prediction limit could be exceeded more often. This situation would indicate that further investigation is warranted. In this manner, the prediction limit count estimated an upper limit of initiating event counts in the year in question that, if reached or exceeded in comparison to the actual number of events divided by that year's critical operating times, would have suggested a potential degradation in plant or industry performance. These prediction limits have rarely been exceeded. In 2003, the prediction limit for PWR general transients was exceeded. Multiple causes appeared to contribute to the large number of such events that year. In 2011, LOOP events also exceeded their prediction limit. Other than that, no initiating event prediction limit has been exceeded for the past 10 years. The final step developed an integrated, risk-informed indicator at the industry level by combining the individual initiating event information with Birnbaum importance measures. This was known as BRIIE Tier 2, or simply BRIIE for short. SPAR models covering U.S. commercial nuclear power plants provided the Birnbaum information. By combining initiating events, BRIIE gave an estimate of the change in CDF for an average plant resulting from the collective change across the initiating events' frequencies of occurrence. The "surrogate CDF" estimate was obtained via simulation. The initiating events' frequency distributions were repeatedly sampled and a histogram of results was generated based upon the equation 9-1 of NUREG/CR-6932 (p. 33) (https://www.nrc.gov/docs/ML0720/ML072080252.pdf). Finally, using this CDF construct, BWR, PWR, and industry baselines could then be normalized to 0.0 so that bars extending above zero represented worse than baseline performance in terms of this construct and bars extending below zero represented better than baseline performance (NUREG/CR-6932). Application: Suppose four events are observed in 1 year that are classified as very small break LOCAs, and each event occurred at a different plant, thus exhibiting plant-to-plant variation. A very-small-break LOCA as an initiating event is so rare that the 95-percent prediction limit is only two events, and so, by exceeding the 95-percent prediction limit, this initiating event is a candidate for further investigation. The NRC would look at these events to see if there were similarities among the events and to provide any lessons learned (NRC IMC 0313, "Industry Trends Program," dated May 29, 2008 (https://www.nrc.gov/docs/ML1025/ML102500670.pdf)).
Question No. 66
For the period of FY 2005 through FY 2014, the staff found a statistically significant increasing trend in the mean occurrence rate of precursors resulting from a loss of offsite power initiating event.

Could you please clarify, what are these precursors and external sources, and what are the plant states (outage or power operation)? Has the problem been resolved? How was it resolved?
Answer: Over the past 10 years, 27 LOOP events occurred at U.S. nuclear power plants. Two additional LOOP events occurred while the plants were shut down. Of these LOOP events, 13 resulted from weather (or external hazards), including lightning, tornados, winter storms, tropical storms, and earthquakes. Electrical-grid-related failures contributed to four LOOPs, and component failures in the switchyard contributed to three LOOPs. The remaining seven LOOPs were the result of plant-centered events. The NRC gives additional information on trends related to operating events in SECY-15-0124, "Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models," dated October 5, 2015 (https://www.nrc.gov/docs/ML1518/ML15187A434.html). The Idaho National Laboratory conducted an annual study of LOOP events for the NRC that investigated the increasing trend of LOOP events during the 2005–2014 period. The report, "Analysis of Loss-of-Offsite-Power Events, 1997–2014" (http://nrcoe.inel.gov/resultsdb/LOSP/), documents the study results. A statistically significant adverse trend (higher LOOP frequencies in more recent years) was observed in LOOP events during critical operations, although none of the subcategories of LOOP (electrical grid-related LOOPs, plant-centered LOOPs, switchyard-related LOOPs, and weather-related LOOPs) showed a statistically significant increase. When limited data are available, it is not unusual for aggregated data to show a statistically significant trend while individual subgroups fail to show such a trend. No statistically significant 10-year trend was found in shutdown LOOP event frequencies. In spring 2017, the NRC will issue a study of LOOP event frequencies and trends during the 2006–2015 calendar-year (CY) period and post it on its LOOP Web page (http://nrcoe.inel.gov/resultsdb/LOSP/). The LERs of LOOP events from 1988 to 2013 are in Table A.17 in the data tables in "Initiating Event Rates at U.S. Nuclear Power Plants 1988–2013" (http://nrcoe.inel.gov/resultsdb/InitEvent/). Only one LOOP occurred in 2014 (see LER 226/2014-006). Publicly available LERs can be downloaded from the public LER search data base (https://lersearch.inl.gov/LERSearchCriteria.aspx).
Question No. 67
What is the cause of the current deferred status of Bellefonte Nuclear Plant (Units 1 and 2) construction?
Answer: Tennessee Valley Authority (TVA) deferred construction of Bellefonte Units 1 and 2 in 1988, in part because of a lower-than-expected electrical load forecast in its service area. TVA has periodically reassessed whether to pursue completion of nuclear units at the Bellefonte site. In August 2015, TVA's Board of Directors approved the TVA 2015 Integrated Resource Plan, which stated that no new nuclear power was needed beyond the completion of Watts Bar Unit 2. In May 2016, TVA announced that it would put the Bellefonte site up for auction. Interested parties submitted bids, and on November 14, 2016, TVA announced the sale of the Bellefonte site to Nuclear Development, LLC. The terms of the sale provide 2 years for TVA and Nuclear Development, LLC, to close the sale. Nuclear Development, LLC, has publicly stated its intention to complete the Bellefonte units; however, as of December 23, 2016, it has not communicated with the NRC about its plans for the Bellefonte site.

Question No. 68
The description of measures introduced at operating NPPs in light of the lessons leant from the Fukushima-Daiichi accident does not allow clear understanding of approach implemented at PWR plants in respect of containment filtered venting systems. Are there any requirements to equip all operating PWRs with these systems, irrespective of the outcomes of deterministic and probabilistic analyses of severe beyond- design- basis accidents?
Answer: The staff determined that potential regulatory requirements for improvements to containment venting systems for other than Mark I and Mark II designs, including engineered filters, do not provide a substantial increase in the overall protection of public health and safety, which is required in the U.S. for the NRC to impose additional requirements on currently operating plants (i.e., as part of a plant-specific or generic backfit). The staff's analysis can be found in SECY-15-0085 (ADAMS Accession No. ML15022A218). Containments other than BWR Mark I and Mark II designs are expected to maintain their integrity by licensees using mitigation strategies before core damage occurs. If the accident progresses to core damage, containment integrity would be maintained during a severe accident for a sufficient time to allow operators to use mitigation measures defined in SAMGs and, if necessary, to take protective actions such as evacuating local populations.
Question No. 69
In case of extended power uprate to 120 percent of the nominal level, modifications are made at a nuclear power plant, and appropriate safety case is submitted to regulator. In this case, are there any amendments in the requirements for the oversight of the specifications or structures, systems and components (SSC), and who establishes these requirements?
Answer: In accordance with the NRC's "Review Standard for Extended Power Uprates, issued December 2002 (ADAMS Accession No. ML023610659), the NRC staff safety evaluation, which documents its review, includes a section titled, "Recommended Areas for Inspection." This section identifies areas for consideration by the NRC's inspection staff. Each area should include a rationale. The identified areas are not intended to be inspection requirements but are provided to give the inspectors insights into important bases for approving the power uprate. NRC IP 71004, "Power Uprate," dated May 21, 2015 (ADAMS Accession No. ML15121A676), provides guidance to inspectors on aspects of a power uprate that should be inspected.
Question No. 70
It is stated in the Report that NRC issued new requirements immediately after the Fukushima Daiichi event to enhance safety. Has prepared corresponding arrangements/programmes on NPPs and to what extent NPPs are in compliance with these requirements.
Answer: Immediately after the accident, the NRC issued INs and Bulletins and performed inspections to determine the preparedness of U.S. plants to withstand a similar event. These have been completed. The NRC also issued three orders and a request for information. Most licensees are in compliance with the Mitigating Strategies Order. A limited number of licensees have received extensions to the order due date of December 31, 2016, because their particular mitigating strategies rely on having the hardened vent installed. All plants are in compliance with the SFP Order. As of February 6, 2017, six units were in compliance with Phase 1 of the hardened

vents order. Plants are required to be in compliance no later than June 30, 2018, for Phase 1, and June 30, 2019, for Phase 2.

The plants have all responded to the request for information, which asked licensees, in part, to reevaluate their seismic and flooding hazards using present-day guidance and methods. For those plants whose hazards are not bounded by their design basis, licensees are performing additional evaluations to determine how the plant would respond to the reevaluated hazard. The NRC will use the results of these additional assessments to determine if further safety enhancements are needed, beyond those associated with the actions discussed above. Section 1.3.3 of the U.S. 7th National Report contains more information.

Question No. 71

Regarding the Reactor Oversight Process annual self-assessment, it is mentioned that it was redesigned in 2015 to develop a more effective process. Why do you think it was not being as effective as it could be and which are the "specific areas of interest" that were reviewed in order to improve the process?

Answer: As noted in SECY-14-0047, "Reactor Oversight Process Self-Assessment for Calendar Year 2013," dated April 18, 2014 (ADAMS Accession No. ML14066A365), the NRC staff initiated its ROP enhancement efforts to take a "fresh look" at several key ROP areas, including but not limited to the self-assessment program. In addition, in calendar year (CY) 2013, ROP benefited from independent evaluations by the Government Accountability Office, the Office of the Inspector General, and a Commission-directed internal independent review. These efforts collectively produced numerous recommendations and suggestions for further ROP improvements, including to the self-assessment process itself. For example, the Commission-directed independent review, "Reactor Oversight Process Independent Assessment 2013," dated February 11, 2014 (ADAMS Accession No. ML14035A571), recommended revising the ROP self-assessment process to better solicit and assess both tactical and strategic feedback. Given the amount of feedback and recommendations received by independent evaluations, the staff recognized that the prior self-assessment process did not provide as deep a review as necessary to identify some of these underlying enhancement opportunities.

In 2015, the NRC staff completed the redesign of the ROP self-assessment process to better assess the effectiveness of a mature program by focusing on the efficacy of recent changes to the program, performing in-depth reviews of specific areas of interest, and verifying NRC staff adherence to program governance documents. The NRC designed the new self-assessment approach to ensure that ROP is being implemented reliably and predictably across all four NRC regional offices, as well as at NRC Headquarters. The staff informed the Commission of its revised approach to, and implementation plans for, the annual ROP self-assessment in SECY-15-0156, "Improvements to the Reactor Oversight Process Self-Assessment Program," dated December 11, 2015 (ADAMS Accession No. ML15310A086).

The self-assessment program is governed by the revisions to IMC 0307, "Reactor Oversight Process Self-Assessment Program," and its appendices, dated November 23, 2015 (ADAMS Accession No. ML15307A023). The revised self-assessment approach consists of three distinct elements: (1) measure the effectiveness of and adherence to the current program, using objective metrics, (2) monitor ROP revisions and assess recent program changes for effectiveness, and (3) perform focused assessments of specific program areas and peer reviews of regional offices. The focused assessment, or "specific area of interest," for CY 2016 is the inspector training and qualification program as selected by senior NRC management.

The recommendations and results from the CY 2016 self-assessment, including the focused training assessment and other aspects of the enhanced self-assessment process, will appear in the annual self-assessment paper that will be issued in early April 2017 and discussed with the Commission in May 2017.
Question No. 72
Audits and vendors supplies. How do you verify the effectiveness of the supply chains? Have you implemented tools to address counterfeit and fraudulent items in nuclear facilities? Just in case, please describe them.
Answer: As required by 10 CFR Part 50, Appendix B, U.S. nuclear reactor facilities are responsible for the establishment and execution of a quality assurance program. They may delegate activities to others (e.g., contractors, agents, and consultants), but they retain the responsibility for quality assurance. The NRC requires these facilities to control purchased material, equipment, and services through audits, surveys, and inspections at routine intervals, based on importance, complexity, and quantity of products or services. The NRC also conducts vendor inspections at companies that supply materials, equipment, and services under a 10 CFR Part 50, Appendix B, quality assurance program. The results of these inspections are communicated to the vendor and the U.S. nuclear reactor facilities to highlight weaknesses in the nuclear supply chain and supply chain oversight. NRC vendor inspection reports are publicly available at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html. Although supply chains for other industrial sectors may be substantially affected by CFSI events, the NRC's position is that adherence to existing NRC regulations provides adequate protection of public health and safety. Specifically, if a U.S. nuclear reactor facility implements a robust quality assurance program as required by 10 CFR Part 50, Appendix B, it should address CFSI concerns, particularly for safety-related parts.
Question No. 73
Regarding the Reactor Oversight Process annual self-assessment, it is mentioned that it was redesigned in 2015 to develop a more effective process. Why do you think it was not being as effective as it could be and which are the "specific areas of interest" that were reviewed in order to improve the process? Regarding the Reactor Oversight Process annual self-assessment, it is mentioned that it was redesigned in 2015 to develop a more effective process. Why do you think it was not being as effective as it could be and which are the "specific areas of interest" that were reviewed in order to improve the process?
Answer: As noted in SECY-14-0047 (ADAMS Accession No. ML14066A365), the NRC staff initiated its ROP enhancement efforts to take a "fresh look" at several key ROP areas, including but not limited to the self-assessment program. In addition, in CY 2013, the ROP benefited from independent evaluations by the Government Accountability Office, the Office of the Inspector General, and a Commission-directed internal independent review. These efforts collectively produced numerous recommendations and suggestions for further ROP improvements, including to the self-assessment process itself. For example, the Commission-directed independent review, "Reactor Oversight Process Independent Assessment 2013" (ADAMS Accession No. ML14035A571), recommended revising the ROP self-assessment process to better solicit and assess both tactical and strategic feedback. Given the amount of feedback and recommendations received by independent evaluations, the

staff recognized that the prior self-assessment process did not provide as deep a review as necessary to identify some of these underlying enhancement opportunities.

In 2015, the NRC staff completed the redesign of the ROP self-assessment process to better assess the effectiveness of a mature program by focusing on the efficacy of recent changes to the program, performing in-depth reviews of specific areas of interest, and verifying NRC staff adherence to program governance documents. The NRC designed the new self-assessment approach to ensure that the ROP is being implemented reliably and predictably across all four NRC regional offices, as well as at NRC Headquarters. The staff informed the Commission of its revised approach to, and implementation plans for, the annual ROP self-assessment in SECY-15-0156 (ADAMS Accession No. ML15310A086).

The self-assessment program is governed by the revisions to IMC 0307 and its appendices (ADAMS Accession No. ML15307A023). The revised self-assessment approach consists of three distinct elements: (1) measure the effectiveness of and adherence to the current program, using objective metrics, (2) monitor ROP revisions and assess recent program changes for effectiveness, and (3) perform focused assessments of specific program areas and peer reviews of regional offices. The focused assessment, or "specific area of interest," for CY 2016 is the inspector training and qualification program as selected by senior NRC management. The recommendations and results from the CY 2016 self-assessment, including the focused training assessment and other aspects of the enhanced self-assessment process, will appear in the annual self-assessment paper that will be issued in early April 2017 and discussed with the Commission in May 2017.

Question No. 74

Please, could you provide additional information on this statement under Vienna declaration on nuclear safety?: Because NRC requirements protect public health and safety through prevention of accidents and by mitigating releases in the event of an accident, the risk of offsite contamination is rendered acceptably low as an indirect benefit, rather than as a direct performance goal.

Answer: The NRC regulatory framework requires that plants be designed with multiple independent and redundant safety systems. Plants must also be designed with multiple barriers, including a reactor containment to prevent a radioactive release, and be designed with systems that would mitigate any potential releases. These features provide a DID approach that reduces the probability of reactor accidents and precludes a large release. To further minimize the risk of an accident, nuclear power plant operators are required to be highly trained and skilled personnel that undergo continual training and testing. This layered approach has been successful in ensuring that plants are designed and operated safely in the U.S. While there have been a small number of incidents at nuclear facilities, because of these regulatory requirements, none of them have resulted in a large release to the public or the environment.

In addition to the safety features of a nuclear power plant, the NRC requires licensees to establish emergency preparedness plans to ensure that protective measures can be taken to protect the public. In the unlikely event of an emergency, these plans will guide the response, including assessing the consequences of the event, promptly notifying the public, and determining protective measures that should be taken to protect the public. These emergency plans require close cooperation among nuclear power plant owners, government agencies, State and local officials, and first responders. As part of the NRC requirements, periodic emergency plan drills are conducted to test the licensee's ability to effectively implement emergency plans. This regulatory requirement provides added assurance that, if an accident were to occur that released radiological material, effective plans would be in place to protect the public.

Through these mechanisms, any potential releases would be mitigated and the public would be protected through well-established emergency preparedness actions. Therefore, while it is not directly measured, the environment is protected by this DID philosophy.

Question No. 75

What are the major goals/issues in the development of a new regulation for mitigating beyond-design basis events.

Answer: The new regulation, described on page 78 in Section 6.5 of the U.S. 7th National Report, is intended to make the requirements of the orders for mitigation strategies and enhanced SFP instrumentation generically applicable to currently operating and new power reactors. These requirements have been imposed on power reactor licensees with licenses issued after the orders through the use of conditions on those licenses (e.g., VC Summer Units 3 and 4). By making the requirements generically applicable, the NRC expects to achieve greater regulatory consistency and a more efficient regulatory process. The new regulation also addresses the treatment of the new seismic and flooding hazards, which were reevaluated for currently operating power reactors to confirm the adequacy of plant design. The new regulation and the regulatory guidance that supports it reflect the U.S. nuclear industry's development and implementation of modifications and guidelines to meet the orders, as well as the NRC's review of them.

Question No. 76

The US NRC currently uses six performance goals and indicators to track the effectiveness of its nuclear safety regulatory programs to determine whether this goal has been met. Of these six, the following four are related to commercial nuclear power plants:
… (4) number of malfunctions, deficiencies, events, or conditions at commercial nuclear power plants (operating or under construction) that meet or exceed abnormal occurrence criteria II.A – II.D
What quantitative criteria are used by the US NRC in its regulatory activity?

Answer: One of the performance goals and indicators that the NRC uses to track the effectiveness of its nuclear safety regulatory programs for nuclear power plants is meeting or exceeding the abnormal occurrence (AO) criteria. An incident or event will be considered an AO if it involves a major reduction in the degree of protection of public health or safety. This type of incident or event would have a moderate or severe impact on public health or safety and could include, but need not be limited to, the following:

(1) moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission

(2) major degradation of essential safety-related equipment

(3) major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission

The NRC identified the criteria for determining an AO and the guidelines for "other events of interest" in a policy statement published on October 12, 2006 (71 FR 60198). Criteria II.A through II.D apply to nuclear power plants:

II. For Commercial Nuclear Power Plant Licensees

A. Malfunction of Facility, Structures, or Equipment

1. Exceeding a safety limit of license technical specification (TS) [10 CFR 50.36(c)].
2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.
3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100, "Reactor Site Criteria," or 5 times the dose limits of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix A, "General Design Criterion for Nuclear Power Plants," General Design Criterion (GDC) 19, "Control Room," could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.
2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod drive mechanism).

C. Any reactor events or conditions that are determined to be of high safety significance.

D. Any operating reactor plants that are determined to have overall unacceptable performance or that are in a shutdown condition as a result of significant performance problems and/or operational event(s).

The NRC's Annual Report to Congress (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0090/) provides the full Appendix A, which lists all of the AO criteria.

Question No. 77

Section 6.3.2 describes the Reactor Oversight Process improvement recommendations from multiple independent and focused assessments. It states, "In 2015, the NRC staff redesigned the self-assessment process to better assess the effectiveness of a mature program by focusing on the efficacy of recent changes to the program, performing in-depth reviews of specific areas of interest, and verifying agency adherence to program governance. The staff will implement the revised process for its calendar year 2016 self-assessment. "How was the assessment performed and what were the recommendations?

Answer: In 2015, the NRC staff completed the redesign of the ROP self-assessment process to better assess the effectiveness of a mature program by focusing on the efficacy of recent changes to the program, performing in-depth reviews of specific areas of interest, and verifying NRC staff adherence to program governance documents. The NRC designed the new self-assessment approach to ensure that the ROP is implemented reliably and predictably across all four NRC regional offices, as well as at NRC Headquarters. The staff informed the Commission of its revised approach to, and implementation plans for, the annual ROP self-assessment in SECY-15-0156 (ADAMS Accession No. ML15310A086).

The CY 2016 self-assessment is being performed in accordance with the governance described in IMC 0307 (ADAMS Accession No. ML15307A023). The revised self-assessment approach consists of three distinct elements: (1) measure the effectiveness of and adherence to the current program, using objective metrics, (2) monitor ROP revisions and assess recent program changes for effectiveness, and (3) perform focused assessments of specific program areas and peer reviews of regional offices. The focused assessment for CY 2016 is the inspector training and qualification program as selected by senior NRC management. The recommendations and results from the CY 2016 self-assessment, including the focused training assessment and other aspects of the enhanced self-assessment process, will be included in the annual self-assessment paper that will be issued in early April 2016 and discussed with the Commission in May 2017.
Question No. 78
Section 6.3.3 describes the Industry Trends Program which will be discontinued in 2016, as a result of Project Aim, which is the NRC's effort to develop an integrated prioritization and re-baselining of agency activities .Please explain how Project Aim will improve the NRC's Reactor Oversight Process and the challenges in implementing it?
<u>Answer</u>: The NRC made several changes to the ROP based on Project Aim. The first item was the elimination of the ITP. The ITP was intended to provide a basis for assessing whether the adoption of ROP led to a degradation in overall operating reactor safety. For the 15 years of the ROP, the ITP demonstrated that overall industry safety performance had improved. Because the ITP did not identify any actionable items over its lifespan, the NRC opted to rely on other parts of the ROP to identify any adverse safety trends that might need to be addressed generically. Another Project Aim-related item relates to ongoing work to create efficiencies during the ROP inspection report writing process and during the implementation of the significance determination process. The NRC is working to provide equally effective results with less effort by automating and streamlining internal processes. The staff will ensure that streamlining does not decrease the effectiveness of these processes. A number of ROP reductions that resulted from Project Aim require adjusting budgeted inspection program resources to better match historical spending trends for various IPs. This will ensure the NRC is properly funding inspections based on the expected level of effort, given current data. This included an item to specifically reduce inspection resources spent on IP 71151, "Performance Indicator Verification," dated May 3, 2017. This reduction better reflects historical spending on this procedure; thus, the staff does not believe there will be any negative impact from this reduction. Finally, the staff stopped conducting ROP midcycle performance assessments. The staff believed that, since many elements of the operating reactor assessment program are continuous, the additional resources used to conduct labor-intensive midcycle assessments could be eliminated with minimal impact on the agency's ability to evaluate licensee performance. In summary, the changes made to the ROP as a result of Project Aim relate to resource adjustments that will improve the effectiveness of the NRC's processes. The staff is confident that the changes made will have minor impact on the agency's ability to evaluate performance and will not compromise regulatory oversight or safety.

Question No. 79
Section 6.3.4 describes the Accident Sequence Precursor Program. It states, “To identify potential precursors, the NRC reviews plant events from licensee event reports and inspection reports.” It refers to SECY-15-0124, “Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models,” which states “NRC developed SPAR models for the AP1000 Advanced Boiling-Water Reactor (ABWR) (for both the Toshiba and General Electric-Hitachi designs), U.S. Advanced Pressurized-Water Reactor (US-APWR), and the U.S. Evolutionary Power Reactor (U.S. EPR). The staff has expanded the capability of the AP1000 SPAR model to include hazards such as seismic, fire, flooding, and low-power shutdown events. A post-core damage severe accident logic model (i.e., Level-2 PRA model) is also being developed for the AP1000 SPAR model." When developing PRA models for these new reactor designs, were there any new or existing precursors identified have shown an in crease in CDF.
Answer: The accident sequence precursor (ASP) program looks at domestic operating events and degraded conditions, typically reported through LERs or inspection reports, for operating nuclear power plants within the United States. The development of new reactor SPAR models has not identified any new precursors nor was the development intended to, and at this time, there are no new reactors (e.g., AP1000, ABWR) operating in the United States. Therefore, the NRC has identified no precursor events for these new reactors, since they are currently outside the scope of the ASP program. However, as new reactors come on line, they will transition to the operating ROP and be within the scope of the ASP program.
Question No. 80
(GOOD PRACTICE): Section 6.3.11 describes the NRC’s attempts at encouraging public participation in the agency’s regulatory process. Many tools and processes are also provided to the public to encourage public participation; in addition, documents related to rulemaking actions that the NRC has conducted.
Answer: Thank you for your comment and observation. Your positive feedback is appreciated.
Question No. 81
Some reactor operators selected the SAFSTOR as decommissioning option. So, if the DECON will be conducted after 50 years, what are measures taken to make sure that after 50 years the Decommissioning Fund will be available to cover all the decommissioning activities?
Answer: The NRC has a comprehensive, decommissioning funding oversight program in place to provide reasonable assurance that sufficient funds will be available for decommissioning each U.S. commercial nuclear facility. As such, this program requires the timely and accurate submittal of information from a licensee on its plans for decommissioning and permanent cessation of operations, and the status of its decommissioning fund. During operations, 10 CFR 50.75(f)(1) requires each licensee to submit a decommissioning funding status report every 2 years, reflecting the status of its decommissioning funding for each reactor as of December 31 of the preceding CY. For a plant that is within 5 years of the projected end of its licensed operating period, or where conditions have changed such that it is expected that the plant will be closed within 5 years, the licensee must submit a decommissioning funding status report annually thereafter, until the license is terminated. During the decommissioning period, licensees remain subject to NRC safety, oversight, and enforcement regulations to ensure decommissioning operations are conducted safely and sufficient funds remain available to decommission the facility and terminate the license.

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.

The United States did not change the legislative framework governing the U.S. nuclear industry as a result of the Fukushima accident. The NRC has taken the necessary regulatory actions in response to the accident, as described in Sections 1.3.1 and 1.3.3 of this report, under the existing framework.

Question No. 82
Was there any change in 2015-2016 in the number of licensee petitions for rulemaking after rulemaking process was made more efficient and effective?
Answer: Yes. Most petitions for rulemaking received by the NRC are from advocacy groups and private citizens, not NRC licensees. The NRC revised its petition for rulemaking process on November 6, 2015 (80 FR 60513). None of the petitions received by the NRC in 2015 (10) and in 2016 (3) were from an NRC licensee. The number of petitions docketed has decreased by approximately 50 percent from past years.
Question No. 83
Is there currently a requirement for obligatory introduction of digital technologies to improve the instrumentation and control systems? What regulatory procedures are currently used by NRC to assess the introduction of these technologies?
Answer: No. The NRC has no regulatory requirements to use digital technologies for I&C systems; the agency has requirements to ensure the function and reliability of either analog or DI&C systems. Some licensees are pursuing digital technology upgrades because replacement parts for their analog I&C systems are no longer manufactured. Some licensees

are pursuing digital technologies to improve the efficiency of systems and overall plant reliability or reduce long-term maintenance costs.

Requirements in 10 CFR Part 50 are applicable to both analog and digital systems. The NRC uses specific guidance documents and U.S. standards that are tailored more specifically to DI&C technologies. For example, the NRC endorses DI&C guidance in IEEE 7.4-3-2 and endorses the software development guidance of IEEE 1012 in RG 1.168, Revision 2, "Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants," issued July 2013 (ADAMS Accession No. ML13073A210), as acceptable methods for ensuring safety. For approving digital upgrades in operating reactors, the NRC specifically applies the interim guidance in DI&C-ISG-06 (ADAMS Accession No. ML110140103) for evaluating the architecture, software development, communications, DID, and compliance with IEEE standards of proposed digital technologies.

Question No. 84

Considering that NRC regulations "do not currently address the possibility of more than two reactors can be controlled from one single control room": Could you explain which applications are "expected to include control of more than two modules in a single control room"? Please provide additional information.

Answer: SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs, dated March 28, 2010 (ADAMS Accession No. ML093290268), states that some small modular reactor (SMR) designs may use multiple modules at one site, but current regulations do not address the possibility of more than two reactors being controlled from one control room.

The NRC staff has engaged in varying degrees of pre-application activities with several SMR designers over the past several years, including NuScale Power, LLC (NuScale). In a letter to the NRC dated September 15, 2015, from NuScale titled, "NuScale Power, LLC Submittal of NuScale Preliminary Concept of Operations Summary and Response to NRC Questions on Control Room Activities (NRC Project No. 0769)" (ADAMS Accession No. ML15258A846), NuScale, proposed having six licensed operators operate up to 12 reactor modules from a single control room. The NRC is currently reviewing the NuScale application and if it accepts it for review, the staff will evaluate how NuScale demonstrates that safe plant operation will occur from a single control room.

Question No. 85

How the licensee (operator) ensures its responsibility for the activities of contractors and sub-contractors whose activities might affect nuclear safety (qualified staff)?

Answer: In the U.S. nuclear industry, the nuclear power plant operator is ultimately responsible for the quality of work performed by contractors. Licensees use a variety of means to ensure needed quality is achieved, including verification of adequate qualification or training of workers, direct observation of contractor performance, verification of equipment or material supplier performance or material quality, identification and selection of preferred service providers who have a proven track record of performance, independent review of supplied engineering supplies, and contracts that have quality-related performance incentives and penalties.

In addition, INPO sponsors a nuclear suppliers' forum that provides a mechanism for the industry and suppliers to develop more effective working relationships. As a result, a document

issued in October 2014 outlines the important principles associated with successful supplier performance. In addition, once a contractor has been on site for 6 months, it comes under the same training program as station personnel.
Question No. 86
What are specifics of issuing combined construction and operating licences?
Answer: By issuing a COL, the NRC authorizes the licensee to construct and (with specified conditions) operate a nuclear power plant at a specific site, in accordance with established laws and regulations. An application for a COL must contain essentially the same information required in applications for a construction permit and an operating license under 10 CFR Part 50. The COL application must also describe the inspections, tests, analyses, and acceptance criteria (ITAAC) that are necessary and sufficient to ensure that the plant has been properly constructed and will operate safely. A COL is valid for 40 years from the date of the Commission finding that the acceptance criteria in the COL are met (10 CFR 52.103 (g): https://www.nrc.gov/reading-rm/doc-collections/cfr/part052/part052-0103.html). A COL can be renewed for an additional 20 years and may be subsequently renewed in accordance with all applicable requirement, as defined in 10 CFR Part 54. To date, the NRC has issued 11 COLs for new AP1000, ABWR, and ESBWR designs at six sites throughout the Unites States. Four AP1000 units are currently under construction at the Vogtle and V.C. Summer sites.
Question No. 87
What is the reason to keep both two steps licensing under 10 CFR 50 and one step licensing under 10 CFR 52? Do you expect or foresee any application for two steps licensing?
Answer: Both the 10 CFR Part 50 and 10 CFR Part 52 licensing regulations provide an equivalent level of safety while being sufficiently flexible to accommodate applicants with a variety of different business plans. The NRC staff is aware that potential applicants for non-LWR designs are evaluating whether the 10 CFR Part 50 licensing process better meets their business needs and would be a more viable approach than 10 CFR Part 52 for a first-of-a-kind facility. While the NRC is not currently reviewing any 10 CFR Part 50 applications, a few potential applicants have informed the NRC of their intentions to use the 10 CFR Part 50 process.
Question No. 88
It is stated that: “The Atomic Energy Act …Section 234 authorizes the NRC to impose monetary civil penalties not to exceed $100,000 per violation per day;” How does the NRC determine the amount of monetary penalty? Is there a regulation or rule set other than Chapter 18 of Atomic Energy Act? Is it possible to change the amount of monetary penalty gradually in accordance with the gravity and severity of the offence?
Answer: Is there a regulation or rule set other than AEA Chapter 18? AEA Section 234 limits the maximum civil penalty (CP) amount that the NRC may issue for violations of the AEA to $100,000 per violation, per day. This amount was changed when Congress passed the Federal Civil Penalties Inflation Adjustment Act in 1990. More recently, these amounts were amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, and maximum CP amounts are now adjusted annually for inflation. The current maximum CP that the NRC can impose is $285,057 for each violation, in accordance with 10 CFR 2.205, “Civil Penalties."

Is it possible to change the amount of monetary penalty gradually, in accordance with the gravity and severity of the offence? Yes. The severity level of an apparent violation is one factor that is considered when determining the amount of a proposed CP.

How does the NRC determine the amount of monetary penalty? The staff implements its statutory and regulatory authority on monetary CPs through the NRC's Enforcement Policy (Policy). The Policy (ADAMS Accession No. ML16271A446) provides Commission direction on the application of the NRC's enforcement authority, and Section 2.3.4 of the Policy describes the process the NRC uses to determine the amount of a CP that may be proposed for a specific enforcement action. The Policy establishes graduated CP amounts by generally taking into account the gravity of the violation as the primary consideration and the ability to pay as a secondary consideration. Thus, operations involving greater nuclear material inventories and significantly higher consequences resulting from a release or exposure to radioactive material receive higher CPs.

The Policy establishes maximum "base" CP amounts, according to the type, or class, of licensee. For example, the maximum base CP amount for power reactors and high-level waste repository licensees is currently $280,000. (Note that the Commission has approved the practice of rounding the statutory maximum amount to the nearest $10,000). The Policy also establishes lesser maximum base amounts for other "smaller" classes of licensees (e.g., the maximum base CP amount for test reactors and industrial radiographers is $28,000, and the maximum base CP amount for small materials users is $14,000). These maximum base CP amounts are further adjusted by considering the severity level (SL) of the underlying violation. For SL I violations, the base CP will be 100 percent of the maximum base amount. For SL II violation, the base CP will be 80 percent of the maximum base, and the base CP for SL III violations will be 50 percent of the maximum base. As an example, the base CP for an SL III violation at an industrial radiographer will normally be 0.50 x $28,000, or $14,000.

In practice, once an apparent violation has been identified, the staff will normally consider CPs for all violations assessed at SL I, II, and III, with SL I being the highest or more significant concern. Violations assessed at SL I, II or III are also referred to as "escalated" enforcement. The CP assessment process considers four major decision points: (1) has the licensee had any previous escalated enforcement actions taken within the past 2 years, or the period between the last two inspections, whichever is longer, (2) should the licensee be given credit for actions related to identification of the violation, (3) were the licensee's corrective actions prompt and comprehensive, and (4) in view of the circumstances of the violation, should the NRC exercise enforcement discretion to either escalate or mitigate the amount of the CP? Notwithstanding the outcome of the normal CP assessment process, the Policy allows the staff to exercise discretion by either escalating or mitigating the amount of the CP.

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., 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., DOE). It discusses the regulatory body's financial and human resources, international responsibilities, ethics rules, and policy for maintaining openness and transparency.

The United States did not change the legislative framework governing the U.S. nuclear industry as a result of the Fukushima accident. The NRC has taken the necessary regulatory actions in response to the accident, including the creation of the Japan Lessons Learned Division, as described in Sections 1.3.1 and 1.3.3 of this report.

Question No. 89
"Strengths from the 2015 Safety Culture and Climate Survey were noted in the areas of mission and objectives, training, and supervision. Areas for improvement included the differing views processes, empowerment and respect, and senior management." Question: Could you elaborate on the process to improve in the areas of differing views processes, empowerment and respect, and senior management?
Answer: The NRC performed a number of analyses using data from both the 2015 NRC Office of the Inspector General's Safety Culture and Climate Survey and the 2015 Federal Employee Viewpoint Survey. Based on those results, representatives from the Offices of the Executive Director for Operations, the Chief Human Capital Officer, Enforcement, and Small Business and Civil Rights, and the National Treasury Employees Union, produced an agency action plan. The focus of the plan is, "Fostering a greater climate of trust at the NRC," in which three specific goals were identified: (1) Strengthen the positive environment for raising concerns. (2) Promote a culture of fairness, empowerment, and respect across the agency. (3) Establish clear expectations and accountability for NRC leaders. The plan listed six distinct actions for the agency to work on to support these goals. Currently, those offices involved in developing the action plan are leading implementation efforts according to how actions may be incorporated into the respective offices. As with previous surveys, offices and regions are expected to address areas of improvement within their organizations, based on these recurring survey assessments, which allow for granular data to be collated at subagency levels.

