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United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1650
Addendum 4

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

Office of Nuclear Reactor Regulation

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Office of Nuclear Reactor Regulation

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 "Fifth National Report" for peer review in September 2010 (NUREG-1650, "The United States of America National Report for the Convention on Nuclear Safety: Fifth National Report, September 2010," Revision 3). Addendum 3 to NUREG-1650 documents the answers to questions raised by contracting parties during their peer reviews of the U.S. national report. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations, the legislative and regulatory framework, the 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, and operation. The Fifth Review Meeting of the CNS was held at the International Atomic Energy Agency in Vienna, Austria, in April 2011.

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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 "Fifth National Report" for peer review in September 2010 (NUREG-1650, "The United States of America National Report for the Convention on Nuclear Safety: Fifth National Report, September 2010," Revision 3), 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/ . Addendum 3 to NUREG-1650 documents the answers to questions raised by contracting parties during their peer reviews of the U.S. national report.

Upon receiving questions from contracting parties, the NRC staff categorized them according to the article of the U.S. 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. These answers were provided to the contracting parties in preparation for the Fifth Review Meeting of the CNS, which was held at the International Atomic Energy Agency in Vienna, Austria, in April 2011.

ACKNOWLEDGMENTS

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ABBREVIATIONS

ABWR	advanced boiling-water reactor
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System (NRC)
ALARA	as low as is reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
ASP	accident sequence precursor
BRAC	BWR radiation and control
BRIIE	Baseline Risk Index for Initiating Events
BWR	boiling-water reactor
CFR	*Code of Federal Regulations*
CLERP	conditional large early release probability
CNS	Convention on Nuclear Safety
COL	combined license
COMM	Operating Experience Communication
ConE	construction experience
CP	construction permit
CSA	complementary self-assessment
DC	design certification
DCR	design certification rule
DI&C	digital instrumentation and control
DOE	U.S. Department of Energy
EDO	Executive Director for Operations (NRC)
EOOS	Equipment Out Of Service
EP	emergency preparedness
EPA	U.S. Environmental Protection Agency
EPU	extended power uprate
EPZ	emergency planning zone
ERB	Executive Resources Board (NRC)
ERO	emergency response organization
ESBWR	economic simplified boiling-water reactor
ESP	early site permit
ESPS	Engineered Safeguards Protection System
EU	European Union
FEMA	U.S. Federal Emergency Management Agency
FR	*Federal Register*
FSAR	final safety analysis report
FSME	Office of Federal and State Materials and Environmental Management Programs
FY	fiscal year
GALL	Generic Aging Lessons Learned

GE	General Electric
GI	generic issue
HERA	Human Event Repository and Analysis
HFE	human factors engineering
HSI	human-system interface
HTGR	high-temperature gas-cooled reactor
I&C	instrumentation and controls
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IEEE	Institute of Electrical and Electronics Engineers
IMC	inspection manual chapter
IN	information notice
INES	International Nuclear and Radiological Event Scale
INPO	Institute of Nuclear Power Operations
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
km	kilometer
LER	licensee event report
LWA	limited work authorization
LWR	light-water reactor
MOSC	management, organization, and safety culture
mSv	millisievert
mrem	millirem
NGNP	Next Generation Nuclear Plant
No.	number
NPP	nuclear power plant
NPSH	net positive suction head
NRC	U.S. Nuclear Regulatory Commission
NRO	Office of New Reactors
NRR	Office of Nuclear Reactor Regulation
NSIR	Office of Nuclear Security and Incident Response
NSPDP	Nuclear Safety Professional Development Program
NUPIC	Nuclear Procurement Issues Committee
OER	operating experience review
OI	Office of Investigations
OIG	Office of the Inspector General
OpE	operating experience
OSART	Operational Safety Assessment Review Team
PPE	plant parameter envelope

PRA	probabilistic risk assessment
PSA	probabilistic safety assessment
PSAR	preliminary safety analysis report
PWR	pressurized-water reactor
PWSCC	primary water stress-corrosion cracking
RG	regulatory guide
RIS	regulatory issue summary
ROP	Reactor Oversight Process
RPM	radiation protection manager
RPS	Reactor Program System
RS-001	“Review Standard for Extended Power Uprates”
SOARCA	State-of-the-Art Reactor Consequence Analyses
SDP	significance determination process
SECY	Office of the Secretary
SEN	significant event notifications
SEP	systematic evaluation program
SER	safety evaluation report
SES	Senior Executive Service
SIIP	site integrated improvement plant
SOER	significant operating experience report
SPAR	standardized plant analysis risk
SRM	staff requirements memorandum
SRP	Standard Review Plan (NUREG-0800)
SSC	structure, system, and component
SSEP	safety, security, and emergency preparedness
SWCMF	software common-mode failure
TEDE	total effective dose equivalent
TMI	Three Mile Island
TVA	Tennessee Valley Authority
U.S.	United States
WANO	World Association of Nuclear Operators

STRUCTURE OF THE REPORT

This report documents the U.S. answers 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: Fifth National Report, September 2010" (NUREG-1650, Revision 3) (hereafter referred to as the U.S. Fifth National Report). Upon receiving questions from contracting parties, the U.S. Nuclear Regulatory Commission (NRC) (hereafter referred to as the NRC, the Commission, the agency, or the staff) staff categorized them according to the article of the U.S. Fifth National 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.

This report follows the format of the U.S. Fifth 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, the legislative and regulatory framework, the regulatory body, responsibility of the licensee, priority to safety, financial and human resources, human factors, quality assurance, assessment and verification of safety, radiation protection, emergency preparedness, siting, design, construction, and operation. Consistent with the U.S. Fifth National Report, this report does not contain sections for Articles 1 through 5. In accordance with Article 1 of the CNS, the U.S. Fifth 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. Fifth National Report fulfilled the obligation of Article 5.

This report also has two appendices. Appendix A identifies contributors, and Appendix B identifies and defines the acronyms used in the report.

This report references 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 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 (PDR). One may contact the PDR by the following:

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INTRODUCTION TO THE U.S. FIFTH NATIONAL REPORT

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

- purpose and structure of the report
- summary of changes since the previous report was written in 2008
- U.S. national policy on nuclear activities
- main national nuclear programs
- conclusions from the Fourth Review Meeting
- current safety and regulatory issues
- status of safety and regulatory issues discussed in the Fourth National Report (NUREG-1650, Revision 2)
- major regulatory accomplishments
- the NRC's main challenges

The questions below were submitted by contracting parties about the Introduction to the U.S. Fifth National Report.

Question Number (No.) 1	
Question/ Comment	The Report indicates under the heading "Knowledge Management" that several skill gaps exist, please provide further clarification on these major short and long term critical skills gap.
Answer	The agency has identified short- and long-term critical skill gaps in the fields of geotechnical engineering, medical physics and medical health physics, nuclear analysis, probabilistic risk analysis, thermal hydraulics–model development, thermal hydraulics–numerics, and seismic engineering, at the doctoral and postdoctoral level.
Question No. 2	
Question/ Comment	In the discussion regarding the NRC's Main Challenges and its Major Management Challenges (pages 38-39) please clarify whether ageing management is in fact a concern for the U.S. NRC.
Answer	The NRC's primary function is to regulate the safe use of radioactive materials for civilian purposes to ensure adequate protection of public health and safety and the environment. To that end, aging management of nuclear power plants (NPPs), as in the context of license renewal of those plants, is important to the agency. Ensuring that there are adequate programs to manage material degradation is a primary consideration in granting a license extension. The aim of the license renewal process is to evaluate whether aging effects are monitored, managed, and controlled such that safety is ensured for the renewed period. It is a continuing challenge for the NRC to ensure that licensees continue to upgrade their aging management programs to incorporate lessons learned from operating experience.
Question No. 3	
Question/ Comment	In the "New Reactor Licensing" section of the Report (page 18) two different approaches - "plant parameter envelope approach" and "plant parameter envelope methodology" – are discussed to refer to Applications being submitted. Please elaborate on the distinction between these two approaches and clarify whether the latter (or both for that matter) is only used when the reactor technology has not

	been selected by applicant.
Answer	The appropriate phrase that should be used in each case is "plant parameter envelope approach." The early site permit (ESP) application may specify a reactor design; however, it is not required by NRC regulations. If a reactor design is not specified in the ESP application, the application may provide a set of plant parameters that are expected to envelop the design of a reactor or reactors that might be later deployed at the site. The set of enveloping plant parameters is defined as the plant parameter envelope (PPE). A PPE is a set of reactor and owner-engineered parameters listed in the ESP that are expected to bound the characteristics of a reactor that might later be deployed at the ESP site. A plant PPE sets forth postulated values of parameters that provide details to support the NRC staff's review of an ESP application. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," allows for approval of a site for future NPPs as a separate licensing action well in advance of decisions on reactor technology and when to build. In those instances in which the ESP applicant has not selected a particular technology, ESP applications may nonetheless use the PPE approach as a surrogate for actual facility information to support required safety and environmental reviews. Under the PPE approach, applications do not reference a specific reactor technology. As a result, the ESP is applicable to a range of reactor designs, including NRC-certified designs, designs for which NRC certification is currently in progress, and future designs. Strong policy basis exists for the PPE approach. First, it provides applicants with essential flexibility to defer technology selection until the decision to build is made. Second, it provides the NRC with the information necessary for its review and issuance of an ESP. Third, the PPE approach facilitates the combined license (COL) process by clearly identifying the set of parameters on which the acceptability of a specific design for a particular site will be based. In a PPE-based ESP application, reference to a "proposed" facility, site, or project is not meant to be restrictive to the reactors discussed but rather encompasses any design bounded by the PPE.
Question No. 4	
Question/ Comment	The Report under "Regulatory Effectiveness" states that the U.S. NRC has grown from 3110 employees in 2004 to more than 4000 today. Please elaborate on measures implemented by the U.S. NRC to meet the challenges of training new staff and maintaining the quality of inspections, evaluations, and investigations.
Answer	During that time period, the agency added significant training resources in the form of staff, contract funds, and facilities to meet the new staff's training requirements. Courses on new reactor designs have been developed and delivered at all levels, and the agency is currently acquiring two full-scale simulators to meet the future demand for training inspectors and examiners. The NRC has also embraced new technologies for the delivery of training to both shorten the time to competency and contain travel costs.
Question No. 5	
Question/ Comment	Regarding INPO's Role within the Federal Regulatory Framework, please elaborate on the type of data that is collected in the Consolidation Data Entry System and used in the Industry Oversight Process.
Answer	The Consolidated Data Entry System captures the data needed for the NRC's Reactor Oversight Process (ROP) performance indicators, the World Association

	of Nuclear Operator's (WANO's) performance indicators, the NRC's monthly operating report, additional indicators used by INPO members, and the equipment performance indicator exchange system. These indicators measure performance in areas such as generation, safety system performance, personnel safety, and equipment reliability.
Question No. 6	
Question/ Comment	The report states: "The early site permits are valid for up to 20 years." During 20 years, the change of environmental condition such as a population growth and siting of chemical factories may be happened. How do you cope with the problem in this case?
Answer	Although an ESP is valid for up to 20 years, the NRC's regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," require COL applicants who reference an ESP to submit any new and significant information for environmental issues related to construction and operation of the facility that were resolved in the ESP. COL applicants must also describe the process used to identify such new and significant information. The NRC will include an analysis of the issues for which new and significant information is identified in the environmental impact statement that it issues in support of the COL. In addition, while an ESP is in effect, the Commission may change or impose new site characteristics, design parameters, or terms and conditions on the ESP if the Commission determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations in effect at the time the permit was issued or if the Commission determines that the modification is necessary to ensure adequate protection of the public health and safety or the common defense and security. Finally, an applicant for a COL who has filed an application referencing an ESP is required to update the emergency preparedness (EP) information that was provided with the ESP application and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements. The Commission may change or impose new site characteristics, design parameters, or terms and conditions on the ESP if it determines that a modification is necessary based on the updated EP information.
Question No. 7	
Question/ Comment	One of the previous challenges for the U.S. was "hiring and developing a qualified workforce (in both industry and regulatory body)". What kind of action do industries take to this challenge?
Answer	The U.S. industry uses candidates from the following areas as potential new employees: • nuclear Navy • Navy retirees • Navy commanding officers • agricultural industry • merchant marine • automotive industry • industry suppliers • engineering firms

	Recently, many utilities are working with local high schools, technical schools, and colleges to promote the nuclear industry as a career path and the opportunities it has to offer.
Question No. 8	
Question/ Comment	It is mentioned that Commission has approved EPUs (extended power up-rates) of up to 20 percent. Can the U.S. provide information which is required from the licensee for approving uprates up to 20 %?
Answer	"Review Standard for Extended Power Uprates" (RS-001), issued December 2003, was created for the NRC staff to use in its review and evalu ation of extended power uprate (EPU) applications. It provides general review guidance and specific guidance by way of references to other NRC review guidance documents for each technical review area. Because RS-001 is publicly available (ADAMS Accession No. ML033640024), it also informs licensees of the guidance documents the staff uses when reviewing EPU applications. These documents provide acceptance criteria for the areas of review. There are many technical review areas, with numerous subareas within each technical area. The technical review areas include materials, chemical, mechanical, civil, and electrical engineering; reactor, plant, containment, habitability, filtration, ventilation, and instrumentation and control (I&C) systems; human performance, health physics, radiological consequences, risk evaluation, and environmental assessment; and power ascension and testing plan. The staff has used RS-001 to review applications for power uprates up to 20 percent, and there is no limit specified in RS-001 on how high an EPU the staff will consider.
Question No. 9	
Question/ Comment	It is mentioned that one partially built plant, Watts Bar Nuclear Plant Unit 2, has resumed construction activities after mid-1980s and is currently pursuing an operating license approval under 10 CFR Part 50. U.S. may inform whether : a. the construction activities would follow the codes and standards approved during the construction permit stage, or; b. the codes and standards would be reviewed in the light of current codes and standards to identify which version would be followed, or; c. New revisions would be followed.
Answer	In a Commission paper (Office of the Secretary (SECY)-07-0096, "Possible Reactivation of Construction and Licensing Activities for the Watts Bar Nuclear Plant Unit 2") dated June 7, 2007, the NRC staff described its plan to implement existing Commission policy on reactivation of deferred plants. In the Commission paper, the staff sought Commission approval on the approach for reactivation of construction, licensing, and inspection activities. After reviewing the staff's recommendations, in Staff Requirements Memorandum (SRM)-SECY-07-096, dated July 25, 2007, the Commission directed the staff to use the current licensing basis for Watts Bar Nuclear Plant (Watts Bar), Unit 1 as the reference basis for the review and licensing of Watts Bar Unit 2. Further, the Commission indicated that the Tennessee Valley Authority (TVA) and the NRC staff should review any exemptions, reliefs, and other actions that were specifically granted for Watts Bar Unit 1 to determine whether the same allowances would be appropriate for Watts Bar Unit 2. Significant changes to this licensing approach

	would be allowed for cases in which the existing Backfit Rule (10 CFR 50.109, "Backfitting") would be met or as necessary to support dual-unit operation. The Commission also indicated that the staff should encourage the applicant to adopt updated standards for Watts Bar Unit 2 where it would not significantly detract from design and operational consistency between Watts Bar Units 1 and 2. With regard to the procurement of new components and systems, the licensee must comply with the requirements of 10 CFR 50.55a(2), which states the following: (2) Systems and components of boiling and pressurized water-cooled nuclear power reactors must meet the requirements of the [American Society of Mechanical Engineers] ASME Boiler and Pressure Vessel Code specified in paragraphs (b), (c), (d), (e), (f), and (g) of this section. Protection systems of nuclear power reactors of all types must meet the requirements specified in paragraph (h) of this section. The Commission also directed the NRC staff to resolve current generic safety issues or security issues that would be much easier to resolve before plant operation. During the licensing period, the NRC staff and TVA should look for opportunities to resolve such issues for which the unirradiated state of Watts Bar Unit 2 makes the issue easier to resolve than at Watts Bar Unit 1.
Question No. 10	
Question/ Comment	It is mentioned that cable failures trend has increased and Licensees applying for a 20-year license renewal have agreed to implement a cable testing program during the period of extended operation, but only a few plants have established a cable testing program for the current operating period. Can U.S. describe what measures are being taken to develop and implement the cable testing program for plants operating under 40 years of design life?
Answer	The NRC staff has provided guidance to NPP licensees on cable condition monitoring techniques for the current 40-year operating license period. In January 2010, the NRC staff issued NUREG/CR-7000, "Essential Elements of an Electric Cable Condition Monitoring Program," regarding the selection of electric cable condition monitoring techniques. The NRC staff plans to issue Regulatory Guide (RG) 1.218 (the draft version of this regulatory guide was issued as DG-1240 in June 2010), "Condition Monitoring Program for Electric Cables Used in Nuclear Power Plants," in calendar year 2011. The purpose of this RG is to provide specific guidance for monitoring the performance of cables during their installed life. In particular, this RG describes a programmatic approach to condition monitoring of electric cable systems and their operating environments. The NRC staff considers the above guidance as one of the acceptable methods for meeting the Commission's regulations. The regulatory basis for implementation of a cable testing program is based on the following NRC regulations in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," that require licensees to assess the condition of systems and components in a manner sufficient to provide reasonable assurance that they are capable of fulfilling their intended functions, and that a test program to ensure

	that components will perform satisfactorily in service is identified and performed. Criterion XI, "Test Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 requires NPP licensees to establish a test program to ensure that all testing required to demonstrate that structures, systems, and components (SSCs) will perform satisfactorily in service is identified and performed. Paragraph (a)(1) of 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" (the "Maintenance Rule"), states that "Each holder of an operating license for a nuclear power plant...shall monitor the performance or condition of structures, systems, or components...in a manner sufficient to provide reasonable assurance that these structures, systems, and components...are capable of fulfilling their intended functions." Licensees may, as an alternative to compliance with paragraph (a)(1) of the Maintenance Rule, comply with the requirements of paragraph (a)(2). That paragraph allows a licensee to avoid monitoring if it can demonstrate that the condition or performance of an SCC within the scope of the rule is being effectively controlled through preventive maintenance.
Question No. 11	
Question/ Comment	It is mentioned that in response to the NRC confirmatory action letters regarding circumferential indications in dissimilar metal welds, the pressurizer surge, spray, safety, and relief nozzle welds, all 40 plants have completed the initial inspections, and 36 have mitigated the welds. Can U.S. describe how NRC has ensured that, in-spite of not taking mitigative measures for remaining four plants, these are safer?
Answer	The four remaining plants that have not mitigated all susceptible dissimilar metal welds at pressurizer operating temperatures are required to inspect these unmitigated welds every 4 years. The 4-year inspection interval is an increase in inspection frequency from the ASME Boiler and Pressure Vessel Code's (ASME Code's) requirement of inspection once every 10 years in order to address the aggressive crack growth rates of primary water stress-corrosion cracking (PWSCC) in nickel alloys. The 4-year inspection frequency was based on a conservative deterministic flaw assessment, assuming that a PWSCC flaw initiates just after the previous inspection for this classification of susceptible pressurizer temperature dissimilar metal welds. The NRC determined that inspections on a 4-year interval would provide reasonable assurance of the structural integrity of each weld of concern. Additional information is available in Regulatory Issue Summary (RIS) 08-25, "Regulatory Approach for Primary Water Stress Corrosion Cracking of Dissimilar Metal Butt Welds in Pressurized Water Reactor Primary Coolant System Piping," dated October 22, 2008, and at the NRC public Web site at the following : http://www.nrc.gov/reactors/operating/ops-experience/pressure-boundary-integrity/weld-issues/index.html
Question No. 12	
Question/ Comment	On page 15 of the report, under "The U.S. National Policy toward Nuclear Activities" it is stated that "The NRC's interpretation of regulations continues to evolve from a prescriptive, deterministic approach toward a more risk-informed

	and performance-based regulatory approach." In 2007, the NRC has published a "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing" (NUREG-1860). Could you please provide some information on the existing or intended use of the outcome of this study?
Answer	In accordance with NRC direction, the NRC staff issued NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," Volumes 1 and 2, in December 2007. This NUREG documents a framework that provides an approach and criteria that (1) could be used to develop an alternative set of technical requirements to 10 CFR Part 50 that are risk informed and performance based and that are applicable for future non-light-water reactor (non-LWR) NPPs and (2) could be used to improve the licensing environment for advanced nuclear power reactors to minimize complexity and uncertainty in the regulatory process. This framework was developed in light of renewed interest in the use of non-LWR technology, including high-temperature gas-cooled reactor (HTGR) technology, in the United States that occurred in the early 2000s. Following enactment of the U.S. Energy Policy Act of 2005, the NRC and the U.S. Department of Energy (DOE) considered applying NUREG-1860 in the licensing strategy required by the Energy Policy Act for the Next-Generation Nuclear Plant (NGNP) prototype—an HTGR prototype being developed by DOE. However, DOE and the NRC jointly determined that the NGNP licensing strategy would not apply probabilistic risk assessment (PRA) insights and information to the degree described in NUREG-1860. Rather, the licensing strategy for the NGNP prototype would use a risk-informed and performance-based technical approach that employs the use of deterministic judgment and analysis, complemented by NGNP-specific PRA information. Nonetheless, in its SRM on COMSECY-08-0018, "Renewal of Full-Power Operating License for Oyster Creek Nuclear Generating Station," the Commission directed the NRC staff to plan how best to capture risk-informed performance-based insights and lessons for use in a technology-neutral framework during the NGNP licensing process and to test the concepts and methods prescribed in NUREG-1860. More recently, the Commission directed the NRC staff to develop a new risk-informed regulatory framework that builds, as a long-term objective, on the NRC reviews of small modular reactor designs, insights gained from review activities associated with the NGNP program, and the earlier technology-neutral framework presented in NUREG-1860 (see NRC memorandum COMGBJ-10-0004/COMGEA-10-0001, "Use of Risk Insights to Enhance Safety Focus of Small Modular Reactor Reviews," dated July 9, 2010). The NRC staff is currently preparing a response to the Commission that will describe plans to test the concepts and methods from the technology-neutral framework (NUREG-1860) during the preapplication and license review of the NGNP prototype, as well as long-term plans for developing a new risk-informed regulatory framework for advanced reactors.
Question No. 13	
Question/ Comment	The report says: "In 2006, to better prepare the agency for the anticipated new reactor licensing and construction inspection work (...)". How many people are employed in the new established NRC Office of New

	Reactors in total? Please specify their professions or areas of expertise. Please state if chemists, radiation protection officers and material scientists are also involved?
Answer	The Office of New Reactors (NRO) was established in 2006 and currently has a staff of approximately 500. The staffing level is expected to decrease to 475 in fiscal year (FY) 2012. The staff is made up of managers, project managers, administrative support staff, and technical experts. The areas of expertise include all areas within the scope of the NRC's review of new reactor applications and include materials engineers, health physicists, and chemical engineers.
Question No. 14	
Question/ Comment	In which phases of the licensing process will the following aspects be assessed: • material selection for the primary circuit to prevent corrosion and to avoid highly activated nuclides • inner surface conditioning (e.g. oxidation, polishing) • fabrication process (e.g. fewer welds imply fewer inspections) • accessibility of components and systems (e.g. for future inspections)
Answer	The NRC would typically assess the applicability, adequacy, and sufficiency of industry codes and standards used for materials selection, inner-surface conditioning, and the fabrication process, as well as how the design permits accessibility of components and systems, during the initial licensing phase. Under 10 CFR Part 50, the assessment would occur during the construction permit (CP) application phase; under 10 CFR Part 52, it would occur during the design certification (DC) phase. Material selection and fabrication techniques are usually known at this phase. However, the full extent of accessibility of components and systems for inservice inspections is typically not known during this initial licensing phase. Consequently, the NRC requires that the CP or DC applicant ensure that major plant components (e.g., the reactor vessel) be designed with accessibility to perform inservice inspections. During plant construction, the NRC will perform inspections to ensure that these and other specific components are designed to enable inservice inspections to be performed in accordance with regulations.