Question No. 90
Taking into account the growth of followers in social media platforms (NRC's Twitter account, NRC's YouTube channel and Flickr photo gallery, Facebook): What is the NRC´s strategy to obtain that NRC´s social media platforms became known to general public? Please provide additional information.
<u>Answer</u>: The NRC promotes its various social media platforms with large icons prominently displayed near the top of the NRC Web site home page, as well as on press releases and other materials issued by the Office of Public Affairs. It also cross-promotes platforms (e.g., a Facebook post or a Tweet might link to a blog article or new video on the agency's YouTube channel. The Office of Public Affairs also promotes these platforms within the agency to sensitize staff to their availability as communication tools.
Question No. 91
The report says that "The agency is encouraging staff involved in preparing such documents to take plain language training, which the NRC offers both online and in a 2-day instructor led course." How is current staff involvement in plain language trainings? How do you assess the current results in that area? Please provide additional information.
<u>Answer</u>: The agency no longer offers the 2-day instructor-led plain language course, but the online course is still available and employees are encouraged to enroll in it. While the agency has no mechanism to measure the effectiveness of the plain language training, written communication is typically included as an element in NRC employees' performance work plans. Work products are generally rated on their accuracy, clarity, thoroughness, efficiency, effectiveness, and organization—all elements that contribute to plain language writing.
Question No. 92
It is described that the US takes into account the IAEA safety standards in the development of new or revised regulations and regulatory guides. Could you provide concrete examples in which US regulations (and which recently updated safety standards) US have taken into account?
<u>Answer</u>: The NRC routinely takes into account the IAEA safety standards in the development of new or revised regulations. The following are some specific examples of IAEA standards in NRC rulemaking in the last 5 years: Export and Import of Nuclear Equipment and Material; 10 CFR Part 110, "Export and Import of Nuclear Equipment and Material" (RIN 3150-AJ04; NRC-2012-0213). On May 9, 2012, the NRC published a final rule (77 FR 27113), effective June 8, 2012, amending its regulations pertaining to the export and import of nuclear materials and equipment. This rulemaking was necessary to reflect the nuclear nonproliferation policy of the Executive Branch on U.S. Government obligations to the IAEA. Physical Protection of Byproduct Material: Final Rule and Guidance; 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73 (RIN 3150-AI12; NRC-2008-0120 (Rule) and NRC-2010-0194 (Guidance)). On March 19, 2013, the NRC published a final rule (78 FR 16922), effective May 20, 2013, amending its regulations to establish security requirements for the use and transport of category 1 and category 2 quantities of radioactive material. Category 1 and category 2 thresholds are based on the quantities established by the IAEA in its Code of Conduct on the Safety and Security of Radioactive Sources, which the NRC endorses. The objective of this final rule was to provide reasonable assurance of the prevention of theft or diversion of category 1 and category 2 quantities of radioactive material.

Export Controls and Physical Security Standards: Final Rule; 10 CFR Part 110 (RIN 3150-AJ33; NRC-2014-0007). On July 10, 2014, the NRC published a final rule (79 FR 39289), effective August 11, 2014, amending its regulations pertaining to the export and import of nuclear materials and equipment. This rulemaking was necessary to conform the export controls of the United States to the international export control guidelines of the Nuclear Suppliers Group, of which the United States is a member, and to incorporate by reference the current version of IAEA's INFCIRC/225/Revision 5, "Nuclear Security Recommendations on Physical Protection of Nuclear Material and Nuclear Facilities," issued January 2011.

Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements: Final Rule; 10 CFR Part 71 (RIN 3150-AI11; NRC-2008-0198). On June 12, 2015, the NRC published a final rule (80 FR 33988), in consultation with the U.S. Department of Transportation (DOT), effective July 13, 2015, amending its regulations for the packaging and transportation of radioactive material. These amendments made conforming changes to the NRC's regulations, based on the IAEA's 2009 standards for the international transportation of radioactive material, and to maintain consistency with DOT regulations. On August 14, 2015, the NRC published a revision to the final rule (80 FR 48683) that corrected minor editorial errors in a calculation, outdated contact information, and outdated information for examining the materials that are incorporated by reference. This correcting amendment took effect on August 14, 2015.

The NRC is also considering a rulemaking on Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards (NRC-2016-0179). This rule would amend the NRC's regulations in 10 CFR Part 71 to harmonize domestic regulations for Type B and fissile radioactive material transportation packaging with the 2012 Edition of the IAEA Safety Standards Regulations for the Safe Transport of Radioactive Material (SSR-6). The NRC will coordinate this rulemaking with DOT.

Furthermore, the NRC rulemaking process involves the completion of five principal tasks: identify the need for a rulemaking; develop a regulatory basis; evaluate the need for a rulemaking plan; prepare a proposed rule package, publish the proposed rule for public comment, and resolve all public comments; and prepare a final rule package and publish the final rule. During the public comment phase, international entities are welcome to comment.

Question No. 93

During the IRRS follow-up mission hosted in 2014 by the NRC, the mission identified as a good practice (as stated in the AIEA report IAEA-NS-2014/01) "the systematic analysis of significant non-nuclear events […] in the entire operating experience program, the coordination and communication of the operating experience analysis through the new Operating Experience Center of Expertise and the diversity of products offered by the Operating Experience Branch to make then suitable for different uses and application inside the NRC". Could USA explain in more details what is the Operating Experience Center of Expertise (is it a part of the NRC?) and give examples of some relevant significant non-nuclear events that have been used by the NRC?

<u>Answer</u>: The Operating Experience Center of Expertise is an effort to align operating experience activities across offices within the NRC to work together to review, evaluate, and communicate operating experience from both new construction and operating reactors. Since the NRC issued the 2016 report, the staff members within the Operating Experience Center of Expertise have been combined into a single NRR branch, which continues to review operating

experience from both construction sites and operating reactors.

Significant nonnuclear events reviewed by the operating experience group include a metro train derailment in 2009 resulting from I&C issues, and the 2010 Deepwater Horizon explosion and oil spill in the Gulf of Mexico resulting from a failure of safety systems.

Question No. 94

Regarding the risk-informed decision-making process, it is stated that "the NRC Risk Informed Steering Committee is also providing direction to the NRC staff concerning efforts to provide credit for mitigating strategies put in place in response to the Commission Orders after the events at the Fukushima Daiichi nuclear power plant". Could the USA give one or more examples of NRC's Risk-Informed Steering Committee recommendations to provide credit for mitigating strategies put in place after the events at the Fukushima Dai-ichi nuclear power plant?

Answer: Licensees have adopted mitigating strategies in response to NRC orders and recommendations relative to the mitigation of beyond-design-basis external events. The NRC Risk-Informed Steering Committee oversees NRC initiatives for crediting the mitigating strategies in regulatory applications beyond their original intent. Aspects of the initiatives include communications efforts within the agency, changes to guidance documents, development of new guidance where needed, and training where necessary. The 2016 RIC included a session on this topic and the 2017 RIC will hold a followup session to capture progress on the project. The session will feature speakers from the NRC, the nuclear industry, and a member of a public interest group. Examples of recommendations provided by the Risk-Informed Steering Committee include crediting mitigating strategies (i.e., credit for FLEX in risk-informed license amendment requests (LARs), Notices of Enforcement Discretion requests, and the significance determination process.

Question No. 95

Developing MS's or newcomers may need guidance on creating communities of practice, capture operating experience, capture critical knowledge (according to the four contributing activities of agency's strategic plan).

Answer: The NRC has a governance document that provides the process and operating procedures for establishing, launching, and viewing Communities of Practice in NRC's Knowledge Center. Specifically, the guide defines Communities of Practices and the rules of engagement for working in the NRC Knowledge Center, and it defines the roles, responsibilities, and expectations for people who work there.

The NRC has an established infrastructure that captures agency standards and guidance for business operations. MDs contain the policies and procedures that govern the internal NRC functions necessary for the agency to accomplish its regulatory mission. Within these MDs, for example, the NRC has a formal lessons-learned program. The program contains a tracking system that is used to capture, store, disseminate, plan, organize, and automate lessons-learned information. In addition, several offices have office instructions or procedures that establish requirements and guidance covering administrative and business processes within that office or region.

- NRC MDs (https://www.nrc.gov/reading-rm/doc-collections/management-directives/)
- MD 6.8, "Lessons-Learned Program," dated August 1, 2006 (https://www.nrc.gov/docs/ML0622/ML062220175.pdf)

The NRC uses a number of methods for capturing critical knowledge from employees departing the agency. The knowledge management program provides best practices and tools to help support the facilitation and development of approaches for knowledge transfer. For example, many offices conduct knowledge capture (exit) interviews, where individuals are asked a series of questions about their career, positions held, or projects they have worked on. These interviews are recorded and made available for the staff to view. Other practices may include activities such as subject matter expert seminars, job shadowing, or mentoring.
Question No. 96
Is the full list of the current knowledge transform activities are available for other member states?
Answer: A comprehensive knowledge transfer activities list is not officially documented for public availability at this time. However, the following materials reference additional practices: • Technical Working Group on Nuclear Knowledge Management (Ben Ficks' Vienna Austria Trip on 2/15–20/15 (ADAMS Accession No. ML15042A212)) https://adamsxt.nrc.gov/WorkplaceXT/getContent?id=current&vsId=%7B162904FF-C3A1-4000-9D1D-D926E09F174F%7D&objectStoreName=Main.__.Library&objectType=document. • "A Model of Effective Governance for Knowledge Management: A Case Study at the U.S. Nuclear Regulatory Commission" (ADAMS Accession No. ML14300A476) https://adamsxt.nrc.gov/WorkplaceXT/IBMgetContent?vsId={9B87A25B-25C9-4106-9997-DD358E94A07A}&objectType=document&id={4E236CB7-66E6-4B68-BFA1-4636F12C2041}&objectStoreName=Main.__.Library. • NUREG/KM Series—Publications Prepared by NRC Staff for Knowledge Management http://www.nrc.gov/reading-rm/doc-collections/nuregs/knowledge/. • SECY-06-0164, "The NRC Knowledge Management Program," dated July 25, 2006. (ADAMS Accession No. ML061550002) https://adamsxt.nrc.gov/WorkplaceXT/getContent?id=current&vsId=%7B58E991DD-2FA5-4BD9-85BC-5522BC535747%7D&objectStoreName=Main.__.Library&objectType=document
Question No. 97
With reference to article 8.1.5.2, page 102 of the American national report, Korea would like to cite the following and inquire the questions below: "(1) Recommendation 2 —Develop a Methodology and Implement a Holistic Management System Review. The NRC is continuing the development of the remaining process maps for the Operating Reactor Program. After the completion of the process map, the NRC will establish and implement a process for periodic, holistic reviews of the effectiveness of the management system." 1) In regards to (Q)MS required by the detailed guidelines of the Convention on Nuclear Safety, what policies do the NRC have and which divisions or departments within the NRC implement these policies? Moreover, how are these policies implemented?

2) According to the follow-up plan of Recommendation 2 of the IRRS mission, it is expected that an overall process to periodically review the effectiveness of the management system will be established and implemented. How will this process be related to the existing OIG program?
Answer: (1) The NRC maintains a management system that aligns with the detailed IAEA guidelines for safety requirements in GS-R-3, “The Management System for Facilities and Activities,” 2006. A description of the NRC management system, including policies and responsibilities for implementation, is at ADAMS Accession No. ML13311A509. (2) The periodic review of the effectiveness of the management system will be different and distinct from the existing Office of the Inspector General (OIG) program. The periodic reviews will evaluate the effectiveness of the processes in meeting and fulfilling its goals and objectives. The purpose of OIG’s audits and investigations is to prevent and detect fraud, waste, abuse, and mismanagement and to promote economy, efficiency, and effectiveness in NRC programs and operations. In addition, OIG reviews existing and proposed regulations, legislation, and directives, and provides comments, as appropriate, on any significant concerns. The only relation between the two programs is sharing the results of the program reviews.
Question No. 98
A finding from the exercise concerned the need to transfer responsibility for coordination of Federal response efforts from the NRC to FEMA. Does this mean that currently NRC bears responsibility for coordination of Federal response efforts?
Answer: The NRC is the primary Federal authority for responding to events at NRC-licensed facilities, including coordination of Federal response efforts. If an event becomes sufficiently complex, requires the support of multiple Federal agencies, or involves offsite consequences, the NRC will coordinate with the Federal Emergency Management Agency (FEMA). FEMA maintains robust offsite response coordination capabilities and emergency management expertise to support the NRC, if needed.
Question No. 99
The NRC has organized its leadership development programs into the Leaders’ Academy, consisting of competency-based training, assessment, and development programs for all levels of leadership, from individual contributors to senior executives. Is the Leader’s Academy a private company or is the subdivision under NRC´s human resource department? Does your leadership programs are obligatory based on regulation or based on demands?
Answer: The NRC Leaders’ Academy is managed by the Office of the Chief Human Capital Officer (previously known as the Office of Human Resources) and uses in-house NRC resources as well as contracts with external non-Federal organizations to deliver leadership training. Most of the leadership programs at NRC are not mandatory. The only required program is the Supervisor Development Program that requires leadership skills training in the first year as a new supervisor. The Federal Workforce Flexibility Act of 2004 directs agencies to provide specific training to develop supervisors and managers as part of a comprehensive succession management strategy. The Act requires agencies to provide training to supervisors and managers on actions, options, and strategies to include mentoring employees, improving employee performance and productivity, conducting employee performance appraisals, and

identifying and assisting employees with unacceptable performance. To implement the requirements of this Act, the U.S. Office of Personnel Management published final regulations on supervisory, management, and executive development (5 CFR Part 412) on December 10, 2009. The revised 5 CFR 412.202, "Systematic Training and Development of Supervisors, Managers, and Executives," requires new supervisors to receive initial supervisory training within 1 year of the new supervisor's appointment and retraining in all areas at least once every 3 years. More information can be found at https://www.opm.gov/wiki/uploads/docs/Wiki/OPM/training/Complete%20508-%20Frameworks,%20Fact%20Sheet,%20learning%20objectives,%20and%20additional%20resources.pdf.

Question No. 100

NRC's organization and established offices are mainly for nuclear reactor facilities. Does the "nuclear reactor" term actually mean "nuclear installations" in the NRC's offices' names? If not, who is responsible for the regulation of other civilian nuclear installations?

Answer: Yes, the term nuclear reactor is equivalent to nuclear installation. The NRC's mission is to license and regulate the civilian use of radioactive materials in the United States to protect public health and safety, promote the common defense and security, and protect the environment. The NRC regulates commercial nuclear power plants; research, test, and training reactors; nuclear fuel cycle facilities; and radioactive materials used in medicine, academia, and industry. The agency also regulates the transport, storage, and disposal of radioactive materials and waste, most Federal agencies' use and possession of radioactive materials, and the export and import of radioactive materials. The NRC's Information Digest for 2016–2017 (https://www.nrc.gov/docs/ML1624/ML16243A018.pdf) contains additional information about the NRC.

Question No. 101

It is stated "Many of the differences in how the safety standards are applied to NRC regulations stem from the fact that NRC regulatory guidance predates most IAEA safety standards." How fast can the NRC react to the improvements in international safety standards? Is it possible to amend the Atomic Energy Act quickly? How effective to modify the regulations without amending the Atomic Energy Act?

Answer: The NRC works with IAEA in developing safety standards that are intended for Member States to use in developing its regulations, which also greatly facilitates developing or updating NRC regulations. For example, the NRC routinely makes appropriate conforming changes to its regulations for export and import, based on revised or updated IAEA standards and guidance. In addition, the NRC periodically revises its transportation regulations to make them compatible with IAEA standards, reflecting knowledge gained in scientific and technical advances and accumulated experience. Compatibility between domestic and international requirements ensures a consistent safety basis for transport. The rulemaking process can be as short as 1 to 2 years but may take longer if the subject matter of the rulemaking is technically complex, significant public comments are received, or NRC staff resources are limited. The NRC's approach to using IAEA safety standards in its regulatory guidance is similar to the rulemaking process, but the guidance development process generally takes less time than the rulemaking process. Some specific examples of IAEA standards in NRC rulemaking in the last 5 years include the following:

Export and Import of Nuclear Equipment and Material; 10 CFR Part 110 (RIN 3150-AJ04; NRC-2012-0213). On May 9, 2012, the NRC published a final rule (77 FR 27113), effective June 8, 2012, amending its regulations pertaining to the export and import of nuclear materials and equipment. This rulemaking was necessary to reflect the nuclear nonproliferation policy of the Executive Branch on U.S. Government obligations to the IAEA.

Physical Protection of Byproduct Material: Final Rule and Guidance; 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73 (RIN 3150-AI12; NRC-2008-0120 (Rule) and NRC-2010-0194 (Guidance)). On March 19, 2013, the NRC published a final rule (78 FR 16922), effective May 20, 2013, amending its regulations to establish security requirements for the use and transport of category 1 and category 2 quantities of radioactive material. Category 1 and category 2 thresholds are based on the quantities established by IAEA in its Code of Conduct on the Safety and Security of Radioactive Sources, which the NRC endorses. The objective of this final rule was to provide reasonable assurance of the prevention of theft or diversion of category 1 and category 2 quantities of radioactive material.

Export Controls and Physical Security Standards: Final Rule; 10 CFR Part 110 (RIN 3150-AJ33; NRC-2014-0007). On July 10, 2014, the NRC published a final rule (79 FR 39289), effective August 11, 2014, amending its regulations pertaining to the export and import of nuclear materials and equipment. This rulemaking was necessary to conform the export controls of the United States to the international export control guidelines of the Nuclear Suppliers Group, of which the United States is a member, and to incorporate by reference the current version of IAEA's INFCIRC/225/Revision 5.

Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements: Final Rule; 10 CFR Part 71 (RIN 3150-AI11; NRC 2008-0198). On June 12, 2015, the NRC published a final rule (80 FR 33988), in consultation with DOT, effective July 13, 2015, amending its regulations for the packaging and transportation of radioactive material. These amendments made conforming changes to the NRC's regulations based on the IAEA's 2009 standards for the international transportation of radioactive material and to maintain consistency with DOT's regulations. On August 14, 2015 (80 FR 48683), the NRC published a revision to the final rule that corrected minor editorial errors in a calculation, outdated contact information, and outdated information for examining the materials that are incorporated by reference. This correcting amendment took effect on August 14, 2015.

The NRC is also considering a rulemaking on "Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards" (NRC-2016-0179). This rule would amend the NRC's regulations in 10 CFR Part 71 to harmonize domestic regulations for Type B and fissile radioactive material transportation packaging with the 2012 Edition of the IAEA Safety Standards Regulations for the Safe Transport of Radioactive Material (SSR-6). The NRC will coordinate this rulemaking with DOT. The existing statutory authority for the NRC's regulations (AEA) provides sufficient regulatory flexibility for the NRC to make revisions to address, as necessary and appropriate, scientific and technical advances, accumulated experience (domestic and international), and changes from applicable IAEA standards and guidance. Therefore, changes to AEA are not required to use or implement IAEA standards. Nonetheless, the NRC also notes that Congress has amended the AEA many times over the decades and that Congress has occasionally adopted new legislation to supplement the authority provided to the NRC under the AEA, such as the Nuclear Waste Policy Act of 1982. However, in the area of transportation, as well as in other areas of nuclear safety, the NRC does not believe that amendments to the AEA or new statutes are needed to effectively regulate the use of nuclear or radioactive materials consistent with IAEA recommendations, standards, and guidance.

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 U.S. NRC, through the AEA, ensures that the primary responsibility for the safety of a nuclear installation rests with the licensee. The overall responsibility of licensees for ensuring the safety of their facilities did not change as a result of the Fukushima accident. U.S. licensees continue to respond to new NRC regulatory requirements and initiatives that confirm and ensure that adequate measures to protect public health and safety are taken, considering the lessons learned following the accident, as described in Sections 1.3.1 and 1.3.3 of this report.

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, discussed below. This section updates the licensee's responsibility for maintaining openness and transparency and for maintaining resources for managing accidents.

Question No. 102

"At several junctions during the enforcement process involving cases of discrimination or willful violation of NRC regulations, the agency offers its licensees (including their contractors) or individuals the opportunity to participate in the Alternative Dispute Resolution Program. The NRC uses mediation, a technique in which a neutral mediator with no decisionmaking authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. "

How often do the licencees use the Alternative Dispute Resolution Program during the enforcement process? How successful is it to use a mediator in contentious cases?

<u>Answer</u>: The alternative dispute resolution (ADR) process used within the NRC's Office of Enforcement is mediation. Mediation uses a neutral third party to facilitate dialogue between two parties to resolve a dispute. The Enforcement ADR program, applicable to willful and discrimination cases after an investigation, as well as to traditional enforcement cases with the potential of a CP, uses mediation to gain an understanding of each party's interest, clarify issues, and explore innovative ways to address the underlying issues of both parties to reach a mutually agreeable settlement agreement. The use of a mediator has been advantageous in resolving enforcement cases, as mediation allows for open dialogue between the parties, driven by both parties' desire to reach a mutually agreeable settlement, and encompasses broader, more comprehensive corrective actions (e.g., instead of only implementing corrective actions at a single plant, the licensee's actions and enhancements may be completed fleetwide). ADR is offered annually for approximately 50 cases, on average. Out of the offers, typically 14 percent (7 cases) are mediated and settled through the ADR program.

Question No. 103

The report states "The license condition in 10 CFR 50.54(w) requires that licensees obtain insurance in an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's reactor, to stabilize and decontaminate the reactor and the reactor site. Licensees are required to report the current levels of insurance or financial security and the sources of the insurance or security to the NRC on April 1 of each year.

Additionally, licensees are required to have and maintain financial protection liability insurance for claims arising from accidents". Does NRC use the inputs on the current levels of insurance or financial security and the sources of the insurance or security in the Regulatory Oversight Process? If so, can U.S. provide more details?
Answer: AEA Section 170 (commonly known as the Price-Anderson Act) and NRC regulations at 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements," govern the sources of financial security and requires each nuclear power plant licensee to have the maximum amount of private insurance available in the private sector. The NRC monitors the private insurance marketplace to determine the maximum amount of private insurance that is available. The NRC verifies, through inspection and audit, that power reactor licensees comply with the levels of insurance and financial security mandated by U.S. statute and NRC regulations. The Act completely relies on the private insurance market to set the maximum available coverage. The NRC requires annual insurance submittals under 10 CFR 50.54(w)(3) and 10 CFR 140.21, "Licensee Guarantees of Payment of Deferred Premiums," and reviews this information to ensure compliance with the regulations. However, the NRC does not currently use this information to provide input to the ROP itself and does not affect the number of safety inspections conducted.
Question No. 104
It is pointed out in para 1.3.1 that licensees must effectively oversee all contractors, subcontractors, and vendors to ensure that they are aware of and meeting regulatory requirements. Does this mean that licensee is fully responsible for the outcome of activities of these participants of NPP construction process?
Answer: Yes, 10 CFR Part 50, Appendix B, Criterion VII, "Control of Purchased, Material, Equipment, and Services," describes the related quality assurance criteria. Further, NRC RG 1.28, "Quality Assurance Program Criteria (Design and Construction), Revision 4, issued June 2010 (ADAMS Accession No. ML100160003), provides clarifying regulatory positions specific to the conduct of external audits of suppliers.
Question No. 105
A description of elements required to licensees to comply with their obligations is provided, including compliance with regulations and terms and conditions of the license, personnel training and qualification and openness and transparency. Is there any requirement in the US for the licensee to develop and maintain a management system, including the mentioned elements and others to comply with their obligations for safety?
Answer: Appendix B to 10 CFR Part 50 requires each licensee to develop and implement a quality assurance program, to be documented by written policies, procedures, or instructions and to be carried out throughout plant life in accordance with those policies, procedures, or instructions. The applicant is to identify the SSCs to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program is to provide control over activities affecting the quality of the identified SSCs, to an extent consistent with their importance to safety. While the requirements of GS-R-3 cover management systems for regulatory bodies, the requirements of Appendix B to 10 CFR Part 50 cover similar activities for licensees.

Question No. 106
A description of elements required to licensees to comply with their obligations is provided, including compliance with regulations and terms and conditions of the license, personnel training and qualification and openness and transparency. Is there any requirement in the US for the licensee to develop and maintain a management system, including the mentioned elements and others to comply with their obligations for safety?
Answer: Appendix B to 10 CFR Part 50 requires each licensee to develop and implement a quality assurance program, to be documented by written policies, procedures, or instructions and to be carried out throughout plant life in accordance with those policies, procedures, or instructions. The applicant is to identify the SSCs to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program is to provide control over activities affecting the quality of the identified SSCs, to an extent consistent with their importance to safety. While the requirements of GS-R-3 cover management systems for regulatory bodies, the requirements of Appendix B to 10 CFR Part 50 cover similar activities for licensees.
Question No. 107
The report states that the licensees have financial responsibilities in the event of an accident. This responsibility includes the stabilization and decontamination of the reactor and the reactor site. In the light of the Fukushima accidents, is it possible in the US to obtain insurance to cover an amount equivalent to the damages caused by the Tsunami?
Answer: The NRC requires two forms of insurance: (1) onsite property insurance and (2) offsite liability insurance, under the Price-Anderson Act. Onsite property insurance: Under 10 CFR 50.54(w), each licensee of a large operating power reactor shall take reasonable steps to obtain insurance for each reactor station site in the amount of $1.06 billion, or the maximum amount of coverage generally available from private sources, whichever is less. In the event of an incident at a licensee’s reactor, the property insurance would be used to stabilize and decontaminate the reactor and the reactor station site where the incident is located. Currently, the maximum amount of coverage for each reactor station site is $1.06 billion. Offsite liability insurance: AEA Section 170 and 10 CFR 140.11(a)(4) require licensees of large operating power reactors to have and maintain financial protection that is derived from two sources: (1) primary financial protection in the amount of $450,000,000 and (2) secondary financial protection consisting of funds from a nuclear industry retrospective rating plan—a form of nuclear industry self-insurance in which the licensee of each large operating reactor covered by the plan would be required to contribute up to $121,255,000 for each large operating reactor (but no more than $18,963,000 per year) in the event of a large nuclear incident at any power reactor station site covered by the plan. Currently, the aggregate amount of financial protection is approximately $13.5 billion. This means that a total of $13.5 billion is authorized to ensure that adequate funds are available to the public to satisfy liability claims if such an incident were to occur. Congress has long recognized that a nuclear incident might involve compensation in excess of the monies available in the primary and secondary layers. For this reason, over time, these layers have incrementally increased. Congress would have to authorize any compensation needed above the amount available in the primary and secondary layers.

Question No. 108
Comment: The NRC might use mediation during the enforcement process. Switzerland understands mediation as an important method for the licensees as well as the NRC to express concern about safety issues. What are the criteria of neutral mediators? In the 2014 report the NRC described an Alternative Dispute Resolution Program. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts outside a court using a neutral third party. What are the experiences made with the alternative resolution program or the use of neutral mediation. Does the use of mediation replace the alternative resolution program?
Answer: ADR is a term that refers to a number of resolution processes used for parties to resolve disputes. The NRC uses mediation as the specific process to resolve applicable disputes within its Office of Enforcement ADR program. Mediation uses a neutral third party to facilitate dialogue between two parties to resolve a dispute. The ADR program comprises two entirely different subprograms: Preinvestigation (“early”) ADR and Enforcement ADR. Early ADR is offered before the initiation of an investigation by the NRC’s Office of Investigations and is only available to allegers and their employers for resolving allegations of discrimination. The goal of the Early ADR is to allow resolution of a discrimination concern as soon as possible to minimize the potential impact the discrimination concern may have on the overall work environment. The Enforcement ADR program, applicable to willful and discrimination cases after an investigation, as well as traditional enforcement cases with the potential of a CP, uses mediation to gain an understanding of each party’s interest, clarify disputes, and explore innovative ways to address the underlying issues of both parties to reach a mutually agreeable settlement. The agency staff manages the ADR program and associated processes and guidance, and the Scheinman Institute on Conflict Resolution (ICR) at Cornell University is under contract to administer neutral services associated with the ADR program. ICR administers the day-to-day activities of the program and also manages a nationwide independent roster of session neutrals (mediators). Typically, the mediators hold at least a bachelor’s degree and complete 40 hours of formal mediation training administered by the ICR (and developed in conjunction with input from the NRC). They also have demonstrated experience in handling complex cases with highly sensitive issues and with senior level personnel and technical matters. The mediators also have a demonstrated ability to effectively encourage communication among parties with varying experience and backgrounds. The use of a mediator has been advantageous in resolving matters, as mediation allows for open dialogue between the parties, driven by both parties’ desire to reach a mutually agreeable settlement. In the case of early ADR, mediation typically aids in addressing matters of miscommunication and stems the inherent damage disputes can inflict on the work environment more quickly than an investigation. Enforcement ADR mediation typically results in broader, more comprehensive corrective actions agreed upon by both parties. Additional information about the agency’s ADR program is available at https://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html.

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.

Policies of the NRC that give due priority to safety covered under this article are PRA policy statements and policies that apply to licensee safety culture and safety culture. Other articles (e.g., Articles 6, 14, 18, and 19) discuss activities undertaken to achieve nuclear safety at nuclear installations.

The NRC has not made specific changes to the priority of its safety programs addressed under this article as a result of the Fukushima accident. However, the actions that the NRC has taken are broadly supportive of the due priority to safety and a strong safety culture. For example, as part of the larger effort discussed in Sections 1.3.1 and 1.3.3, the NRC has ensured that licensees have adequate staffing to respond to emergencies and have clearly defined roles and responsibilities for those responders. Similarly, the NRC requested that nuclear power plant licensees reevaluate potential seismic and flooding hazards and perform a mitigation strategies assessment of the reevaluated hazards.

Question No. 109
What is the status of the development of the level 3 PSA for the Vogtle plant? Are there any results already available? Will the outcome of the level 3 PSA, in particular as related with DEC, be used to update the offsite emergency preparedness?
Answer: The Level 3 PRA for the Vogtle plant is in development. Since this project involves approximately 20 different PRA models, it is difficult to characterize the overall status of the effort. Several models have been completed and subjected to a peer review to the ASME/American Nuclear Society (ANS) PRA standards (i.e., the Level 1, 2, and 3 PRA models for internal events and internal floods; the Level 1 PRA model for high winds; and the qualitative screening analysis of other hazards). Other models are near completion (e.g., Level 1 PRA models for internal fires and seismic events, a Level 1 low-power and shutdown PRA model for internal events, and a dry cask storage PRA that encompasses all PRA levels and all hazards). Other models are in the very early stages (e.g., a Level 2 low-power and shutdown PRA model for internal events and a combined Level 1 and Level 2 SFP PRA model), while some have yet to begin (e.g., Level 2 and Level 3 PRA models for internal fires and external hazards). Unfortunately, all of the results to date involve proprietary information and are not publicly available. However, a publicly available report will document the final study results. The current anticipated completion date for the study is January 2020. The Level 3 PRA study is a research project and does not have a direct regulatory application. However, an extensive set of potential applications of the study results to the NRC's regulatory framework, including informing agency activities related to emergency preparedness, are in SECY-12-0123, "Update on Staff Plans To Apply the Full-Scope Site Level 3 PRA Project Results to the NRC's Regulatory Framework," dated September 13, 2012 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0123scy.pdf).

Question No. 110
Use of Risk insights in prioritising regulatory oversight, and in particular allowing licensees to use risk insights in categorisation and treatment of SSCs (50.69) and in performance based fire protection programme (50.48c), can be seen as area of good performance for USA.
Answer: Thank you for your comment and observation. We appreciate the positive feedback.
Question No. 111
Commitment of the NPP operators to undertake a Safety culture self-assessment every two years, and conduct monitoring panels in accordance with the NEI 09-07 document, can be seen as area of good performance for USA.
Answer: Thank you for your comment and observation. We appreciate the positive feedback.
Question No. 112
Revision 1 of RG 5.74 issued in April 2015, which includes cyber security as a part of the safety and security assessment, can be seen as good performance for USA.
Answer: Thank you for your comment and observation. We appreciate the positive feedback.
Question No. 113
When the U.S. Nuclear Regulatory Commission (NRC) expects the licensee to conduct a third-party independent assessment of its safety culture, is this a completely independent assessment, or is someone from the NPP on the assessment team? Is there someone from the U.S. NRC on the assessment team?
Answer: For licensees in columns 3 and 4 of the ROP Action Matrix, the NRC will ask the licensee to conduct an independent assessment, usually by a consulting company with expertise in survey design and analysis. NRC safety culture assessors are not included as members of the third-party assessment but may monitor portions of it to inform the NRC's evaluation of the quality of the third-party assessment methodology and determine the scope of the NRC's graded safety culture assessment. However, the NRC does review the assessments and uses them as inputs into how to scope its inspection activities. The NRC will conduct its own independent assessment, as required by IP 95003, "Guidance for Conducting an Independent NRC Safety Culture Assessment."
Question No. 114
It is mentioned that "Safety and security have always been the primary pillars of the NRC's regulatory programs. Safety and security activities are closely intertwined, and it is critical that consideration be given to the integration of safety and security activities so as not to diminish or adversely affect either." Question: How to consider the interfaces between safety and security?
Answer: Regulations in 10 CFR 73.58, "Safety/Security Interface Requirements for Nuclear Power Reactors," requires nuclear power plant licensees to assess and manage the potential for adverse effects on safety and security before implementing changes to plant configurations, facility conditions, or security. In addition, 10 CFR 73.55(m) prescribes requirements for the review of each element of a nuclear power plant licensee's physical protection program at least every 24 months. Specifically, the review must include an audit of the effectiveness of the safety and security interface activities. RG 5.74, "Managing the Safety/Security Interface," Revision 1, issued April 2015 (ADAMS Accession No. ML14323A549), provides guidance to nuclear power plant licensees to assess and manage changes to safety and security activities so as to prevent or mitigate potential adverse effects that could negatively impact either plant safety or security.

The interface between safety and security is an important element of both programs to ensure public health and safety. Nuclear power plant licensees should address plant activities that could compete or conflict with the capability of the site security program to provide adequate protection of the common defense and security. Conversely, changes in the site security program could also adversely affect plant operations, safety-related SSCs, operator actions, or emergency responses necessary to prevent or mitigate postulated design-basis accidents and to protect public health and safety and the environment.

More information on RG 5.74 can be found at https://www.nrc.gov/docs/ML1432/ML14323A549.pdf.

Question No. 115

It's mentioned in section 10.5: "Revision 1 of RG 5.74 was issued in April 2015, to include cyber security as part of the safety and security assessment."
Question: Is RG5.74 applicable for all NPPs in USA? What actions have been taken on cyber security by operators?

Answer: RG 5.74 is a regulatory guidance document that provides an acceptable approach (but likely not the only possible approach) for nuclear power plant licensees to assess and manage changes to safety and security activities. The most recent update to this guidance document explained that "security" encompasses both physical security and cybersecurity.

Information specific to cybersecurity appears in RG 5.71, "Cyber Security Programs for Nuclear Facilities," issued January 2010 (ADAMS Accession No. ML090340159), and NEI-08-09, "Cyber Security Plan for Nuclear Power Reactors." Both of these documents provide acceptable approaches for complying with the NRC's cybersecurity regulations, as specified in 10 CFR 73.54, "Protection of Digital Computer and Communication Systems and Networks." All power reactor licensees either currently maintain a fully compliant cybersecurity program or are in the process of completing one on an NRC-approved schedule.