ARTICLE 6. EXISTING NUCLEAR INSTALLATIONS

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

This section explains how the United States ensures the safety of nuclear installations in accordance with the obligations in Article 6. It covers the reactor licensing and major oversight processes in the United States. This section also discusses programs for rulemaking, fire protection regulation, decommissioning, research, and programs for public participation.

The NRC posts the major results of assessments on the agency's public Web site at http://www.nrc.gov. This update includes expectations about ESPs and DC applications, current experience, and revised details about programs.

<table>
<tr><td colspan="2">Question No. 15</td></tr>
<tr><td>Question/ Comment</td><td>The Industry Trends Program described in this Section demonstrates its importance in establishing performance measures that are reported to Congress, please identify some of these trends, regardless of whether they were statistically significant or not.</td></tr>
<tr><td>Answer</td><td>The latest results reported for the Industry Trends Program (ITP), including trends for all of the performance indicators qualified for use in the ITP, are available in SECY-10-0028, "Fiscal Year 2009 Results of the Industry Trends Program for Operating Power Reactors," dated March 16, 2010. This document provides both the 10-year trends and the short-term performance of the ITP performance indicators.

As stated in SECY-10-0028, no statistically significant adverse trends were observed in the ITP performance indicator data from the most recent 10 years (FY 2000 to FY 2009). All ITP performance indicators continued to show an improving trend for this 10-year period.</td></tr>
<tr><td colspan="2">Question. No. 16</td></tr>
<tr><td>Question/ Comment</td><td>Please identify the most common events of the Industry Trends Program, first level (Tier 1), that have had an impact on plant safety during the reporting year 2009.</td></tr>
<tr><td>Answer</td><td>The events that are tracked in the first-level (Tier 1) ITP Baseline Risk Index for Initiating Events (BRIIE) are the following:

<u>Pressurized-Water Reactors (PWRs)</u>

(1) loss of offsite power
(2) loss of vital alternating current bus
(3) loss of vital direct current bus
(4) loss of main feedwater</td></tr>
</table>

	(5) very small loss-of-coolant accident (6) PWR general transient (7) PWR loss of condenser heat sink (8) PWR stuck-open safety/relief valve (9) PWR loss of instrument air (10) steam generator tube rupture Boiling-Water Reactors (BWRs) (1) loss of offsite power (2) loss of vital alternating current bus (3) loss of vital direct current bus (4) loss of main feedwater (5) very small loss-of-coolant accident (6) BWR general transient (7) BWR loss of condenser heat sink (8) BWR stuck-open safety/relief valve (9) BWR loss of instrument air In general, these risk-significant initiating event types cover approximately 60 percent of the internal event core damage risk (excluding internal flooding) for the operating commercial NPPs in the United States. Also, these initiating events do not overlap.
Question No. 17	
Question/ Comment	This Section provides a broad overview of the Reactor Licensing process, please describe the differences between "early site permits" and "limited work authorization" and indicate how the latter fits within the regulatory framework.
Answer	An ESP allows an applicant to attain finality and resolution of certain environmental and siting issues and, optionally, of emergency planning issues before submitting a COL application. To the extent that these issues are resolved, they are not subject to further review or hearing at the CP or COL proceeding stage. The degree of finality that can be achieved depends on several factors, such as the extent to which the ESP includes design details, and whether new and significant information relating to the environmental effects of reactor construction and operation is identified at the CP or COL application and review stage. The ESP also allows an applicant to “bank” (i.e., reserve) a site for up to 20 years for future siting of a reactor. An applicant may also seek a limited work authorization (LWA) as part of the ESP. This could allow preparation and preconstruction activities that otherwise would have to await a CP or COL. Certain preconstruction activities can be conducted without an LWA, such as site clearing, transmission line routing, road building, and construction of support buildings, such as warehouse and shop facilities. Construction of safety-related SSCs would require an LWA.
Question No. 18	
Question/ Comment	In your description of the “Reactor Oversight Process” you indicate that resident inspectors are stationed at the nuclear plants, Please describe at which point in the evolution of the nuclear power plant (NPP) development these inspectors are assigned and role played by NRO in the transition from construction overseers to

	compliance oversight.
Answer	The licensing process under 10 CFR Part 52 has several specific milestones. The key points from an oversight aspect are the issuance of an LWA, the issuance of a COL, and the Commission's decision under 10 CFR 52.103(g). The LWA allows a licensee to do specific construction tasks that may be safety related before issuance of the COL. The NRC will perform inspections to oversee the activities of the LWA. The COL allows a licensee to build and operate, with conditions, an NPP. The conditions that must be met are primarily made up of the completion of all specified inspection, test, analysis, and acceptance criteria (ITAAC). NRC construction inspectors from the Region II office will perform inspections to verify that construction activities are performed in accordance with the license and regulations. The NRC plans to use a mix of construction resident inspectors, specially trained construction inspectors, and operating reactor inspectors from the region that will perform oversight for the operating life of the NPP. As the plant construction approaches completion (within a year of initial fuel load), the initial operating plant resident inspectors will be assigned and report to the site. This will allow the operating resident inspectors sufficient time to familiarize themselves with the site and prepare for turnover of oversight responsibility from NRO to the Office of Nuclear Reactor Regulation (NRR). The transition of organizational responsibility from NRO to NRR will occur following the Commission's 10 CFR 50.103(g) decision. Although NRR will have the responsibility for oversight after the 10 CFR 50.103(g) decision, the NRC expects that NRO construction inspectors will remain on site for an appropriate amount of time to ensure that a smooth transition occurs from NRO to NRR.
Question No. 19	
Question/ Comment	Once revisions to the Standard Review Plan and the Generic Ageing Lessons Learned (GALL) Report are made will the lessons learned affect the recent license renewals that have been issued?
Answer	The NRC published Revision 2 to "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (NUREG-1800) and the "Generic Aging Lessons Learned (GALL) Report" (NUREG-1801) in December 2010. The lessons learned from these documents affect license renewals in the following ways: (1) for license renewal applications that are currently under review, the NRC is asking the applicants to demonstrate that their applications have incorporated the lessons learned from the revised documents, and (2) for those plants that have already received a renewed license, the agency is evaluating a range of options to ensure that these plants take advantage of the lessons learned from the revised guidance documents. The options include, but are not limited to, issuing generic communication to the plants that highlight the key aspects of the renewed aging management guidance and methodology, and inspecting the licensee's programs before entering the extended period of operation to verify that the plant's aging management programs have been expanded to incorporate relevant operating experience.
Question No. 20	
Question/ Comment	In article 6, page 47, it is said: "The NRC performance and accountability report notes if this combined industry value reaches or exceeds a threshold value of $1x10^{-5}$ per reactor critical year, along with action that have already been taken or are planned in response. " Please clarify how to obtain the combined industry

	value, in other words that based on which model and/or frequencies of initiating events the value is estimated.
Answer	The quantification method used for formulating the related changes in core damage frequency is given by a formula found in NRC Inspection Manual Chapter (IMC) 0313, “Industry Trends Program,” Appendix D, “Baseline Risk Index for Initiating Events (BRIIE),” page D1-3. The index of Inspection Manual Chapters can be found at following link, see IMC 0313 for the BRIIE formulation: http://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/index.html BWRs and PWRs have different core damage frequencies, which depend to some extent on different initiating event types. The risk weights for various initiating events also are different for the two types of reactors. Therefore, BRIIE results are provided for each reactor type, and the two BRIIE results are also combined into a single index that provides an indication of overall industry performance. The BRIIE formulation uses PWR- or BWR-average Birnbaum importance measures and combines the industrywide data to generate the “common industry current frequency” for each initiating event category.
Question No. 21	
Question/ Comment	In the previous reports, the U.S. have indicated that they did not carry out Periodic Safety Review since Reactor Oversight Process enables maintaining the safety level of the installations. Nevertheless, do the U.S. have the objective to enhance safety by re-examining the former design assumptions through new design studies in order to bring the safety level of the older units to the level of the recent ones?
Answer	The Fifth National Report, Section 14.1.3, “The United States and Periodic Safety Reviews,” discusses NRC processes that substantially accomplish, on an ongoing basis, the shared objectives associated with the International Atomic Energy Agency (IAEA) and Western European Nuclear Regulators’ Association periodic safety review guidance. Specifically, Section 14.1.3.7 states that “the NRC’s regulatory process provides a robust foundation for ongoing assessments, evaluations, and, when appropriate, imposition of new requirements.” When there is information that results in an NRC determination that new requirements should be imposed, the NRC will act on that determination; however, there is no NRC program to reexamine NPP design assumptions absent new information.
Question No. 22	
Question/ Comment	"The report states that the NRC staff identifies potential precursors by calculating the probability of an event leading to a core damage state, this after reviewing the licensees events and inspection reports. Does it mean that a calculation is carried out for all the events analysed? What is the percentage of events reported that are subject to a calculation?"
Answer	The NRC does not perform calculations for all events reported in licensee event reports (LERs) and/or inspection reports. During an initial screening performed by an NRC contractor, LERs are eliminated from further consideration as accident sequence precursor (ASP) events if they

	involve one of the following: • component failure with no loss of redundancy • short-term loss of redundancy in only one system • an operational event that occurred prior to initial reactor criticality • design or qualification error that was small relative to what was predicted (e.g., an error of a few percent in an actuation setpoint) • an initiating event bounded by a general reactor trip or a loss of main feedwater • an operational event with no appreciable impact on safety systems • an operational event involving only post-core-damage impacts The initial screening typically eliminates 75 percent to 85 percent of all LERs. All operational events not eliminated from the ASP Program using the rejection criteria undergo detailed analysis. If a licensee performance deficiency is identified, then an associated significance determination process (SDP) assessment is performed. For events that fall outside the scope of the assessments performed within the SDP (e.g., initiating events, concurrent equipment unavailabilities due to separate performance deficiencies, and safety-related equipment unavailabilities with no licensee performance deficiency), LERs and inspection reports are reviewed to determine if an ASP analysis is required.
Question No. 23	
Question/ Comment	"The U.S. NRC screens carefully the operating experience of foreign facilities. Past events show the need of such a screening." Could the U.S. give an example of lessons learnt from foreign experience? For instance, the report does not present the lessons learnt or actions taken after Forsmark event.
Answer	The NRC screens events from foreign facilities primarily through review of reports submitted to the International Reporting System for Operating Experience and through the International Nuclear and Radiological Event Scale (INES). Events that are deemed to be safety significant and to have possible generic applicability to U.S. plants are screened in for further evaluation to allow for full analysis of the event by the relevant technical personnel and to determine the best method for applying the lessons learned. The Forsmark event was screened in for such evaluation. NRC staff gave a presentation on the event causes and consequences to members of NRC management, and the electrical engineering branch performed an exhaustive evaluation to determine the vulnerability of U.S. plants to such an event and any preventive measure that should be taken. The NRC published Information Notice (IN) 2006-18, "Significant Loss of Safety-Related Electrical Power at Forsmark, Unit 1, in Sweden," on August 17, 2006, to inform industry and the public of the event and the information that was available about it at the time, and IN 2006-18, Supplement 1, on August 10, 2007, once more information was available. The engineering analysis determined that the actual failure mechanism involved at Forsmark was not applicable to U.S. plants; however, other lessons learned were incorporated into the INs. Lessons learned from international events have been included in several recent

	NRC generic communications. IN 2010-27, "Ventilation System Preventive Maintenance and Design Issues," dated December 16, 2010, describes issues with the automatic alignment of the control room ventilation system at Kruemmel Nuclear Plant during a transformer fire in 2007, a scenario tat was deemed plausible at some older U.S. plants. IN 2010-20, "Turbine-Driven Auxiliary Feedwater Pump Repetitive Failures," dated September 24, 2010, discussed a series of events with the turbine-driven auxiliary feedwater pump at Tihange Nuclear Station from 2007 to 2008 in the context of similar failures at two U.S. plants. IN 2010-01, "Pipe Support Anchors Installed Improperly", dated March 1, 2010, was written following review of a German report on problems with the installation of anchor supports at multiple plants.
Question No. 24	
Question/ Comment	The present paragraph shows an improving trend according to the last three indicators. Could the U.S. NRC indicate whether these positive trends result from specific actions such as better maintenance, training, better analysis of the operating experience or else?
Answer	The specific programmatic cause(s) of the positive precursor trends were not identified. The ASP Program remains alert for commonalities and would alert NRR staff if it observed any. However, ASP is just one of many regulatory tools and would be much more sensitive to negative than positive trends. Please note that some of the precursor trends are influenced by a large number of outlier events (e.g., control rod drive mechanism cracking events and Northeast blackout loss-of-offsite-power events) that occurred at the beginning of the trending period (i.e., during FYs 2001–2003).
Question No. 25	
Question/ Comment	It is observed that there was significant decreasing trend in accident precursors for PWRs. Were similar trends observed for older generation BWRs?
Answer	Trend analysis for subgroups of plant types, such as older generation BWRs, was not performed as part of the work of SECY-10-0125, "Status of the Accident Sequence Precursor Program and the Standardized Plant Analysis Risk Models," dated September 29, 2010. BWR precursor counts were examined, and no significant trend was observed.
Question No. 26	
Question/ Comment	It is said that the NRC developed an internal Web site to provide a centralized source for accessing reactor operating experience information. How do you utilize this web site in the process of the reflection to collection, evaluation and regulation of the information? How do you share the information of the operating experience between NRR and NRO?
Answer	The Operating Experience Gateway is a Web site providing a central location for accessing various databases and reports relevant to reactor operating experience. The site provides links to event and inspection report databases and collections of generic communications and international reports. It also hosts the Operating Experience Communication (COMM) forum. The site is useful for determining whether similar events have occurred in the past, whether an issue has been previously noted at other plants, whether NRC evaluation of a similar issue has

	taken place in the past, or for analyzing trends in data over time. The COMM forum contains 1–2 page summaries of events of interest that have been noted by the operating experience branch and include an analysis of the event, diagrams of systems involved, relevant pictures, and links to related operating experience. NRO participates in the daily screening of operating experience. Any information from events examined by the operating experience branch that is determined to be of potential interest to NRO is forwarded to contacts established within NRO to ensure their awareness. In addition, NRO developed a construction experience (ConE) database containing information from past operating experience that has been reviewed and determined to be applicable to the construction of new reactors. In 2010, NRO stared posting operating experience (OpE)/ConE COMM reports to the Operating Experience COMM forum. The NRO staff performs a similar role to that of the NRR operating experience staff in managing and processing OpE/ConE under the "Issue for Resolution" evaluation process.
Question No. 27	
Question/ Comment	The report states, "the effective use of operating experience is important for agency's safety mission…and coordinates NRC operating experience activities with other organizations performing related functions." INPO and WANO also analyze operating experience and get lessons. Do you cooperate with them in this area? If so, what role does NRC play?
Answer	The relationship between the NRC and INPO is established by a memorandum of agreement between the two organizations. The NRC operating experience branch maintains communication with the INPO groups that analyze operating experience. This communication occurs through biweekly phone calls to exchange information on events of interest or trends that have been noted, and through an annual meeting between the two groups to present ongoing projects and upcoming work. Communication with WANO is conducted primarily through INPO. The NRC also receives INPO operating experience reports for consideration of the relevant operating experience.
Question No. 28	
Question/ Comment	Five strategic outcomes are established for NRC's safety objective and six performance measures are used to determine that safety objective has been met. 1) How are safety outcomes and performance measures related? 2) For the first measure, analyzing nuclear power plant performance: how are performance indicators and findings consolidated into only one measure? 3) As mentioned in the report the first four measures are indicatives that power plants are operated safely. So, how do they measure NRC´s performance?
Answer	(1) How are safety outcomes and performance measures related? The agency achieves safety goals by ensuring that the performance of licensees is at or above acceptable safety levels. The performance measures quantify the agency's success in achieving its safety outcome. (2) For the first measure, analyzing nuclear power plant performance: how are performance indicators and findings consolidated into only one measure? Individual plant performance is characterized in terms of the action matrix column

	assigned to the plant. The action matrix column is determined based on plant-specific inputs (inspection findings and performance indicators) to the NRC's performance assessment process. The NRC's performance under Safety Measure 1 is a reflection of industry performance. According to "Congressional Budget Justification: Fiscal Year 2011" (NUREG-1100, Volume 26), Safety Measure 1 is defined as the "number of new conditions evaluated as red by the NRC's Reactor Oversight Process." The new condition could be either an NRC inspection finding or a performance indicator. (3) As mentioned in the report the first four measures are indicatives that power plants are operated safely. So, how do they measure NRC´s performance? Three of the performance measures focus on performance at individual NPPs. Inspection results show that all of the NPPs are operating safely. The fourth measure tracks the trends of several key indicators of NPP safety. This measure is the broadest measure of the safety of NPPs, incorporating the performance results from all plants to determine industry average results.
Question No. 29	
Question/ Comment	Could you please provide some information on the status of the State-of-the-Art Reactor Consequence Analyses (SOARCA) project?
Answer	As its name implies, the State-of-the-Art Reactor Consequence Analyses (SOARCA) research project is designed to develop realistic estimates of the potential public health effects that might result from an NPP accident, in the event of very unlikely scenarios that could release radioactive material into the environment. Toward that end, this project is also designed to evaluate and improve, as appropriate, methods and models for realistically evaluating both the plant response during such severe accidents, including protective actions for the public (such as evacuation and sheltering), and the potential public health risk. To be analyzed in SOARCA, an accident scenario had to have a probability of occurring more than once in a million reactor years. The study also focuses on some lower probability accidents for analysis because of their potential to result in very high consequences. Thus, for the less likely severe accidents (such as containment bypass or early containment failure scenarios) that could have significantly greater consequences, the staff used a lower core damage frequency criterion of 10^{-7} (i.e., one in ten million) per year to select scenarios for analysis. The NRC staff is currently addressing comments from the SOARCA Peer Review Committee and fact-check responses from Peach Bottom Atomic Power Station and Surry Power Station. Work has also begun on an uncertainty analysis for the SOARCA project. When all comments have been addressed, the NRC staff plans on holding a final meeting with the SOARCA Peer Review Committee and releasing the draft SOARCA NUREG for public comment. Please visit the NRC Web site for additional and updated information on the SOARCA Project: http://www.nrc.gov/about-nrc/regulatory/research/soar/overview.html
Question No. 30	
Question/ Comment	To what extent the risk monitoring technology is applied at U.S. NPPs?

Answer	Most risk-monitoring technology for the day-to-day operation of plants is applied to comply with 10 CFR 50.65(a)(4)—the Maintenance Rule requirement for managing and assessing workweek risk. The staff has found that most licensees use a software-derived monitor. The most popular ones are EOOS (Equipment Out Of Service) and Safety Monitor. Less popular is Paragon (formerly ORAM-Sentinel). These packages are used primary at the site work control center; some licensees run them in the control room as well. The extent to which these packages are used is to assess the overall increase in risk due to scheduled maintenance and surveillances. Operations personnel in the control room uses them in the event that something fails at times when workweek managers are unavailable to run the software to make an assessment of plant risk status. Currently, other than what the NRC requires as part of the Maintenance Rule, the vast majority of licensees have no need to continuously monitor changes in overall risk.
Question No. 31	
Question/ Comment	It is stated in the National Report that a quality Standard for PRA was endorsed in 2009. Up to that moment, how was the quality of different plant PRA verified by the NRC? Is there an specific inspection programme?
Answer	In the context of licensing actions for currently operating plants (i.e., those plants licensed under 10 CFR Part 50), the guidance related to the technical adequacy (quality) of the PRAs and probabilistic safety assessments (PSAs) used in risk-informed decisionmaking appears in RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," which endorses the PRA quality standards. The initial version of this RG, issued in early 2004, addressed internal initiating events at full-power operation. The NRC has revised this RG as the PRA quality standard has been revised and expanded to incorporate external initiating events (e.g., fires, seismic). Before the initial standard was issued, the review of the quality of the licensee's PRA and PSA relied heavily on the expertise and knowledge of individual NRC staff members. These staff typically had decades of experience developing and using plant-specific PRAs. For currently operating plants, there is no overarching regulation that requires a PRA and PSA and, thus, there is no specific inspection program on PRA and PSA quality. Rather, PRA and PSA quality is addressed when licensees request risk-informed licensing actions. RG 1.200, which endorses the ASME/American Nuclear Society (ANS) PRA standards, provides guidance on what an acceptable program to maintain and upgrade the PRA should include. An acceptable process for maintaining and upgrading the PRA is expected to include the following characteristics and attributes, as listed in the RG: (1) monitor PRA inputs and collect new information, (2) ensure that the cumulative impact of pending plant changes is considered, (3) maintain configuration control of the computer codes used in the PRA, (4) identify when PRA needs to be updated based on new information or new models, techniques, or tools, and (4) ensure that peer review is performed on PRA upgrades. All of these aspects are evaluated by the NRC staff in the review of a licensee's risk-informed licensing action.