Question No. 116

It seems positive that reactor oversight process has been further developed to cover also organizational and safety culture aspects.

Answer: Thank you for your comment and observation. We appreciate the positive feedback.

Question No. 117

Has NRC collected feedback information from its licensees' concerning the safety culture oversight activities? Do the licensees feel that the process NRC uses is transparent, understandable, objective and predictable?

Answer: NRC RESPONSE: The NRC collects feedback on oversight activities on a regular basis through the annual reactor oversight self-assessment process, which may include feedback from licensees concerning safety culture activities. The NRC also conducts monthly ROP meetings with stakeholders and industry representatives. This is an opportunity for members of the nuclear community to discuss issues with the NRC.

INPO RESPONSE:
In the U.S., stations use a variety of means to understand the condition of their nuclear safety culture. Each station has implemented a safety culture monitoring panel that reviews a wide variety of station information to detect signs of degrading nuclear safety culture and monitor the effectiveness of any needed actions. In addition, stations typically perform surveys of all station personnel to gain feedback from workers on issues or conditions that could impact the

health of nuclear safety culture. As part of INPO's plant evaluation process, observation of station performance, review of station performance history, and employee surveys are used to gain insights of safety culture at a station and those results are discussed with the utility CEO following the plant evaluation.

Question No. 118

With reference to article 10.3.5, page 125 of the American national report, it is understood that one of the objectives of the Full-scope Site Level 3 PRA Project is to make a risk assessment on whole site including multi-units which is not considered in the existing PRA. Korea would like to inquire the following questions regarding this project:

1) Are safety goals under development for whole site risk assessment? If so, what is the current status of safety goal development for whole site including multi-units? If not, how is whole site risk assessed to determine whether it is acceptable?
2) What is the current development status for multi-unit risk assessment methodology?

Answer: (1) Site-level safety goals are not currently in development in the United States. Because U.S. nuclear power plants are licensed on a unit-specific basis, whole-site risk is not used to support regulatory decisionmaking. The NRC applies subsidiary metrics of CDF and LERF to make licensing decisions only on a per-unit basis (e.g., see RG 1.174 (https://www.nrc.gov/docs/ML1009/ML100910006.pdf)).

(2) The NRC is currently pursuing a multiunit risk assessment methodology as part of the full-scope, site Level 3 PRA project. At present, the agency is in the early stages of exploring various approaches to modeling multiunit (and multisource, including SFPs and dry cask storage) risk. This work was presented at a Reliability and PRA Subcommittee meeting of the Advisory Committee on Reactor Safeguards (ACRS) on December 13, 2016 (the presentation is available at https://www.nrc.gov/docs/ML1700/ML17004A028.pdf. Additional background on the site Level 3 PRA project can be found in the Technical Analysis Approach Plan at https://www.nrc.gov/docs/ML1329/ML13296A064.pdf.

Question No. 119

With reference to article 10.4.1, page 126 of the American national report, it is stated that Safety Culture Policy Statement considers both safety and security as underlying principles. With respect to the information provided in the article in question, Korea would like to inquire the following questions:

1) What are the endeavors of the NRC to develop oversight on licensees, as well as endeavors within the regulatory authority to harmonize safety culture and security culture? It would be appreciated if examples of conflict between safety culture and security culture factors are shared when providing an answer to this question.
2) How does the NRC improve 'Just Culture'? Does the NRC conduct reviews on whether licensees implement 'Just Culture'? Is 'Just Culture' reflected on polices relevant to regulation enforcement?

Answer: (1) The NRC recognizes that it is important for all organizations performing or overseeing regulated activities to establish and maintain a positive safety culture. The NRC's approach to safety culture is based on the premise that licensees bear the primary responsibility for safety.

The Safety Culture Policy Statement (SCPS) (76 FR 34773; June 14, 2011) sets forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. The SCPS is not a regulation. It applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, and vendors and suppliers of safety-related components, as well as applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. In addition, the Commission encourages the Agreement States (States that assume regulatory authority over their own use of certain nuclear materials), their licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture within their regulated communities.

The SCPS addresses both safety and security. Organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities. Safety and security activities are closely intertwined. While many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. It is important that consideration of these activities be integrated so as not to diminish or adversely affect either; thus, mechanisms should be established to identify and resolve these differences. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities.

The SCPS defines nuclear safety culture as the core values and behavior resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. The SCPS includes a list of nine traits further defining a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production vs. safety, schedule vs. safety, and cost of the effort vs. safety). The Commission expects that all organizations and individuals overseeing or performing regulated activities involving nuclear materials should take the necessary steps to promote a positive safety culture by fostering these traits. Additionally, it should be noted that, although the term “security” is not expressly included in the traits, safety and security are the primary pillars of the NRC’s regulatory program. Consequently, consideration of both safety and security issues commensurate with their significance, is an underlying principle of the SCPS.

(2) James Reason defines the concept of “Just Culture” as “an atmosphere of trust in which people are encouraged, and even rewarded, for providing essential safety-related information, but in which they are also clear about where the line must be drawn between acceptable and unacceptable behavior.” The NRC does not use the Just Culture terminology. Instead, the NRC focuses on safety culture. The tenants of a Just Culture could be presumed to be in the safety culture traits of “Environment for Raising Concerns” and “Personal Accountability” in the NRC’s SCPS, as these two traits represent many of the elements of establishing a Just Culture.

Question No. 120

With reference to article 10.3.5, page 125 of the American national report, it is stated that Vogtle Electric Generating Plant Units 1 and 2 volunteered to be the subject of the Level 3 PRA study. With respect to the provided information in the article in question, Korea would like to inquire the following questions:

1) When is the expected completion date of the study?

2) What is the NRC's stance on how the study results will be incorporated into the regulatory system?
Answer: (1) The current anticipated completion date for the study is January 2020. (2) The Level 3 PRA study is a research project and does not have a direct regulatory application. However, SECY-12-0123 documents an extensive set of potential applications of the study results to the NRC's regulatory framework (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0123scy.pdf).
Question No. 121
With reference to article 10.4.3, page 129 of the American national report, it is stated that 'NRC conducts assessments of our safety culture and continually reviews results and develops action plans to improve'. Korea would like to cite the following and inquire the question below based on the quoted excerpt: "The NRC conducts assessments of our safety culture and continually reviews results and develops action plans to improve." With respect to the quoted excerpt, what are the methodologies (i.e. survey with questionnaires, interviews, field observation, etc.) used by the NRC to conduct nuclear safety culture assessment?
Answer: The agency uses the NRC's Office of the Inspector General's triennial Safety Culture and Climate Survey to assess the effectiveness of new and existing safety culture efforts. In 1998, the Office of the Inspector General conducted the first in a continuing series of Safety Culture and Climate Surveys to identify areas for additional organizational improvements. The surveys are voluntary, provide for anonymity, and are offered to all NRC employees, supervisors, and managers. The Office of the Inspector General has conducted the Safety Culture and Climate Survey six times since 1998 and most recently in 2015. The Government-administered Federal Employee Viewpoint Survey also provides an annual pulse on organizational aspects such as leadership, employee engagement, and job satisfaction. The U.S. Office of Personnel Management has conducted the Federal Employee Viewpoint Survey since 2002 and annually since 2010. A survey such as this makes it possible to compare results over time to assess increasing or decreasing trends. Postsurvey assessment activities such as listening sessions, focus group discussions, interviews, differing views program self-audits, and exit interviews are used as deep dives into data coming from these surveys. These self-assessments are a critical component of NRC's efforts to measure changes to maintain a culture of safety.
Question No. 122
With reference to article 10.4.3, page 129 of the American national report, Korea would like to inquire the following question: In Korea, Safety culture assessments have been periodically implemented based on the safety culture assessments guideline developed by NPP licensees incorporating the assessment methodologies such as survey with questionnaire, interview. What are the methodologies (i.e. survey with questionnaires, interviews, field observation, etc.) used by NPP licensees to conduct nuclear safety culture assessment?
Answer: In the United States, stations use a variety of means to understand the condition of their nuclear safety culture. Each station has implemented a safety culture monitoring panel that reviews a wide variety of station information to detect signs of degrading nuclear safety culture and monitor the effectiveness of any needed actions. In addition, stations typically

perform surveys of all station personnel to gain feedback from workers on issues or conditions that could affect the health of the nuclear safety culture. As part of INPO's plant evaluation process, observation of station performance, reviews of station performance history, and employee surveys are used to gain insights as to the safety culture at a station and those results are discussed with the utility chief executive officer following the plant evaluation.
Question No. 123
It is mentioned that "NRC conducts assessments of its safety culture and continually reviews results and develops action plans to improve". USA may like to share some of the activities planned in the areas identified for improvement under the action plan.
<u>Answer</u>: The NRC conducts post-survey assessment activities, such as listening sessions, focus group discussions, interviews, differing views program self-audits, and exit interviews to help determine appropriate ways to improve NRC's safety culture and increase employee engagement. The current agency action plan identified the following actions to address areas of improvement: • Develop a clear, shared understanding using multiple mechanisms (e.g., training, facilitated dialogues) of some key concepts and what they mean in terms of implementation by the NRC (i.e., "Environment for Raising Concerns," "Collaboration," "Empowerment," "Consensus"). • Continue to develop and enhance activities that address concerns of retaliation and chilling effect for raising concerns, as well as support continuous improvement of differing view programs. • Develop and enhance activities to cultivate respect and inclusion, such as "Diversity Dialogue Project," "Advisory Committees/Employee Resource Groups," "Executive Sponsor Program," "Participation in Special Emphasis Programs," and "Educational Diversity and Inclusion" events. • Establish and communicate a clear agency leadership vision in which leadership is expected and demonstrated at all levels, and there is shared mutual accountability.
Question No. 124
Status of safety culture is treated as very important aspect in overall safety assessment. However, traits of adequate safety culture are defined only qualitatively. How this important though qualitative constituent can be allowed for, eg., during assessment of quantitative safety targets?
<u>Answer</u>: The safety culture traits are defined qualitatively, in part, to provide a richer and more complete description of the types of attitudes, values, and behaviors that would be present in a positive safety culture. However, the NRC also acknowledges that organizations can be vastly different, and fostering the safety culture traits should be tailored to a licensee's unique organizational environment. As a result, the NRC does not specify quantitative requirements for safety culture, because quantitative indicators may not be universally applicable.
Question No. 125
Currently special risk-informed requirements for categorizing structures, systems, and components have been adopted by some operators on a voluntary basis.

Are there any plans to develop a process to make these requirements mandatory, and if so, then will these requirements be applicable to not only new plants but operating nuclear units as well?
Answer: The NRC has no plans to make the provisions in 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," mandatory. The licensee may voluntarily comply with the rule in 10 CFR 50.69, which generally constitutes a relaxation in regulatory requirements by allowing SSCs categorized as having low safety significance to be removed from the scope of the special treatment requirements, which are summarized in 10 CFR 50.69(b).
Question No. 126
Do these "special requirements" cover aging management for safety-significant components?
Answer: The special treatment requirements, as listed in 10 CFR 50.69(b), do not include explicit requirements for aging management. However, according to 10 CFR 50.69(d)(2), the licensee or applicant is required to ensure, with reasonable confidence, that SSCs of low safety significance remain capable of performing their safety-related functions under design-basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. The licensee or applicant is required to take corrective actions if conditions occur that would prevent an SSC of low safety significance from performing its safety-related functions.
Question No. 127
What was the reason to change the list of safety culture traits, and what does NRC imply by 'common safety culture language': is it an unquestionable requirement for licensee to feature all 10 safety culture traits, or is it a demand to keep to same terminology in safety culture discussions?
Answer: Before the publication of the 2011 SCPS (76 FR 34773; June 14, 2011), the nuclear reactor power industry approached the NRC about starting to develop a shared set of terms to describe safety culture. This effort was deferred while the SCPS was being developed. With insights gained during the development of the SCPS, the NRC hosted a series of public workshops, beginning in December 2011, to discuss a safety culture common language. These four public workshops included a panel of representatives from INPO, NEI, all four NRC regional offices, and several offices within NRC Headquarters. All were open to public participation. The panel used the nine traits of a positive safety culture described in the SCPS as the basis of the discussion. The panelists also identified an equally important trait, Decision-Making, in describing a healthy safety culture in nuclear reactor power organizations. This tenth trait was added to the common language for the nuclear reactor industry. The safety culture common language effort was intended to align terminology between the NRC's inspection and assessment processes within the ROP and the industry's safety culture language described by INPO as "Principles for a Strong Nuclear Safety Culture." The industry used these INPO Principles in its evaluation and assessment processes through NEI 09-07, "Fostering a Strong Nuclear Safety Culture." The safety culture common language described in NUREG-2165, "Safety Culture Common Language," issued March 2014, documents the agreed-upon common language from the common language workshops discussed previously. INPO has also published this common language in INPO 12-012, "Traits of a Healthy Nuclear Safety." This effort has allowed the NRC and the nuclear reactor industry to have a common language when discussing safety culture, including during an NRC inspection/assessment or an INPO evaluation/assessment.

The NRC's SCPS, which includes nine traits, is an expectation for the regulated community, not a requirement. The SCPS notes that these traits are not all inclusive. Some organizations may find that one or more of the traits resonate with their activities more than other traits might. There may also be traits not included in the SCPS that are important in a healthy safety culture. The tenth trait, "Decision-Making," added by the nuclear reactor industry through the common language effort is an example of a trait not included in the SCPS but that is an important safety culture trait for the reactor community.

Question No. 128

How does USA implement Vienna Declaration on Nuclear Safety principle that national requirements and regulations on safety culture should take into account relevant IAEA Safety Standards?

<u>Answer</u>: Many of the differences in how the safety standards are applied to NRC regulations stem from the fact that NRC regulatory guidance predates most IAEA safety standards. Furthermore, the NRC requirements were written with a greater level of detail than the IAEA's safety standards. The NRC participates in IAEA and other international guidance development meetings to ensure that the NRC policy continues to align with international best practices.

The principles of the Vienna Declaration do not specifically address safety culture. However, the NRC recognizes the importance of a healthy safety culture in addition to the importance of IAEA safety standards. The NRC developed the SCPS (76 FR 34773; June 14, 2011), which sets forth the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. The SCPS is not a regulation. It applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, and vendors and suppliers of safety-related components, as well as applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. In addition, the Commission encourages the Agreement States (States that assume regulatory authority over their own use of certain nuclear materials), their licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture within their regulated communities.

Consistent with CNS principles, the NRC's approach to safety culture is based on the premise that licensees bear the primary responsibility for safety. The ROP is the NRC's program for assessing the performance of operating commercial nuclear power reactors. The ROP uses inputs from performance indicators and inspection findings to develop conclusions about a licensee's safety performance. The ROP evaluates performance systematically and on a continuous basis through planned inspections and end-of-year assessment meetings. Based on the NRC's assessment of safety performance, licensees are assigned to a column in the ROP Action Matrix, and that placement determines the level of NRC oversight for that particular licensee. The NRC's approach to safety culture assessment is a graded process. The extent and complexity of a safety culture assessment is generally based on a licensee's placement in the ROP Action Matrix. The scope and complexity increases with increased oversight, and the focus of the assessment may be tailored based on the original performance deficiency. An assessment may focus more heavily on one part of the plant or on one area of safety culture, such as a safety-conscious work environment. Qualified NRC safety culture assessors evaluate the licensee's third-party safety culture assessment and then determine the scope of the NRC assessment, based on that evaluation. The NRC assessors conduct the

assessment on site and identify and document safety culture themes in the inspection report. The assessors also review the licensee's planned and completed corrective actions to evaluate whether they address the identified safety culture themes and whether the licensee needs to develop follow-up actions to address any remaining concerns. The 21 volumes of NUREG-1556, "Consolidated Guidance About Materials Licenses," include management responsibility for safety culture. Although the SCPS is not incorporated into regulations, the expectation to maintain a strong safety culture applies to all of the materials users. Each of the 21 volumes includes examples that reflect the SCPS traits.
Question No. 129
Does the present Risk informed methodology applications, as presented in 10.3.1 - 3, take into account beside the safety aspects also other attributes such as cost benefit issues, etc.?
Answer: Sections 10.3.1 through 10.3.3 of the U.S. 7th National Report describe the risk-informed methodologies for special treatment, inservice inspection, and TS (completion times and surveillance frequencies). These risk-informed methodologies focus on ensuring that plant safety is maintained. They rely on assessment of risk of core damage or large early release, combined with other safety considerations such as maintaining DID and safety margins, as described in RG 1.174. These methodologies do not directly consider cost-benefit issues. However, these voluntary risk-informed applications are expected to provide benefits, such as increased operational flexibility and reduction in personnel dose, and, therefore, are expected to provide cost savings for the nuclear power plants adopting them.
Question No. 130
The very large and time consuming analysis are important tools. However, it then take rather longtime before the implementations that improve the safety status are in place. What is the US view of that and experience?
Answer: Although such research studies can be time consuming and difficult to conduct, the NRC believes that such studies, when properly planned and executed, can maintain and enhance the NRC's technical competence and regulatory decisionmaking capabilities. In preparing to perform the Level 3 PRA study, the staff conducted an extensive feasibility scoping study to identify potential options for conducting a study of this complexity (documented in SECY-11-0089, "Options for Proceeding with Future Level 3 Probabilistic Risk Assessment Activities," dated July 11, 2001 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0089scy.pdf)). The Commission ultimately approved the conduct of the study in SRM-SECY-11-0089, dated September 21, 2011 (https://www.nrc.gov/reading-rm/doc-collections/commission/srm/2011/2011-0089srm.pdf), but directed that the staff provide a clear articulation of how the results of the analysis can be applied consistent with the NRC's Principles of Good Regulation. In response to this direction, the staff provided SECY-12-0123 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0123scy.pdf), which summarizes potential regulatory uses of the Level 3 PRA project.
Question No. 131
Is the safety culture and attitudes considered in the reqruiting process?
Answer: The recruiting process at the NRC and at other Federal agencies involves the review and evaluation of candidates' qualifications (i.e., education and experience) necessary for successful performance in the position to be filled. To the extent possible, candidates' qualifications should be quantifiable or measurable, such that they may be appropriately ranked to determine if they are among the best qualified. This may involve consideration of

relevant undergraduate and graduate degrees and specific types and years of experience related to the position to be filled. Attitudes about safety culture are likely too difficult to measure or quantify properly and, therefore, would not be appropriate as screening tools for determining whether applicants meet initial qualifications requirements. However, they may be more appropriately considered during interviews.
Question No. 132
The reports states that there was developed a common safety culture language using the Safety Culture Policy Statement. What is meant by "common safety culture language"? Where is this safety culture language apparent? Please explain.
Answer: The intent of the safety culture common language effort was to align terminology between the NRC's inspection and assessment processes within the NRC's ROP and the reactor industry's safety culture language described by INPO as "Principles for a Strong Nuclear Safety Culture." The industry uses these INPO Principles in its evaluation and assessment processes through NEI 09-07. Before the NRC's publication of the 2011 SCPS (76 FR 34773; June 14, 2011), the nuclear reactor power industry approached the NRC about starting to develop a shared set of terms to describe safety culture. This effort was deferred while the SCPS was being developed. With insights gained during the development of the SCPS, the NRC hosted a series of public workshops beginning in December 2011 to discuss a safety culture common language. These four public workshops included a panel of representatives from INPO, NEI, all four NRC regional offices, and several offices within NRC Headquarters. All were open to public participation. The panel used the nine traits of a positive safety culture described in the SCPS as the basis of the discussion. This group ultimately added an additional trait, Decision-Making, for the nuclear reactor industry. The safety culture common language described in NUREG-2165 documents the agreed-upon common language from the common language workshop. The NRC's revised ROP to reflect this common language, as well, and INPO published it in INPO 12-012. This effort has allowed the NRC and the nuclear reactor industry to have a common language when discussing safety culture, including during an NRC inspection/assessment or an INPO evaluation/assessment.
Question No. 133
The report states that for licensees with more significant performance degradation, the NRC will expect the licensee to conduct a third-party independent assessment of its safety culture. This means, NRC can only expect not enforce a third-party safety culture independent assessment. Did NRC ever expect such an assessment? What was the outcome? Was it satisfactory in the sense that it showed the weaknesses and blind spots of the licensee, i.e. the underlying causes for its performance degradation? Please comment on the outcome of third-party safety culture independent assessment.
Answer: For plants in column 3 of the Action Matrix, the NRC can request that the licensee conduct an independent third-party safety culture assessment. For plants in column 4 of the Action Matrix, the NRC expects that the licensee will conduct an independent third-party assessment, which it will then evaluate to determine the scope for its inspection activities. The NRC defines an independent safety culture assessment in IMC 0305, "Operating Reactor Assessment Program," as "one performed by qualified individuals that 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)." The NRC defines a third-party safety culture

assessment in IMC 0305 as, "one performed by qualified individuals who are not members of the licensee's organization or utility operators of the plant (licensee team liaison and support activities are not team membership)." As such, a third-party assessment does not include members from the nuclear power plant that is being assessed. NRC safety culture assessors are not included as members of the third-party assessment but may monitor portions of it to inform the NRC's evaluation of the quality of the methodology and determine the scope of the NRC's graded safety culture assessment (Section 02.07a, "Inspection Preparation," of IP 95003.02, "Guidance for Conducting an Independent NRC Safety Culture Assessment," April 3, 2014 (ADAMS Accession No. ML14090A072)). The NRC recently reviewed the results of an independent third-party nuclear safety culture assessment at Arkansas Nuclear One. The NRC inspection report is at ADAMS Accession No. ML16161B279.
Question No. 134
The report states that the NRC culture includes a system of shared values, beliefs, and behaviors that demonstrate their collective commitment to emphasize safety as the overriding priority in their regulatory decision making. How does the NRC ensure that the above statement is implemented in every day decision making? I.e. how does the NRC guarantee that this statement is applied in the management system?
<u>Answer</u>: The NRC actively fosters a culture in which all employees live the NRC's values, demonstrate a positive safety culture, and adhere to the Principles of Good Regulation to support the NRC's mission to protect public health, safety, and the environment. The NRC strives to establish and maintain an environment that encourages all employees and contractors to raise safety-related concerns and differing views without fear of negative consequences via a management open door policy (ADAMS Accession No. ML15219A454), a nonconcurrence process (ADAMS Accession No. ML13176A371), and a differing professional opinion program (ADAMS Accession No. ML15132A664). The agency nurtures these efforts through a strong collective commitment to its mission; open communication on its priorities, values, and behaviors; recognition of the important role each individual plays in the NRC's success; and efforts such as reinforcing its values by developing agency action plans for strengthening agency culture. The NRC also implements this philosophy through formal decisionmaking guidance, such as NRR's Office Instruction, LIC-504 (ADAMS Accession No. ML14035A143,) which is used when emergent issues arise at nuclear power plants and a regulatory course of action must be selected. The NRC's commitment to safety forms the basis for this procedure. The values, principles, and processes described above are an integral part of the NRC management system. The NRC's record of success in fulfilling its mission demonstrates that the agency's safety culture, values, principles of good regulation, and related behaviors and activities are an integral part of its culture and guide everyday decisionmaking at the NRC.
Question No. 135
Section 10.3.1 describes 10 CFR 50.69, which allows the application of risk insights to assign the special treatment requirements in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," for SSCs according to their safety significance. It also states, "On December 17, 2014, the NRC issued a license amendment approving the Vogtle Electric Generating Plant, Units 1 and 2, pilot application of 10 CFR 50.69. As necessary, the lessons learned from this pilot will be incorporated into future revisions of the industry guidance and the

NRC's regulatory and inspection guidance." What were the objectives, scope and lessons learned from this pilot program?
Answer: In May 2006, the NRC issued the current RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," Revision 1, for trial use. The RG endorses the guidance in NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," issued July 2005. The objective of the NRC review of the pilot Vogtle application was to establish whether the licensee's categorization process is acceptable to establish the safety significance of SSCs, is consistent with the NRC-endorsed guidance in NEI 00-04 guidance, and therefore satisfies the regulatory requirements of 10 CFR 50.69(c). An additional objective was to establish whether any revisions to the endorsed guidance are necessary. The NRC staff reviewed the categorization process proposed by the licensee, audited the licensee's trial categorization of two systems, and reviewed the quality of the licensee's PRA to be used in the categorization. The NRC has identified the following potential enhancements to the guidance in RG 1.201 and NEI 00-04: • The NEI guidance provides a set of seven deterministic questions to be used in the categorization process to ascertain whether the candidate SSCs of low safety significance are not implicitly relied upon for safety. Questions 4 and 5 address the determination as to whether an active function/SSC provides the "sole means" of accomplishing a specific mitigation function. The NRC staff found that additional guidance is needed to specify when licensees can credit alternative means for achieving the mitigation actions and specified that alternative means can be credited only if they are proceduralized and included in operator training. • The categorization process described in the NEI guidance contains a number of steps, such as component categorization based on risk, function categorization, assessment of DID and safety margin, and the final assessment by the integrated decisionmaking panel, which are to be executed in a specified order. The NRC staff found that executing the categorization process in a different order than specified in NEI 00-04 may be acceptable if certain conditions are met. The NRC staff found that additional guidance to that specified in NEI 00-04 is needed to specify acceptable categorization methods for passive components.
Question No. 136
Section 10.3.3 describes risk-informed Technical Specification changes. It mentions Initiative 4b, "Risk-Informed Completion Times" which states, "The NRC staff is nearing completion of its review of the application, and is actively working to resolve any remaining technical issues and provide clarifying guidance." Please summarize any significant technical issues?
Answer: The main NRC safety concern with risk-informed TS Initiative 4b (TSTF-505) relates to ensuring that adequate DID and safety margins are maintained when the plant enters a configuration that represents a loss of a specified safety function or inoperability of all required trains of a system required to be operable (TS loss-of-function configuration). In the current TS, entry in such a configuration typically requires prompt reactor shutdown. In the proposed changes to the TS through Initiative 4b, unplanned (emergent) operation in TS loss-of-function conditions can be extended based on PRA calculations, by declaring one or more inoperable trains "PRA Functional." The NRC staff found that the phrase "PRA Functional" is too broadly defined in the industry guidance documents supporting the initiative. Without additional detailed information from the applicants for each TS condition, and without imposing additional

restrictions on PRA functional, the NRC staff was unable to conclude that DID and safety margins are adequately maintained while operating in TS "loss-of-function conditions," as specified by the risk-informed principles of RG 1.174, Revision 2. The NRC has engaged with the industry to address the concern. The industry has agreed to remove the TS loss-of-function conditions from the scope of the 4b program until further guidance is developed.
Question No. 137
Section 10.3.5 describes Level 3 Probabilistic Risk Assessment Project Consistent. It states, "the Level 3 PRA study is largely being carried out using current PRA state-of-practice methods, tools, and data. However, there are several gaps in PRA technology, along with other challenges, that require advancement in the PRA state-of-practice." What are the gaps and challenges the NRC has identified regarding the current PRA technology?
Answer: As stated in Enclosure 1 to SECY-11-0089 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2011/2011-0089scy.pdf), some gaps in existing PRA technology include the following: • modeling of consequential or concurrent (overlapping) initiating events at multiple units (or other major radiological sources on site (e.g., SFPs or dry cask storage) • modeling of multiunit dependencies • modeling of human failure events following external hazards (e.g., seismic, high winds, external flooding) • modeling of human failure events with postcore damage • modeling SFP accident scenarios • modeling aqueous transport and dispersion of radioactive materials Some additional gaps include the following: • modeling of consequential steam generator tube rupture (e.g., severe-accident-induced steam generator tube failures) • operational data for low-power and shutdown plant operating states • CCF modeling (and data) for large CCF component groups • modeling uncertainty in Level 2 and Level 3 PRA

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

The NRC has made no changes to licensee financial resource considerations as a result of the Fukushima nuclear accident. Sections 1.3.1 and 1.3.3 of this report describe training related to the orders and the proposed rulemaking related to Fukushima lessons learned.

Question No. 138
Since the economic situation of the licensees has been decreased, has there been any indications that it has had some effects on e.g. licensees' willingness of making some plant improvements at the US NPPs? Or is there any increased discussion on the cost of regulatory work?
Answer: The NRC's goal is to minimize the regulatory burden placed on licensees while still acting as an effective and independent regulator. Licensees operate in a dynamic environment in which they must continually adjust to the varying economics of power generation. As such, during times of increased economic burden, licensees seek to gain additional operational and process efficiencies without affecting the safe operations of the plant.
Question No. 139
Could you please provide more information on the ways of knowledge accumulation and knowledge transfer applied by nuclear operators and regulating organizations?
Answer: NRC'S RESPONSE: The NRC has robust training and qualification programs that facilitate knowledge transfer. The qualification program requirements comprise classroom, individual self-study, and on-the-job training that cover the knowledge, skills, and attitudes needed to successfully achieve full inspector qualification. One of the best approaches for knowledge transfer is to learn directly from the experts who have years of regulatory experience in the field. The programs require on-the-job activities and follow a training method that uses these structured hands-on activities to develop the required job-related knowledge and skills. These activities are completed with and supervised by subject matter experts in the field. Through this process, the experience of the qualified inspector is shared and transferred to the individual in training. In addition, individuals participate in a rotational assignment, often in the field, to learn about different aspects of a job and gain skills and experience. During this time, they job-shadow experts, participate in hands-on activities, and are mentored. An example of on-the-job training is in IMC 1245, "Qualification Program for New and Operating Reactor Programs," Appendix C-1, "Reactor Operations Inspector Technical Proficiency Training and Qualification Journal," dated December 19, 2016

(https://www.nrc.gov/docs/ML1630/ML16301A167.pdf). IMC 1245 (https://www.nrc.gov/docs/ML1517/ML15177A317.pdf) defines training and qualification requirements for inspectors and operator licensing examiners performing activities in NRR, the Office of New Reactors, and the Office of Nuclear Security and Incident Response programs. A full list of IMCs, including qualification programs, is available at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/. INPO'S RESPONSE: U.S. operators use a variety of techniques to accomplish knowledge transfer. For example, one utility hired new personnel equivalent to 60 percent of their work far enough in advance so that they could be trained and replace other station personnel as they moved up to replace retired workers. One thing that has happened in the U.S. is that several plants were shutdown in the U.S. in the last several years and personnel from these plants with 10-15 years of experienced were hired to strengthen the mid-career worker. Utilities use a shadowing process where a worker will shadow a very experience individual for about six months to transfer the knowledge.
Question No. 140
The section says that the NRC has noticed increased examples of nonconservative decisions that facility licensee personnel have made over the past few years. Could you please clarify of what kind are these decisions? What is meant by "nonconservative decisions"? Could you give examples of such decisions?
Answer: NUREG-2165 defines the attribute of "Conservative Bias" as, "Individuals use decision making practices that emphasize prudent choices over those that are simply allowable. A proposed action is determined to be safe to proceed, rather than unsafe in order to stop" (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2165/). Nonconservative decisions are those that run contrary to this definition. This language is derived in part from the principle of a good nuclear safety culture described in IAEA 75-INSAG-3, "Basic Safety Principles for Nuclear Power Plants," Revision 1, issued October 1999 (http://www-pub.iaea.org/mtcd/publications/pdf/p082_scr.pdf), which states, "When any possible conflict in priority arises, safety and quality take precedence over schedule and cost," but it applies to a broader sample of decisions than just those that directly weigh safety and cost against each other. Recent examples include operators failing both to declare equipment inoperable and to take the appropriate actions in accordance with TS, and operators failing to appropriately consider the risk involved with running multiple systems in abnormal configurations.

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 explains the NRC program on human performance. This program has seven major areas: (1) human factors engineering, (2) emergency operating procedures and plant procedures, (3) staffing, (4) fitness for duty, (5) the Human Factors Information System, (6) support for event investigations and for-cause inspections, and (7) training. This section also discusses lessons learned from Fukushima.

Question No. 141
On which NRC requirements about human factors engineering are based to approve power uprates?
Answer: The NRC treats power uprate applications, such as measurement uncertainty recapture, stretch power uprate (SPU), and extended power uprate (EPU), as LARs. Consequently, the NRC reviews and approves them by using processes used to review LARs. The LAR submittal and review processes are governed by 10 CFR 50.90, "Application for Amendment of License, Construction Permit, or Early Site Permit";10 CFR 50.91, "Notice for Public Comment; State Consultation"; and 10 CFR 50.92, "Issuance of Amendment." Additional regulatory guidance for review of power uprates includes Review Standard-001, "Review Standard for Extended Power Uprates," Revision 0, and Regulatory Issue Summary-02-03, "Guidance on the Content of Measurement Uncertainty Recapture Power Uprate Applications," dated January 31, 2002. The NRC has no specific guidance for SPUs. The staff uses previously approved SPUs, along with Review Standard-001, for guidance in reviewing SPU applications. Although it is not a requirement, the NRC staff also uses the guidance provided in NUREG-1764, "Guidance for the Review of Changes to Human Actions," Revision 1, issued September 2007, where applicable. For human factors engineering reviews, the NRC staff uses guidance provided in NUREG-0800, Chapter 18, "Human Factors Engineering," and NUREG-0711, "Human Factors Engineering Program Review Model," issued November 2012.
Question No. 142
Does NRC staff use also double checking to prepare inspections activities related with human performance? How do they include safety culture into the work planning? Do human factors inspections and assessment include also periodic audits to human performance subjects?
Answer: The NRC staff uses the Human Factors Information System (HFIS) to store, sort, and analyze human performance information obtained from NRC inspection and licensee event reports. However, the NRC staff does not conduct routine inspections of human performance to verify or validate the information stored in the HFIS. Similarly, the NRC staff does not routinely conduct safety culture inspections; however, inspections may be informed by the information obtained from the HFIS, as necessary. The staff does not conduct periodic audits of human performance. The staff may initiate audits related to implementation of human factors engineering programs by licensees or applicants on a case-by-case basis, when necessary, usually to support other activities, such as review of license amendment requests submitted by licensees, under 10 CFR 50.90.

Question No. 143
About people involved in event investigations and for-cause inspections: Which professional expertise and competences in safety culture are necessary and required? Please describe in detail.
Answer: The NRC staff members who participate in safety culture evaluations and assessments as part of inspection activities are qualified as safety culture assessors through the NRC's inspection qualification program. There are two levels of qualification: Level 1 safety culture assessors are qualified to lead safety culture assessments, while Level 2 safety culture assessors are qualified to participate in safety culture assessments. The qualification program involves a number of training courses, individual study activities, and on-the-job training. A complete list of the knowledge, skills, and abilities required to be a safety culture assessor are in IMC 1245, Appendix C-12, "Safety Culture Assessor Training and Qualification Journal," dated November 9, 2016 (ADAMS Accession No. ML16259A016).
Question No. 144
The U.S. report describes a comprehensive program for human factors. In particular the discussion about human factors engineering is instructive. However, the absence of discussion about certain human performance program elements is notable. Can the Contracting Party explain why there is no emphasis on various aspects including human performance indicators; human actions in safety analysis; low level event trending; coaching and use of human performance event-free tools (EFTs)?
Answer: The NRC staff uses the Human Factors Engineering Program Review Model, as described in NUREG-0711, to review the human factors engineering (HFE) aspects of the plant that are developed, designed, and evaluated in a structured manner, using HFE principles that are acceptable to the NRC staff. The criteria that the NRC staff uses to determine the acceptability of such programs are based on the relevant requirements found in the NRC regulations, as described in NUREG-0800, Chapter 18. The licensees and applicants may choose to use various human performance tools in their human error prevention and detection programs and to improve organizational performance. The use of such tools is common in the industry and is advocated by various industry groups; for example, INPO (INPO 05-005, "Guidelines for Performance Improvement at Nuclear Power Stations"). The NRC does not require the use of such tools.
Question No. 145
The U.S. Report states that based on review, maintenance of severe accident management guidelines (SAMGs) was inconsistent from site-to-site. Subsequently proposed requirements were issued for comment in 2015. Assuming that enforcement of these requirements would reduce the inconsistency, can the Contracting Party provide the interim measures which are being applied to mitigate the current gap?
Answer: In SECY-15-0065, "Proposed Rule: Mitigation of Beyond-Design-Basis Events," dated May 15, 2015, submitted for Commission approval to publish for public comment, the staff included a proposed requirement related to SAMGs. In SRM-SECY-15-0065, dated August 27, 2015 (ADAMS Accession No. ML15239A767), the Commission directed the staff to remove the proposed SAMG requirement and to instead update the ROP to oversee the voluntary initiative of the SAMGs. With the oversight, the NRC will be able to ensure consistency. Section 16.3 on page 188 of the U.S. 7th National Report describes the measures taken in the United States with regard to SAMGs.