	New reactor applicants and licensees are subject to specific PRA requirements. DC or COL applicants are required to provide a description of the design-specific or plant-specific PRA and its results (per 10 CFR 52.47, “Contents of Applications; Technical Information,” and 10 CFR 52.79, “Contents of Applications; Technical Information in Final Safety Analysis Report,” respectively). The NRC staff reviews this documentation in accordance with Chapter 19 of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (SRP or “the Standard Review Plan”), which refers to RG 1.200. After a license is issued, a COL holder is required to develop a Level 1 and 2 PRA no later than its scheduled date for initial loading of fuel (per 10 CFR 50.71, “Maintenance of Records, Making of Reports”). This PRA must cover initiating events and modes for which NRC-endorsed consensus standards on PRA exist 1 year before that scheduled date for initial loading of fuel. There are additional requirements for maintaining the PRA and upgrading it to cover consensus standards endorsed beyond this point. As discussed above, the NRC staff endorses these consensus standards in RG 1.200.
Question No. 32	
Question/ Comment	What training is used for inspectors to receive and treat concerns and allegations relating to safety issues?
Answer	Inspection Manual Chapter (IMC) 1245, “Qualification Program for Operating Reactor Programs,” identifies the required training for all Operating Reactor Program inspectors and Appendix A, “Basic-Level Training and Qualification Journal,” to IMC 1245 requires the completion of an individual study activity on allegations. The purpose of this activity is to familiarize the inspector with the procedures, guidance, and activities applicable to handling the receipt, processing, review, and closure of allegations. The study activity helps the inspector candidate to effectively interact with individuals bringing concerns to the NRC and to appropriately respond to those concerns. Additionally, the agency requires annual Web-based allegations refresher training for all NRC employees so that they are prepared to deal with an allegation, if necessary.
Question No. 33	
Question/ Comment	In the regards to the ASP program, is there any ongoing development to include MOSC (Management, Organizational and Safety Culture) factors and their potential safety impact?
Answer	To date, there has been no effort to explicitly include management, organizational, and safety culture (MOSC) factors into the ASP Program. However, if MOSC factors are observed at an NPP experiencing an operational event, they sometimes can be taken into account in the human reliability analysis portion of the ASP analysis. Some specific MOSC factors can be linked to performance-shaping factors in the NRC’s human reliability analysis.
Question No. 34	
Question/ Comment	It is stated that certain changes have been made in Reactor Oversight Process in 2009. What were the main reasons for the changes?
Answer	The NRC staff performs an annual self-assessment of the ROP and presents the results in a Commission paper and subsequent public briefing of the Commission. The staff conducts numerous activities and obtains data from many diverse

	sources to ensure that it performs a comprehensive and robust self-assessment. Data sources include the ROP performance metrics described in IMC 0307, “Reactor Oversight Process Self-Assessment Program,” feedback received from internal and external stakeholders, and direction and insight contained in several Commission SRMs. The staff analyzes the information from these various sources to gain insights on ROP effectiveness and potential areas for improvement. Based on each self-assessment, the staff develops a consolidated list of significant actions or ongoing activities that the staff commits to focus on in the following year to improve the efficiency and effectiveness of the ROP. The staff reports back to the Commission on the status of past commitments and provides a list of new commitments in each annual ROP self-assessment. The staff’s annual self-assessment for calendar year 2009 is publicly available (ADAMS Accession No. ML100550404) and contains more discussion about the specific reasons for the more significant changes made to the ROP in 2009.
Question No. 35	
Question/ Comment	The Accident Sequence Precursor Program considers an event with a conditional core damage probability or an increase in core damage probability greater than or equal to 1×10^{-6} to be a precursor. The Accident Sequence Precursor Program defines a significant precursor as an event with a conditional core damage probability or an increase in core damage probability greater than or equal to 1×10^{-3}. Please explain why the Accident Sequence Precursor Program analyzes precursors only in relation to the conditional core damage probability and disregards the conditional larger early release probability (CLERP)? Hence, events related to confining safety, ventilation, and other systems that influence the CLERP but are not significant for CCDP can be excluded from consideration.
Answer	Post-core-damage conditional larger early release probability (CLERP) evaluations are not within the scope of the ASP Program. However, the NRC uses available risk tools and methods, as appropriate, to help inform regulatory decisions. The ASP Program currently uses the standardized plant analysis risk (SPAR) models to perform its analyses. The current SPAR models are Level 1 models. There have been developmental efforts to expand the SPAR models to beyond Level 1; however, the NRC currently does not have the modeling capabilities to analyze events in relation to CLERP or large early-release frequency.
Question No. 36	
Question/ Comment	The report says that “The Executive Director for Operations [EDO] is authorized to approve final rules that do not involve policy changes.” Could the U.S. provide a definition of that which does “not involve policy changes” and give a few examples of the kind of final rules that the EDO has approved? What is the approximate percentage of final rules that are approved by the EDO rather than the Commission?
Answer	As stated in Management Directive 6.3, “The Rulemaking Process” (June 2, 2005), a rule involves a significant question of policy and must be submitted to the Commission for approval and issuance if it does the following: Represents a major change in existing Commission policy,…

	Addresses a major new issue, or… Results in a major commitment of resources by a class of licensee. In determining whether a rule is considered to involve a significant question of policy, the lead office considers the following: Impact of the action on licensees and the public;… Degree of controversy that may be associated with the action;… Existence of significant public health, safety, environmental, or common defense and security questions;… Applicability of existing precedent; and… Resources that will be required for implementation. Examples of rules issued by the EDO include administrative rules to correct errors or make conforming changes to nomenclature, rule changes related to reorganizing, and rules that periodically update the editions of certain sections of the ASME Code with which licensees must comply. Aside from administrative rule changes (e.g., rules to address very minor editorial corrections), the vast majority of final rules are approved by the Commission.

ARTICLE 7. LEGISLATIVE AND REGULATORY FRAMEWORK

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

2. The legislative and regulatory framework shall provide for:

(i) the establishment of applicable national safety requirements and Regulations

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

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

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

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

Question No. 37	
Question/ Comment	What criteria are used to classify events under the following event categories: • Significant Operating Experience Reports (SOERs) • Significant Event Reports (SERs) • Significant Event Notifications (SENs)
Answer	The above non-NRC documents are used to report significant events or significant trends to INPO. These report types have been replaced by INPO Event Reports that are chosen based on the level of response expected of the utility. Event significance is determined through a process of escalating reviews, the highest of which is a board of INPO managers. An INPO-published “significance guide” helps establish the importance of events but is not used as the sole criterion for assigning significance. Rather, the effect or possible effect on nuclear safety is the prime consideration, though the effects of the event on reliability are also considered.
Question No. 38	
Question/ Comment	What’s the licensing approval process to construction plant? In regulation document, what’s the difference between constructing plant licensing process and operation plant licensing process?
Answer	The NRC assumes that this question is asking about the two-step licensing process set forth in 10 CFR Part 50, not the one-step licensing process set forth in 10 CFR Part 52. For further information about the differences between these two licensing processes, please see the NRC’s answer to Question No. 40.

	Under the 10 CFR Part 50 two-part licensing scheme, an applicant needs to acquire a CP before beginning construction of an NPP. The process is as follows. First, the applicant submits a preliminary safety analysis report (PSAR) along with its CP application. The PSAR includes technical information about the safety of the site and the safety of the plant design. In 10 CFR 50.34(a), the NRC details what the applicant must put in its application and PSAR. The NRC will grant a CP to an applicant if the NRC has reasonable assurance that the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public. However, under the 10 CFR Part 50 licensing scheme, a CP does not authorize actual operation. After construction, the applicant must submit a separate operating license application and a final safety analysis report (FSAR). The FSAR finalizes any preliminary information from the PSAR and includes the final safety information about the plant and operation. The regulation at 10 CFR 50.35, "Issuance of Construction Permits," explains that the NRC cannot grant an operating license until it determines that the final design (as specified in the FSAR) provides reasonable assurance that the health and safety of the public will not be endangered by operation of the facility in accordance with the requirements of the license and NRC regulations.
Question No. 39	
Question/ Comment	It is said that 10 CFR Part 52 provides for "Standard Design Certifications" and "Combined Licenses". How do you reflect the safety review of COL refers the certified design, in the case of finding the issues and the matter which should be modified?
Answer	The NRC assumes that this question is asking about the scope of the NRC's safety review of a COL application that (1) references a final design certification rule (DCR) but (2) proposes to use a design approach in some limited aspect that is different from the DCR (i.e., is "departing" from the DCR). First, in a COL proceeding, the NRC reviews those portions of the proposed NPP's design that are outside the scope of the referenced DCR. For example, the referenced DCR would not cover site-specific design elements (e.g., the ultimate heat sink). Therefore, the NRC reviews these site-specific design elements during the COL application proceeding. In addition, the DCR does not address nondesign-related NRC requirements (e.g., EP, security programs, operational programs). Therefore, the NRC also reviews the COL applicant's compliance with these nondesign requirements during the COL application review. Second, any departures from the design of a referenced DCR that are proposed by the COL applicant must be reviewed by the NRC during the COL application review. The departures are evaluated against current NRC requirements. Finally, to the extent that the COL applicant proposes that the NRC make a finding as part of the COL issuance that one or more acceptance criteria of the ITAAC in the DCR have been met, the NRC would determine whether it could make such a finding.
Question No. 40	
Question/ Comment	It is reported that recently the NRC amended 10 CFR Part 52 to improve the effectiveness of its processes for licensing future NPPs.

	What is meant by the statement, the amendments clarify the overall regulatory relationship between 10 CR Part 50 and 10 CFR Part 52? We have understood that these were two different, alternative ways of licensing? What lessons learned led to the updates of 10 CFR Part 52?
Answer	It is true that the NRC regulations contain two alternative ways of licensing NPPs. The first approach, which the NRC (and, before it, the U.S. Atomic Energy Commission) used for all currently operating NPPs, is a two-step licensing process in which the applicant first gets a CP and then gets an operating license (the 10 CFR Part 50 process). The second approach, which involves ESPs, DCs, COLs, and manufacturing licenses, is given in 10 CFR Part 52. Under the old 10 CFR Part 50 process, most design issues were not resolved until *after* construction began. The aim of the original 10 CFR Part 52 was both standardization of design and early resolution of design and site issues. The 2007 rulemaking to amend 10 CFR Part 52 addressed the concern that the overall regulatory relationship between 10 CFR Part 50 and 10 CFR Part 52 was not always clear. This rulemaking clarified whether 10 CFR Part 50's safety requirements apply to each of the licensing processes in 10 CFR Part 52 (those licensing processes include early site permitting, standard design approval, standard DC, COL, and manufacturing license). But the alternative licensing process in 10 CFR Part 50 was *not* amended in the rulemaking to update 10 CFR Part 52. Specifically, the 2007 amendments to 10 CFR Part 52 clarified that plants licensed under 10 CFR Part 52 procedures must nonetheless comply with the generally applicable technical requirements from 10 CFR Part 50 (these applicable requirements are identified in 10 CFR Part 52 so that there is no ambiguity in what constitutes an "applicable requirement"). For example, 10 CFR Part 52 provides that the general design criteria in Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 apply to NPPs licensed under 10 CFR Part 52. The 2007 amendments also clarified that plants licensed under the 10 CFR Part 52 process must comply with certain administrative requirements in 10 CFR Part 50. By identifying the specific 10 CFR Part 50 requirements that are applicable, the 2007 amendments removed the ambiguity of determining what requirements in 10 CFR Part 50 are "technically relevant" to NPPs approved or licensed under the procedures of 10 CFR Part 52.
Question No. 41	
Question/ Comment	It is mentioned in the report that there are 4 & 3 nuclear power plants got the life extension permission during 2009 and 2010 respectively. Are these nuclear power plants got the same permission of 20years life extension? What's the stipulation in regulation documents?
Answer	To date, all NPPs that have requested a 20-year license extension have received one (following NRC approval of their license renewal applications). As NRC regulations (10 CFR 54.31, "Issuance of a Renewed License") state, the renewal period cannot exceed 20 years. The precise language in the regulation is as follows: (a) A renewed license will be of the class for which the operating

	license or combined license currently in effect was issued. (b) A renewed license will be issued for a fixed period of time, which is the sum of the additional amount of time beyond the expiration of the operating license or combined license (not to exceed 20 years) that is requested in a renewal application plus the remaining number of years on the operating license or combined license currently in effect. The term of any renewed license may not exceed 40 years. (c) A renewed license will become effective immediately upon its issuance, thereby superseding the operating license or combined license previously in effect. If a renewed license is subsequently set aside upon further administrative or judicial appeal, the operating license or combined license previously in effect will be reinstated unless its term has expired and the renewal application was not filed in a timely manner. (d) A renewed license may be subsequently renewed in accordance with all applicable requirements.
Question No. 42	
Question/ Comment	It is said that resident inspectors and regional inspection specialists conduct the inspection respectively. How do you have different coverage from each inspector under their inspection? How do you communicate among headquarter, Regional offices, and Resident inspectors?
Answer	Resident and regional inspectors are assigned different inspection procedures (IPs) in the NRC baseline inspection program. All baseline inspections that require completion are identified in Appendix A, "Risk-Informed Baseline Inspection Program," to IMC 2515, "Light-Water Reactor Inspection Program—Operations Phase." A subset of these baseline inspections identified in Appendix A to IMC 2515 is normally completed by regional inspectors. The baseline inspections that are normally completed by regional inspectors are identified in paragraph 8.1 of IMC 2515. An inspection plan consisting of approximately 15 months of activities (from the issuance of the annual assessment letter) is used to communicate what inspections the NRC plans to perform at each of the operating sites. The inspection plan will consist of Report 22, "Inspection/Activity Plan," from the NRC database program, Reactor Program System (RPS). The proposed inspection plan is reviewed during the end-of-cycle and midcycle meetings that are attended by staff from both Headquarters and regional offices (resident inspectors participate in these meetings as well). These inspection plans are included in the NRC's end-of-cycle and midcycle letters to the licensees and are also publically available on the NRC Web site. In addition, resident inspectors and regional offices communicate on a daily basis on activities and plant performance. NRC Headquarters and the regions

	communicate regularly, at least biweekly during counterpart phone calls.
Question No. 43	
Question/ Comment	At what stage in the NPP life-cycle do the resident inspectors operate? Do they follow site-preparation, construction work etc. (i.e. pre-commissioning stage) or do they begin their inspection during commissioning and start-up?
Answer	There are two types of resident inspectors assigned to the site where a licensee is constructing an NPP under 10 CFR Part 52. Initially, construction resident inspectors are assigned to the site to perform all inspections necessary to support satisfactory completion of inspection requirements related to the construction of the facility as identified in NRC IMC 2503, "Construction Inspection Program: Inspections of Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)," and IMC 2504, "Construction Inspection Program—Inspection of Construction and Operational Programs." Operations resident inspectors are assigned in a timeframe (about 6 months to a year) before the NRC—specifically, the Commission—makes a decision on whether the acceptance criteria in the COL were met (the 10 CFR 52.103(g) finding). Assignment of operational resident inspectors before the Commission makes its 10 CFR 52.103(g) finding ensures an orderly transition from construction to operational oversight.

ARTICLE 8. REGULATORY BODY

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

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

This section explains the establishment of the U.S. regulatory body (i.e., the NRC). It also explains how the functions of the NRC are separate from those of bodies responsible for promoting research, development, and advancement of nuclear energy (e.g., DOE).

Question No. 44	
Question/ Comment	“Since 1999, the NRC has participated in more than 20 Integrated Regulatory Review Teams or Integrated Regulatory Review Service (IRRS) missions, sending high-level technical experts on approximately four missions per year. In October 2010, the United States will host an IRRS mission, focused on the U.S. operating reactor program.” Could the U.S. clarify how many of the high-level technical experts per year were involved in IRRS missions in European Union (EU) Member States? How many IRRS missions have been carried out in the U.S. prior to the one scheduled for October 2010? How many nuclear reactors are involved in the program and what type of power reactor (PWR or BWR) is being submitted to the IRRS missions and how long has (have) it (they) been in operation? How many NRC staff is involved in the missions as a percentage of the overall effort and are any high-level technical experts from EU Member States also involved? Could you provide an estimate of the extra effort, expressed as a percentage of overall annual NRC regulatory mission costs, an IRRS mission entails (Domestic program and international assistance)?
Answer	The United States sent high-level technical experts to the Integrated Regulatory Review (IRRS) missions and followup missions in France (2006, followup 2008, one expert), Germany (2008, one expert), Spain (2008, followup 2011, two experts), and the United Kingdom (2006, followup 2009, one expert). The October 2010 IRRS mission was the first IRRS mission carried out in the United States. The October 2010 IRRS mission to the United States focused on the U.S. operating power reactor program. Therefore, it assessed regulations pertaining to

	the entire U.S. fleet of 104 operating reactors. A complete list of U.S. operating power reactors can be found in the Fifth National Report, as well as by following this link: http://www.nrc.gov/reactors/operating/list-power-reactor-units.html. Of the nearly 4,000 NRC employees, approximately 10 percent were involved in preparing for and/or participating in the IRRS mission. Of those NRC staff members that were involved, an estimated 35 percent had significant involvement. If the mission had addressed additional programs besides the operating power reactor program, then even more NRC staff would have been involved. The IRRS mission team to the United States included multiple senior experts from European Union (EU) member states, including the Czech Republic, Finland (two experts, including the team leader), France, Germany, Italy (observer), Slovenia, Spain, Sweden, and the United Kingdom. The U.S. mission, which was only on the operating power reactor program, entailed less than 1 percent per year of the NRC's budget for 2 years. For senior NRC experts participating in foreign IRRS missions, the overall level of effort was 2 weeks of travel time for the mission (or 1 week for a followup mission), plus approximately 1 week of preparation (e.g., reading advance reference materials, formulating questions, consulting with NRC experts about the country's regulatory program).
Question No. 45	
Question/ Comment	It is said that the NRC holds leadership roles in the four IAEA Safety Standards Committees and the Commission on Safety Standards. How do you implement to ensure consistency with international standards such as comparing between international standards and domestic standards in the U.S?
Answer	The NRC derives great benefit from participation in the IAEA Commission on Safety Standards, as well as through participating in the individual safety standards committees. NRC staff members participate with their international counterparts to help draft many of the safety standards and safety guides developed by IAEA. Once an IAEA safety standard or safety guide is drafted and provided to the member countries for review and comment, the NRC also performs a detailed review of the document and creates a gap analysis to (1) evaluate whether the document aligns with any existing NRC regulations or guidance, or with any other relevant U.S. agency documents or positions, and, if not, (2) identify any key differences between the IAEA document and NRC or other U.S. agency regulations and guidance documents. The NRC staff then uses the results of the gap analysis to develop comments on the draft IAEA document or to develop NRC positions to be discussed by NRC representatives at the various IAEA safety committees and the Commission on Safety Standards. The NRC staff also considers the results of the gap analysis, as appropriate, when contemplating future revisions to NRC regulations and guides. The NRC collects and organizes the information obtained from its review of each IAEA safety standard in an agencywide knowledge management database that is later consulted when a revision to an NRC regulation or RG is being considered, in order to address any potential gaps between the proposed NRC documents and the IAEA safety standards, as appropriate.

Question No. 46	
Question/ Comment	How do you prepare for each training program for university graduates and native of industry? How do you think about staffing whole human resource in the NRC although it is thought that there will be a remarkable trend concerning construction of new reactors and disposal of radioactive waste in recent year?
Answer	The agency uses its Nuclear Safety Professional Development Program (NSPDP) as the guide for orienting and training recent university graduates. The curriculum is developed in conjunction with the program offices and is composed of a set of core and discipline-specific requirements that must be completed within the first 2 years of employment. NSPDP participants usually attend classes with more experienced NRC employees as part of their acclimation and socialization experience. Natives of industry, referred to as midcareer hires, attend an abbreviated set of new-employee courses, any courses specific to qualifications for their job function, and additional courses that they identify jointly with their immediate supervisors. To address staffing on the whole, the NRC is constantly seeking to identify workforce trends and changes in the nuclear industry, while assessing the agency's future needs. Strategic workforce planning is the process used to ensure that the right number of people with the right knowledge, skills, and abilities are in the right jobs to successfully fulfill the agency's mission. Accordingly, strategic workforce planning provides management with a basis for making human resource decisions. Strategic workforce planning has the following goals: • Identify short- and long-term critical skill gaps. • Identify workforce trends and projections. • Develop strategies to close skill gaps. • Address succession planning. This proactive approach is supported at the highest levels of the agency, and, in 2006, the agency formed the Human Capital Council, which comprises senior managers from the NRC offices. The council ensures that agencywide human capital goals and strategies align with the agency's mission.
Question No. 47	
Question/ Comment	It was heard that IAEA's IRRS mission was conducted in October 2010. How will you implement for the future and prepare for the follow-up mission concerning recommendations and suggestions by review team in the NRC?
Answer	The NRC is considering each recommendation and suggestion contained in the IRRS mission report and will develop actions to address them, where appropriate. The NRC will provide a summary of its actions to address the recommendations and suggestions to the followup IRRS mission team.
Question No. 48	
Question/ Comment	The report states pension offset waiver (rehiring annuitants without reduction of salary or pension)" in the "Recruitment and Hiring Process". Is this system established by the original judgment of NRC or under the consensus among related ministries?
Answer	The authority to reemploy Federal civilian retirees was provided to the NRC under

	the Energy Policy Act of 1985. The NRC uses this authority in positions for which there is exceptional difficulty in recruiting or retaining a qualified employee, or when a temporary emergency hiring need exists. Employing rehired annuitants is especially useful for knowledge retention and transfer efforts.
Question No. 49	
Question/ Comment	The report states: "A major challenge is the multigenerational population now working together, each with different ways of learning and approaching work." What kind of measures do you take for this challenge as a organization?
Answer	The NRC has added significant training resources in the form of staff, contract funds, and facilities to meet the new staff's training requirements. Courses on new reactor designs have been developed and delivered at all levels, and the agency is currently acquiring two full-scale simulators to meet the future demand for training inspectors and examiners. The NRC has also embraced new technologies for the delivery of training to both shorten the time to competency and to contain travel costs, including the following: expanded use of online learning, video teleconferencing live courses, and course delivery via webinar. At the NRC, employees are empowered to manage their own careers. Employees have a wide range of developmental opportunities available to them, including training courses, a mentoring program, career counseling, individual development plans, rotational assignments, and formal leadership development programs. Individual development plans are used and are available to all staff. Employees, working with their management, identify long-term and short-term goals and the actions the employee will take to meet those goals. These include activities such as technical training, rotations, details, self-study, and specific work assignments. In addition to the internal training, external training funds are available for all employees to request courses offered outside of the agency. These requests are prioritized based on office skill needs. Typically, senior employees, rather than supervisors or managers, lead task forces, working groups, focus groups, inspections, and allegation responses. These situational leadership experiences help prepare employees for future leadership positions.
Question No. 50	
Question/ Comment	U.S. may like to describe the procedure of executive succession planning process, through which NRC identifies skills needed and potential successors for senior leadership positions.
Answer	The NRC's Executive Resources Board (ERB), the governing body of the Senior Executive Service (SES), engages in ongoing executive succession planning activities to identify potential successors for executive positions. Succession planning guides executive development and informs SES staffing decisions. The ERB determines skill sets needed and coordinates, monitors, validates, and reviews the results of succession planning and developmental activities. Office directors and regional administrators, or their designees, hold ongoing succession planning discussions with executives in their respective organizations to share ERB succession planning activities, discuss career goals, and identify specific development, assessment, mentoring, or coaching needed. Executives actively participate in the succession planning process by providing input on their career goals and by working with their supervisors to develop executive development plans tailored to their individual interests, learning