Question No. 146
The U.S. NRC has a newly revised procedure (IP 95003) that describes how the regulator undertakes safety culture assessment activities. The U.S. Report states that “Insights gained from the inspections were used as a basis to substantially update IP 95003 and Inspection Manual Chapter 0305 in December 2015.” What were the insights that motivated the changes in the procedure? Have these changes in the procedure motivated any change to the U.S. NRC policy on safety culture?
<u>Answer</u>: The assessment of the NRC’s performance associated with the Browns Ferry Red Finding, up to and including the 95003 Supplemental Inspection, identified “Best Practices.” The NRC revised IP 95003 to provide additional guidance associated with inspection preparation, in-plant observations, and inspection readiness. The NRC made no significant changes to the guidance associated with safety culture assessment activities. However, the staff continuously evaluates the guidance to determine whether changes are needed, based on the results of 95003 inspections and operating experience. The NRC regularly updates its procedures based on lessons learned from implementing them. The agency updated the safety culture portions of IP 95003 in December 2015 primarily to align the safety culture terms in the IP with the results of the safety culture common language initiative, which established a common terminology for the NRC and the U.S. nuclear industry to use in discussing safety culture. Other updates to IP 95003 included (1) clarifying expectations for the timing of supplemental inspections for Column 4 of the ROP Action Matrix, or portions thereof, to ensure that the NRC’s assessment of continued operation and consideration of additional regulatory actions are completed in a timely manner, and (2) additional consideration of inspection preparation activities, as outlined in IMC 2515, “Light-Water Reactor Inspection Program—Operations Phase,” Appendix B, “Supplemental Inspection Program,” Attachment 2, “Supplemental Inspection Best Practices,” dated December 18, 2015. The changes to the procedure do not reflect any changes to the NRC’s SCPS.
Question No. 147
The use of subcontracting may have an impact on organizational reliability and safety. New regulations in France now provide that (a) major safety related activities can only be performed by first or second tier subcontractors and that (b) the control of NPP operation, including analysis of incidents of safety related findings, and emergency preparedness and response matters cannot be dealt by contractors or subcontractors. Is there any requirement in the US nuclear regulation that aims at a better control of contractors and subcontractors activities at NPP sites? Has subcontracting been identified as a potential issue regarding nuclear safety?
<u>Answer</u>: As required by 10 CFR Part 50, Appendix B, U.S. nuclear reactor facilities are responsible for the establishment and execution of a quality assurance program. They may delegate activities to others (e.g., contractors, agents, and consultants), but they retain the responsibility for quality assurance. Appendix B to 10 CFR Part 50 requires licensees that procure material, equipment, or services from contractors or subcontractors to conduct audits to ensure that suppliers implement an effective quality assurance program, consistent with the requirements of Appendix B and the licensee’s technical requirements. Criterion VII of Appendix B describes the current quality assurance criteria for control of purchased, material, equipment, and services. There is no limit to the tiers of subcontractors and their ability to perform certain work, so long as it meets the requirements of 10 CFR Part 50, Appendix B.

The NRC considers control of procured materials, parts, and services to be important to quality and thus to overall nuclear safety.

Question No. 148

The USA report that in case of changes in the ownership, organisational changes may hamper nuclear safety. It would be appreciated if the USA could share their experiences in this field with their licensees. Was there a need for the U.S.NRC to require corrective actions from their licensees, and if so, what were the main findings?

Answer: During the review of a license transfer request, the NRC will examine the acceptability of any proposed changes to the technical organization or personnel qualifications. The objective of this review is to ensure that the corporate management is involved with, informed of, and dedicated to the safe design, construction, testing, and operation of the nuclear plant. The review also ensures that sufficient technical resources have been, are being, and will continue to be provided to adequately accomplish these objectives. The NRC's guidance for the review of organizations and changes thereto is in Chapter 13, "Conduct of Operations," of NUREG-0800 (ADAMS Accession No. ML15005A449). To date, the NRC has not encountered any proposed organizational changes during the LAR process that would have hampered or interfered with the safe operation of a nuclear power plant.

Question No. 149

In chapter 12.3.1, the USA report on evaluations of requests to transfer facility operating licences. Could the USA report for which plants in the reporting period such evaluations were performed and what where the main findings with respect to organisational issues?

Answer: During the period from August 1, 2013, through July 31, 2016, the NRC has approved the direct or indirect transfer of licenses for the following operating reactor units:

- Comanche Peak Nuclear Power Plant, Units 1 and 2 (ADAMS Accession No. ML16096A266)
- Perry Nuclear Power Plant, Unit 1 (ADAMS Accession No. ML16078A092)
- Brunswick Steam Electric Plant, Units 1 and 2 (ADAMS Accession No. ML15161A121)
- Shearon Harris Nuclear Power Plant, Unit 1 (ADAMS Accession No. ML15161A121)
- Waterford Steam Electric Station, Unit 3 (ADAMS Accession No. ML15138A440)
- River Bend Station, Unit 1 (ADAMS Accession No. ML15138A440)
- Susquehanna Steam Electric Station, Units 1 and 2 (ADAMS Accession No. ML15054A058)
- R.E. Ginna Nuclear Power Plant (ADAMS Accession No. ML14106A119)
- Nine Mile Point Nuclear Station, Units 1 and 2 (ADAMS Accession No. ML14106A053)
- Calvert Cliffs Nuclear Power Plant, Units 1 and 2 (ADAMS Accession No. ML14105A472)

Some license transfers involve changes to the operational organization. For these transfers, the NRC evaluates the changes and documents its findings in the safety evaluation. Included above are the ADAMS accession numbers for the approval of the license transfers, including the safety evaluations. In general, for the license transfers that involved organizational changes, the NRC found that the new owners were technically and financially qualified to be the licensed owner or operator of the nuclear power plant(s). For the transfers listed above, the NRC did not encounter any issues with the organizational changes.
Question No. 150
The seventh Report of the USA reported on a human-factors aspect of the 2010 event at the H.B. Robinson NPP. It was stated that the loss of a reactor coolant pump seal cooling was not recognised by the operators due to a nonstandard emergency operating procedure. With respect to the quoted document 05000261/2010501, it seems to be rather more a failure in the procedure than a wrong execution of the procedure due to a nonstandard format. Could the USA discuss in more detail the reason why the operator was misled due to the nonstandard format and why it was not a fault in the procedure itself? Does this have an impact on other NPPs relying on similar emergency operating procedures as used at the H.B. Robinson NPP?
Answer: The NRC inspection reports 05000261/2010004 and 05000261/2010501 detail the finding at the H.B. Robinson Steam Electric Plant (ADAMS Accession No. ML103160382) and identify the apparent violation for failure to establish and maintain an adequate EOP. Also, the NRC inspection found that inadequate training on EOPs contributed to operators inadequately implementing the steps of the licensee's PATH-1 procedure, which is a complication of Westinghouse Owners Group procedures E-0, "Reactor Trip or Safety Injection," and E-1, "Loss of Reactor or Secondary Coolant," during the events of March 28, 2010. From the human performance perspective, this violation is indicative of issues related to both Element 9, "Procedure Development," and Element 10, "Training Program Development," of the HFE program described in NUREG-0711. The NRC staff determined that the issues identified at H.B. Robinson were plant specific. To date, the NRC staff has not identified any generic issues related to the 2010 event at H.B. Robinson.
Question No. 151
With reference to article 12, page 144 of the American national report, it is mentioned in the second paragraph of page 144 that the US NRC published new requirements to establish mitigation strategies against beyond-design-basis external events (BDBEEs). With respect to the information provided in the article in question, Korea would like to inquire the following questions: 1) Are there any regulatory documents which describe specific requirements to systematically address human performance issues in the development and implementation process of the mitigation strategy against beyond-design-basis external events? If not, what is the current regulatory position in addressing human performance issues related to the mitigation strategy? 2) Is there any plan to revise the current regulatory documents related to human factors (e.g., NUREG-0711, ISGs, etc.) to systematically address human performance issues in the development and implementation of the BDBEE mitigation strategy?
Answer: (1) The regulatory documents that govern the development and implementation process for mitigating strategies to address beyond-design-basis external events are JLD-ISG-2012-01, which endorsed industry guidance document NEI 12-06. Both JLD-ISG-2012-01 and NEI 12-06 have been revised several times, to incorporate the lessons learned in the course of developing and implementing the mitigating strategies under Order EA 12-049. The currently effective version of JLD-ISG-2012-01 is Revision 1, which is

available at ADAMS Accession No. ML15357A163; NEI 12-06, Revision 2, is available at ADAMS Accession No. ML16005A625.

(2) The NRC is currently updating NUREG-0800, Chapter 18, to more specifically address the applicability of NRC guidance documents to the review of beyond-design-basis events. For example, NUREG-0800, Chapter 18, Draft Revision 3, Section I.5, "Important Human Actions," states, in part, "This review guidance may also be useful in reviewing operator manual actions associated with…beyond design basis events." Further, Attachment B, "Methodology To Assess the Workload of Challenging Operational Conditions in Support of Minimum Staffing Level Reviews," of Chapter 18, Section 1, states that the applicant should consider various plant conditions, personnel tasks, and situational factors in its sample of challenging conditions for workload analysis, including I&C and human-system Interface failures and degraded conditions that encompass reasonable, risk-significant, beyond-design-basis events. There are no plans to revise NUREG-0711 to address human performance issues in the development and implementation of mitigation strategies for beyond-design-basis external events. The NRC is currently developing JLD-ISG-2012-01, Revision 2, to endorse NEI 12-06, Revision 4 (ADAMS Accession No. ML16354B421). This will be the last revision to this ISG document; RG 1.226, "Flexible Mitigation Strategies for Beyond-Design-Basis Events," will contain future guidance and will be issued in conjunction with the MBDBE rulemaking. In addition, the NRC has ongoing research to examine human performance under extreme environmental conditions. Upon completion, the relevance of research findings will be assessed for use in future regulatory guidance.

Question No. 152

With reference to article 12, page 144 of the American national report, it is described in the third and fourth paragraphs of page 144 that there are various regulatory documents which address staffing issues of operating shifts such as 10 CFR 50.54(m), NUREG-1791, NUREG/CR-6838. The Near Term Task Force (NTTF) Report points out staffing issues related to emergency response organization in severe accident situations like Fukushima. With respect to the information provided in the article in question and the points made in the Near Term Task Force Report, Korea would like to inquire the following questions:

1) Are there any regulatory documents on how to address staffing issues related to emergency response personnel (e.g., staffing plan validation related to the implementation of BDBEE mitigation strategy) identified from the lessons learnt from the Fukushima accident? If there are no such regulatory documents, then what is the current regulatory position on the validating the quality of emergency response organization staff?
2) Is there any plan to revise the current regulatory documents related to human factors (e.g., NUREG-0711, ISGs) to address staffing issues related to the lessons learnt from Fukushima?

Answer: (1) The NRC addresses onshift staffing for personnel assigned emergency plan implementation functions in 10 CFR Part 50, Appendix E, Section A.9 (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appe.html), which requires nuclear power reactor licensees in the United States to perform a detailed analysis to confirm the adequacy of the staffing. The regulatory guidance for this analysis is in NSIR/DPR-ISG-01 (ADAMS Accession No. ML113010523), supported by the industry guidance document NEI 10-05 (ADAMS Accession No. ML111751698). The NRC issued a request for information on the related subject of staffing for the beyond-design-basis event mitigation strategies by letter dated March 12, 2012, under 10 CFR 50.54(f). NEI 12-01 (ADAMS Accession No. ML12125A412), which the NRC endorsed in a letter dated May 15, 2012 (ADAMS Accession No. ML12131A043), contains the guidance for performing the analysis requested in

that letter. The NRC discusses the suitability of the guidance in NEI 12-01 for use in staffing for the MBDBE rulemaking in DG-1319, which the NRC expects to issue as RG 1.228 in conjunction with the final MBDBE Rule. In addition to the guidance for staffing analyses for emergency plan implementation, the NRC has endorsed guidance for the validation of the licensees' strategies and guidelines under the MBDBE Rule. That guidance appears in Appendix E to NEI 12-06, Revision 2 (ADAMS Accession No. ML16005A625), which the NRC endorsed in JLD-ISG-2012-01 (ADAMS Accession No. ML15357A163). (2) The proposed endorsement of the validation process in NEI 12-06, Appendix E, was included in DG-1301, "Flexible Mitigation Strategies for Beyond-Design-Basis Events," issued November 2015 (ADAMS Accession No. ML13168A031), for use in the MBDBE Rule. The NRC will publish this guidance as RG 1.226 in conjunction with the MBDBE Rule when it is finalized. The agency has no current plans to update NUREG-0711 for staffing issues related to lessons learned from Fukushima.
Question No. 153
This section mentions an alternative method for managing cumulative fatigue of NPP personnel. Could you please explain this method?
<u>Answer</u>: The NRC regulatory requirements for managing fatigue are codified in 10 CFR Part 26, "Fitness for Duty Programs," Subpart I, "Managing Fatigue." The specific requirements for work hour controls are found in 10 CFR 26.205, "Work Hours." The original requirements for managing cumulative fatigue that were instituted when the NRC issued the rule in 2008 are in 10 CFR 26.205(d)(3). The alternative method for managing cumulative fatigue is described in 10 CFR 26.205(d)(7), which allows the licensees and other entities subject to the rule to choose whether or not to implement the alternative approach, in lieu of compliance with the requirements for minimum days off in 10 CFR 26.205(d)(3). Additional information on the Fitness-for Duty Rule, including some frequently asked questions on the implementation of the rule, are available at https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty.html.
Question No. 154
In the report it is mentioned that: "The NRC has been processing a few industry requests to transfer operating licenses due to changes of ownership of nuclear power plants". Please, could you elaborate on this issue, with some additional information: 1) Technical bases for the potential impact of changes of ownership on nuclear power plants safety, 2) Rulemaking, governing documents and process and 3) Recent experience and, when publicly available, links to safety evaluation reports.
<u>Answer</u>: The provisions of AEA Section 184 and the NRC's regulations at 10 CFR 50.80, "Transfer of Licenses," stipulate that NRC approval is required to transfer control of the ownership and operating authority responsibilities within the facility operating license. Specifically, 10 CFR 50.80(a) states that "no license for a production or utilization facility, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission shall give its consent in writing" (https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0080.html).

Transfer requests can include either “direct” transfers, which are generally those that involve transfer of ownership or operating authority of the plant itself from one entity to another (e.g., the sale of a plant), or “indirect” transfers, which generally involve transfers of ownership or control of the licensee itself rather than the facility (e.g., the formation of a new parent holding company above a licensee).

An application for transfer of a license is required by 10 CFR 50.80(b) to include as much of the technical and financial qualifications information on the proposed transferee as would be required for an initial license. After appropriate notice to interested persons (e.g., members of the public), an application for the transfer of a license may be approved, if the Commission determines that (1) the proposed transferee is qualified to be the holder of the license and (2) the transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto. For indirect license transfers, the Commission has held, with respect to the first determination, that it will approve an application if the Commission determines that the proposed transaction that would affect an indirect transfer of control of the license will not affect the qualifications of the licensee to hold the license. An approval of the transfer of the license will be accomplished through an order authorizing the transfer and, as necessary, a conforming license amendment will be approved by the Order and will be issued when the transfer is completed.

Other Federal (e.g., Federal Energy Regulatory Commission, Federal Trade Commission, and U.S. Department of Justice) and State (e.g., Public Service Commissions) approvals may be needed before the proposed transfer can be executed. These organizations have jurisdiction over issues such as antitrust, rates, and any public benefit. The NRC reviews and authorizes, if acceptable, the proposed transfer within the NRC’s jurisdiction. However, transfer cannot be executed until the applicant has received regulatory approvals from all the governmental agencies with jurisdiction.

Processing of applications for approval of the transfer of an operating license is, in many respects, similar to the processing of other licensing actions. Submittals are made to the NRC under oath and affirmation by applicants (current and proposed licensees). If the application is not made by the current licensee, the applicant should clearly show and state that the request is being made on behalf of the current licensee, unless there is a hostile acquisition involved, which would be extremely rare. The NRC conducts staff evaluations and prepares a safety evaluation that will accompany the order. Differences are primarily because of the content of the staff review (which deals predominately with financial assurance for operations and decommissioning, foreign ownership, and onsite and offsite financial protection in the form of insurance and ownership capabilities). In direct transfers, a license amendment will likely be issued upon consummation of the transfer to conform the license and TS to reflect the new owner and operator.

The transfer of the license, direct or indirect, normally does not result in any physical changes to the plant or any changes to the conduct of operations. Thus, license transfers do not involve the type of technical issues that would affect operation. Usually, the onsite organization and plant staff, including senior managers, will remain essentially unchanged by the license transfer, and plant procedures and policies typically do not change. Further, the NRC’s safety regulations and licensee compliance responsibilities do not change as a result of a license transfer. Therefore, the license transfer will most likely not adversely affect the safety and health of the public.

Office Instruction LIC-107, “Procedures for Handling License Transfers,” Revision 1, December 2008 (ADAMS Accession No. ML081910478) contains the NRC’s procedure for handling and processing license transfer requests.

ADAMS accession numbers for license transfers issued during the reporting period are provided below:

- Comanche Peak Nuclear Power Plant, Units 1 and 2 (ADAMS Accession No. ML16096A266)
- Perry Nuclear Power Plant, Unit 1 (ADAMS Accession No. ML16078A092)
- Brunswick Steam Electric Plant, Units 1 and 2 (ADAMS Accession No. ML15161A121)
- Shearon Harris Nuclear Power Plant, Unit 1 (ADAMS Accession No. ML15161A121)
- Waterford Steam Electric Station, Unit 3 (ADAMS Accession No. ML15138A440)
- River Bend Station, Unit 1 (ADAMS Accession No. ML15138A440)
- Susquehanna Steam Electric Station, Units 1 and 2 (ADAMS Accession No. ML15054A058)
- R.E. Ginna Nuclear Power Plant (ADAMS Accession No. ML14106A119)
- Nine Mile Point Nuclear Station, Units 1 and 2 (ADAMS Accession No. ML14106A053)
- Calvert Cliffs Nuclear Power Plant, Units 1 and 2 (ADAMS Accession No. ML14105A472)

Question No. 155

In the sub-article 12.4, Fukushima Lessons Learned, it is mentioned that “There are human factors considerations to many of the Fukushima lessons learned”.

Please, could you provide some additional information on: 1) The role played (and the reasoning supporting that role) by NRC human factors specialists on the Fukushima accident assessment, on the orders issued and on the assessments and inspections of the US nuclear facilities improvement plans, and 2) Are there organizational factors considerations (at the licenses level, at the utilities level, at the regulatory body level, at the government level and at the society level) to many of the Fukushima lessons learned? If yes, please, explain.

Answer: (1) The NRC established a senior level task force (NTTF) following the events at Fukushima in 2011. The NTTF developed a set of recommendations, which led to the NRC issuing, among other items, Order EA-12-049 (ADAMS Accession No. ML12054A736). In developing its recommendations, NTTF benefitted from insights from a broad range of NRC experts, including HFE and operator licensing specialists. Further, HFE specialists participated in the development of the MBDBE proposed rule (80 FR 70609; November 13, 2016). In particular, HFE specialists emphasized the importance of including the requirements for an integrated response capability, which would require the integration of beyond-design-basis events response capabilities with the EOPs, staffing, and supporting organizational structure

requirements. HFE specialists further supported the NRC staff during the development of JLD-ISG-2012-01 (ADAMS Accession No. ML15357A163). NRC inspectors used input from HFE specialists during the conduct of audits and inspections at licensees' sites. (2) The industry has set up National Strategic Alliance for FLEX Emergency Response (SAFER) Centers. The National SAFER Centers manage additional portable equipment that can be used to provide offsite mitigation capability. Various owners groups developed generic guidance for using mitigating strategies. The NRC formed JLD, with the focus on the recommendations for enhancing U.S. commercial nuclear power plant safety, including overseeing the industry's implementation of the orders. The NRC considered organizational factors in developing the MBDBE proposed rule, which would establish new requirements for an integrated response capability, to include beyond-design-basis response capabilities, sufficient staffing, EOPs, and a supporting organizational structure with defined roles, responsibilities, and authorities for directing and performing the actions required by the rule.
Question No. 156
The report states the Human Factors information System, which is designed to store, retrieve, sort and analyze human performance information extracted from NRC inspection and licensee event reports. Do the data in this system also help to show trends of licensees' deteriorating safety performance? Please comment on this issue.
<u>Answer</u>: The NRC analyzes the data consolidated in the HFIS for trends in human performance on an annual basis. This trend analysis is conducted for overall industry performance and is summarized by the Human Factors Technical Review Group, comprising NRC staff. The data are analyzed to determine if there are any industrywide trends that may be indicative of potential generic issues. Occasionally, data may be used to support inspector requests for licensee-specific data. The NRC management uses this information to inform decisions on additional regulatory oversight and focused inspection activities. The NRC staff notes that the HFIS is used as a performance information database and has not been validated as a method for identifying deteriorating performance.
Question No. 157
On November 13, 2015, the US NRC published for public comment proposed requirements related to the mitigation of beyond-design-basis events. New strategies for the mitigation of beyond-design-basis external events (also known as diverse and flexible coping strategies or FLEX guidelines) are integrated with emergency operating procedures, such that they support an integrated accident response capability. Are there any results from the public comments? When FLEX procedures are going to be implemented at US NPPs?
<u>Answer</u>: The NRC published its resolution of public comments on the MBDBE Rule in conjunction with the final rule in 2017 (ADAMS Accession No. ML16301A005). Nuclear power plants in the United States implement FLEX procedures under NRC Order EA-12-049, which the NRC plans to make generically applicable in the MBDBE Rule in 2017. Most licensees are in compliance with the Mitigating Strategies Order. A limited number of licensees have received extensions to the order due date of December 31, 2016, because their particular mitigating strategies rely on having the hardened vent installed.
Question No. 158
Section 12.3.3 describes Shift Staffing. It states, "The staff made revisions to its RG, as needed, to address control room staffing for small modular reactors in preparation for receipt of

the NuScale small modular reactor design certification application." What are the revisions that were made and will additional guidance be needed for other designs?
Answer: In 2015, the NRC revised the regulatory guidance in NUREG-0800, Chapter 18, which resulted in draft Revision 3 (ADAMS Accession No. ML13108A095). Revision 3 includes Attachment B, "Methodology to Assess the Workload of Challenging Operational Conditions In Support of Minimum Staffing Level Reviews," which describes a methodology to identify high-workload operational conditions and analyze the workload associated with them. The NRC intends to use the guidance in Attachment B of NUREG-0800, Chapter 18, with the regulatory guidance in NUREG-1791, "Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m)," issued July 2005 (ADAMS Accession No. ML052080125), to evaluate whether a staffing plan meets performance requirements and acceptably supports safe operation. NUREG/CR-7126, "Human-Performance Issues Related to the Design and Operation of Small Modular Reactors," issued June 2012 (ADAMS Accession No. ML12179A170), identifies a set of potential human-performance issues that may be considered in the NRC's reviews of SMR designs and future research activities. Future research activities may result in the publication of additional guidance that would be applicable to SMRs and possibly to other designs.

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.

The NRC has made no changes to the quality assurance regulatory guidance or licensees' quality assurance programs as a result of the Fukushima accident. However, continued compliance with existing programs and requirements is an important aspect of implementation of the lessons learned from Fukushima, which are further discussed in Sections 1.3.1 and 1.3.3 of this report.

Question No. 159
Can the Contracting Party clarify if the overall quality assurance program focuses on all risks, or is there a graded approach being applied based on the risk of the program to impact safety? Does the program allow for additional auditor effort and time on the higher risk areas and therefore is the frequency of audits adjustable based on program risk to safety?
Answer: The overall quality assurance program focuses on all activities affecting the safety-related functions of those SSCs that are relied upon to ensure (1) the integrity of the reactor coolant pressure boundary, (2) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (3) the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guideline exposures of 10 CRF 50.34(a)(1) or 10 CFR 100.11, " Determination of Exclusion area, Low Population Zone, and Population Center Distance." Therefore, Appendix B to 10 CFR Part 50 establishes the quality assurance requirements for the design, manufacture, construction, and operation of nuclear power plant SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. While 10 CFR Part 50, Appendix B, does not explicitly define a risk-informed, graded approach for quality assurance, it does allow flexibility to the level of effort to ensure quality. For instance, Criterion VII requires, in part, that measures for control of such items include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor source, and examination of products upon delivery. Therefore, licensees and contractors are able adjust their focus and level of effort to ensure quality based on safety importance and the safety function of procured material, equipment, and services. Normally, the level of quality applied to safety-related SSCs by licensees is governed by requirements in Appendix B to 10 CFR Part 50 and less stringent requirements may be applied to other SSCs, depending on their safety classification in Chapter 3 of the FSAR. The NRC's inspections for compliance with Appendix B to 10 CFR Part 50 may be applied in a graded fashion based on the safety significance of an SSC, in combination with other factors, should the NRC desire to do so. If an operating license or COL for a commercial nuclear power plant has been modified to allow a licensee to voluntarily comply with requirements in 10 CFR 50.69, as an alternative to the requirements in Appendix B, then a graded approach may be applied in accordance with the requirements in 10 CFR 50.69 and the guidance in RG 1.201 (ADAMS

Accession No. ML061090627). Likewise, the NRC's inspections for compliance with requirements in 10 CFR 50.69 may be applied in a graded fashion, based on the safety significance of an SSC, in combination with other factors, should the NRC desire to do so.

Question No. 160

This article of the report states that the U.S. NRC inspectors "do not inspect other aspects of quality assurance program implementation in the baseline inspection program". Does the U.S. NRC need to provide an annual or regular update to its Commission on the adequacy of the nuclear reactor licensees' Operations Quality Assurance Program? If so, how does the U.S. NRC reach the conclusion on the licensees' compliance with 10 CFR Part 50, especially for elements that are not specifically related to the performance of items important to safety, e.g. Organization, Control of Measuring and Test Equipment, and Audits?

Answer: The Commission does not require nor receive an annual or regular update specific to the adequacy of the licensees' quality assurance programs. It does, however, receive regular updates on licensees with safety-significant performance issues, regardless of whether or not those issues are attributed to licensee quality assurance programs.

The NRC's ROP baseline inspection program does not seek nor produce a programmatic assessment of licensee compliance with 10 CFR Part 50. Rather, it relies on a risk-informed, performance-based sample inspection process in which findings are individually evaluated for safety significance and compliance with regulatory obligations, including 10 CFR Part 50. The inspection program is designed to augment performance indicators to ensure all cornerstones of safety are adequately evaluated for all licensees. Findings of significance (i.e., greater than Green) are input into the Action Matrix to determine the appropriate level of, for example, follow-up inspections and escalation of internal and external communications.

The focus of the NRC's inspection efforts are meant to be performance based and target ongoing activities, rather than specifically evaluating the 18 criteria of Appendix B to 10 CFR Part 50. The core of the NRC inspection program for nuclear power plants is carried out by resident (onsite) inspectors; at least two inspectors are assigned to each site. Inspection specialists from the regional offices review plant security, emergency planning, radiation protection, environmental monitoring, periodic testing of plant equipment and systems, fire protection, construction activities, and other specialized areas. During the course of a year, NRC specialists may conduct 10 to 25 routine inspections at each nuclear power plant, depending on the activities at the plants and problems that may occur. Team inspections regularly review fire protection, plant design, and corrective actions. Special team inspections may focus on a specific plant activity, such as maintenance or security, or a team may be sent to the plant to look at a specific operating problem or accident. Therefore, the NRC inspects the nuclear power plant as follows:

- Continuously, resident inspectors monitor licensee activities in accordance with the baseline inspection program.
- Periodically, regional inspection specialists conduct inspections of each plant in their region.
- Semiannually, each region formulates a schedule of specialist inspections for assessing plant performance for the following year. They factor into their schedule plant performance for the previous year so that inspection resources are focused on plants with declining performance.

- As needed, the regional inspectors conduct special (supplemental) inspections of those plants that exceeded established thresholds during routine inspections and, therefore, require heightened agency scrutiny.

The NRC documents the findings for an inspection in a report. Routine inspection reports are typically issued every quarter. Other reports are issued within weeks of the inspection. Regardless of a plant's performance, inspectors document their findings in a report for every plant in their region following their inspection and give that report to the licensee for information and action, as appropriate.

Lastly, the significance of each inspection finding is established using the NRC's significance determination process. The number and significance of the findings are used collectively with performance indicators to determine the agency's response.

Question No. 161

AP1000 design comprises some RTNSS SSCs and special QA rules are applied for them. Question: How to determine the RTNSS SSCs? Is there any regulations and standards for RTNSS SSCs? and what's the regulatory requirements for RTNSS SSCs?

Answer: Regulations do not govern the regulatory treatment of nonsafety systems (RTNSS). The NRC documents listed below establish the scope, criteria, and process used to determine RTNSS for passive plant designs. Applicants submit their evaluation of RTNSS in the final SAR, and the NRC reviews the evaluation using procedures and acceptance criteria in NUREG-0800, Section 19.3.

(1) SECY-94-084, "Policy and Technical Issues Associated with the Regulatory Treatment of Nonsafety Systems in Passive Plant Designs," dated March 28, 1994 (ADAMS Accession No. ML003708068) and associated SRM, June 30, 1994 (ADAMS Accession No. ML003708098).

(2) SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Nonsafety Systems (RTNSS) in Passive Plant Designs," dated May 22, 1995 (ADAMS Accession No. ML003708005), and associated SRM, June 28, 1995 (ADAMS Accession No. ML003708019).

(3) SECY-96-128, "Policy and Key Technical Issues Pertaining to the Westinghouse AP600 Standardized Passive Reactor Design," June 12, 1996 (ADAMS Accession No. ML003708224), and associated SRM, January 15, 1997 (ADAMS Accession No. ML003755486).

Requirements for AP1000 RTNSS SSCs vary among the SSCs. The applicable requirements are in Chapter 22 of NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," issued September 2004, and Supplement 1 and Supplement 2 to that report, issued December 2005 and September 2011, respectively. All of these documents are available at https://www.nrc.gov/reactors/new-reactors/design-cert/ap1000.html.

Question No. 162
The report states “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.” Question: Could you provide more details about the approaches to accomplishing this objective?
Answer: A fundamental goal of the ROP is to establish confidence that each licensee is effectively detecting, correcting, and preventing problems that could affect cornerstone objectives. A key ROP premise is that weaknesses in licensees’ problem identification and resolution programs will manifest themselves as performance issues that will be identified during the baseline inspection program or performance indicators crossing predetermined thresholds. However, several aspects of problem identification and resolution are not specifically addressed by either the individual cornerstone performance indicators or other baseline inspections. The NRC performs routine problem identification and resolution reviews, semiannual trend reviews, annual followup of selected issues, and biennial team inspections, as required. Furthermore, NRC inspections include samples from issues identified through NRC and industry operating experience exchange mechanisms (e.g., NRC generic communications, reports associated with 10 CFR Part 21, nuclear steam system supplier vendor reports, EPRI reports and operating experience reports from similar facilities, NRC operating experience smart samples). This sample selection is intended to help ensure that the NRC can obtain insights into a licensee’s corrective action program throughout an assessment cycle. • IP 71152, dated February 26, 2015 (ADAMS Accession No. ML14316A042), objectives include the following: 01.01 To evaluate the effectiveness of the licensee’s corrective action program in identifying, prioritizing, evaluating, and correcting problems. 01.04 To confirm the licensee’s appropriate use of industry and NRC operating experience. 01.07 To follow up on corrective actions for selected previously identified compliance issues (e.g., noncited violations). • Associated IP 71152 inspection requirements include the following: Routine Review (integrated into all baseline IPs): a. Screen each item entered into the corrective action program to select the best samples for follow-up. b. Verify that corrective actions commensurate with the significance of the issue have been identified and implemented. f. In completing a. through e., above, evaluate whether the licensee should perform an evaluation in accordance with 10 CFR Part 21 of any defect or nonconformance that has been identified. [C3] Semiannual Trend Review Perform a semiannual review to identify trends (either NRC- or licensee-identified) that might indicate the existence of a more significant safety issue. Annual Follow--up of Selected Issues

Ensure that the licensee has planned and/or implemented corrective actions commensurate with the significance of identified issues. Select four to eight issues (i.e., samples) per year for an in-depth review. Biennial Team Inspection Use risk insights to select issues that have been processed through the licensee's corrective action program since the last biennial team inspection. For a subset of the chosen samples, the scope of the review should be expanded to at least 5 years.
Question No. 163
The report discusses ISO 9001 standard, but does not discuss another international standard GS-R-3(GSR PART 2). Question: How to consider the GS-R-3 and its compliance with 10 CFR 50 Appendix B?
Answer: IAEA GS-R-3 was superseded by IAEA GSR Part 2, "Leadership and Management for Safety." Both documents addressed management systems at a high level, quality assurance being one of those systems. As discussed in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," dated July 9, 2003(https://www.nrc.gov/reading-rm/doc-collections/commission/secys /2003/secy2003-0117/2003-0117scy.pdf#pagemode=bookmarks), the NRC performed a comparison on a lower tier IAEA document, IAEA 50-C-Q, "Code on the Safety of Nuclear Power Plants: Quality Assurance" (now superseded). While the comparison of IAEA 50-C-Q with 10 CFR Part 50, Appendix B, was not documented, the criteria in the two documents were found to complement each other. While the requirements of GS-R-3 cover management systems for regulatory bodies, the requirements of Appendix B to 10 CFR Part 50 cover similar activities for licensees. However, the NRC has not performed a documented comparison of 10 CFR Part 50, Appendix B, and IAEA GSR Part 2.
Question No. 164
In the 7th national report it is reported that the NRC reviewed options for adapting the widely accepted international quality standard ISO 9001:2000. Could the USA explain whether a review of the latest version ISO 9001:2015 was also considered? What supplemental requirements does NRC see when applying ISO 9001 in the nuclear industry, especially regarding nuclear power plants?
Answer: SECY-03-0117 reports the results of the NRC staff's effort to review international quality assurance standards against the existing framework in 10 CFR Part 50, Appendix B. In doing so, the NRC staff assessed approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework. More specifically, the NRC staff reviewed International Standards Organization (ISO) 9001:2000, "Quality Management System (QMS)—Requirements," and compared it to Appendix B quality requirements. The staff reported the results of that review in SECY-03-0117, which also identifies supplemental requirements when applying ISO 9001. To date, the NRC has not made a similar comparison of ISO 9001:2015, as there was no compelling reason to further consider the ISO 9001 standard, following the comparison reported in SECY-03-0117.
Question No. 165
Could the USA discuss the objective of the NRC's vendor inspection programme in the context of the responsibility of the licensee for quality assurance of his manufactures and suppliers?
Answer: Licensees must implement 10 CFR Part 50, Appendix B, for activities affecting safety-related plant equipment. The objective of the NRC's vendor inspection program is to

encourage licensee oversight of its suppliers and to encourage compliance by nuclear vendors. In 10 CFR Part 50, Appendix B, the NRC states that licensees may delegate quality assurance activities to contractors, vendors, and agents, but the licensee retains responsibility for the quality assurance program. As such, licensees, either individually or as a joint effort, take measures (e.g., audits, surveys, inspections) to ensure control of purchased materials, equipment, and services. Each year, the NRC performs vendor inspections at contractors, manufacturers, and suppliers that supply materials, equipment, and services in accordance with 10 CFR Part 50, Appendix B. Based on NRC findings, the agency communicates directly with the vendor and with the nuclear industry's Nuclear Utilities Procurement Issues Committee (NUPIC). Other stakeholders, including the public, are also able to access NRC inspection reports at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html.

Question No. 166

Does NRC specify requirements related to Licensees' Organizational Structure for construction stage of NPPs, as a part of Quality Assurance Program?

Answer: The NRC does specify requirements related to licensees' organizational structure for the construction stage of nuclear power plants, as a part of the quality assurance program in Appendix B to 10 CFR Part 50 and, in particular, Criterion I, "Organization." Appendix B to 10 CFR Part 50 establishes the overall quality assurance requirements for the design, manufacture, construction, and operation of nuclear power plant SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

RG 1.28 (ADAMS Accession No. ML100160003) describes methods that the NRC staff considers acceptable for complying with 10 CFR Part 50, Appendix B, during the design and construction of nuclear power plants.

Question No. 167

The report states "The NRC has developed or endorsed quality assurance guidance for use by the NRC staff, applicants for construction permits or operating licenses, and licensees. This guidance is applicable to the design, construction, and operational phases of a nuclear power plant."

It may be noted that the QA requirements for construction phase and commissioning phase are significantly different.

How does the existing guidance address the QA requirements for commissioning phase of NPPs?

Answer: Appendix B to 10 CFR Part 50 establishes the overall quality assurance requirements for the design, manufacture, construction, and operation of nuclear power plant SSCs that prevent or mitigate the consequences of postulated accidents that could cause undue risk to public health and safety. RG 1.28, Revision 4 (ADAMS Accession No. ML100160003), describes methods that the NRC staff considers acceptable for complying with 10 CFR Part 50, Appendix B, during the design and construction of nuclear power plants, which would also cover the commissioning phase. RG 1.28, Revision 4, endorses ASME NQA-1-2008/2009 addenda, "Quality Assurance Requirements for Nuclear Facility Applications." Since ASME NQA-1 directly addresses the 18 criteria in 10 CFR Part 50, Appendix B, the NRC staff has found that it provides sufficient guidance for commissioning phases.

Question No. 168
The report states "The NRC has conditionally endorsed the consensus standard ANSI N18.7-1976, “Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants,” issued in February 1976, through RG 1.33, “Quality Assurance Program Requirements (Operations),” Revision 2, issued in February 1978, as complying with the requirements of Appendix B to 10 CFR Part 50". In the light of the recent revision of the IAEA standards on Management system (e.g. GS-R-3, superseded by GSR Part2), did NRC undertake any assessment /comparison of the above mentioned standards/ regulatory guides?. If so can USA elaborate the salient observations?
Answer: In RG 1.33 (ML13109A458), the NRC endorsed American National Standards Institute (ANSI)/ANS 3.2-2012, “Managerial, Administrative and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants.” Within RG 1.33, the NRC staff noted the RG incorporates administrative and quality assurance controls for the operational phase that is consistent with the basic safety principles provided in IAEA GS-R-3 (2006). However, RG 1.33, Revision 3, did not elaborate on the similarities.
Question No. 169
"The NRC has reviewed options for adopting more widely accepted international quality standards, such as International Organization for Standardization Standard 9001, 2000 edition, by considering how international standards compare with the existing framework in Appendix B to 10 CFR Part 50." International Standard ISO 9001, 2008 edition was valid in the reported period (2013 - 2016).
Answer: SECY-03-0117 reports the results of the NRC staff’s effort to review international quality assurance standards against the existing framework of 10 CFR Part 50, Appendix B. In doing so, the staff assessed approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework. More specifically, the NRC staff reviewed ISO 9001:2000 and compared it to Appendix B quality requirements. The staff reported the results of that review in SECY-03-0117, which also identifies supplemental requirements when applying ISO 9001. To date, the NRC has not performed a similar comparison of ISO 9001:2008 or 2015 versions.
Question No. 170
Could you please clarify: Licensees perform audits of all vendors / suppliers to verify that they have effective quality assurance programme in place. Are these audits performed before or after contract is signed with vendor / supplier?
Answer: NRC RESPONSE: NRC requirements do not specify when audits of vendors or suppliers should occur. However, signing a contract with a supplier without first evaluating its quality assurance program could place the licensee at a business risk. INPO RESPONSE: Licenses perform audits of vendors and suppliers both before and after the contracts are signed.
Question No. 171
page 152. Which are the criteria to implement supplemental QA Inspections out of baseline inspection program? How many of this supplemental QA inspections had been performed during the last two years? The pursuit of them are always the same QA criteria or the focus varies?

Answer: As described in IMC 2515, Appendix B, the NRC conducts supplemental inspections above the baseline inspections when licensees have one or more inspection findings or performance indicators that exceed the "Green" band (see https://www.nrc.gov/docs/ML1520/ML15204A007.pdf). Quality assurance is not the only aspect covered by supplemental inspections; a wide range of nuclear safety aspects are also addressed. Supplemental inspections will typically focus on the following quality assurance criteria: organization, design control, procedures, corrective action, and audits. The NRC conducted 39 supplemental inspections in 2015 and 2016. The focus of the quality assurance elements may change depending on the issues observed at the licensee's facility.
Question No. 172
page 152 How do you regulate the "augmented quality control" of elements important to safety, yet non safety-relate. Have you regulation for those elements? If not how do you regulated? Are those elements listed in the Q-List of the NPP´s with any indication o requirement. Do you inspect with an specific procedure how has been implemented this "augmented quality control"?
Answer: To meet some NRC regulations, such as 10 CFR 50.62, licensees may use equipment that is not safety related to meet those regulations, In such cases, 10 CFR Part 50, Appendix B, would not apply to this equipment since it is not safety related, but the associated NRC regulation may address quality aspects. For example, if a licensee installs an ATWS mitigation system to meet the requirements of 10 CFR 50.62, it is required to "perform its function in a reliable manner." To address this reliability aspect, and hence, quality, the NRC issued GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety-Related," dated April 16, 1985 (https://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1985/gl85006.pdf), to address the "augmented quality" of such equipment. In general, that guidance includes portions of 10 CFR Part 50, Appendix B. Since that time, many licensees have incorporated augmented quality assurance criteria into their quality assurance programs similar to the guidance in the GL. If the NRC finds an issue with the quality of such nonsafety-related equipment, it would need to address the quality issue through the specific regulation associated with that nonsafety-related equipment. Licensees are not required to include such augmented quality components in their Q-list, and the NRC does not have a specific regulation or IP to inspect materials, equipment, and services that fall under an "augmented quality control" process.
Question No. 173
Which are the criteria to implement supplemental QA Inspections out of baseline inspection program? How many of this supplemental QA inspections had been performed during the last two years? The pursuit of them are always the same QA criteria or the focus varies?
Answer: As described in IMC 2515, Appendix B, the NRC performs supplemental inspections above the baseline inspections when licensees have one or more inspection findings or performance indicators that exceed the "Green" band (see https://www.nrc.gov/docs/ML1520/ML15204A007.pdf). Quality assurance is not the only aspect covered by supplemental inspections; a wide range of nuclear safety aspects are also

addressed. Supplemental inspections will typically focus on the following quality assurance criteria: organization, design control, procedures, corrective action, and audits. The NRC conducted 39 supplemental inspections in 2015 and 2016. The focus of the quality assurance elements may change depending on the issues observed at the licensee's facility.
Question No. 174
How do you regulate the "augmented quality control" of elements important to safety, yet non safety-relate. Have you regulation for those elements? If not how do you regulated? Are those elements listed in the Q-List of the NPP´s with any indication o requirement. Do you inspect with an specific procedure how has been implemented this "augmented quality control"?
<u>Answer</u>: To meet some NRC regulations, such as 10 CFR 50.62, licensees may use equipment that is nonsafety related to meet those regulations, In such cases, 10 CFR Part 50, Appendix B, would not apply to this equipment as it is nonsafety related, but the associated NRC regulation may address quality aspects. For example, if a licensee installs an ATWS mitigation system to meet the requirements of 10 CFR 50.62, it is required to "perform its function in a reliable manner." To address this reliability aspect, and hence, quality, the NRC issued GL 85-06 to address the "augmented quality" of such equipment (see https://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1985/gl85006.pdf). In general, that guidance includes portions of 10 CFR Part 50, Appendix B. Since that time, many licensees have incorporated augmented quality assurance criteria into their quality assurance programs similar to the guidance in the GL. If the NRC finds an issue with the quality of such nonsafety-related equipment, it would need to address the quality issue through the specific regulation associated with that nonsafety-related equipment. Licensees are not required to include such augmented quality components in their Q-list, and the NRC does not have a specific regulation or IP to inspect materials, equipment, and services that fall under an "augmented quality control" process.
Question No. 175
The NRC has reviewed options for adopting more widely accepted international quality standards, such as International Organization for Standardization Standard 9001, 2000 edition, by considering how international standards compare with the existing framework in Appendix B to 10 CFR Part 50. On the basis of this review, the NRC concluded that supplemental quality requirements would be needed when implementing Standard 9001 within the existing regulatory framework. What supplemental quality requirements are you refering to? The report mentions the ISO 9001: 2000 edition. Why not consider the newest edition of ISO 9001 from 2015, which contains significant changes?
<u>Answer</u>: The NRC summarized its evaluation of the differences between Appendix B and ISO 9001:2000 in the attachment to SECY-03-0117. One important difference concerns independence in the area of design control: Appendix B, Criterion III, "Design Control," requires measures for independently verifying or checking the adequacy of design, which ISO 9001:2000 did not require. Appendix B, Criterion VII, requires suppliers to pass requirements consistent with Appendix B to sub-suppliers, which ISO 9001:2000 did not. Another significant difference is in the area of independence of inspections. Appendix B,

Criterion X, “Inspection,” requires that inspections be performed by individuals other than those who performed an activity, which ISO 9001 did not require.

In addition to the differences between Appendix B and ISO 9001 requirements per se, related issues must be addressed. One issue concerns the actual independence of the ISO audits. Whereas Appendix B suppliers are audited independently by licensees, who bear the ultimate liability for the safety of procured items, auditors review and audit ISO programs under a commercial contract to the supplier. These auditors would have no direct liability for defective components delivered to operating nuclear plants. Also, ISO auditors do not use standard checklists or criteria, which could result in more subjective ISO 9001 audit results than those performed under Appendix B and its implementing standards. SECY-03-0117 contains the full comparison of 10 CFR Part 50, Appendix B, and ISO 9001:2000, which also includes the supplemental quality requirements needed in ISO 9001:2000.

To date, the NRC has not evaluated ISO 9001:2015.

Question No. 176

Appendix B to 10 CFR Part 50 requires licensees that procure material, equipment, or services from contractors or subcontractors to perform audits to ensure that suppliers implement an effective quality assurance program, consistent with the requirements of Appendix B and the licensee’s technical requirements.
Is there a regulatory limitation in the number of tiers? How does the NRC oversee the contractor audit programm of the licensees next to his own Vendor Inspection Program?

Answer: There is no regulatory limitation to the number of tiers. The NRC conducts inspections of safety-related materials, equipment, and service suppliers to U.S. nuclear licensees and also periodically accompanies a NUPIC team to observe selected licensee audits of contractors. In doing so, the NRC ensures the audit process complies with the requirements of 10 CFR Part 50, Appendix B. The NRC staff continues to rely on the effectiveness of the NUPIC joint utility process to evaluate the quality assurance programs of suppliers to the nuclear industry. The NRC issues trip reports to document the results of NUPIC joint utility audits. NRC NUPIC oversight activities are described at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/nupic-industry.html.

Question No. 177

Licensees perform these activities by using their own technical and quality assurance staff. Industry initiatives to promote effective and efficient standardization of these audit activities have resulted in licensees sharing their technical resources through joint audits of suppliers. What is your experience with the joint audits in terms of effectiveness?

Answer: NUPIC was formed in 1989 by a partnership involving all domestic and several international nuclear utilities. The NUPIC program evaluates suppliers furnishing safety-related components and services and commercial-grade items to nuclear utilities. The NRC periodically accompanies a NUPIC team to observe selected audits and ensure that the audit process complies with 10 CFR Part 50, Appendix B. The NRC staff has found the NUPIC joint utility process to be acceptable for conducting audits of suppliers and continues to rely on the effectiveness of the NUPIC joint utility process to evaluate the quality assurance programs of suppliers to the nuclear industry. The NRC issues trip reports to document the results of NUPIC joint utility audits. NRC NUPIC oversight activities are described at https://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/nupic-industry.html.

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 assurance 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 discusses lessons learned from Fukushima and addresses the Vienna Declaration on Nuclear Safety, issued in February 2015.

Other articles in this report (e.g., Articles 6, 10, 13, 18, and 19) also discuss activities to achieve safety at nuclear installations.

Question No. 178
What is the NRC position on re-evaluation the site conditions as it is now recommended by ENSREG to be done within the PSR in the EU? Does NRC believes such an approach would be warranted in particular when considering that some indications of possibly inadequate consideration of site related issues might be present (e.g. the US east coast earthquake)?
Answer: NTTF Recommendation 2.2 suggested that the NRC initiate a rulemaking to require licensees to confirm seismic and flooding hazards every 10 years and address any new and significant information, including, if necessary, updating the design basis for SSCs important to safety to protect against the updated hazards. In SECY-12-0095, the staff discussed other external hazards, such as those caused by meteorological effects, which should be included in the licensees' periodic updates that the NRC would require once the agency implemented Recommendation 2.2 (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0095scy.pdf). Subsequently, in SECY-15-0137 (ADAMS Accession No. ML15254A006), the staff stated that the use of rulemaking to address Recommendation 2.2 was not necessary. Rather, the staff proposed to develop a method to leverage and enhance existing NRC processes and programs to ensure that information related to natural external hazards is proactively and routinely evaluated in a systematic manner. In response to the SRM to SECY-15-0137, the NRC staff developed a framework that expands upon the concepts described in SECY-15-0137. The framework provides a graded approach that will allow the NRC to proactively, routinely, and systematically seek, evaluate, and respond to new information on natural hazards.

Although the framework is intended to allow for ongoing assessment of new information, it is recognized that performance of certain activities (e.g., technical engagement activities and development of summary reports) on a defined or periodic schedule provides important institutional structure. As such, the framework paper (SECY-16-0144, ADAMS Accession No. ML16286A586) outlines the staff's intention to develop an office instruction that will provide details on (1) the types of activities that will be performed, (2) the review approach to be used to assess new information, and (3) the periodicity of documentation of the work under the framework. If the Commission approves its proposal, the staff plans to develop the office instruction to implement the framework in 2017.

Question No. 179

In some parts of your National Report the use of a "graded approach" is mentioned, for instance in view of emergency preparedness, the Reactor Oversight Process, and some other activities. However, in the information provided concerning Article 14 on "Assessment and verification of safety", we did not find any reference towards a graded approach. Has the USNRC any formalised method or practices to apply a graded appoprach in review and assessment of different projects and topics? If an approach is being used, is it supported by some decision criteria? Is it oriented towards an optimum use of manpower resources ?

Answer: The NRC uses a graded approach in the performance assessment of operating nuclear reactors, as described in IMC 0305 (ADAMS Accession No. ML16257A522). The Action Matrix describes a graded approach for addressing performance issues and was developed with the philosophy that, within a certain level of safety performance (e.g., the licensee response band), licensees would address their performance issues without additional NRC engagement beyond the baseline inspection program. NRC actions beyond the baseline inspection program will normally occur only if assessment input thresholds are exceeded. The Action Matrix identifies the range of NRC and licensee actions and the appropriate level of communication for varying levels of licensee performance. More safety-significant inspection findings and performance indicators result in increased regulatory oversight in the form of additional inspection and greater NRC management engagement.

The NRC also uses a graded approach in following up on traditional enforcement violations. Using an escalating approach similar to that in the Action Matrix, the number, SL, and similarities among the violations will allow one of three levels of inspection response to be used, as appropriate.

The increase in oversight of operating reactors based on declining licensee performance does not consider optimization of manpower resources. Additional NRC resource expenditures are commensurate with the licensee's safety performance and ensure the necessary manpower is used to protect public health and safety.

Question No. 180

The Contracting Party's approach to NPP life extension is robust and sound.

Were there specific issues which would be useful for others to consider?

Answer: Thank you for your comment. We appreciate the positive feedback.

As stated in the U.S. 7th National Report (Section 14.1.4.1, page 162), the GALL Report documents lessons learned from the review of renewal applications. The GALL Report has undergone two revisions since its original issuance in 2001. All revisions of the GALL Report are available at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1801/.

In between each revision, the NRC staff also documents new lessons learned that might influence the staff's reviews of current and future LRAs through the issuance of ISGs. The latest list of effective license renewal ISGs and the issues addressed by them are available at http://www.nrc.gov/reading-rm/doc-collections/isg/license-renewal.html. Some of the ISG topics include steam generators; buried and underground piping and tanks; and the integrity of internal coatings and linings of piping, heat exchangers, and tanks.

In the last several years, the NRC staff, the nuclear industry, and other stakeholders have reached consensus that the significant aging management and technical issues to provide assurance of safe operation of nuclear power plants for operation from 60 to 80 years are as follows:

- neutron embrittlement of the reactor pressure vessel
- stress-corrosion cracking and other types of degradation of reactor pressure vessel internals
- concrete and containment degradation
- electrical cable qualification and condition monitoring.

The NRC works with the nuclear industry to implement the technical resolutions of these issues into the license renewal process. The NRC is also collaborating on research activities with both domestic industry organizations (i.e., EPRI, NEI) and international partners on aging-related research activities.

Question No. 181

We fully agree that a high level of nuclear safety has a strong positive impact on the economics of a nuclear power plant. However, we are surprised by the claim that the competitive and free-market U.S. energy industry is a driver for a high level of safety. Usually, competition creates pressure on the economic situation of the utility. Especially the low electricity prices in the USA due to the low gas prices are, as stated in the 7th national report of the USA, the main reason for permanently shutting down nuclear power plants. Consequently, would this not lead to the conclusion that in case of a declining economic situation, nuclear safety will no longer go beyond the NRC's regulation but will be reduced to the mandatory regulatory requirements because additional safety is on a voluntary basis only?

Answer: INPO RESPONSE:
Throughout the changes that have occurred in the U.S. electric industry, including electric deregulation, the industry has reaffirmed INPO's mission to promote the highest levels of safety and reliability in the operation of nuclear power plants. Even with U.S. utilities now in completion in certain areas, these plant operators clearly understand the need to continue sharing pertinent operational information to continuously strengthen safety and reliability. Nuclear utility owners believe that this cooperation is fundamental to the industry's continued success.

Question No. 182
With reference to articles 14.4 and 18.6, respectively pages 174 and 221 of the American national report, it was found that the articles in question do not cover principle 1 of the IAEA Vienna Declaration on Nuclear Safety(VDNS), which stipulate that radioactive releases large enough to require long-term protective measures and actions should be avoided for new reactors. With regards to principle 1 of the VDNS, Korea would like to inquire the following question: How is principle 1 of the VDNS implemented?

Answer:

NRC RESPONSE: To provide additional information to help the NRC determine if new plant designs adequately address the need for prevention and mitigation of accidents with the potential for core damage, the NRC requires applicants for design certification, COL, and manufacturing license under 10 CFR Part 52 to perform a PRA for their proposed design (10 CFR 52.47(a)(27) and 10 CFR 2.79(a)(46) respectively). Applicants are required to submit a summary of the PRA and its results to the NRC in their application. The objective of this requirement is that applicants use the PRA to implement the design principles listed below. The NRC confirms that this objective has been met as part of its safety evaluation of the design.

- Identify and address potential design features and plant operational vulnerabilities; for example, vulnerabilities in which a small number of failures could lead to core damage, containment failure, or large releases (i.e., assumed individual or CCFs could drive plant risk to unacceptable levels with respect to the Commission's goals).

- Reduce or eliminate the significant risk contributors of existing operating plants applicable to the new design by introducing appropriate features and requirements.

- Select among alternative features, operational strategies, and design options.

- Demonstrate that the risk associated with the design compares favorably to the Commission's goals of less than 1 x 10^{-4} per year (/yr) for CDF and less than 1 x 10^{-6}/yr for LERF.

Lastly, with regard to prevention and mitigation of severe accidents that may possibly include releases of radionuclides causing long-term offsite contamination, early radioactive releases or radioactive releases large enough to require long-term protective measures and actions, it is important to note that, for a new plant to be licensed by the NRC under 10 CFR Part 52, it must include design features to the prevent or mitigate severe accidents. Indeed, NRC regulations in 10 CFR 52.47(a)(23) and 10 CFR 52.79(a)(38), require applicants for design certification or a COL, respectively, under 10 CFR Part 52 to provide, in their application, a description and analysis of design features for the prevention and mitigation of severe accidents (e.g., challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass). In its safety evaluation of the design, the NRC evaluates an applicant's analysis of the effectiveness of these design features in preventing and mitigating severe accidents and confirms that a balance between prevention and mitigation has been achieved.

INPO RESPONSE: New reactor designs being built in the U.S. use passive cooling features that significantly lower the risk profile, as they are not as reliant on active components and electric power to maintain cooling in the event of an accident. Additionally, small modular reactors have cooling capabilities that rely on passive cooling and pools so as to not require active systems and power to maintain safety. Advanced non-light water reactors are being developed where the safety mitigation features are inherent in the design and thus, are not expected to be self-limiting if an event were to occur.
Question No. 183
Were the lessons learned from Fukushima included in the license renewal processes for the plants that were granted the renewal since the Fukushima accident?
Answer: The NRC has not included the recommendations from the lessons learned from the Fukushima Dai-ichi event in the license renewal process. The regulations in 10 CFR Part 54 focus on the management of adverse aging effects to ensure that long-lived structures and components continue to perform their intended functions during the period of extended operation. Issuing a renewed license under 10 CFR Part 54 does not exempt the plants from any requirements issued under 10 CFR Part 50, including the safety enhancements required in response to the lessons learned from Fukushima. As such, during the license renewal period, the requirements will remain in effect.
Question No. 184
Immediately after the event, using the existing Reactor Oversight Process, the NRC conducted inspections and issued orders, INs, and bulletins to aid in determining the preparedness of U.S. nuclear power plants to withstand a similar event. Furthermore, the Reactor Oversight Process will be used to assess and verify that changes currently being implemented in response to lessons learned from the accident were completed properly Has the NRC made any estimate of the resources that has devoted to Lessons Learned at Fukushima Dai-ichi events (inspections and issued orders, INs, and bulletins)?
Answer: From FY 2012 through FY 2016, the NRC budgeted approximately $120 million for post-accident inspections, issuing and implementing the orders, issuing the request for information and reviewing the responses, and related support work. This does not include the billions of dollars spent by the industry to enhance safety in response to the new NRC requirements.
Question No. 185
The controls on generic backfitting include a Committee to Review Generic Requirements review, which is a committee of senior managers from different NRC offices. Established in 1981, this committee operates under a charter that specifically identifies the documents to be reviewed and the analyses, justifications, and findings to be supplied to this committee by the NRC staff. Its objectives include eliminating unnecessary burdens on licensees, reducing radiation exposure to workers while implementing requirements, and optimizing use of NRC and licensee resources to ensure safe operation. Therefore, the Committee to Review Generic Requirements' charter is a key implementing procedure for generic backfitting, although the primary responsibility for proper backfit considerations belongs to the initiating organization. Indicate some specific recent examples of application on optimizing NRC resources to ensure safe operation
Answer: The Committee to Review Generic Requirements (CRGR) ensures that proposed generic backfits to be imposed on NRC-licensed power reactors, new reactors, or nuclear materials facilities are appropriately justified, based on the backfit provisions of applicable NRC regulations (i.e., 10 CFR 50.109, "Backfitting"; 10 CFR 52.39, "Finality of Early Site Permit

Determinations"; 10 CFR 52.63, "Finality of Standard Design Certifications"; 10 CFR 52.98, "Finality of Combined Licenses; Information Requests"; 10 CFR 70.76, "Backfitting"; 10 CFR 72.62, "Backfitting"; or 10 CFR 76.76, "Backfitting") and the guidance contained in NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Draft Report for Comment," issued April 2017; (https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/br0058r4.pdf), or the Commission's backfit policy. The CRGR's primary responsibilities are to recommend to NRC's Executive Director for Operations either approval or disapproval of the staff proposals and to provide guidance and assistance to the NRC program offices to help them implement the Commission's backfit policy.

The backfit regulations contain requirements that the NRC must satisfy to impose backfits on licensee facilities. In general, the NRC has two standards to evaluate when considering modifications. The modification is either required to ensure adequate protection or is cost beneficial. The adequate protection standard establishes the minimum level of public safety that the NRC must maintain. Cost beneficial modifications consider both safety benefits and the economic costs of the modification to the licensed facility. Lastly, the regulations state that the NRC shall always require backfits to ensure adequate protection and without regard to licensee cost.

Generic documents reviewed by the CRGR generally include generic communications, agency procedures, and RGs to ensure that they meet backfitting provisions. The CRGR reviews staff proposals approximately once a month; the committee uses either an informal or formal review process, depending on the potential backfit implications. A recent review (ADAMS Accession No. ML16032A047) example included endorsement of proposed ISG, "Guidance for the Evaluation of Acute Chemical Exposures and Quantitative Standards," (ADAMS Accession No. ML15293A314). Public stakeholders expressed concerns that the ISG would impose additional regulatory requirements for chemical safety for dermal and ocular exposures at fuel facilities. The committee reviewed the draft ISG to ensure that the guidance did not impose new requirements on licensees for protecting personnel. The CRGR asked the staff to revise its proposed ISG to narrow the guidance to apply only to license renewals, new license applications, and new processes outside a particular licensee's current licensing basis. The CRGR review on this ISG helped to ensure effective use of agency and licensee resources by limiting the ISG to future licensee changes. A complete list of documents reviewed by CRGR can be found at http://www.nrc.gov/about-nrc/regulatory/crgr/previous-reviews/reviewed-items.html.

In addition to CRGR reviews of generic documents, the backfit rule is used to analyze other policy decisions, including rulemaking and evaluation of potential safety issues. Analysis of cost benefit is used in the process of developing new Commission rules. The NRC staff prepared a regulatory analysis for the 10 CFR 50.46c draft final rule (ADAMS Accession No. ML15323A122) to identify the benefits and costs of the particular regulatory approach for addressing emergency core cooling system performance. The regulatory analysis focuses on the marginal difference in benefits and costs for each alternative relative to the "no action" baseline alternative for the three major portions of the rule, which is consistent with the requirements of the Backfit Rule (10 CFR 50.109), Commission direction, and the ongoing revisions to the agency's cost-benefit guidance (e.g., NUREG/BR-0058). The regulatory analysis considered the industry's responses to the NRC's multiple requests for cost information associated with implementing the draft final rule. Another area where backfit considerations were applied in NRC decisionmaking included the review of Fukushima lessons learned, one example of risk-informed decisionmaking being the evaluation of a requirement for vents for containment designs other than Mark I and Mark II designs. In SECY-16-0041 (ADAMS Accession No. ML16049A291), the staff provides the analysis that concluded that additional regulatory requirements for containment venting capabilities at plants with other than Mark I and Mark II containments and requirements for hydrogen control and mitigation beyond those already imposed would not significantly change the margins between the overall risks from nuclear power plants and the established safety goals.

Question No. 186

Due to Power Uprates, modifications on several operational equipment (turbine, feedwater, main pumps, etc.) is required. Modifications can also be required for safety equipment, especially for ECCS, since they are associated with the decay power. Is there a plant specific or a generic deterministic and probabilistic re-assessment of the DBA spectrum for the Power Uprates?

Answer: EPU applications include the licensee’s deterministic reassessment of the spectrum of design-basis accidents under EPU conditions. Certain design-basis accidents can be dispositioned generically, while others need to be evaluated on a plant-specific basis. Although power uprates are not submitted as risk-informed licensing applications, licensees are expected to assess the risk impact of the proposed EPU, in large part, to determine if there are any issues that would potentially refute the presumption of adequate protection provided by the licensee meeting the deterministic requirements in the regulations.

Question No. 187

Renewal of operating license, Operation beyon 40 and 60 years
Plants designed in 60's and 70's usually have older design features , e.g. single heat sink, 2x100% safety equipment, etc., than nowadays internationaly required for new plants. How or in which rate are the new international standards and requirments considered and integrated into the lifetime prolongation evaluation process?

Answer: Rulemaking (regulations), licensing, guidance, oversight (inspections), generic communications, event assessment, operating experience, and orders are tools in the current regulatory framework used by the NRC to ensure reasonable assurance of adequate protection since the first commercial reactors were built. The application of the current regulatory processes has demonstrated effectiveness in monitoring operations across the current fleet to identify and address safety issues in a timely fashion. Both the NRC and the licensees monitor and inspect plants. When safety issues are identified, they are addressed through the quality assurance program and placed in the corrective action program to ensure that the issues are properly evaluated, resolved, and documented. In addition, safety issues that may arise from plant events are reported, documented, evaluated, and resolved, and the events shared across the industry so that all stakeholders have the opportunity to address the issue to ensure public health and safety.

The success of these processes and programs throughout the initial operating period provides confidence that they will continue to ensure plant safety in the first and subsequent renewal periods, as is stated in the first principle of the license renewal program. For operation beyond the initial 40 years, the NRC found that aging of passive, long-lived structures and components, along with the current oversight of active components, would ensure safety for 40–60 years and for operation from 60–80 years.

The NRC participates in the development and evaluation of international codes and standards, along with other stakeholders. The NRC reviews codes and standards to ensure that they are soundly based and to determine whether substantial safety improvements can be identified and for possible endorsement in regulatory documents (e.g., rules and regulations: CFR, RGs, SRPs and generic communications), such as 10 CFR 50.55a.

Question No. 188

In the "Review and Evaluation of Safety Research Plan" (NUREG-1635, Vol.2), "NRC clearly stipulates that independent validation of important issue related safety must be carried out by a third party independent of the design unit and the operating unit in the design process of a nuclear power plant, such as validation of safety acceptance criteria, verification of technical problems related to pressure vessel integrity and steam generator integrity."
Question: Which organization is responsible for organizing the independent verification? For AP1000 units currently under construction, which organizations have participated in independent verification as the third party when independent verification of safety assessment is implemented during the design process? Are these organizations required to be engaged in the relevant design before? What methods have been adopted for independent verification ? How to ensure that third party independent verification organization to protect trade secrets and intellectual property rights of nuclear power plant design and operating organizations?

Answer: Approximately every 2 years, the ACRS reviews ongoing and planned research by the Office of Nuclear Regulatory Research (RES) for the upcoming 2 years and issues its evaluation in NUREG-1635, “Review and Evaluation of the Nuclear Regulatory Commission Safety Research Program: A Report to the U.S. Nuclear Regulatory Commission.” The most recent edition of NUREG-1635 is Volume 11, issued December 2014 (ADAMS Accession No. ML15007A146). (Volume 12, the 2016 version, is in preparation.) Volume 2, mentioned in the question, was published in 1999 and is no longer technically relevant. The independent verification referred to in NUREG-1635, Volume 2, refers to the ability of the NRC to verify the acceptability of industry proposals independent of the industry. While industry organizations may on occasion organize their own independent peer review activities for specific issues, the NRC does not require that a “third party” organization outside of the NRC perform an independent safety assessment of the design or construction of a nuclear power plant.

Through RES, the NRC ensures that it has the technical capability to perform its independent verification function in an effective and efficient manner. RES assists the Office of New Reactors and NRR in evaluating the technically complex issues that arise from design reviews or degradation processes that manifest during the operation of nuclear power plants, such as stress-corrosion cracking, thinning, denting. Much research has been undertaken in the area of materials degradation for the primary system and for steam generator tube degradation. RES has executed several 5-year research plans for steam generator tube degradation mechanisms and independently verified assessment methodologies. This has also been the case for reactor coolant system materials. RES works in conjunction with and assists the Office of New Reactors and NRR in developing these research plans. In addition, RES develops analytical tools that may be used during the NRC staff review of new designs, such as the MELCOR code for containment post-accident response, or the TRACE code for thermal-hydraulic issues. Proprietary and trade secret information is protected during all NRC review activities as discussed in 10 CFR 2.390, “Public Inspections, Exemptions, Requests for Withholding.”

Question No. 189

The report discusses how regulatory approach in the US fulfils the goals of periodic safety reviews widely applied in the international community. One of the main goals and the basic principle of the periodic safety reviews is that licensee conducts the assessment and sends the results to the regulator for review and assessments. According to the text, periodic safety

reviews are not conducted as required by the IAEA safety standards and guides (e.g. comprehensively and typically every ten years), instead it is said that the same result is reached with the other tools applied in the US regulatory approach and licensee initiatives. Based on the text it seems that it is mainly the NRC that conducts the assessments (except in license renewals and backfittings and continuous quality assurance and auditing programs of the licensee) and not the licensee. Could you clarify how licensee's role and responsibility is seen in making comprehensive overall safety assessments periodically where potential improvement measures can be identified and assessed as a whole?
<u>Answer</u>: The NRC does not require licensees to perform PSRs at predefined intervals. Instead, it has established processes to ensure that licensees perform continuous review and maintenance of safety of their facilities and their licensing bases. 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 the continuing NRC regulatory activities, as well as the activities of the licensee. Licensees implement quality assurance program requirements (in accordance with Appendix B to 10 CFR Part 50) and the Maintenance Rule (10 CFR 50.65) for active structures and components. 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 of, and the NRC's review and issuance of, LRAs.
Question No. 190
With reference to article 14, page 161 of the American national report, it is stated that 'The NRC's current schedule is to complete the review of a license renewal application within 30 months of receipt of the application if a hearing is conducted and within 22 months if a hearing is not conducted.' With respect to the information provided in the article in question, Korea would like to inquire the following questions: 1) Is the time required by the licensee to prepare answers included in the NRC's 30 month or 22 month schedule to complete the review of a license renewal application? 2) Are reviews actually completed within the 30 or 22 month schedule?
<u>Answer</u>: (1) Yes, the time required by the licensee to prepare answers is included in the NRC's 30-month or 22-month schedule to complete the review of an LRA. (2) From 2000 to 2010, the NRC, on average, completed reactor LRA reviews in 24 months. The increased review time has several causes, which are described below. The first reason for the delayed schedules affected all LRAs, caused by issuance of the NRC's August 2012 Order (CLI-12-16) (ADAMS Accession No. ML12220A100), which suspended final licensing actions pending completion of the continued storage rulemaking. Final decisions could not be made until the Continued Storage Rule was approved on August 26, 2014.

In addition, several recent LRAs have had complex adjudicatory issues that have taken more NRC staff resources to resolve satisfactorily.

As a third cause, the NRC staff has identified safety concerns with individual LRAs that warranted additional review time and requests for additional information. The technical issues include neutron fluence calculations using unapproved methods, ASR in concrete, and selective leaching in aluminum-bronze components.

After the resolution of the Continued Storage Rule, and for plants unaffected by the rulemaking, the NRC staff has completed the review of LRAs on an average of 30 months.