	preferences, and needs. Executives are encouraged to consider a wide range of developmental activities, such as reassignments or rotations within the NRC, formal training, mentoring, or coaching. Developmental assignments may include international assignments and interagency projects, details, or rotations. Each executive is provided access to a mentor or executive development coach. The NRC is implementing an Executive Pairing Program to match experienced SES leaders with other executives so that both maximize their growth as leaders. Training was conducted in October 2009 to initiate executive pairings.
Question No. 51	
Question/ Comment	In the last paragraph of page 72 of the report there is a mention of a “NRC Knowledge Center” web page that has been established to support the knowledge management programme. This is seems like an interesting tool for disseminating knowledge among staff. Could you please provide more information on how the information was structured by areas of expertise and what is the user feedback from the staff?
Answer	The NRC Knowledge Center is a Web-based tool that facilitates the agency’s communities of practice. The information is structured by the staff, typically by discipline or area of practice rather than by strict alignment with agency offices or regions. This structure gives staff the ability to share knowledge across different organizations within the NRC. Currently, access to the Knowledge Center is only available internally on the NRC local area network. Participation in the Knowledge Center continues to grow as more communities of practice find that a Web-based presence can add value to their work processes. Because participation in the NRC Knowledge Center is voluntary and user-based, user feedback is generally positive.
Question No. 52	
Question/ Comment	The NRC FY 2010 budget figures are presented in the subsection 8.1.5. What amount of this budget is planned to be spent on R&D activities in 2010?
Answer	The total cost of NRC research activities in FY 2010 is $126.4 million.
Question No. 53	
Question/ Comment	The subsection 8.1.7 reads that NRC performed a complementary self-assessment in 2009 in the course of preparations to the IAEA IRRS Mission. What criteria were used for this complementary self-assessment?
Answer	Approximately 300 questions appropriate for the operating power reactor program were selected from the IAEA question databank for the complementary self-assessment (CSA) conducted in accordance with the IAEA guidance for an IRRS issued in February 2008. IAEA procedures used as reference insight for responding to the questions are (1) GS-R-1, “Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety,” (2) GS-R-2, “Preparedness and Response for a Nuclear or Radiological Emergency,” (3) GS-R-3, “The Management System for Facilities and Activities,” (4) GS-G-1.1, “Organization and Staffing of the Regulatory Body for Nuclear Facilities,” (5) GS-G-1.2, “Review and Assessment of Nuclear Facilities by the Regulatory Body,” (6) GS-G-1.3, “Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body,” and (7) GS-G-1.4, “Documentation for Use in Regulating Nuclear Facilities.”

	Because GS-R-1 was undergoing revision, the NRC staff decided to use the draft GS-R-1 available in early 2009 for the CSA. Because the questions referenced the GS-R-1 dated October 2000, the staff created a document that referenced the paragraph in the draft version of GS-R-1 that corresponded to the paragraph in the 2000 version. In addition, the 2009 CSA was performed based on the module alignment contained in the 2008 guidance for IRRS missions. Following the issuance of the new 2010 guidance for IRRS missions, the NRC staff realigned the questions and responses to conform to the 2010 guidance module alignment. The realigned CSA was provided to the IRRS review team as part of the advance reference material.
Question No. 54	
Question/ Comment	Offices of the Executive Director for Operations How many investigations does the Office of Investigations deal with in average annually? Can employees make formal anonymous complaints before the NRC?
Answer	The Office of Investigations (OI) is an independent, national investigations program, which consists of four regionally based field offices headed by field office directors who report to senior management staff in OI Headquarters located in Rockville, MD. OI comprises experienced Federal criminal investigators and a professional and specialized investigation support staff. OI develops and implements policies, procedures, and quality control standards for investigations of licensees' certificate holders and their contractors or vendors. OI conducts thorough, quality, and timely investigations of wrongdoing and makes referrals of substantiated criminal cases to the U.S. Department of Justice for prosecution consideration. OI keeps the NRC principals informed of matters under investigation as they affect public health and safety. On average, OI closes about 186 cases (investigations and assists to staff) per year, but cases are unpredictable and reactive in nature, so the number of cases closed by OI per year may vary. OI provides investigative assistance directly to the NRC staff when requested. Generally, OI's assists to staff are matters of regulatory concern for which the NRC staff has requested OI's specialized, investigative expertise but may not involve specific indications of willful wrongdoing. In addition, NRC employees may make formal or anonymous complaints or report suspected fraud, waste, and abuse of NRC programs and operations to the NRC's separate Office of the Inspector General (OIG).
Question No. 55	
Question/ Comment	Financial and Human Resources Could you provide further information on the virtual orientation center?
Answer	To assist new employees, the NRC has developed a virtual orientation center. This advanced training tool allows new hires to enter a computer-generated or virtual world in which they can obtain information about the NRC's organization, its mission, and employee benefits before starting their first day of work. The virtual world is designed to look like an office building, with a reception area and office space. The user navigates from room to room, where they obtain the information described above.

Question No. 56	
Question/ Comment	Human Resources Do you carry out annual surveys on working climate at NRC and staff perception of the organization?
Answer	In regular intervals (every 1–3 years), a number of surveys are administered to obtain feedback from employees on the organizational culture. Among these are Human Capital Surveys administered by the U.S. Office of Personnel Management and the Safety Culture and Climate Survey administered through the NRC´s OIG. The NRC was rated the best place to work in the Federal Government by the last two Federal Human Capital Surveys and also showed substantial improvement in most areas from one survey to the next. It should be noted that the OIG climate survey includes a qualitative phase, in which a random sample of NRC employees and managers are interviewed, and a quantitative component, consisting of a survey administered to all NRC employees. Since the 2002 survey, OIG issued a final report identifying "key areas for improvement" and recommended areas of focus for NRC senior management. In addition, the Office of Enforcement formed a Safety Culture Task Force in 2009, which completed a series of data-collection activities to solicit ideas agencywide about enhancing safety culture. The Task Force also benchmarked external organizations. These ideas have been taken forward in staff training and a number of internal programs.
Question No. 57	
Question/ Comment	It is reported for the NRC that the sum of all funds available to obligate for FY 2009 was $ 1,165.2 million, which is a $136.4 million increase over the FY 2008 amount of $1,028.8 million. In the 4th U.S. CNS national report the reported sums for FY 2005 and 2006 were $722.9 million and $809 million, respectively. The new figures would then amount to more than a 40 % increase in a 3-year period? Is this increase due to the activities with license extensions and new build or does it reflect other aspects as well?
Answer	The majority of the increase over the 3-year period was to address licensing and inspection requirements for new reactors. Most of the remaining increase addressed licensing amendments for existing reactors and related programs such as reactor oversight.
Question No. 58	
Question/ Comment	The self-assessment for 2009 was carried out by updating the previous self-assessment for 2007. Please provide information how the self-assessment took into account new IAEA standards, for example, revised the standard «Governmental, Legal and Regulatory Framework for Safety. General Safety Requirements. Part 1» regarding the GSR Part? Please confirm that the self-assessment conducted in 2009 is also relevant for the IRRS mission in 2010.
Answer	See the response to Question No. 53.
Question No. 59	
Question/ Comment	The report says that the U.S. "…intends to continue to plan for an Operational Safety Assessment Review Team (OSART) mission in the United States every

	3 years." Noting that there is an extensive program of INPO evaluations at U.S. reactor sites every two years (page 181), would the U.S. give the reasons for its decision to invite an OSART mission only once every three years, when, for example, France (with a reactor fleet roughly half the size of that in the U.S.) has invited one OSART mission per year, plus follow-up missions, in every year since 2002? Does the U.S. consider the INPO evaluations provide more useful feedback than the OSART missions, or are there other reasons for the difference in approach?
Answer	In 2003, the NRC made a decision to encourage licensees to request an Operational Safety Assessment Review team (OSART) mission every 3 years to coincide with the 3-year cycle of the CNS. The NRC believes that it is beneficial for the U.S. nuclear power industry to continue its participation in the OSART missions. OSART inspections provide a different type of review of licensee performance than that provided through either the NRC's ROP baseline inspection program or the independent peer reviews provided by INPO. OSART reviews are focused on the operation of the plant and the performance of plant management and staff, while NRC inspections and reviews focus on the plant's design and compliance with its design basis. There is some overlap between OSART missions, INPO evaluations, and the NRC's ROP baseline inspection program. However, because the objectives and missions of these three types of activities are sufficiently different, the NRC believes that comparisons and discussions of whether one type of evaluation is more useful than another are not appropriate. The NRC supports the OSART program and believes that OSARTs benefit the industry and the NRC by providing an independent, third-party perspective on the operation of U.S. nuclear power reactors. However, because participation by U.S. licensees in an OSART mission is voluntary, it is not the NRC's decision nor can the NRC require that these missions be accomplished on any periodicity. The NRC works with the U.S. nuclear industry to accomplish one OSART mission every 3 years. Considering the NRC ROP baseline inspection program that is in place, the INPO reviews, and the voluntary nature of OSARTs, the NRC believes that the current goal of encouraging an OSART mission every 3 years is reasonable for U.S. power plants.

ARTICLE 9. RESPONSIBILITY OF THE LICENSE HOLDER

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

The NRC, through the Atomic Energy Act of 1954, as amended, ensures that the prime responsibility for the safety of a nuclear installation rests with the licensee. Steps that the NRC takes to ensure that each licensee meets its primary responsibility include the licensing process (discussed in Articles 18 and 19), the ROP (discussed in Article 6), and the enforcement program (discussed below). This update revises the debt collection dollar amount and discusses the Alternative Dispute Resolution Program and current experience.

Question No. 60	
Question/ Comment	NRC enforcement program allows for imposing civil penalties and criminal proceedings. Were there any situations / conditions during the past three years wherein NRC was required to impose civil penalties and criminal proceedings?
Answer	After the NRC has made a final decision on how to disposition a violation of an NRC regulation, the NRC informs the licensee (or other applicable party) of the decision. If this determination involves a civil penalty, the NRC will issue the notice of violation and/or order (if applicable) and a proposed imposition of the civil penalty amount. The notice of violation advises the licensee charged with the violation that the civil penalty may be paid in the amount specified, or the proposed imposition of a civil penalty may be contested in whole or in part, by a written response that either denies the violation or shows extenuating circumstances. The NRC will evaluate the response and use that information to determine if the civil penalty should be mitigated, remitted, or imposed by order. Thereafter, the licensee may pay the civil penalty or request a hearing. If the NRC does not receive payment or a written response of the civil penalty amount by the due date, the NRC will proceed to issue an imposition order, an order that imposes the proposed civil penalty amount. Between calendar year 2007 and calendar year 2009, the NRC issued four orders that imposed civil penalties (all material licensees). Specific cases in which civil penalties were imposed are described in the NRC Office of Enforcement's annual reports, http://www.nrc.gov/reading-rm/doc-collections/enforcement/annual-rpts/. The NRC does not have authority to pursue any criminal prosecutions. In accordance with the memorandum of understanding between the NRC and the U.S. Department of Justice (DOJ), the NRC provides cases involving investigations for DOJ review, and DOJ makes the determination to pursue a case for criminal action.
Question No. 61	
Question/ Comment	It is stated that the NRC has enforcement powers, such as notice of violation, civil penalties and orders. How does the NRC identify, evaluate and take enforcement action against applicants, license holders and vendors before the implementation of the Reactor Oversight Process?
Answer	Unlike the Operating Reactor Oversight Program, which focuses on monitoring and evaluating the performance of existing NPPs, regulatory oversight for new