Question No. 191

Does NRC require the licensee to submit Updated SAR or parts of SAR like chapter 15 when considering the application of power uprate?

Answer: The NRC does not require a licensee to submit the updated SAR or parts of the SAR when considering the application of a power uprate. The NRC's decision on the power uprate request is based on the information provided in the licensee's application. SAR submittals reflect changes already made in the plant. The time requirements for SAR submittals are in 10 CFR 50.71(e)(4).

Question No. 192

It is unclear if those remaining "22 SEP lessons learned" has been resolved by plant operators since 1991?

Answer: All 22 systematic evaluation program (SEP) issues have been addressed and resolved under Generic Issue (GI)-156, "Systematic Evaluation Program" (https://www.nrc.gov/sr0933/Section%203.%20New%20Generic%20Issues/156r8.html). NUREG-0933, "Resolution of Generic Safety Issues," issued August 2010, provides a synopsis of the historical background, prioritization process, and final disposition of the each of these issues (https://www.nrc.gov/sr0933/). Out of the 22 issues under GI-156, 18 were dropped from further consideration; 3 were addressed in the resolution of other GIs. The last SEP issue (GI-156.6.1) was closed with no changes to existing regulations or guidance on December 21, 2007 (ADAMS Accession No. ML073130570).

In the process of screening the SEP issues, PRA studies were applied to some of these issues. In an RES evaluation, consideration of a 20-year license renewal period did not change these conclusions or the priority of the issues.

Question No. 193

The section mentions that the NRC is currently evaluating the plant-specific, first-of-a-kind, alkali-silica reaction aging management programme proposed by the Seabrook NPP. Could you communicate the key aspects of this programme? What the programme is about?

Answer: As stated in paragraph 1.3.1 (pages 20–22) of the U.S. 7th National Report, the key aspects of this aging management program encompass detailed inspections to verify the adequacy of the licensee's planned actions related to the ASR structures monitoring program and large-scale testing to reconcile the design and licensing basis.

In addition, the NRC has embarked on a broader scope research program to formulate an agency position on the effects of ASR on concrete structures in nuclear power plants. This program focuses primarily on the structural consequences with respect to the structural performance under design-basis loads and load combinations throughout its service life, including the period of extended operation for license renewal. The scope of the research program includes, but is not limited to, identification and evaluation methods for determining the state and severity of the ASR reaction upon discovery, determination of the impacts of ASR on concrete's mechanical properties, development of criteria to assess the severity of the ASR degradation, and the severity rating of the degraded structure with respect to structural performance.

Question No. 194

The section mentions a safety project under the auspices of NEA "SAfety REsearch Opportunities post-Fukushima" (SAREF) that has two objectives: (1) to address safety research gaps and advance safety knowledge base, and (2) to support Japan in achieving safe and prompt decommissioning. A report summarizing the results of these studies is in preparation'.
What is the current status of this report? If it has already been issued, is it publicly available? If "Yes", could you give a reference to it; if "No", what are the key results of the studies?

Answer: The Nuclear Energy Agency (NEA) is preparing the final SAREF report and expects to publish it in early 2017. NEA will make the report publicly available. The NEA study of fast-running software tools used to model radionuclide release during nuclear accidents is an ongoing activity. It is the NRC's understanding that NEA will complete the study in 2017. However, it is best to consult NEA on this matter.

Question No. 195

As stated in this section, "the NRC temporarily suspended the annual self-assessment process for calendar year 2014 to develop a more effective self-assessment process with more meaningful metrics, and to address Reactor Oversight Process improvement recommendations from multiple independent and focused assessments."
What are these recommendations to improve effectiveness of the self-assessment process? What is to be (or already has been) improved?

Answer: As noted in SECY-14-0047 (ADAMS Accession No. ML14066A365), the NRC staff had initiated its ROP enhancement efforts to take a "fresh look" at several key ROP areas, including but not limited to the self-assessment program. In addition, in CY 2013, the ROP benefited from independent evaluations by the Government Accountability Office, OIG, and a Commission-directed internal independent review. These efforts collectively produced numerous recommendations and suggestions for further ROP improvements, including improvements to the self-assessment process itself. For example, the Commission-directed independent review, "Reactor Oversight Process Independent Assessment 2013" (ADAMS Accession No. ML14035A571), recommended revising the ROP self-assessment process to better solicit and assess both tactical and strategic feedback. Given the amount of feedback and recommendations received by independent evaluations, the staff recognized that the prior self-assessment process did not provide as deep a review as necessary to identify some of these underlying enhancement opportunities.

In 2015, the NRC staff completed the redesign of the ROP self-assessment process to better assess the effectiveness of a mature program by focusing on the efficacy of recent changes to the program, performing in-depth reviews of specific areas of interest, and verifying NRC staff adherence to program governance documents. The new self-assessment approach is designed to ensure that the ROP is being implemented reliably and predictably across all four NRC regional offices, as well as at NRC Headquarters. The staff informed the Commission of

its revised approach to, and implementation plans for, the annual ROP self-assessment in SECY-15-0156 (ADAMS Accession No. ML15310A086). The self-assessment program is governed by the revisions to IMC 0307 and its appendices (ADAMS Accession No. ML15307A023). The revised self-assessment approach consists of three distinct elements: (1) measure the effectiveness of and adherence to the current program, using objective metrics, (2) monitor ROP revisions and assess recent program changes for effectiveness, and (3) perform focused assessments of specific program areas and peer reviews of regional offices. This approach also addresses the recommendation from the Commission-directed independent review. Specifically, the first element provides for a tactical review of how ROP is currently operating (from a data collection and analytical perspective). The second and third elements provide for a more strategic review and assessment of the efficacy of recent program changes and specific areas of management focus.
Question No. 196
The section says that U.S. licensees establish performance expectations above the thresholds required by the NRC. What are these expectations? What were the target values for such expectations in 2015?
<u>Answer</u>: The U.S. nuclear industry's commitment to go beyond regulatory compliance and continually strive for excellence, with INPO's support, has resulted in substantial performance improvements over the last 35 years. For example, in the early 1980s, the typical nuclear plant had a capacity factor of 63 percent, had experienced six automatic scrams a year, had high collective radiation doses, and had experienced numerous industrial safety accidents. Today, the median industry capacity factor is above 92 percent, most plants have no automatic scrams a year, and collective radiation doses and industrial accident rates are both lower by a factor of 7 when compared to the rates of the 1980s. The conduct of plant and corporate evaluations is one of INPO's most important functions; and the function is closest to the role of a regulator. Although the two roles—evaluation and regulation—may appear similar, they differ in some ways. The industry and INPO jointly develop numerous performance objectives and criteria (PO&C). (These are similar to the WANO PO&C). INPO then conducts regular, extensive, and intrusive evaluations to determine how well they are being met. These PO&C are broad statements of conditions reflecting a higher level of overall plant performance—striving for excellence and often exceeding regulatory requirements. These PO&C, by their very nature, are difficult to achieve consistently.
Question No. 197
Para 6.3.4 mentions The Accident Sequence Precursor Program, including PRA. Could you please give PRA quantitative data for each operating unit – for instance, integral probability of a severe core damage.
<u>Answer</u>: A summary of CDF distributions for internal events, at-power, by plant design class appears in Table 6-1 on page 34 of Volume 2 of NUREG/CR-6890, "Reevaluation of Station Blackout Risk at Nuclear Power Plants, Analysis of Station Blackout Risk," issued December 2005 (https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr6890/). The NRC SPAR models were used to generate CDF distributions for eight plant classes for U.S. nuclear steam supply system vendors, combined BWRs, combined PWRs, and combined U.S. nuclear power industry. The SPAR models are NRC-developed plant-specific models that support NRC's PRA efforts. These models use standardized modeling conventions and industry average parameter estimates for initiating event frequencies and equipment failure

probabilities and rates. The SPAR model results are in general agreement with the licensee's PRA model results.

The mean internal-event, at-power, CDF from NUREG/CR-6890 for the vendor class ranged from 2 x 10^{-6} to 3 x 10^{-5} per reactor-critical-year (/rcry). The mean CDF for the BWR and PWR classes were 1E-05 and 2E-05/rcry, respectively. The industrywide class had a CDF of 2E-05/rcry. The average mean CDF from recent SPAR models is in general agreement with those presented 10 years ago in Table 6-1 in Volume 2 of NUREG/CR-6890.

Question No. 198

The National Report Article 14, License Renewal, section 14.1.4.1, states that research has concluded that aging phenomena are readily manageable and do not pose technical issues that would prevent life extension for nuclear power plants. Also it states that studies have also found that facilities deal adequately with many ageing effects during the initial license period and that credit should be given for these existing programs, particularly those under the NRC's Maintenance Rule, 10 CFR 50.65.
Please provide information on what ageing mechanisms has the research identified for (Instrumentation and Control) I&C equipment and components and does this vary for different components such as electromechanical devices and electronic circuits/components.

Answer: As stated in Section 14.1.5.4 of the U.S. 7th National Report (pages 169–170), the license renewal process focuses on passive long-lived SSCs at the nuclear power plants because failures of active components are more readily detected through routine surveillance, maintenance, and corrective action programs that will continue throughout the lifetime of the plant under the NRC's Maintenance Rule, 10 CFR 50.65. I&C equipment is considered to be active components that are outside the scope of the License Renewal Rule. Hence, the aging research efforts to date have not extensively examined the aging mechanisms and effects of I&C equipment.

However, the NRC staff has ongoing research projects to identify techniques for cable condition monitoring that could track degradation as a function of time. The cables will be aged in an environment to simulate up to 80 years of operation and subjected to simulated LOCA tests while periodic measurements are made using selected condition monitoring techniques.

Question No. 199

The report explains that research programmes have been undertaken to address ageing phenomena in nuclear power plants and the results of these programmes broadly suggests that there are no technical impediments to plant life extension. The research also suggests that facilities deal with ageing effects adequately.
However, the report does not describe the key findings from the research programmes on ageing and degradation.

Please provide information on research outcomes which support the justification that there are no technical impediments to plant life extension, with the focus on of ageing management related to pressure retaining systems and components.

Answer: In NUREG/CR-6923, "Expert Panel Report on Proactive Materials Degradation Assessment," issued February 2007 (ADAMS Accession No. ML070710257), referred to as the PMDA report, the NRC conducted a comprehensive evaluation of potential degradation modes for core internal components, as well as primary, secondary, and some tertiary piping systems, considering operation up to 40 years. The PMDA report supports the NRC staff

evaluations of licensees' aging management programs and allowed for prioritization of research needs. On October 2014, the NRC published the Expanded Materials Degradation Assessment (EMDA), which broadens the scope of the PMDA report. The analytical timeframe was expanded to include 80 years of nuclear power plant operation. The EMDA evaluated a broader range of SSCs, including core internals, piping systems, the reactor pressure vessel, electrical cables, and concrete and civil structures. Factors considered in the assessment included the reactor environment, existing operational experience and laboratory data, and models of materials behavior. Each separate assessment provided an analysis of key degradation modes for current and expected future service, key degradation modes expected for extended service, and suggested research needs to provide technical information for operation up to 80 years. The five volumes of NUREG/CR-7153, "Expanded Materials Degradation Assessment (EMDA)," issued October 2014 (https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr7153/), detail the scope, background, and analysis for each of these four areas. Further, the NRC conducted an assessment of the adequacy of the aging management programs for subsequent license renewal at several representative nuclear power plants. The Review of Aging Management Programs Compendium Report, dated June 15, 2016 (ADAMS Accession No. ML16194A149), identified dozens of insights (e.g., cable condition monitoring, coatings, lower head and bottom-mounted instrumentation monitoring) that were considered for the subsequent license renewal guidance documents. The NRC provides additional information in the responses to the following questions: (1) No. 61 from the Russian Federation: What are specific features of aging management in case of second subsequent license renewal, and what significant issues have made the NRC plan to issue by mid-2017 "Generic Aging Lessons Learned (GALL) Report" and "Standard Review Plan" for operations beyond 60 years? (2) No. 62 from the Russian Federation: Para 1.2.2 gives a list of nuclear units that had their licenses renewed in the reported period. Could you please give information about major activities carried out at each operating nuclear unit to justify service life of equipment, perform refurbishment and enhance safety?
Question No. 200
The National Report Article 14, License Renewal, section 14.1.4.1, Governing Documents and Process states that the standard review plan for license renewal incorporates by reference NUREG-1801, "Generic Aging Lessons Learned (GALL) Report," Revision 2, issued in December 2010, which documents the basis for determining when existing programs are adequate for license renewal and when they should be augmented. Please provide further information on how the 'GALL' Report influences the In-Service inspection to identify ageing effects and ageing mechanisms on (Instrumentation & Control) I&C equipment and components.
Answer: I&C equipment is considered as active components that are outside the scope of the License Renewal Rule. Active components are maintained through routine surveillance, maintenance, and corrective action programs that will continue throughout the lifetime of the plant under the NRC's Maintenance Rule, 10 CFR 50.65. As NUREG-1801 lists generic aging management reviews of SSCs that are within the scope of license renewal, the GALL Report

does not contain information on the aging mechanisms of I&C equipment and components. However, the GALL Report does cover electrical cables and connections that functionally interface with all plant systems that rely on electrical power or I&C. A generally accepted aging mechanism for electrical cables is reduced insulation resistance when exposed to adverse plant conditions (e.g., high temperatures, radiation, moisture). Chapter VI, “Electrical Components,” of NUREG-1801, Revision 2, issued 2010 (ADAMS Accession No. ML103490041), provides additional information.

Question No. 201

Could you please explain what exactly are "certain" circumstances and conditions under which licensees may make changes to the facility or procedures and conduct tests or experiments without prior NRC approval, and how the compliance is verified?

Answer: As stated in 10 CFR 50.59(c)(1), a licensee may make changes to its facility or to its procedures as described in the final SAR (as updated) and conduct tests or experiments not described in the final SAR (as updated) without obtaining a license amendment (approval from the NRC) only if the TS are not changed and the proposed changes do not meet any of the following criteria (10 CFR 50.59(c)(2)):

> (i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);
> (ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety previously evaluated in the final safety analysis report (as updated);
> (iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);
> (iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);
> (v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);
> (vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);
> (vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or
> (viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

As stated in 10 CFR 50.59(d)(1) and (d)(3), licensees are required to maintain records of their evaluations and the bases for the determination that the change does not require a license amendment (approval from the NRC). The licensee is required to maintain records of changes to the facility until the termination of its operating license. The licensee is also required to maintain records of changes to procedures and records of tests and experiments for 5 years. The NRC resident inspectors verify compliance with these regulations on a routine basis as part of their inspections. IP 71111, “Reactor Safety-Initiating Events, Mitigating Systems, Barrier Integrity,” Attachment 18, “Plant Modifications,” dated November 17, 2016 (http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html), or (https://www.nrc.gov/docs/ML1630/ML16306A185.pdf) provides guidance to the resident inspectors for conducting annual inspections of the implementation of modifications to the plant and procedures, particularly for those modifications that the licensee determined did not

require NRC approval. In addition, every 3 years, regional specialist inspectors inspect the program by using IP 71111, Attachment 17T, "Evaluations of Changes, Tests, and Experiments," dated December 8, 2016 (https://www.nrc.gov/docs/ML1634/ML16340A998.pdf).
Question No. 202
The report explains that the US Nuclear Regulatory Commission requires industry codes and standards to be applied to nuclear power reactors during design, construction, and operation. The report explains that codes such as Section III and Section XI of the ASME Operation and Maintenance Code for nuclear power plants have been used as part of this requirement, and the in-service inspection programmes were derived from these codes. The report does not discuss how ageing management has been incorporated and implemented into the in-service inspection programmes. Please provide further information on how ageing management is incorporated into the in-service inspection programme and any significant findings from the inspections related to systems which constitute a pressure boundary.
<u>Answer</u>: Regulations in 10 CFR 50.55a impose the in-service inspection requirements of ASME Code, Section XI, "Rules for In-service Inspection of Nuclear Power Plant Components," for Class 1, 2, and 3 pressure-retaining components, which include welds; pump casings; valve bodies; integral attachments; and pressure-retaining bolting using volumetric, surface, and/or visual examinations and leakage testing. 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. Inspection of these components is covered in Subsections IWB, IWC, and IWD. Regulations in 10 CFR 50.55a impose additional conditions and augmentations of in-service inspection requirements specified in ASME Code, Section XI. The ASME Section XI in-service inspection program, in accordance with Subsections IWA, IWB, IWC, and IWD, has been shown to be effective in managing aging effects. The GALL Report includes Aging Management Program XI.M1, "ASME Section XI In-service Inspection, Subsections IWB, IWC, and IWD," as codified in 10 CFR 50.55a. In certain cases, the ASME in-service inspection program is augmented in the GALL Report to manage effects of aging for license renewal. During the NRC staff evaluation of the LRA, the staff reviews the applicant's claim that the plant's existing in-service inspection program is consistent with the GALL Report. The staff compares and confirms that each of the elements of the applicant's program is consistent with the corresponding program elements of the GALL Report Aging Management Program XI.M1. The NRC safety evaluation report documents the staff conclusion for the plant's license renewal.

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 of radiation protection, which include the regulatory framework, regulations, and radiation protection programs for controlling radiation exposure for occupational workers and members of the public. This section also discusses lessons learned from Fukushima. Article 17 of this report discusses radiological assessments that apply to licensing and facility changes.

Question No. 203
It is mentioned that "the ALARA requirement lead to the establishment of numerical objectives (in example, 0.00005 sieverts (Sv) (0.005 rem) in a year for the most highly exposed individual". What models or measurements are used to determine the dose of the most highly exposed individuals? Please provide additional information.
Answer: An NRC licensee's TS require it to have an Offsite Dose Calculation Manual, which includes an annual land-use census within a 5-mile radius around the nuclear plant. The purpose is to identify the location of the nearest homes, gardens, milk animals, and water pathway uses (for example, drinking water, irrigation, fishing) in each of 16 downwind sectors. Each licensee is required to have a meteorological tower that measures the wind speed, wind direction, and air dispersion characteristics. Data from the meteorological towers are compiled and summarized into annual meteorological summaries. The average concentration of airborne effluent releases at the location of each home in each sector is calculated per standard release rate. The home with the highest relative airborne concentration is selected as the location of the most highly exposed individual. At the plant, measurements of each of the airborne radioactive radionuclides are continuously performed throughout the year. At the end of the year, the total radioactive release is calculated for each radionuclide. Based on the total release for each radionuclide, the annual average release rate of each radionuclide is determined. The annual average release rate for each radionuclide is then multiplied by the annual average concentration per standard release rate to obtain the annual average concentration of each radionuclide at the highest home location. The annual average concentration of each radionuclide (at that highest location) is then multiplied by each radionuclide's dose coefficient (mrem/year per uCi/cc) to determine the external dose and the internal dose. If there is any additional dose from any water exposure pathway or the direct radiation exposure pathway, then the dose from these additional pathways is added to the dose from the airborne pathway to determine the total dose to the most highly exposed individual. The NRC provides licensees with guidance on measuring effluent releases and performing dose calculations in a series of RGs as listed below.

RADIOACTIVE EFFLUENT RELEASES

(1) RG 1.21, "Measuring, Evaluating, and Reporting Radioactive Material in Liquid and Gaseous Effluents and Solid Waste."

(2) NUREG-1301, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors," April 1991, ADAMS Accession No. ML091050061.

(3) NUREG-1302, "Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Boiling Water Reactors," April 1991 ADAMS Accession No. ML091050059.

(4) RG 1.111, "Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors."

(5) RG 1.113, "Estimating Aquatic Dispersion of Effluents from Accidental and Routine Reactor Releases for the Purpose of Implementing Appendix I."

(6) RG 1.109, "Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I."

ENVIRONMENTAL MONITORING

(1) RG 4.1, "Radiological Environmental Monitoring for Nuclear Power Plants."

(2) RG 4.15, "Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment."

Electronic copies of NRC RGs and other recently issued guides are available through the NRC's public Web site under the RGs document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doccollections/reg-guides/ and through ADAMS at http://www.nrc.gov/reading-rm/adams.html.

Question No. 204

The report states "In 2014, 174,851 workers at nuclear plants were monitored for radiation exposure. Of these, 70,844 workers received a collective measureable dose of 71.24 person-Sv (7,124 person-rem) for an average of 0.0010 Sv (0.10 rem) per worker."

May US also provide information on the percentage of internal dose contribution to total dose and what percentage of radiation workers received the internal dose?

Answer: In 2014, 174,851 workers were monitored at nuclear power plants for total effective dose equivalent (TEDE):

- 70,844 had measurable TEDE (40.5 percent)
- 53,764 were monitored for committed effective dose equivalent (CEDE)
- 38 individuals had measurable CEDE (0.07 percent)
- 38/70,844 = 0.05 percent of individuals with measurable TEDE had measurable CEDE

• total collective CEDE at nuclear power plants was 0.00419 person-Sievert (Sv) (0.419 person-rem) • average measurable CEDE per worker was 0.00011 Sv (0.011 rem) • percentage of collective CEDE to collective TEDE for 2014 is 0.006 percent (0.00419 Sv/0.7124 Sv)
Question No. 205
With reference to article 15, page 180 of the American national report, according to article 15.3(Regulation), it seems USA is using the internal dose conversion factor specified in FGR 11 and ICRP 30. The ICRP provides internal dose coefficients for six age groups. With respect to the information provided in the article in question, Korea would like to inquire the following question: Korea's understanding of FGR 11 and ICRP 30 is that they only provide dose coefficients for adults. What are the documents which were referenced for the dose coefficients for the pediatric & adolescent population?
Answer: The NRC has not adopted the latest International Commission on Radiological Protection (ICRP) radiation protection recommendations, including the six age groups mentioned in the question. Licensees can demonstrate that they have met the NRC dose limit for a member of the public by maintaining the annual average concentrations of radionuclides in liquid and airborne effluents below those values given in 10 CFR Part 20, “Standards for Protection Against Radiation,” Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage, Table 2. The model used to calculate the Table 2 concentrations included a factor of 0.5 to adjust the adult dose coefficients to account for other age groups. In addition, the guidance in RG 1.109 provides age-dependent dose factors for four age groups (adult, adolescent, child, and infant) to adjust for differences in physical and metabolic characteristics. These dose factors are used to calculate doses for the hypothetical most exposed member of the public for comparison to the dose base effluent system design criteria given in 10 CFR Part 50, Appendix I.
Question No. 206
With reference to article 15, page 182 of the American national report, Korea would like to inquire the following questions: 1) Among nuclear installations under construction or operation, are there installations in which RG4.21 and 4.22 are applied? 2) What are the major issues in the design and operations of nuclear installations in which RG4.21 and 4.22 are applied?
Answer: RG 4.21, “Minimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning,” issued June 2008 (ADAMS Accession No. ML080500187), provides design and operational guidance to be applied to all new license applications and to all new facilities under construction since 2008. RG 4.22, “Decommissioning Planning During Operations,” issued December 2012 (ADAMS Accession No. ML12158A361), implements the 2012 decommissioning planning regulations for all facilities in operation. The major impetus for both RGs was to provide guidance to minimize contamination and prevent contamination of the environment, thereby ensuring decommissioning funds are reasonably available to prevent

legacy sites. Legacy sites are those facilities that either have inadequate decommissioning funds or technical issues that prevent the decommissioning from being completed.

Question No. 207

With reference to article 15, page 183 of the American national report, in the case of the USA, the dose limit for emergency workers is prescribed in USNRC information No 84-40(1984) "Emergency Workers and Lifesaving Activity Protective Action Guides (25 rem whole-body dose for emergency workers and 75 rem for lifesaving activities)". However, the ICRP does not recommend any dose guidance in case of lifesaving activities. With respect to the mentioned information, Korea would like to inquire the following questions?

1) Is the dose guidance in US NRC information No 84-40 applicable to lifesaving in real accident conditions?
2) Table IV.2(Guidance values for restricting exposure of emergency workers) in IAEA GSR Part 3 provides graded guidance values for emergency workers. Does the US NRC have any plans to reflect and legalize IAEA recommendation or other standards in its regulations?

<u>Answer</u>: Planning standard 10 CFR 50.47(b)(11), which addresses the control of emergency worker exposures, requires the licensee to use exposure guidelines consistent with EPA emergency worker and lifesaving activity PAGs. These guidelines are included in EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," issued 1992, and EPA-400/R-17/001, "PAG Manual Protective Action Guides and Planning Guidance for Radiological Incidents," issued January 2017. Both of these documents provide graded guidance values:

Guideline Value–Activity
5 rem (50 mSv)—all occupational exposures
10 rem (100 mSv)—protecting critical infrastructure necessary for public welfare
25 rem (250 mSv)—lifesaving or protection of large populations with all appropriate actions taken to reduce dose
Greater than 25 rem (greater than 250 mSv)—lifesaving or protection of large populations only if affected individuals are fully aware of the risks involved

The NRC did not issue IN 84-40, "Emergency Worker Doses," dated May 30, 1984, to establish exposure guidelines. Rather, the agency issued the notice to explain that, under current NRC regulations, all occupational doses, including emergency doses, are required to be included as part of a worker's exposure history and hence can affect the worker's subsequent allowable exposure.

The reference in the notice to 25 rem and 75 rem became outdated with the issuance of the 1992 EPA PAG Manual. The current values are as listed above.

Question No. 208

How are gas aerosol releases accounted for when their measured values are below instrument measurement range?

<u>Answer</u>: In accordance with RG 1.21 (ADAMS Accession No. ML091170109), the radioactive effluent measurement results for gas aerosols that are below detectable levels should be reported as non-detectable (N/D) with an accompanying footnote to denote that measurements were performed but no activity was detected. Therefore, for purposes of dose assessments for members of the public, measurement results that are below detectable values are assumed to be zero.

Question No. 209
Normally, values of radiological risk per unit dose estimated using UNSCEAR and BEIR models are greater than those calculated using the models recommended by ICRP. Does this mean that dose constraints and limits for U.S. public and personnel shall be lower than dose constraints and limits recommended by ICRP?
Answer: No. The United States does not use the risk values from the United Nations Scientific Committee on the Effects of Atomic Radiation or the Committee on the Radiological Effects of Ionizing Radiation as the basis for its dose limits or constraints. The values of radiological risk used by the NRC are those in the applicable ICRP Recommendations.
Question No. 210
As stated in the Report, "the Commission initially approved the staff's development of the regulatory basis for a revision to 10 CFR Part 20 and parallel alignment of 10 CFR Part 50, Appendix I, to reflect the most recent methodology and use consistent terminology for dose assessment. However, in light of comments and feedback received on contemplated changes to 10 CFR Part 20, the NRC staff is no longer developing a regulatory basis for the revision to this rule. The staff has determined that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment". Does this mean that the term "effective dose" and classification of exposure situations (planned, existing, emergency), recommended in ICRP Publication 103, are not expected to be used in the U.S. radiological protection system in near future?
Answer: In 2015, the NRC directed the staff to perform a one-time rebaselining of work performed across the agency, focusing not only on statutory mandates and Commission direction but also on its safety and security mission. The Commission noted that the staff should prioritize and rebaseline the agency's work in an integrated manner and consistent with the agency's mission, values, and the Principles of Good Regulation. In response to Commission direction, the staff, in part, recommended discontinuing efforts to develop a regulatory basis for the revision to 10 CFR Part 20. The staff concluded that the proposed methodology and terminology changes went beyond that needed to provide for adequate protection and that additional resource expenditure in this area would not result in a recommendation for a revised rule. In April 2016, the Commission concurred with this recommendation. The Commission believes that the current NRC regulatory framework continues to provide adequate protection of the health and safety of workers, the public, and the environment. Hence, the NRC does not expect to incorporate the term "effective dose" and classification of exposure situations (planned, existing, or emergency) into 10 CFR Part 20 in the near future.

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 (1) the background of emergency planning in the United States, (2) offsite emergency planning and preparedness, (3) emergency classification system and emergency action levels, (4) recommendations for protective action in severe accidents, (5) inspection practices and regulatory oversight, (6) response to an emergency, (7) communications with neighboring states and international arrangements, (8) communications with the public, and (9) lessons learned from the Fukushima event.

Question No. 211
With reference to article 16.4, page 190 of the American national report, Korea would like to inquire the following questions: 1) Does the licensee submit an evaluation on evacuation time estimates to NRC during licensing process? 2) How is the evaluation on evacuation time estimates verified?
Answer: (1) Section IV.2 of Appendix E to 10 CFR Part 50 requires an applicant for an operating license under 10 CFR Part 50, an early site permit, or a COL under 10 CFR Part 52 to analyze the time required to evacuate various sectors and distances within the 10-mile plume exposure pathway emergency planning zone. (2) The staff reviews the submitted evacuation time estimate against published guidance to assess the acceptability of the applicant's submittal. The agency asks the applicant to respond to requests for additional information should the staff identify deviations from the guidance provided in NUREG/CR-7002, "Criteria for Development of Evacuation Time Estimate Studies," issued November 2011 (https://www.nrc.gov/reading-rm/doc-collections/nuregs/contract/cr7002/).

Question No. 212
With reference to article 16.5, page 190, it is stated that Emergency Preparedness is one of the Reactor Oversight Process' cornerstones and oversight of this cornerstone is achieved through 3 indicators, one of which is Emergency Response Organization Drill Participation. It is also stated that the indicator for evaluating Emergency Response Organization Drill Participation is the "percentage of key members" in the emergency response organization who have participated in proficiency-enhancing drills, exercises, training opportunities or an actual event over a determinant amount of time. With respect to the information provided in the article in question, Korea would like to inquire the following question: Is Emergency Response Organization Drill Participation "just simply" evaluated based on the percentage of key members who have participated in proficiency-enhancing drills, exercises, training opportunities or an actual event? If that is the case, then what is the minimum adequate percentage of key members in emergency response organization considered by the US NRC?
<u>Answer</u>: Yes. The indicator represents the number of ERO members assigned to key positions that have participated in a drill, an exercise, or actual events for the previous eight calendar quarters divided by the total number of key positions assigned to ERO members. The performance of the ERO members in making classifications, notifications, and protective action recommendations is tracked separately under the Drill/Exercise Performance indicator. A participation of less than 80 percent would cause the indicator to be termed “White.” A White indicator can be characterized as having low-to-moderate safety significance, but the performance remains acceptable. A participation of less than 60 percent would cause the indicator to be “Yellow.” A Yellow indicator can be characterized as having substantial safety significance. For a Yellow indicator, the performance is considered acceptable, but a reduction in safety margin exists. Under the ROP Action Matrix, NRC management oversight would be increased as long as the participation was less than 80 percent.
Question No. 213
Section 16.3 describes Emergency Classification System and Emergency Action Levels. In light of the Vienna Declaration on Nuclear Safety and lessons learned from Fukushima, please summarize the status of SAMGs in the US nuclear regulatory framework, for example are they required or are commitments expected from licensees?
<u>Answer</u>: SAMGs are not required in the U.S. nuclear regulatory framework. All licensees of nuclear power plants in the United States have made regulatory commitments to the NRC to implement and maintain the SAMGs. The NRC is incorporating the oversight of SAMGs into the NRC’s ROP.
Question No. 214
Section 16.9 describes the lessons learned from Fukushima. It states, “the NRC staff identified lessons learned applicable to the NRC Incident Response Program not covered under the NTTF recommendations. What were the lessons learned and is there are reasons why they were not identified during the Near-Term Task Force (NTTF) recommendations?
<u>Answer</u>: The NTTF specifically examined the events at Fukushima Dai-ichi to determine lessons that would be applicable to U.S. nuclear power plants. In contrast, the report (ADAMS Accession No. ML112580203) examining the NRC’s incident response program focused on the NRC actions in response to the incident to identify improvements to its own programs. Several areas were noted for improvement, including planning to respond to an international

event and communicating about such an event to U.S. States. The Office of Nuclear Security and Incident Response has since addressed these areas.

Question No. 215

Section 16.1, second paragraph references that "there is reasonable assurance that adequate measures to protect public health and safety can and will be taken in a radiological emergency".

Are there assurances required earlier in the licence approval cycle for this commitment? Is there a requirement in the initial phase such as construction licence approval that emergency preparedness plans are appropriate to the site and technology being used?

Answer: The NRC must make a reasonable assurance determination before issuing the initial operating license under 10 CFR Part 50, an early site permit containing a complete and integrated emergency plan, or a COL under 10 CFR Part 52. The NRC will base the determination on its assessment that the applicant's onsite plans are adequate and on whether there is reasonable assurance that the applicant can implement onsite plans. In addition, FEMA will base its determinations as to whether State and local emergency plans are adequate and whether there is reasonable assurance that the applicant can implement these plans.

A construction permit is issued under 10 CFR Part 50. Section II of Appendix E to 10 CFR Part 50 requires that the preliminary SAR contain sufficient information to ensure the compatibility of the proposed emergency plan for both onsite areas and the emergency planning zones, with facility design features, site layout, access routes, and population distributions. However, the NRC will review the emergency plan as part of the operating license application review.

An applicant for an early site permit must demonstrate that no impediments to the development of an emergency plan exist. The applicant has the option to submit (1) no emergency plan, (2) the major features of an emergency plan, or (3) a full and integrated emergency plan. If the application does not contain a major features plan or a full and integrated plan, the NRC, in consultation with FEMA, will defer the requisite reasonable assurance determination until the COL phase.

Question No. 216

The NRC site team – How quickly can the NRC site team reach the facility?
Does the NRC site team have some special equipment?
Is there any training for the team?
How many people are on the team?

Answer: The timeline for establishing a site team in response to an event varies based upon the magnitude of the event and specific details of the scenario, among them being when the decision is made to send a site team and the distance from the NRC regional office to the affected facility. A site team is expected to leave from the NRC regional office within hours of notification to deploy.

The NRC site team deploys with robust communications capability. The site team maintains communications with the NRC regional office, NRC Headquarters, and the licensee. Site team members receive periodic general and position-specific response training and participate regularly in incident response exercises.

Site team staffing in response to an event will depend upon the magnitude of the event and the specific scenario. A full site team comprises about 15–20 positions, which may include engineers, scientists, health physicists, and public relations specialists.
Question No. 217
The plan for handling emergency conditions are described in detail in this section. May U.S. provide information on the aspects/criteria related to termination of emergency and normalization of site and off-site after an emergency?
Answer: In 10 CFR 50.47, “Emergency Plans,” the NRC requires that nuclear power reactor licensees develop plans for recovery and reentry. Specifically, 10 CFR 50.47b(13) is the planning standard that nuclear power reactor licensees must incorporate into their onsite and offsite emergency response plans. In these plans, nuclear power reactor licensees are to describe the criteria used to determine when, following an accident, reentry of the facility would be appropriate or when operation could be resumed. The NRC does not inspect licensees’ recovery and reentry plans.
Question No. 218
Could you please give specific criteria used to judge emergency preparedness equipment and facilities to be sufficient for dealing with multi-unit and prolonged SBO scenarios?
Answer: The NRC is proposing to amend its regulations that establish regulatory requirements for nuclear power reactor applicants and licensees to mitigate “beyond-design-basis events.” The NRC is proposing to make generically applicable requirements in Commission orders for MBDBEs and for reliable SFP instrumentation. This proposed rule would establish regulatory requirements for an integrated response capability, including supporting requirements for command and control, drills, training, and change control. The proposed rule would also establish requirements for enhanced onsite emergency response capabilities. This rulemaking is applicable to power reactor licensees, power reactor license applicants, and decommissioning power reactor licensees. Th rulemaking combines two activities that the NRC has documented in the FR—“Onsite Emergency Response Capabilities” (RIN 3150-AJ11; NRC-2012-0031), and “Station Blackout Mitigation Strategies” (RIN 3150-AJ08; NRC-2011-0299). If the rule goes into effect, the NRC will determine the sufficiency of licensees’ facilities and equipment to respond to these events during the normal course of drill and exercise evaluations, as each site will have specific equipment based on the site-specific responses developed. SECY-16-0142 (https://www.nrc.gov/docs/ML1630/ML16301A005.html) provides additional information on the MBDBE rulemaking .
Question No. 219
Considering that many U.S. plants constructed to 1970s designs are located on the coasts of surface water bodies, have you taken measures to modernize reliable service water supply systems of the plants to enhance their viability (for example, by equipping the systems with pumps capable of underwater operation)?
Answer: Generally, the NRC has not directed plants to modernize the reliable service water supply system, in the absence of a performance deficiency (although some plants may have service water pumps that are capable of operating underwater). However, the Mitigating Strategies Order requires all plants to develop strategies to maintain or restore core cooling, SFP cooling, and the containment function following a beyond-design-basis event that results, in part, on loss of normal access to the ultimate heat sink. Those strategies may include the use of pumps that are capable of operating underwater.

The NRC previously considered service water issues in GL 89-13, "Service Water System Problems Affecting Safety-Related Equipment," dated April 4, 1990 (https://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1989/gl89013.html).
Question No. 220
The Report states that in respect to all power units the development of methods to maintain (or restore) core cooling is needed, such as installation of portable electrical AC power sources, installation of additional pumps for water supply and routing of hoses. How many power units are currently equipped with emergency response equipment as needed (diesel-generators, pumps, hose routes)?
Answer: As of December 31, 2016, 84 out of 99 units are fully in compliance with the Mitigating Strategies Order, which includes obtaining all the necessary equipment to meet the requirements of the order. The remaining sites have the equipment available but have not yet completed all aspects of their plan for MBDBEs. For example, some plants will not be in compliance with the Mitigating Strategies Order until they have installed a hardened vent (because for those plants, the vent is needed to remove heat from the containment to ensure the mitigating strategies can be implemented as required). Those plants have the necessary emergency response equipment on site.
Question No. 221
The report states "Section IV.F.2(d) of Appendix E to 10 CFR Part 50, requires the offsite response agencies to participate in biennial exercises of their plume exposure pathway plans every 2 years, and for the State to participate in an ingestion pathway exercise with a nuclear power plant located within its State every 8-year exercise cycle". May US elaborate on ingestion pathway exercise?
Answer: FEMA is responsible for evaluating ingestion exposure pathways. Licensees generally have no involvement in these exercises. An ingestion pathway exercise may be a continuation of a plume exposure pathway exercise, often on the day following the plume exercise. FEMA publishes FEMA-P-1028, "Program Manual: Radiological Emergency Preparedness," January 2016 (https://www.fema.gov/media-library-data/1452711021573-a9b920f4f7ac34ea9f32738f51982afe/DHS_FEMA_REP_Program_Manual_Jan2016_Secure.pdf). States are tasked to demonstrate their ability to assess the radiological consequences for the ingestion exposure pathway, relate them to the appropriate PAGs, and make timely protective action decisions. States are also tasked to demonstrate their ability to implement protective actions, based on criteria recommended by the U.S. Food and Drug Administration, within the 50-mile ingestion exposure pathway emergency planning zone. States demonstrate the ability to obtain and use current information on locations such as farms, fisheries, and food processing plants. The States must also demonstrate the ability to control, restrict, or prevent distribution of contaminated foods. Other assessment criteria relevant to any exercise, such as mobilization and communications, may be evaluated as part of exercise play. FEMA observes and evaluates the conduct of the exercise. Some scenarios may involve public relocation or reentry decisions.

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

The United States reviewed the results of the CNS 2015–2016 consultancy meetings that developed a template to support drafting Articles 17 and 18 of the contracting parties' national reports. The group of CNS experts helped correlate each subsection of Articles 17 and 18 with relevant IAEA safety requirements. The United States has taken into consideration the template and its supporting information. No changes to the U.S. National Report were made as a result of this effort.

Question No. 222
In the discussion on the Vienna Declaration on Nuclear Safety, NRC said it discourages siting in locations where there is unacceptable risk of offsite contamination. Does this apply in the sense that new plants would be acceptable even in e.g. a case that the releases cannot be prevented or mitigated, but the site is remote enough so that the (large) population would not be affected? This seems not to comply with the Vienna Declaration principle 1, which requires that plants are designed to prevent and mitigate releases to avoid long term contamination.
Answer: The U.S. licensing requirements assess the adequacy of the design and of the site. The NRC has licensed U.S. nuclear power plants with reasonable assurance that unacceptable radiological releases could be prevented or mitigated. In other words, the

United States has not relied upon nor will it rely upon (in future nuclear power plant licensing) an unusually remote location to ameliorate what would otherwise be considered unacceptable radiological risks of either early radioactive releases or long-term offsite contamination from a proposed plant.

As discussed in 10 CFR Part 100, Subpart B, "Evaluation Factors for Stationary Power Reactor Site Application on or After January 10, 1997," the NRC considers many factors in the site evaluation process. These factors include those relating both to the proposed reactor design and to the characteristics peculiar to the site, such as areas of low population density. The NRC expects that reactor design, construction, and operation will reflect an extremely low probability for accidents that could result in a release of significant quantities of radioactive fission products. In addition, all natural phenomena that might affect the design or operation of the plant must be characterized, so that 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. Consequently, the site location and the engineered features included as safeguards against the hazardous consequences of an accident, should one occur, assure a low risk of public exposure. By taking this approach, the NRC's regulations effectively discourage the siting of new plants at locations where there is an unacceptable risk of long-term offsite contamination or large releases requiring long-term protective actions, which is consistent with Vienna Declaration Principle 1.

Question No. 223

Further elaboration on the post-Fukushima assessment of non-seismic external would be helpful.

Can the Contracting Party provide specific examples related to non-seismic hazards as was done in other sections of the Contracting Party's report?

Answer: In response to the events at the Fukushima Dai-ichi nuclear power plant following the March 11, 2011, earthquake and subsequent tsunami, the NRC undertook a series of actions to reevaluate the capability of operating nuclear plants to withstand the effects of external flooding events. Among these activities, the NRC staff issued a request for information (ADAMS Accession No. ML12053A340) to all power reactor licensees and holders of construction permits under 10 CFR 50.54(f) to request that respondents do the following:

(1) Perform plant walkdowns to verify the capability of their plants to respond to the flood events for which they were designed and licensed.

(2) Reevaluate flooding hazards at their nuclear power plant sites using updated flooding hazard information and present-day regulatory guidance and methodologies consistent with those used to review applications for new nuclear reactors. The reevaluations considered the following flood hazard mechanisms: local intense precipitation; flooding in streams and rivers; dam failures and breaches; storm surge; seiche; tsunami; ice-induced flooding; channel mitigation or diversion; and combined events.

The flood hazard reevaluations have been completed for all nuclear power plant sites. At sites for which the reevaluated flood is not bounded by the current design basis, licensees are now performing focused evaluations or integrated assessments of the plant response to the reevaluated flooding hazards (ADAMS Accession No. ML15254A006). Licensees will submit focused evaluations in 2017 and the more detailed integrated assessments in 2018. The aforementioned process developed for reevaluating flooding hazards is conceptually similar to the process developed to address seismic hazards.

For natural hazards other than seismic and flooding, the staff used a four-step review process:

(1) Define natural hazards (other than seismic and flooding) that potentially pose a threat to nuclear power plants and perform a screening to determine which of those should be reviewed generically.

(2) Determine and apply screening criteria to appropriately exclude certain natural hazards from further generic evaluations or exclude some licensees from considering certain hazards.

(3) Perform a technical evaluation to assess the need for additional actions if the hazard or licensee was not screened out generically in Task 2.

(4) Based on the results of Task 3, determine if additional regulatory actions are needed.

Based on the results of Tasks 1 and 2, the NRC staff concluded that, other than seismic and flooding, only those natural hazards associated with high winds and snow loads warranted further assessments and stakeholder interactions (ADAMS Accession No. ML16102A297). Upon subsequent evaluation, the staff concluded that regulatory action to provide additional protection against high winds and snow loads is not warranted (ADAMS Accession No. ML15254A006). The staff provided further confirmation in SECY-16-0074, "Assessment of Fukushima Tier 2 Recommendation Related to Evaluation of Natural Hazards other than Seismic and Flooding," dated June 17, 2016 (ADAMS Accession No. ML16102A297).

Question No. 224

Does protection against flooding events and the General Design Criterion 2, "Design Bases for Protection against Natural Phenomena" consider bio-fouling of the cooling water intake structure.

Answer: The potential for biofouling of cooling water intakes is a consideration for the hydrology safety assessment, if safety-related water is needed from a source where the intake screens could be blocked by biological debris or drift. NUREG-0800, Section 2.4.11, addresses low-water considerations, which include the evaluation of natural phenomena such as sediments or debris that could potentially block water intakes (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/). Bio-fouling would be considered a "debris" phenomenon and would be evaluated for compliance with both GDC 2, "Design Bases for Protection Against Natural Phenomena," and GDC 44, "Cooling Water."

Question No. 225

A RFI of March 12, 2012 required each reactor licensee to reevaluate the seismic and flooding hazards at its site using present-day guidance, methods and information. Did the RFI lead to differences between the reevaluated hazards and the hazards used up to that time? What are the reasons for the differences? Did the reevaluations lead to additional regulatory actions to ensure that the plants are adequately protected from seismic and flooding events?

Answer: The U.S. nuclear power plants were licensed and began operation over a span of several decades. The request for information issued in March 2012 asked, in part, that licensees reevaluate seismic and flooding hazards using present-day guidance, methods, and information. The available information on seismic and flooding hazards has evolved since the licensing of older plants, as have available analytical models and regulatory guidance. In a number of cases, the reevaluated hazards were different than the hazards used for the initial design and licensing of a given plant (for information on specific plants, see https://www.nrc.gov/reactors/operating/ops-experience/japan-dashboard/japan-plants.html). For those plants where reevaluated hazards were not bounded by the existing hazards, the licensee is performing additional evaluations to determine how the plant would respond to the reevaluated hazards. Based on those evaluations, the NRC will determine whether additional regulatory actions are warranted.

In addition, the NRC is requiring that the mitigation strategies being developed for beyond-design-basis external events address the reevaluated seismic and flooding information resulting from the reevaluations described in the request for information. Guidance for addressing the reevaluated seismic and flooding hazards within the mitigating strategies is in Revision 3 to NEI 12-06 (ADAMS Accession No. ML16267A274), endorsed by the NRC staff in Revision 2 to JLD-ISG-2012-01 (ADAMS Accession No. ML12229A174).

Question No. 226

It is stated that all natural phenomena that might affect the design or operation of the plant must be appropriately characterized, so that the plant's design basis appropriately considers the most severe natural phenomena at the site with sufficient safety margin for the limited accuracy, quantity and period of time in which historical data have been accumulated.
How is the most severe natural phenomena (such as extreme wind, precipitation, air temperature, etc.) at the site determined, based on the historical data accumulated?

Answer: For the majority of natural phenomena, the most severe characteristics are represented by very low likelihood events. To appropriately consider the limited accuracy, quantity, and period of time in which historical data have been accumulated, modeling is used to supplement information in the historical record for the site. These modeling approaches and supporting data are used to assure that the most severe natural phenomena at the site are represented by very low likelihood events, which are based on physical processes that either did or could occur at the site. These hypothetical events are maximized by approaches described in NRC guidance. These low likelihood but physically possible events are then used to develop the design bases and operational conditions for the proposed facility.

The following details the approaches used for determining the most severe natural phenomena at the site:

- Earthquakes: The SSE (most severe design-basis earthquake) represents a ground motion that has an exceedance frequency of approximately 10^{-4} per year, as outlined in RG 1.208, “A Performance-Based Approach To Define the Site-Specific Earthquake Ground Motion,” issued March 2007 (ADAMS Accession No. ML070310619).

- Tornado Winds: The design-basis tornado wind speeds for new reactors correspond to an exceedance frequency of 10^{-7} per year, as outlined in RG 1.76, “Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants,” Revision 1, issued March 2007 (ADAMS Accession No. ML070360253).

- Hurricane Winds: The design-basis hurricane wind speeds correspond to an exceedance frequency of 10^{-7} per year, as outlined in RG 1.221, “Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants,” issued October 2011 (ADAMS Accession No. ML110940300).

- Floods: Methodologies for calculating design-basis water levels associated with flood-causing mechanisms are discussed in NUREG-0800, Section 2.4. Each flood-causing mechanism has a separate subsection (e.g., Section 2.4.5 is storm surge, Section 2.4.6 is tsunami). Current NRC guidance focuses on deterministic approaches, but probabilistic methods are not prohibited (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/).

- Snow Loads: Normal and extreme winter precipitation loads on the roofs of seismic Category I structures are calculated deterministically in accordance with ISG DC/COL-ISG-7, “Assessment of Normal and Extreme Winter Precipitation Loads on the Roofs of Seismic Category I Structures,” dated June 23, 2009 (ADAMS Accession No. ML091490565).

In contrast to other natural phenomena, ambient temperature and humidity statistics are derived primarily from historical data recorded at nearby representative climatic stations or obtained from appropriate standards with suitable corrections for local conditions (e.g., American Society of Heating, Refrigerating, and Air-Conditioning Engineers Handbook—Fundamentals). Either historic extreme or calculated 100-year return period values are chosen for the design basis, depending on which values are bounding.

Question No. 227

It is stated that because a seismic probabilistic risk assessment requires site-specific hazards information, seismic margin analyses are required. Are the seismic margin analyses conducted without site-specific hazards information?

Answer: Seismic margin analysis is carried out without site-specific information during the design certification stage, as the site-specific information is not available. Seismic margin methods do not use probabilistic seismic hazard, but they use a deterministic review-level earthquake, which is higher than the design basis. This review-level earthquake can be based on site-specific information, but for most applications, it is defined using a broad-shaped spectra. For the design certification, the review level earthquake is 1.67 * certified seismic design response spectra. In the design certification, the seismic margin analysis is carried out using the PRA-based approach, as described in DC/COL-ISG-020, “Implementation of a Probabilistic Risk Assessment-Based Seismic Margin Analysis for New Reactors,” dated March 15, 2010 (ADAMS Accession No. ML100491233). Note that demonstration of high confidence of low probability of failure of 1.67 * certified seismic design response spectra is at the plant level, based on a Level 1 PRA model for core-damage sequences. There are subsequent analyses at the COL stage and before the fuel load to bring site-specific features and as-built conditions in the PRA models. DC/COL-ISG-020 describes these approaches.

Question No. 228

According to ANSI/ANS-2.15-2013 American National Standart published by American Nuclear Society in 2013 which is related to atmospheric dispersion calculation of routine releases and modeling criteria, If the result of straight-line Gaussian models is greater than 10% of regulatory limits and if the complex flow (due to complex terrain: valleys & mountains, land water circulation) occurs more frequently than 15% of the year, variable trajectory modeling shall be performed.
Do you have any complex terrain proposed for NPP site or any NPP constructed to complex terrain in USA and if yes how do you perform the review and assessment of atmospheric

dispersion calculations during siting and the analysis of radiological consequences of NPP for complex terrains? Can you give a specific model name to be used as variety trajectory modeling accounting the land-sea breeze effect and complex terrain features for routine releases and accidental releases?
<u>Answer</u>: The NRC has not endorsed ANSI/ANS-2.15-2013, “Criteria for Modeling and Calculating Atmospheric Dispersion of Routine Radiological Releases from Nuclear Facilities.” The NRC’s guidance for performing atmospheric dispersion calculations of routine releases can be found in RG 1.111, Revision 1, issued July 1977 (ADAMS Accession No. ML003740354). Most of the NRC’s applicants have performed their atmospheric dispersion calculations for routine releases using the XOQDOQ model, which is described in NUREG/CR-2919, “XOQDOQ: Computer Program for the Meteorological Evaluation of Routine Effluent Releases at Nuclear Power Stations.” The XOQDOQ dispersion model is a straight-line Gaussian plume model that implements the guidance for the constant mean wind direction models described in RG 1.111 and is referenced in NUREG-0800, Section 2.3.5, “Long-Term Atmospheric Dispersion Estimates for Routine Releases,” Revision 3, issued March 2007 (ADAMS Accession No. ML070730713). Section 2.3.5 states that, for unusual topographic and meteorological conditions, correction factors to the straight-line Gaussian XOQDOQ model or a variable trajectory model may be used on a case-by-case basis. Nuclear power plant applicants planning to site a proposed facility in complex terrain have generally used the default open-terrain correction factors from the straight-line Gaussian XOQDOQ dispersion model to account for unusual topographic and meteorological conditions associated with river valley and coastal sites. This means that all the atmospheric dispersion factors (?/Q values) and deposition factors (D/Q values) out to a distance of 1 kilometer were multiplied by a factor of four and all ?/Q and D/Q values between 1 and 10 kilometers were multiplied by a factor that deceased logarithmically from four at 1 kilometer to one at 10 kilometers. Local temporal and spatial dependencies of individual sea (lake) breezes do not significantly affect long-term average dispersion analyses because they average out over the year. The NRC has determined that the use of the default XOQDOQ open-terrain correction factors conservatively account for possible recirculation caused by land-water boundaries at coastal sites. A recent NRC applicant’s site is surrounded by complex terrain, with alternating ridges and valleys resulting in up-valley and down-valley flow patterns. This applicant used EPA’s CALPUFF modeling system to model its complex terrain site (https://www3.epa.gov/scram001/dispersion_prefrec.htm) as a method to confirm results from the XOQDOQ dispersion model. CALPUFF is a nonsteady-state puff dispersion model that simulates the effects of time- and space-varying meteorological conditions on pollution transport. According to EPA, CALPUFF can be applied for long-range transport and for complex terrain. The NRC is currently reviewing the acceptability of CALPUFF and its appropriateness for use at an applicant’s complex terrain site. The following two models could be used as a variable trajectory model to account for complex terrain features are listed below, although the NRC has not approved these models for new reactor applications:

- The Hybrid Single-Particle Lagrangian Integrated Trajectory model was developed by the U.S. Department of Commerce, National Oceanic and Atmospheric Administration's Air Resources Laboratory (http://ready.arl.noaa.gov/HYSPLIT.php). This model has been used in a variety of simulations describing the atmospheric transport, diffusion, and deposition of pollutants and hazardous materials, including radioactive material. The model calculation method is a hybrid between the Lagrangian approach, using a moving frame of reference for the advection and diffusion calculations as the trajectories or air parcels move from their initial location, and the Eulerian methodology, which uses a fixed three-dimensional grid as a frame of reference to compute pollutant air concentrations. The model's default configuration assumes a three-dimensional particle distribution (horizontal and vertical).

- The U.S. National Nuclear Security Administration's National Atmospheric Release Advisory Center uses the atmospheric dispersion model, LODI, to provide timely and accurate real-time assessment advisories to emergency managers for rapid decisionmaking during an emergency response involving a nuclear or chemical release (https://nnsa.energy.gov/aboutus/ourprograms/emergencyoperationscounterterrorism/respondingtoemergencies-0-2). The LODI model solves the three-dimensional advection-diffusion equation using a Lagrangian stochastic, Monte Carlo method with continuous representation of terrain on a grid with greater resolution near the hazard release point.

These two models are intended to analyze single-release events and may need to be reconfigured to produce annual average atmospheric dispersion results typically used to model routine releases. These models would also need adequate regional topographic and meteorological data to appropriately model local complex terrain effects

COL application assessments using Gaussian models are typically within regulatory limits and the use of more sophisticated atmospheric dispersion modeling is unlikely to result in differences that will alter this conclusion. Once a nuclear power plant becomes operational, licensees use their radiological environmental monitoring program to monitor radiation and radioactivity levels in the environs of the plant associated with gaseous effluent releases to help demonstrate verification with regulatory requirements.

Question No. 229

In response to the Fukushima accident, the NRC used its existing regulatory processes to request that licensees reevaluate the seismic and flooding hazards at their sites using present-day regulatory guidance and methodologies and, if necessary, perform a risk evaluation. The results of these reevaluations will be used to determine whether additional regulatory actions are necessary.
When the results of the site reevaluations are going to be available? If they are already available, when the US NRC is going to take additional regulatory actions if necessary?

Answer: All sites have completed their seismic and flooding reevaluations. Those evaluations that are publicly available may be found on the site-specific Web pages at https://www.nrc.gov/reactors/operating/ops-experience/japan-dashboard/japan-plants.html. The NRC has completed its review of the licensee responses for all of the seismic reevaluation reports and many of the flooding reports; these, if public, are also available on that Web site.

If the existing design basis did not bound the licensee's hazards, the licensees are performing additional evaluations to determine how the plant would physically respond to the new hazards. The NRC will review those additional evaluations to determine if additional regulatory action is warranted. The timeframe for when the additional evaluations will be reviewed varies depending on the evaluation. Section 1.3.3 of the U.S. 7th National Report contains more information on the additional evaluations and other activities.

Question No. 230

The specified value of "1.67 times the ground motion acceleration of the design basis" SSE that the plant must withstand", does it refers to sequences leading to core damage or sequences leading to containment failures? Please provide additional information.

Answer: The demonstration of a 1.67 margin in ground motion acceleration applies to both sequences leading to core damage and sequences leading to containment failure. The NRC states this expectation in SECY-93-087 (ADAMS Accession No. ML003708021) (i.e., "PRA insights will be used to support a margins-type assessment of seismic events. A PRA-based seismic margins analysis will consider sequence-level High Confidence, Low Probability of Failures (HCLPFs) and fragilities for all sequences leading to core damage or containment failures up to approximately one and two-thirds the ground motion acceleration of the Design Basis SSE").

Question No. 231

At the RIC conference 2015, one of the NRC commissioners discussed about the possibility of introducing periodic assessments of external hazards in the US regulatory approach. Section 17.4 does not describe the periodical reassessments of the external hazards at the operating US NPPs, only the reassessment made after the Fukushima accident. Are there any plans to introduce periodical reassessments in the US? Would it be the responsibility of the licensee or the regulator to make the reassessment?

Answer: Following the accident at Fukushima Dai-ichi, NTTF Recommendation 2.2 proposed that the NRC initiate a rulemaking to require that licensees confirm seismic and flooding hazards every 10 years. Specifically, Recommendation 2.2 suggested that licensees address any new and significant information and, if necessary, take actions that could include updating the design basis for SSCs important to safety to protect against the updated hazards. This recommendation stems from recognition that, as the state of knowledge with regard to natural hazards evolves, there is benefit in incorporating this new information into the models used to assess these hazards and evaluating whether there are any changes significant enough to warrant additional regulatory action.

The staff's subsequent assessment concluded that the NRC can meet the underlying intent of Recommendation 2.2 using an approach other than rulemaking. In SECY-15-0137, Enclosure 2 (ADAMS Accession No. ML15254A008), the staff found that current practices to assess new natural hazard information and its significance are generally effective but identified a number of ways to enhance existing processes. Specifically, in SECY-15-0137, the staff proposed to enhance existing processes and develop associated staff procedures to ensure that the staff proactively and routinely aggregates and assesses new natural hazard information. The staff proposed that the enhanced internal process would leverage and augment existing programs and agreements with domestic and international organizations.

Enclosure 2 of SECY-16-0144 (ADAMS Accession No. ML061770301) provides the Commission with additional details on the staff's plan to enhance existing processes to ensure ongoing assessment of new information and reconfirmation of natural hazards consistent with Recommendation 2.2. The proposed framework consists of three primary components:

(1) Knowledge-based activities, which include (1) a series of preparatory, near-term activities to develop an infrastructure that will collect and archive materials that have been docketed by licensees or developed by the staff as part of activities associated with NTTF Recommendations 2.1 and 2.3, new reactor reviews, and other regulatory activities related to natural hazards, and (2) longer term activities to maintain and update the archives.

(2) Active technical engagement and coordination, which involves leveraging and enhancing ongoing interactions with internal and external partners (including other Federal agencies, academia, industry, regulators from other countries, and other technical and scientific organizations) to ensure that the staff routinely and systematically collects pertinent new hazard information from a variety of sources.

(3) Assessment activities, which include aggregation and evaluation of the significance of new information (e.g., data, models, and methods) as well as referral of potentially significant issues to appropriate regulatory programs.

The proposed framework will allow the NRC staff to systematically and efficiently gather and evaluate information on an ongoing basis and will require licensees to provide information only when the responsible program office deems it necessary to make a decision on a regulatory action.

The process outlined in Enclosure 2 of SECY-16-0144 will guide the staff in collecting, aggregating, reviewing, and assessing information on an ongoing basis. The process will establish a more routine, proactive, and systematic program for identifying and evaluating new information related to natural hazards.

Question No. 232

It is recognised that according to 10 CFR 50.109, the NRC has a regulatory instrument to require necessary backfits in case a re-evaluation of site-specific hazards will identify the need to increase the protection of public health and safety. Nevertheless, no regulatory requirements for a periodic re-evaluation of site-specific hazards exist in the USA. However, the awareness of changed site-specific hazards is the prerequisite for any activity under 10 CFR 50.109. Could the USA explain how detrimental alterations of hazards at a specific site will be recognised without a periodic re-assessment?

Answer: The NRC has long recognized the importance of protecting NRC-licensed facilities from natural phenomena. Following initial licensing, the NRC has historically evaluated external hazard information as it has been identified and taken actions to update guidance or to impose regulations, as needed, consistent with the regulatory processes in 10 CFR 50.54(f) and 10 CFR 50.109. Further, the NRC monitors plant performance and operating experience on a daily basis through its oversight program, and this program provides a mechanism for the NRC to identify new information and refer it to the appropriate regulatory process for consideration. The NRC's regulatory framework also provides for licensee review of new hazard information and, as necessary, consideration and resolution of new information in a variety of ways. Moreover, the NRC has considered multiple GIs related to natural hazards, including recently identified GIs related to seismic hazards (GI-199, "Implication of Seismic Hazard Estimates") and dam failures. The NRC has several research programs related to natural hazards and has worked collaboratively with Federal partners and the industry (through

EPRI) on projects to assess the impact on plant safety of the latest understanding of certain natural phenomenon hazards, analytical advances, and evaluation tools.

A number of natural events have affected nuclear sites around the world. These events include tsunamis, flooding, high winds, and seismic events. The NRC and the industry routinely conduct investigations to identify the lessons learned from these events. Recent examples have included the 2004 Sumatran tsunami; ground motions experienced at Japan's Kashiwazaki-Kariwa site during a large earthquake in 2007; the 2011 Mineral, VA, earthquake; and recent flooding at Fort Calhoun. Following the accident at Fukushima Dai-Ichi, NTTF Recommendation 2.2 proposed that the NRC initiate a rulemaking to require that licensees confirm seismic and flooding hazards every 10 years. Other studies conducted after the Fukushima Dai-Ichi accident also include recommendations that emphasized the importance of assessing new information. The staff's subsequent assessment concluded that the NRC can meet the intent of Recommendation 2.2 using an approach other than rulemaking. As discussed above, the NRC and its licensees continually evaluate new information as it becomes available to assess its potential impact on risk and overall plant safety. Thus, in SECY-15-0137, Enclosure 2 (ADAMS Accession No. ML15254A008), the staff found that current practices to assess new natural hazard information are generally effective but identified a number of ways to enhance existing processes to be more proactive. Specifically, the staff proposed to enhance existing processes and develop associated staff procedures to ensure that the staff proactively and routinely aggregates and assesses new natural hazard information. The staff proposed that the enhanced internal process would leverage and augment existing programs and agreements with domestic and international organizations.

Enclosure 2 of SECY-16-0144 (ADAMS Accession No. ML061770301) provides the Commission with additional details on the staff's plan to enhance existing processes to ensure the ongoing assessment of new information and reconfirmation of natural hazards consistent with Recommendation 2.2. The proposed framework consists of three primary components:

(1) Knowledge-based activities, which include (1) a series of preparatory, near-term activities to develop an infrastructure that will collect and archive materials that have been docketed by licensees or developed by the staff as part of activities associated with NTTF Recommendations 2.1 and 2.3, new reactor reviews, and other regulatory activities related to natural hazards, and (2) longer term activities to maintain and update the archives.

(2) Active technical engagement and coordination, which involves leveraging and enhancing ongoing interactions with internal and external partners (including other Federal agencies, academia, industry, regulators from other countries, and other technical and scientific organizations) to ensure that the staff routinely and systematically collects pertinent new hazard information from a variety of sources.

(3) Assessment activities, which include aggregation and evaluation of the significance of new information (e.g., data, models, and methods) as well as referral of potentially significant issues to appropriate regulatory programs.

While licensees' regulatory responsibilities related to identifying and evaluating new information have not changed, the proposed framework will be implemented primarily by NRC staff subject matter experts. The proposed framework will allow the NRC staff to systematically and efficiently gather and evaluate information on an ongoing basis and will require licensees to provide information or take action only when the responsible program office deems it necessary, consistent with existing regulatory processes (e.g., backfit, operability). Thus, the proposed framework will enable the staff to achieve the underlying intent of Recommendation 2.2 in a manner that is timely, integrates well with NRC’s existing regulatory framework, and is less burdensome on the agency and licensees than imposing a new rule. Moreover, the proposed framework provides an alternative to requiring that licensees evaluate information at a predefined periodicity, regardless of its potential significance to a site or group of sites.

The process outlined in Enclosure 2 of SECY-16-0144 will guide the staff in collecting, aggregating, reviewing, and assessing information on an ongoing basis. The process will establish a more routine, proactive, and systematic program for identifying and evaluating new information related to natural hazards. To ensure the process is durable and executed consistently, the proposed enhanced process would be institutionalized via office instruction and by necessary additional documents that will define a series of activities associated with periodic technical engagement, information collection and management, risk-informed assessment of information, and documentation of program activities.

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 DID philosophy and how it is embodied in the GDC of U.S. regulations. It explains how applicants meet the DID 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 man-machine interface, lessons learned from Fukushima, and the Vienna Declaration on Nuclear Safety, issued in February 2015. Article 12 of this report also provides information on the human factors obligations.

Finally, the United States reviewed the results of the CNS 2015-2016 consultancy meetings that developed a template to support drafting Articles 17 and 18 of the contracting parties' national reports. The group of CNS experts helped correlate each subsection of Articles 17 and 18 with relevant IAEA safety requirements. The United States has taken into consideration the template and its supporting information. No changes to the U.S. National Report were made as a result of this effort.

Question No. 233
In terms of the requirements of the Vienna Declaration on Nuclear Safety, does NRC consider Watts Bar 2 NPP, which just entered commercial operation, a new plant that fulfils the principles or not? Could you please give examples of the safety enhancements that resulted where it was feasible to adopt updated standards, and of those updated standards that were considered but decided not feasible to adopt?
Answer: The NRC does not consider Watts Bar Nuclear Plant, Unit 2 (WBN2), to be a new plant under Principle 1 of the Vienna Declaration. The plant's fundamental design was approved in 1973 and a construction permit was issued. Construction on WBN2 proceeded until 1985, with a majority of the structures built and significant components, such as the reactor pressure vessel and reactor coolant system piping, installed. Nonetheless, the NRC believes that the fundamental intent of Principle 1 is met under the NRC's regulatory approach, which resulted in reevaluations of certain siting matters and the upgrading and modernization of portions of the WBN2 design. In addition, the NRC implemented an approach to oversight of

construction completion to provide reasonable assurance that the long interval between the cessation and reactivation of construction would not adversely affect public health and safety.

In July 2007, the NRC decided to use the current licensing basis of Watts Bar Nuclear Plant, Unit 1 (WBN1), as the reference basis for reviewing and licensing WBN2. TVA, the licensee for WBN1 and the applicant for the WBN2 operating license, was also encouraged to adopt updated standards for Unit 2 where it would not significantly detract from design and operational consistency between Units 1 and 2; specifically, for new systems and equipment that are different from WBN1. SRM-SECY-07-0096, "Possible Reactivation of Construction and Licensing Activities for the Watts Bar Nuclear Plant Unit 2," dated June 7, 2007 (https://www.nrc.gov/reading-rm/doc-collections/commission/srm/2007/), provides more information. Among the considerations that led to this decision is the fact that the WBN1 licensing basis has been upgraded over time by the NRC through the issuance of new regulations that were backfit on WBN2, as well as by the licensee, to reflect lessons learned though operation. Since 2007, the NRC has further upgraded the licensing basis of WBN2 by backfitting amended regulations (e.g., the Emergency Planning Rule change, 10 CFR 50.47, 76 FR 72559), new regulations (e.g., cybersecurity, 10 CFR 73.54, 74 FR 13970), current generic safety issues (e.g., GSI-191, "Assessment of Debris Accumulation on PWR Sump Performance"), and orders (e.g., Fukushima Orders: EA-12-049, on "Mitigation Strategies," dated March 12, 2012; EA-13-109, on "Containment Venting Systems, dated June 6, 2013; and EA-12-051, on "Spent Fuel Pool Instrumentation," dated March 12, 2012 (https://www.nrc.gov/reactors/operating/ops-experience/japan-dashboard/priorities.html)) that occurred during the course of the review. The NRC's decision was consistent with the Commission's 1987 Policy Statement on Deferred Plants (https://www.nrc.gov/reading-rm/doc-collections/commission/policy/#power). This Policy Statement describes the information to be provided by a licensee when a project is being reactivated and staff actions when notified of reactivation. The information required to be provided by the licensee includes a description of outstanding licensing issues, including any new requirements applicable to the plant. The Policy Statement also sets an expectation that a facility where construction is reactivated will be subject to all applicable current regulations, standards, policies, and guidance. If the reactivated plant does not meet current regulatory criteria, the plant will be evaluated on a case-by-case basis, with appropriate consideration of backfitting.

Apart from NRC-required updates to the licensing basis, TVA made several enhancements as a result of updated technology or design. These enhancements include installation of a safety-related digital post-accident monitoring system; use of an updated hydrology methodology for the site flooding analysis to match the work being performed to respond to the Fukushima Orders and demand for information; improvements in the I&C system to improve reliability or because some equipment was no longer available; installation of a digital rod position indication system and a digital distributed control system; and installation of an updated in-core instrumentation system. Thus, in many respects, those portions of the WBN2 design that could practically be upgraded, meet the NRC's current requirements for new power plants and therefore satisfy Principle 1 of the Vienna Declaration. Portions of the plant that were impractical to upgrade, given the state of construction at the time that construction ceased (e.g., reactor vessel already procured and installed), are acceptable under Principle 2 of the Vienna Declaration, which refers to "reasonably practicable or achievable safety improvements."

The NRC's oversight of construction after reactivation meets current NRC requirements applicable to new plants as well as the NRC's Policy Statement on Deferred Plants. Because plant construction was inactive for a long interval, TVA developed and submitted for NRC review and approval its Construction Refurbishment Program to ensure that the updated WBN2 design and licensing basis, including original equipment design specifications, would be met. The Construction Refurbishment Program was intended to refurbish or replace most active components and instruments. For other equipment, the program determines the potential degradation mechanism for each category of components, taking into account the environmental conditions, the acceptance criteria, and the refurbishment or inspection activities necessary to demonstrate compliance with applicable vendor and design specifications or requirements. The NRC staff reviewed TVA's program and on July 2, 2010, issued its evaluation, which concluded that, upon proper implementation, the Construction Refurbishment Program would provide reasonable assurance that the equipment would meet its design criteria and perform its intended functions (see ADAMS Accession No. ML101720050). Based in part on the staff's determination that the Construction Refurbishment Program was successfully implemented during the reactivated construction to complete the plant, the NRC issued an operating license for WBN2 on October 22, 2015 (81 FR 28905). The NRC staff's safety evaluation, which documents its findings for the operating license review for Watts Bar, can be viewed at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0847/. Based on the above, although it considers WBN2 to be an existing installation rather than a new power plant under Principle 1 of the Vienna Declaration, the NRC believes that its regulatory approach with respect to licensing of the operation of WBN2 to be fully consistent with Principle 1.
Question No. 234
Can the Contracting Party elaborate on the application of defence in depth, reflecting post-Fukushima design enhancements and overall improvements to safety margins?
Answer: The DID philosophy, as applied in regulatory practice, is a fundamental element of the NRC's safety philosophy that employs successive provisions to prevent or mitigate accidents that release radiation or hazardous materials, if a malfunction, accident, or naturally caused event occurs at a nuclear facility. The NRC does not impose the DID philosophy on applicants and licensees through an explicit requirement in its regulations. Rather, it embodies the philosophy in its regulatory requirements, associated guidance, and regulatory programs. These requirements provide reasonable assurance that licensed nuclear power plants will have adequate design features and operational programs to prevent and mitigate accidents to protect public health and safety. The NRC issued new requirements in response to lessons learned from the March 2011 accident at Japan's Fukushima Dai-ichi facility. These requirements have led to inclusion of additional provisions for prevention and mitigation of accidents at U.S. plants, which has enhanced the level of DID at these plants. These requirements are summarized below. The current status of the implementation of these requirements, including NRC oversight, is provided in the NRC's latest 6-month status update on response to lessons learned from Japan's March 11, 2011, Great Tohoku Earthquake and Subsequent Tsunami (ADAMS Accession No. ML16054A296). The next 6-month status update will be issued shortly.

On March 12, 2012, the NRC issued the following orders in response to lessons learned from the March 2011 accident at Japan's Fukushima Dai-ichi facility:

- EA-12-049, "Issuance of Order to Modify Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events" (ADAMS Accession No. ML12054A735)

- EA-12-050, "Issuance of Order to Modify Licenses with Regard to Reliable Hardened Containment Vents" (ADAMS Accession No. ML12054A694)

- EA-12-051, "Issuance of Order to Modify Licenses with Regard to Reliable Spent Fuel Pool Instrumentation" (ADAMS Accession No. ML12054A679)

On June 6, 2013, the NRC issued Order EA-13-109, "Issuance of Order to Modify Licenses with Regard to Reliable Hardened Containment Vents Capable of Operation under Severe Accident Conditions" (ADAMS Accession No. ML13143A321), which modified and superseded Order EA-12-050.

Order EA-12-049 requires all U.S. nuclear power plants to implement strategies that will allow them to cope without their permanent electrical power sources for an indefinite amount of time. These strategies must keep the reactor core and spent fuel cool, as well as protect the thick concrete containment buildings that surround each reactor. The mitigation strategies are expected to use a combination of currently installed equipment (e.g., steam-powered pumps), additional portable equipment that is stored on site, and equipment that can be flown in or trucked in from support centers.

Order EA-12-050 required all U.S. nuclear power plants with the Fukushima-style containment design to install a reliable, hardened vent that can remove heat and pressure before potential damage to a reactor core occurs. This not only helps preserve the integrity of the containment building but can also help delay reactor core damage or melting. After issuing the order, additional NRC evaluations examined the benefits of venting after reactor core damage occurs. In June 2013, the NRC issued Order EA-13-109, which modified Order EA-12-050 to ensure those vents will remain functional in the conditions following reactor core damage.

Order EA-12-051 requires all U.S. nuclear power plants to install water-level instrumentation in their SFPs. The instrumentation must remotely report at least three distinct water levels: (1) normal level, (2) low level but still enough to shield workers above the pools from radiation, and (3) a level near the top of the spent fuel rods where more water should be added without delay.

Order EA-13-109 defines requirements related to containment venting before and during severe accident conditions, which is a subset of the issues related to containment performance during severe accidents outlined in SECY-12-0157. Other issues include improving licensees' severe accident management capabilities and filtering strategies to limit the release of radioactive materials when venting is necessary. This Order rescinds the requirements imposed in Section IV and Attachment 2 of EA-12-050 and replaces them with the requirements in Section IV and Attachment 2 of this Order.

Section 1.3.3 of the U.S. 7th National Report contains more information on the orders and the status of implementation.

Question No. 235
"In 2007, the NRC began developing a construction experience (ConE) program to focus on collecting, analyzing, and applying lessons learned from the design and construction of new reactors. In recent years, the ConE program was expanded to include reviews of events at operating reactors that were related to latent design and construction issues. The NRC staff values close cooperation with the international community for the exchange of information on design and construction of new reactors and continues to work closely with several countries that are currently building new nuclear power plants." What is your experience about the ConE (New Reactor Construction Experience) program? Does the program eventuate real, practicable information?
<u>Answer</u>: The Operating Experience Center of Expertise is an effort to align operating experience activities across NRC offices to work together to review, evaluate, and communicate operating experience from both new construction and operating reactors. Since issuing the 2016 report, the staff within the Operating Experience Center of Expertise has been combined into a single branch within NRR, which continues to review operating experience from both construction sites and operating reactors. This includes reviewing issues identified during construction, both domestically and internationally, as well as issues in operating reactors that date back to their design and construction. The issues are evaluated to determine appropriate actions and communications both within the agency and with licensees and public stakeholders, with an emphasis on communicating information that can be readily translated into discrete actions to promote safety. Actions resulting from the Construction Experience Program evaluations have included generic communications to inform the industry of issues that can arise during construction and guidance for inspectors based on problems that have been observed.
Question No. 236
Arts of cyber attack seem to advance rapidly. How frequent are requirements and guides on cyber security expected to be revised? The report says the NRC has developed an oversight program collaboratively with stakeholders.
<u>Answer</u>: The NRC reviews and revises its regulatory and guidance documents on a 5-year cycle. Both the NRC and the licensees maintain cybersecurity expertise. NRC experts typically receive, at a minimum, annual cybersecurity training. Licensee experts are trained in accordance with the specifications of their respective cybersecurity programs.
Question No. 237
Under Article 18 of the CNS, as specified in INFCIRC/572/Rev. 5, inter alia the following information was required: Describe how internal and external events are taken into account in the design, including natural external hazards and consequent combinations thereof (i.e. not simultaneous). Describe how the design of the plants provide for an adequate margin to protect items important to safety against levels of external hazards to be considered for design, taking into account the site hazard evaluation.

Describe to what extent it has been possible to prevent or mitigate design extension conditions by the original design measures or by means of design changes during plant modification or backfitting.

Describe the main design improvements made since the nuclear installations were commissioned.

The guidance given in INFCIRC/572/Rev.5 encompasses several more items to be described in the National Report. Switzerland would therefore encourage the United States to provide additional, specific information as stipulated by Article 18 and INFCIRC/572/Rev.5.

Answer: NRC RESPONSE: The NRC conducted a thorough evaluation of the guidance provided in INFCIRC 572, Revision 5, and considers that the U.S. 7th National Report provides a robust discussion of how the United States meets the objectives of the CNS.

ITEM 1
The plants are designed to various load combinations, considering conditions such as construction loads, normal operations, severe environmental (e.g., operating-basis earthquake, design wind, and design snow), extreme environmental (e.g., SSE, design tornado wind and missiles, hurricane wind and missiles), and abnormal conditions (e.g., high-energy pipe-rupture loads, pressure and temperature associated with design-basis accidents) as discussed in NUREG-0800.

The various combinations of the loads resulting from the above conditions include construction loads, normal operating loads, normal operating loads with severe environmental loads, normal operating loads with extreme environmental loads, normal operating loads with abnormal loads, normal operating loads with severe environmental and abnormal loads, and normal operating loads with extreme environmental and abnormal loads.

For example, the NRC's guidance on the applicable loads and load combinations and structural acceptance criteria for seismic category I structures is specified in NUREG-0800, Sections 3.8.1, 3.8.2, 3.8.3, 3.8.4, and 3.8.5, for concrete containment, steel containment, concrete and steel internal structures of steel or concrete containments, other seismic category 1 structures, and foundations, respectively.

ITEM 2
Typically, the margins are incorporated in plant design by selecting a conservative design-basis hazard, incorporating conservative factors in developing plant responses (loads) to the design-basis hazard, combining various operational and extreme loads, or designing SSCs by using industry codes and standards that incorporate safety factors. The following example of a seismic design approach used for new reactors demonstrates these concepts:

(1) The site-specific seismic design basis is derived from a probabilistic seismic hazard analysis. The ground motion is defined by a response spectrum that has frequency of exceedance no greater than 1×10^{-4}/year in the full range of spectrum frequencies. For a standard design, the spectrum used in the standard design is expected to envelop the site-specific spectra, providing additional margins.

(2) The plant response analysis uses conservative factors to select parameters such as damping values, a combination of three directional responses, and variability in soil and structural properties.

(3) The seismic loads are combined in various load combinations considering normal, operational, and accident conditions. For example, the seismic loads are combined with LOCA pressure loads in a containment design.

(4) The components and structures are designed using the codes such as American Concrete Institute and ASME. These codes include safety factors that provide capacity beyond design loads determined in Step 3.

(5) For new reactors, an additional step related to the seismic design requires demonstration of high confidence, low probability failure margin of 1.67 x design motion at the plant level (this is determined through using a PRA-based margin approach). That is, there is a very low probability of failure at the ground motion level of 1.67 x design-basis motion.

The NRC established the design basis for operating reactors using a deterministic process considering maximum historical events and including additional margin to account for incomplete knowledge. Conceptually, the steps used in the design generally followed the steps 2, 3, and 4 above, using the then-applicable methods, models, and standards. Although, the explicit evaluation of margins was not a part of the licensing process, the subsequent evaluations, such as individual plant examination for external events, show that generally significant margin (capacity) exists beyond design basis.

ITEM 3
After the events at Fukushima, the NRC ordered all licensees to have mitigating strategies to address beyond-design-basis events. The licensees are required to maintain key safety functions indefinitely, using installed equipment, then portable equipment, and, if needed, additional offsite resources. The staff has sent to the Commission a proposed rule that would make that order generically applicable. Section 1.3.3 of the U.S. 7th National Report contains more information on the NRC's application of the lessons learned from the Fukushima accident.

ITEM 4
Design improvements are made throughout the life of a facility and incorporated into the facility updated final SAR, as appropriate. Some are initiated by regulatory action; for example, changes associated resulting from the generic issues program at https://www.nrc.gov/about-nrc/regulatory/gen-issues.html. The resolutions of all resolved generic safety issues and the partial assessments of all remaining unresolved GIs are in NUREG-0933 (https://www.nrc.gov/sr0933/). Other design improvements are initiated by the operators and captured in the updated final SARs, but the regulatory body does not maintain a database of such improvements; thus, it would be extremely challenging to compile such a list for the entire fleet of U.S. nuclear power plants.

INPO RESPONSE:
Internal and external events such as seismic events, flooding, fires among other events, are taken into account in PRAs and other evaluations to ensure safety margins are maintained. In response to the events at Fukushima, U.S. plants have installed additional FLEX equipment to provide core, containment, and SFP cooling for the plant in the event of an extreme natural hazard. The plants will make necessary modifications to ensure the protection of key safety equipment and gain additional margin to meeting regulatory requirements. This will also allow

for additional flexibility in plant maintenance and operations through maintaining additional margin in their PRA risk profiles.

Examples of significant design improvements since the nuclear plants were commissioned are in the areas of more robust fuel designs; containment sump modifications and modifications that affect sump ability post-accident; additional instrumentation and control for monitoring conditions; redundant and diverse reactor trip/scram capability; improved materials in steam generators and other equipment that maintain better integrity; ancillary equipment, such as pumps and power, to respond to a large aircraft impact; emergency preparedness communications equipment; security modifications, such as ballistic resistant towers at the sites and hardened vehicle barriers; and most recently, the post-Fukushima FLEX equipment. However, many safety enhancements are not design improvements, and those are: operator procedures and training, emergency preparedness training and exercises with local and State personnel, configuration control through strict protocols implemented through procedures and processes, use of PRA insights and risk management in work management of plant maintenance activities, the corrective action program in which safety issues are tracked and corrected in a prioritized manner, the inception and role of INPO in driving industry standards of excellence and evaluating all U.S. plants against those standards, the use of EPRI in addressing technical issues, and the use of NEI in facilitating industrywide working groups that address generic industry issues.

Question No. 238

Section 18.3.2.3 discusses Cyber Security including the statement, "The NRC has developed an oversight program for cybersecurity that includes an inspection program, inspector training, and a process for evaluating the significance of inspection findings. " How does the Cyber Security program improve the NRC's Reactor Oversight Program (ROP) and what were the challenges during development and implementation?

Answer: Development of the cybersecurity oversight program provides challenges because of the dynamic nature of cybersecurity. As a learning and improving organization, the NRC has a formal process for periodic self-assessment of the Inspection and Oversight Program. Through this process, the NRC continuously reviews its programs and enhances them.

Question No. 239

What are the concrete deterministic severe accident management requirements for new NPPs in US? Could you give examples of requirements for containment integrity and management of the cooling of the molten core. Are there any independency requirements for specific SAM systems (independent from other systems including their supporting systems)? Could you also give examples of SAM design solutions at the NPPs under construction /entering construction phase that fulfill the US severe accident management requirements (e.g. residual heat removal from the containment, management of molten core).

Answer: For the NRC to license a new plant under 10 CFR Part 52, the plant must include design features for the prevention and mitigation of severe accidents. Indeed, NRC regulations in 10 CFR 52.47(a)(23) and 10 CFR 52.79(a)(38) require applicants for design certification or a COL, respectively, under 10 CFR Part 52 to provide, in their application, a description and analysis of design features for the prevention and mitigation of severe accidents (e.g., challenges to containment integrity caused by core-concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass. The NRC evaluates an applicant's analysis of the effectiveness of these design features in preventing and mitigating severe accidents in accordance with guidance in NUREG-0800, Section 19.0, "Probabilistic Risk Assessment and Severe Accident Evaluation for New

Reactors," Revision 3, issued December 2015, and confirms that a balance between prevention and mitigation has been achieved. The NRC has no specific requirements for features to prevent severe accidents to be independent of features designed to mitigate design-basis accidents (typically known as engineered safety features). However, depending on the specific accident condition (e.g., station blackout), additional features beyond those dedicated to mitigation of design-basis accidents may be required. Features for the mitigation of severe accident conditions that could reach a core melt condition are expected to be independent from those where failure may lead to the core melt condition in order for the design to satisfy the NRC's objectives for severe accident mitigation. Severe accident design features for designs recently certified by the NRC (i.e., the Advanced Passive 1000 (AP1000) and Economic Simplified Boiling-Water Reactor (ESBWR) are described in Chapter 19 of the respective DCDs submitted to the NRC with their application and are available at https://www.nrc.gov/reactors/new-reactors/design-cert.html.
Question No. 240
SSR2/1 Rev.1 contains specific requirements for the design basis. For example the design basis for each item important to safety shall be systematically justified and documented. Is this information contained in a document (design basis) prepared originally by the vendor of the NPP and subsequently updated by the operator or this information is contained in different documents like SAR, QA documentation, etc?
Answer: For existing nuclear power plants, the design basis for a plant is documented in the final SAR (see 10 CFR 50.34(b)) and is updated periodically to reflect the as-built plant as required by 10 CFR 50.71(e)). For new reactor designs, an applicant (typically a vendor) submits an application for design certification. Applicants must provide enough information to show their design meets the NRC's safety standards (10 CFR 52.47). Applicants must also show that their design resolves any existing generic safety issues, as well as issues that arose after the Three Mile Island accident. Applications must closely analyze the design's appropriate response to accidents or natural events, including lessons learned from the Fukushima accident. Applications must also lay out the ITAAC that will verify the construction of key design features. The NRC requires design certification applicants to assess how the designs protect the reactor and SFP from the effects of a large commercial aircraft impact. Certification reviews identify key information to consider in site-specific reviews for operating licenses. The NRC certifies acceptable reactor designs by adding them to agency regulations through a rulemaking. This rulemaking certifies a design for 15 years, and a reactor vendor can seek renewal of a certified design (https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/new-nuc-plant-des-bg.html). Applicants that wish to construct and operate a certified design plant must file a COL application in accordance with the regulations in Subpart C, "Combines Licenses," of 10 CFR Part 52. As provided in 10 CFR 52.73, "Relationship to Other Subparts," an applicant for a COL may, but does not need to, reference a standard design certification or standard design approval. However, as required by 10 CFR 52.79, "Contents of Applications; Technical Information in Final Safety Analysis Report," the application must contain a final SAR that describes the facility, presents the design bases and the limits on its operation, and presents a

safety analysis of the SSCs of the facility as a whole. After a COL is issued, the final SAR is required to be updated periodically in accordance with 10 CFR 50.71(e).
Question No. 241
WB 2 was a special case. What additional requirements were given to the original design concept, are they also part of review of other plants, e.g. in the process of License Renewal?
Answer: The Commission provided the NRC staff with a framework (SRM-SECY-07-0096) (https://www.nrc.gov/reading-rm/doc-collections/commission/secys/2007/secy2007-0096/2007-0096scy.pdf), which stated that the staff was to use the current licensing basis of WBN1 as the reference basis for reviewing and licensing WBN2. Beyond that, only applicable changes to regulations (e.g., Emergency Planning Rule change), new regulations (e.g., cybersecurity), and orders (e.g., Fukushima) that occurred during the course of the review were included as additional requirements to the original design. The applicability of these requirements to other plant reviews vary per requirement and would have to be evaluated on a case-by-case basis.
Question No. 242
With reference to article 18.3.2.3, pages 218 and 219 of the American national report, Korea would like to inquire the following question: How are cyber security requirements applied to the design of safety and Instrument and Control (I&C) equipment (i.e., design change or alternative measures to reflect cyber security technical measures)?
Answer: Operating reactor licensees are not currently required to submit design information used to address cybersecurity requirements as part of the NRC licensing review. The inclusion of such regulatory requirements is still under internal agency consideration.

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, test, 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 nuclear installation and in monitoring its safe operation throughout its life. This section describes the most significant regulations and programs corresponding to each obligation of Article 19. It also includes a discussion on the Vienna Declaration on Nuclear Safety, issued in February 2015.

Immediately after the accident at Fukushima in Japan, the NRC took actions that verified nuclear power plant operators’ preparedness to respond to and mitigate the consequences of beyond-design-basis events. Sections 1.3.1 and 1.3.3 of this report discuss these actions.

Question No. 243
In response to the Fukushima accident a significant safety analysis appears to have been completed to determine the required mitigating actions, subdividing actions between short-, medium- and long-term plans.

However, much of the corrective actions are to be implemented as part of the long-term plan. Can the Contracting Party provide the plan timelines showing when facilities are to have their long-term actions completed?
Answer: The majority of the most safety-significant improvements have already been made. In particular, approximately 85 percent of plants are in compliance with the Mitigating Strategies Order. The longer term actions that remain include fully implementing the Hardened Vent Order, some additional evaluations for seismic and flood hazards (if needed), and any regulatory actions that may result from those additional evaluations. Licensees have begun implementing the Hardened Vent Order, and it will be fully implemented no later than June 30, 2019. In addition, the MBDBE Rule, which makes the requirements of the Mitigating Strategies and SFP Instrumentation Orders generically applicable and includes other improvements, will be implemented within 3 years for the majority of sites, if approved by the Commission.
Question No. 244
Could you please elaborate on the composition, mission and purpose of the Advisory Committee on Reactor Safeguards regarding the license application process?
Answer: The ACRS is statutorily mandated by AEA Section 29. Under Section 29, the Committee is independent of the NRC staff and reports directly to the Commission, which appoints its members. Under the statute, the ACRS does the following: • reviews and reports on safety studies and reactor facility license and license renewal applications referred to it by the NRC • advises the NRC on the hazards of proposed and existing production and utilization facilities and the adequacy of proposed safety standards • performs other duties as the NRC may request The Commission has authorized the ACRS to, among other things, provide advice in the areas of health physics and radiation protection, and on the ACRS's own initiative, initiate reviews of specific generic matters or nuclear facility safety-related items (10 CFR 1.13, "Advisory Committee on Reactor Safeguards"). The ACRS's independent advice is considered in the Commission's decisionmaking process. The ACRS is organized around multiple technical subcommittees, the purpose of which is to obtain, analyze, and organize information for consideration by the full Committee. ACRS membership currently includes expertise in nuclear engineering; risk assessment; chemistry; facility operations management; severe accident phenomena; materials science and metallurgy; DI&C systems; thermal-hydraulics and heat transfer; and mechanical, civil, and electrical engineering. The ACRS may engage consultants to provide technical assistance on specific issues when required. ACRS members are appointed for 4-year terms and normally serve no more than three terms. Most ACRS meetings are open to the public and any member of the public may request an opportunity to make an oral statement during a committee or subcommittee meeting.

The ACRS has a significant role in the review and resolution of key technical issues associated with the licensing of nuclear power plants. As mentioned in the U.S. 7th National Report, the ACRS (including relevant subcommittees) reviews each application to construct or operate a nuclear power plant as well as each application for design certification. The ACRS begins its review early in the licensing process by selecting the proper stages at which to meet with the applicant and the NRC staff. The NRC staff and the applicant typically meet with the ACRS once the staff has completed its initial review of an application, has received responses from the applicant to requests for additional information, and has developed its safety evaluation report. If the staff has developed a safety evaluation report with open items, the NRC staff and applicant will meet with the ACRS before resolution of the open items and then, once all open items have been resolved and the staff has developed its advanced safety evaluation report. Upon completion of its review of the application and meetings with the NRC staff and applicant, the ACRS will issue a letter to the Chairman of the Commission, which reports on those portions of the application that concern safety. This letter provides the Commission with the ACRS's conclusions and recommendations on its review and may identify any areas where the ACRS disagrees with the NRC staff's findings.
Question No. 245
Regarding the mention of "Improved Technical Specifications" could you please elaborate on what are the areas, aspects or requirements in which the technical specifications have been improved?
Answer: On July 22, 1993, the NRC published in the FR a "Final Policy Statement on Technical Specifications Improvements for Nuclear Power Reactors." It states that the improved Standard Technical Specifications (STS) were the result of extensive technical meetings and discussions among the NRC staff, industry owners groups, vendors, and the Nuclear Management and Resources Council. The improved STS are expected to enhance the safety of nuclear power plants through the use of more operator-oriented TS, improved TS bases, reduced action statement induced plant transients, and more efficient use of NRC and industry resources. Some specific examples of improvements include defining criteria for inclusion in the TS. The use of this criterion to rewrite and streamline the STS resulted in many requirements being transferred from the TS to control by other mechanisms, including the final SAR, operating procedures, and quality assurance program, and the remaining STS to be focused on those plant conditions most important to safety. Additionally, the format of the STS was changed using a human factors approach that resulted in the tabular format that is used today. The STS (https://www.nrc.gov/reactors/operating/licensing/techspecs/current-approved-sts.html) for the five reactor types can be found on the NRC public Web page where Volume 1 contains the specifications and Volume 2 contains the bases: Babcock and Wilcox Plants, Revision 4 STS (NUREG-1430), Volume 1, Specifications; Babcock and Wilcox Plants, Revision 4 STS (NUREG-1430), Volume 2, Bases; Westinghouse Plants, Revision 4 STS (NUREG-1431), Volume 1, Specifications; Westinghouse Plants, Revision 4 STS (NUREG-1431), Volume 2, Bases; Combustion Engineering Plants, Revision 4 STS (NUREG-1432), Volume 1, Specifications; Combustion Engineering Plants, Revision 4 STS (NUREG-1432), Volume 2, Bases; General Electric Plants, BWR/4, Revision 4 STS (NUREG-1433), Volume 1, Specifications; General Electric Plants, BWR/4, Revision 4 STS (NUREG-1433), Volume 2, Bases; General Electric Plants, BWR/6, Revision 4 STS (NUREG-1434), Volume 1, Specifications; General Electric Plants, BWR/6, Revision 4 STS (NUREG-1434), Volume 2, Bases; Westinghouse Advanced Passive 1000 (AP1000) Plants,

Revision 0 STS (NUREG-2194), Volume 1, Specifications; Westinghouse Advanced Passive 1000 (AP1000) Plants, Revision 0 STS (NUREG-2194), Volume 2, Bases. Additional information related to TS is at https://www.nrc.gov/reactors/operating/licensing/techspecs.html.
Question No. 246
Could you please describe the participation of NPP personnel in the development of operation, maintenance, inspection and testing procedures. How mature is this practice?
Answer: In the U.S. industry, each station is responsible for developing the procedures necessary to safely and reliably operate its nuclear units. However, these procedures may be based on vendor-recommended procedures or practices, such as EOP guidelines. Each station has established process controls on the development, approval, and revision of such procedures that are based on their type and significance.
Question No. 247
Could you please explain why did the NRC direct that severe accident management guidelines (SAMGs) continue to be implemented voluntarily rather than being imposed as a requirement?
Answer: In the United States, the imposition of additional requirements on licensees for nuclear power plants is limited by the backfitting regulations in 10 CR 50.109 . Under this rule, the NRC will only impose additional requirements on licensees after determining that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the new requirements and that the direct and indirect costs of implementation are justified in view of the increased protection. The NRC may impose additional requirements if it is necessary to ensure that the facility provides adequate protection of public health and safety, or if the Commission defines or redefines the level of protection that is regarded to be adequate, or if it is necessary to bring the facility into compliance with an existing requirement. The potential risk of a severe accident, which has diminished since the Three Mile Island accident through the imposition of additional precore damage safety requirements over the years, does not rise to the level at which it would be appropriate to require SAMGs. This is because the low level of the potential risk results in a potential increase in overall protection that the NRC does not conclude to be a substantial increase that would be cost justified. In addition, the low potential risk of a severe accident does not rise to the level that would be considered appropriate for imposition of additional requirements to adequately protect public health and safety. The Commission has directed the staff in SRM-SECY-15-0065 (ADAMS Accession No. ML15239A767) to update the ROP to provide oversight of the voluntary implementation of the SAMGs. The agency could, therefore, take additional regulatory action if it found that the commitments were not being maintained. Section 16.3 on page 188 of the U.S. 7th National Report describes the measures taken in the United States with regard to SAMGs. Notwithstanding the regulatory treatment of SAMGs for currently operating reactors, SAMGs are required for newly issued reactor licenses by license condition (for example, see ADAMS Accession No. ML14100A106).
Question No. 248
With reference to article 19.4, page 227 of the American national report, Korea would like to inquire the following questions: 1) Is there an automatic reactor trip system in place for earthquakes?

2) If so, would it possible to provide an explanation on the system (ex: system configuration, and safety or non-safety system) and criteria including setpoints for automatic reactor trip? 3) What is the criteria(including setpoints) for a manual reactor trip due to earthquakes? 4) Is there any guidelines for NPP response to earthquakes? If so, what are the specific guidelines?
<u>Answer</u>: If a plant does not trip because of a seismic event itself (e.g., caused by LOOP), procedures call for a manually and orderly shutdown. These procedures are based on criteria and guidance provided in RG 1.166, "Pre-Earthquake Planning and Immediate Nuclear Power Plant Operator Postearthquake Actions," issued March 1997 (ADAMS Accession No. ML003740089). This document provides guidance acceptable to the NRC staff for a timely evaluation, after an earthquake, of the recorded instrumentation data and for determining whether 10 CFR Part 50 requires plant shutdown. Paragraph IV(aX3) of Appendix S, "Earthquake Engineering Criteria for Nuclear Power Plants," to 10 CFR Part 50 requires the shutdown of the nuclear power plant if vibratory ground motion exceeding that of the operating-basis earthquake ground motion or significant plant damage occurs. Before resuming operations, the licensee must demonstrate to the NRC that no functional damage has occurred to those features necessary for continued operation without undue risk to the health and safety of the public. The guidance includes criteria for determining operating-basis earthquake exceedance based on instrumental recordings, preshutdown inspections, and criteria for plant shutdown. The guidance focuses on an orderly shutdown; it also addresses a situation in which instrumental data are not available. The NRC provides guidance on postshutdown inspections and plant restart in RG 1.167, "Restart of a Nuclear Power Plant Shut Down by a Seismic Event," issued March 1997 (ADAMS Accession No. ML003740093). This document provides guidance acceptable to the NRC staff for performing inspections and tests of nuclear power plant equipment and structures before restart of a plant that has been shut down by a seismic event. It identifies both short-term and long-term activities. One of the objectives is that, coincident with the long-term evaluations, the plant should be restored to its current licensing basis. Exceptions to this must be approved by the Director, NRR. Both of the above guidance documents are based on EPRI NP-6695, "Guidelines for Nuclear Power Plant Response to an Earthquake," issued 1989 and later revised in 2012 as EPRI 1025288, "Guidelines for Nuclear Plant Response to Earthquake." IAEA has also published guidance on the response and restart of nuclear plants following a seismic event in Safety Reports Series No. 66, "Earthquake Preparedness and Response for Nuclear Power Plants," issued 2011. As discussed in the updated final SAR, the seismic trip system at Diablo Canyon operates to shut down reactor operations, should ground accelerations exceed a preset level in any two of the three orthogonal directions monitored (one vertical, two horizontal). The preset level is indicated in the TS. The value of nominal trip setpoint in the TS is 0.35g. Three triaxial sensors (accelerometers) are anchored to the containment base in three separate locations 120 degrees apart. Each senses acceleration in three mutually orthogonal directions. Output signals are generated when ground accelerations exceed the preset level. These signals are transmitted to the Trains A and B Solid State Protection System. If two of the three sensors in any direction produce simultaneous outputs, the logic produces Trains A and B reactor trip signals. The seismic reactor trip system was designed in compliance with IEEE 279-1971, "IEEE Standard: Criteria for Protection Systems for Nuclear Power Generating Status," and

IEEE 344-1975, “IEEE Recommended Practices for Seismic Qualifications of Class 1E Equipment for Nuclear Power Generating Stations,” but will not be required to function during or following a LOCA or fire. The safety analysis took no credit for operation of the seismic trip; however, the system’s functional capability at the specified trip settings is required to enhance the overall reliability of the reactor protection system.
Question No. 249
Could you please clarify what category of NPPs personnel in USA deals with severe accident management guidelines (SAMG) and symptom-based emergency operating procedures (EOP)?
Answer: At U.S. nuclear plants, most personnel have three jobs—their regular job, their outage job, and their ERO job. Personnel from many plant organizations have to be trained on their ERO function. SAMGs are dealt with primarily by operations and maintenance personnel. EOPs are primarily dealt with by operations and chemistry personnel. All procedures at a nuclear power plant in the United States are reviewed, developed, and approved by key station personnel from a variety of organizations. The station review process involves managers from the key station departments. U.S. stations also have FLEX support guidelines and extensive damage mitigating guidelines. These procedures require implementation by many station departments.
Question No. 250
Regarding the proposed rule to develop mitigating strategies to respond beyond-design-basis events at all units at a site for an indefinite period of time, it is mentioned that it will be inspected “at a later date, after the rule has been finalized”. Do you know at this moment when could the order requirements be implemented in all the plants?
Answer: Licensees are being inspected for compliance with the Mitigation Strategies and SFP Instrumentation Orders, which are being made generically applicable in the rule, as they come into compliance with those orders (as of December 31, 2016, 14 inspections have been completed). Once the rule is in place and rule compliance is required of licensees, oversight will become part of the baseline ROP. The inspections at that time will be based on the rule, rather than the orders, as is currently the case.
Question No. 251
Regarding incident reporting, it is stated that “the NRC reviews each reported reactor-related event and assigns a rating of 1 through 7 or below scale on the International Nuclear and Radiological Event Scale”. Does that mean that operators are not involved in the process of events rating? Could this situation lead to disagreements between licensees and the NRC? Moreover, could USA give some details about the NRC policy regarding events notifications to the public within the US?
Answer: The operators at the facilities are required to report conditions that meet the criteria outlined in 10 CFR 50.72, “Immediate Notification Requirements for Operating Reactors.” The nuclear power plant licensee is not required to and does not rate a reactor-related event against the International Nuclear and Radiological Event Scale (INES). The NRC assigns INES ratings to each applicable event. The NRC reviews and evaluates reactor-related reports against the INES reporting criteria, develops the INES rating, and submits the INES report to IAEA. INES ratings of 2 or greater are reported to IAEA. Past communications with the industry (e.g., IN-09-27, “Revised International Nuclear and Radiological Event Scale User’s Manual,” dated November 13, 2009 (ADAMS Accession No. ML092510055)) have served to make the industry aware of NRC involvement in INES and

the thresholds at which events will be reported to the international community. There has been no disagreement to date over assigned INES ratings, including those that have been submitted to IAEA's INES Web site. Reported conditions that meet the criteria outlined in 10 CFR 50.72, called event reports, are available on the NRC's public Web site unless specific criteria are met that require them to be withheld from the public (such as security-related issues). The NRC will issue periodic press releases to communicate with the public when warranted.
Question No. 252
Could the USA give some statistical data about events notifications during the past 4 years? In particular, how many level 1 and level 2 events have been notified over this period of time? Is there any lessons learned from the statistical analysis of notified events (events number, typologies/categories, date of occurrence – during operation or outages)?
Answer: Over the past 4 years, 24 INES reports have been made. Of these, 23 reports involved overexposures; 3 overexposures were to members of the public, and 20 were occupational exposures, primarily to radiographers. Further review found that an additional event did not involve an actual overexposure. Of the 24 INES reports over the past 4 years, 23 events were rated level 2, and 1 event had a final rating level of 1 (downgraded from a provisional rating of 2). No power reactor events have been rated level 2 or higher in the past 4 years. The NRC generally does not report events below level 2 to IAEA unless there is significant international public interest.
Question No. 253
The section describes the results of the OSART mission at Clinton 1. The IAEA report on this mission, referenced in the US NR, asserts that the plant is not using (lacks) indicators that would evaluate effectiveness of using external operating experience. What is the situation now? Is the plant using, or plans to use, these indicators? Could you describe indicator calculation methodology?
Answer: The licensee for Clinton entered the specific issue from the OSART mission on the evaluation of external operating experience into its corrective action program to evaluate what actions, if any, should be taken. With the plant's existing process to evaluate internal and external operating experience, coupled with the enhancement that INPO implemented to include the international events from the WANO Significant and Noteworthy Events report into the INPO Nuclear Network Daily Download, the licensee determined that no further changes to its process would be necessary. In accordance with IMC 2515 (ADAMS Accession No. ML16006A284), the NRC does not specifically follow up on OSART findings as part of the inspection process unless they involve a significant safety issue or a violation of NRC requirements. However, the NRC performs an in-depth review of the licensee's corrective action program every 2 years as part of the baseline inspection process (IP 71152 (ADAMS Accession No. ML14316A042)) and has consistently found that the licensee's program meets established regulatory requirements for the review of internal and external operating experience (see Inspection Reports: 2015, ADAMS Accession No. ML15313A435; 2013, ADAMS Accession No. ML13274A698; and 2011, ADAMS Accession No. ML11189A129).

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10. SUPPLEMENTARY NOTES

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 seventh national report for peer review in October 2016 (NUREG-1650, “The United States of America National Report for the Convention on Nuclear Safety: Seventh National Report, October 2016,” Revision 6). Supplement 1 to NUREG-1650 Revision 6 documents the answers to questions raised by contracting parties during their peer reviews of the United States’ 7th 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. The International Atomic Energy Agency held the seventh review meeting of the CNS in Vienna, Austria, from March 27 through April 7, 2017.

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Convention on Nuclear Safety, CNS, nuclear plants, programs, challenges, reviews, legislation, regulation, reactor oversight, ROP, public participation, probabilistic risk assessment, PRA, performance-based, quality, safety, knowledge management, human capital, security, siting, design, construction, operations, new reactors, radiation protection, emergency preparedness, financial, human factors, INPO, Institute of Nuclear Power Operations, peer review, international, IAEA, International Atomic Energy Agency, Contracting Parties, Vienna Declaration

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