	reactors focuses on the construction of reactor facilities (that is, the period between licensing and initial operation). Additional information about the NRC oversight of applicants, license holders, and vendors is located at http://www.nrc.gov/reactors/new-reactors/oversight.html. For applicants, vendors, and issues not under the ROP at operating reactor license holders, the NRC identifies, evaluates, and takes enforcement action as a result of information gathered through inspection, review of applicants' (or applicable party's) programs and/or submitted documents, or through information provided to the NRC by allegations or requests by members of the public. Any identified apparent violations are evaluated and dispositioned using the traditional enforcement process. The traditional enforcement process assigns severity levels that reflect the assessment of the significance of the violation. For significant violations (Severity Level I, II, or III), the traditional process involves a panel review by members of the regional and program offices and the Office of Enforcement that will recommend the appropriate action, such as issuing a notice of violation, civil penalty, or order. For less significant violations (Severity Level IV or minor), the responsible office will take the action it deems necessary, such as issuing a noncited violation or notice of violation. Also, in certain cases involving vendors and contractors, the NRC may issue a notice of nonconformance for failures to meet commitments that are not legally binding requirements of the NRC. Additional information about the enforcement processes is located at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.
Question No. 62	
Question/ Comment	The report says that The NRC's regulatory programs continue to be based on the premise that the safety of commercial nuclear power reactor operations is the responsibility of NRC licensees, and the licensee is ultimately responsible for the safety of its activities and the safeguarding of nuclear facilities and materials used in operation. Where and how are "the premise" and "being ultimately responsible" stipulated in the legislative framework?
Answer	There is no legislation that assigns the prime responsibility for safety to the licensee, as is the case in many European countries. In the United States, the prime responsibility for safety is conveyed through the license, rather than through the Atomic Energy Act of 1954, as amended. Despite this, the primary responsibility for safe design and operation is clearly assigned to the operator. This assigning is achieved principally through licensing and continuing regulatory oversight and enforcement throughout all stages in the lifetime of a facility. No license is granted unless the applicant can show that the applicant will comply with the relevant statutes and the NRC's rules and orders that implement those statutes and that constitute the body of standards the agency believes are necessary and useful for ensuring public health and safety and the common defense and security. Also, under the statutory provisions for liability payments in the event of a major nuclear accident, the industry bears the liability (see Section 170 of the Atomic Energy Act and the implementing regulations at 10 CFR Part 140, "Financial Protection Requirements and Indemnity Agreements").
Question No. 63	
Question/ Comment	It is stated in your national report that "the NRC's regulatory programs continue to be based on the premise that the safety of commercial nuclear power reactor

	operations is the responsibility of NRC licensees. The NRC is responsible for regulatory oversight of licensee activities to ensure that safety is maintained." We were also informed that recent IRRS mission suggested your agency to provide a consistent, clear message to the licensees that they have responsibility to take their own initiatives to improve safety whenever reasonably practicable. However, NRC Chairman made important remarks in this October that the NRC's regulatory failures had contributed to the Three Mile Island (TMI) accident and that those failures were deeply rooted in the agency's institutional dysfunctions. Identifying fundamental organizational weaknesses, he said, the Administration and Congress then established by law a clearly defined management structure for the agency. It seems that your agency recognizes and admits regulatory body's responsibility when significant accident occurs, although prime responsibility rests with the licensees. We understand that after the Davis Besse's reactor vessel head degradation was found, there were also many self-speculations and debates on the organizational aspects of your agency. How do you view the degree of regulatory body's responsibility when significant accident occurs? Do you have plan to stipulate the regulatory body's responsibility on safety to avoid the regulatory failures that might contribute to the occurrence of significant accident?
Answer	The interplay between the regulatory body's failure and the licensee's failure when a significant accident occurs is complex and defies easy interpretation. For instance, regulatory failures did, in fact, contribute to the Three Mile Island (TMI) accident. The U.S. Congress concluded as much when it amended the organizational structure of the Commission through its Reorganization Plan of 1980. Yet not all significant accidents are necessarily the result of institutional defects in the regulatory body. Even an optimal regulator cannot *guarantee* that *no* significant accident will occur. This is why safety ultimately lies with the license holder. What the agency can do, however, is ensure that it is constantly evaluating past mistakes to ensure that those mistakes are not repeated in the future. The NRC does this by constantly evaluating the lessons learned from past regulatory experiences, both good and bad.
Question No. 64	
Question/ Comment	The NRC considers requesting the licensees to adopt parts of the improved standard technical specifications. Does NRC think this conflicts with article 9 about the responsibility of the license holder? Is so, how is this conflict handled?
Answer	The NRC does not request that licensees adopt the improved technical specifications in whole or in part. Licensees are responsible for initiating any change from plant-specific technical specifications to improved technical specifications, which is in accordance with the responsibility of the license holder discussed in Article 9. However, the NRC encourages licensees to use the improved Standard Technical Specifications (STS) because doing so allows the licensee to take advantage of the evolutions in policy and guidance concerning the required content and preferred format of the technical specifications. The licensee needs to provide justification for any change to the plant specific technical specifications. The NRC would consider changes consistent with the improved STS, but would not approve changes based on a justification of

	compliance with improved STS as the sole basis. The technical specifications for new reactors use the existing STS as a starting point for development, and the new reactors obviously must tailor the STS to reflect the new designs and systems. The technical specifications generated for the new designs reflect the existing STS format and content and become the generic technical specifications that are approved with the DC rule. The new plants are required to adopt the generic technical specifications. The adoption of subsequent STS changes (TSTFs; that is, Technical Specification Task Force Owners Group proposed changes that are NRC staff approved) will be optional, as are current TSTF changes to the existing STS.

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.

NRC policies 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 at the NRC.

Other articles (e.g., Articles 6, 14, 18, and 19) also discuss activities undertaken to achieve nuclear safety at nuclear installations.

Updates to this section discuss new regulations, developments in PRA, and safety culture.

Question No. 65	
Question/ Comment	Please explain the changes to the ROP process due to licensee safety culture weaknesses. Will the NRC review this ROP when the new safety culture policy is approved?
Answer	In 2004, the staff submitted to the Commission SECY-04-0111, “Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture,” dated July 1, 2004. This paper sought Commission direction on the development of possible options for enhancing oversight of a safety conscious work environment and safety culture. The paper noted that a weak safety culture was identified as a root cause of the reactor vessel head degradation at the Davis-Besse Nuclear Power Station (Davis-Besse). The NRC’s Davis-Besse Lessons Learned Task Force report recommended that the staff review NRC inspections and plant assessment processes to determine whether sufficient processes are in place to identify and appropriately disposition the types of problems experienced at Davis-Besse. On August 30, 2004, the Commission provided direction in an SRM on SECY-04-0111 that included the following actions: • Enhance the ROP treatment of cross-cutting issues to more fully address safety culture. • Continue to monitor industry efforts to assess safety culture. • Include, as part of the enhanced inspection activities for plants in the degraded cornerstone column (referred to as Column 3) of the ROP action matrix, a determination of the need for a specific evaluation of the licensee’s safety culture and develop a process for making the determination and conducting the evaluation. • Continue to monitor developments by foreign regulators. Following receipt of SRM SECY-05-0187, “Status of Safety Culture Initiatives and Schedule for Near-Term Deliverables,” dated December 21, 2005, the staff held frequent public meetings with external stakeholders and, with the full participation of these stakeholders, developed an approach to enhance the ROP to more fully

	address safety culture. This resulted in modifications to selected IMCs and IPs. The staff submitted to the Commission SECY-06-0122, "Safety Culture Initiative Activities To Enhance the Reactor Oversight Process and Outcomes of the Initiatives," dated May 24, 2006, which described the status of the staff's activities and plans to enhance the ROP to more fully address safety culture. The staff implemented the changes to the ROP on July 1, 2006. On July 31, 2006, the NRC issued RIS 2006-13, "Information on the Changes Made to the Reactor Oversight Process To More Fully Address Safety Culture" (ADAMS Accession No. ML061880341), which provides a summary of these changes. NRR has developed a Safety Culture Implementation Team composed of staff from NRR, the Office of Enforcement, and all four regions. This team is working to develop options for implementation and a list of components or traits to align with the Safety Culture Policy Statement. Once the Safety Culture Policy Statement has been issued in 2011, the staff plans to work closely with industry representatives and other stakeholders to develop possible changes to the ROP based on Commission direction.
Question No. 66	
Question/ Comment	Which safety culture indicators used to monitor plant performance?
Answer	The ROP safety culture cross-cutting components that are used to evaluate findings at licensed facilities can be found in IMC 0310, "Components within the Cross-Cutting Areas," and currently include the following: • <u>Decisionmaking</u>—Licensee decisions demonstrate that nuclear safety is an overriding priority. • <u>Resources</u>—The licensee ensures that personnel, equipment, procedures, and other resources are available and adequate to ensure nuclear safety. • <u>Work Control</u>—The licensee plans and coordinates work activities consistent with nuclear safety. • <u>Work Practices</u>—Personnel work practices support human performance. • <u>Corrective Action Program</u>—The licensee ensures that issues potentially impacting nuclear safety are promptly identified, fully evaluated, and that actions are taken to address safety issues in a timely manner, commensurate with their significance. • <u>Operating Experience</u>—The licensee uses operating experience information, including vendor recommendations and internally generated lessons learned, to support plant safety. • <u>Self- and Independent Assessments</u>—The licensee conducts self- and independent assessments of its activities and practices, as appropriate, to assess performance and identify areas for improvement. • <u>Preventing, Detecting, and Mitigating Perceptions of Retaliation</u>—A policy

	for prohibiting harassment and retaliation for raising nuclear safety concerns exists and is consistently enforced. IMC 0310 also describes four “Other” components that are considered during the conduct of the supplemental inspection program, while the cross-cutting area components are considered during the conduct of both the baseline and supplemental inspection programs. They include the following: • Accountability—Management defines the line of authority and responsibility for nuclear safety. • Continuous Learning Environment—The licensee ensures that a learning environment exists. • Organizational Change Management—Management uses a systematic process for planning, coordinating, and evaluating the safety impacts of decisions related to major changes in organizational structures and functions, leadership, policies, programs, procedures, and resources. Management effectively communicates such changes to affected personnel. • Safety Policies—Safety policies and related training establish and reinforce that nuclear safety is an overriding priority.
Question No. 67	
Question/ Comment	“U.S. NRC has developed a public website for the risk-informed and performance plan.” Could U.S. indicate if this site is frequently consulted and give some feedback on this action?
Answer	The staff updates the information on this Web site as new information is made available and frequently uses the information in developing related briefing packages, plans, and so forth. At a minimum, the Web site is updated about every 6 months because that is the frequency with which the staff provides the Commissioners with an update on the status of risk-informed activities. The NRC does not maintain a count of Web site “hits” or the frequency with which the staff or members of the public visit the Web site.
Question No. 68	
Question/ Comment	“Industry has developed 8 separate initiatives to improve existing technical specifications.” How does the U.S. NRC make sure that these initiatives have a positive effect on safety?
Answer	Each of the initiatives, as it was developed, was submitted to the NRC by several industry organizations in the form of topical reports, industry methodology documents, and/or specific proposed changes to the STS. The NRC technical staff provided extensive review and comment, often resulting in requests for additional information and follow-on submittals by the industry. In some cases, the industry made changes to the original proposed initiative. The final product was approved by the NRC by the issuance of a safety evaluation, which documents how the proposed initiative impacts plant safety and, in some cases, identifies plant-specific analyses or other requirements needed to support safe implementation. Implementation of any of these risk-informed technical specification initiatives at

	an NPP requires a plant-specific license amendment, which also provides an opportunity for the NRC to ensure that plant safety is not adversely impacted and to ensure that the initiative is being implemented on a plant-specific basis consistent with the NRC staff's safety evaluation. After issuance of a plant-specific amendment, the inspection and reactor oversight processes are used by regional NRC staff to ensure that the licensee is properly applying the initiative.
Question No. 69	
Question/ Comment	Article 10.4.1.2 describes the components of safety culture that are followed in the enhanced reactor oversight process. For German NPPs it was identified that the organization of the licensee and in particular the lines of responsibility including the relation between the NPP and its headquarter are of high safety relevance. Does the reactor oversight process reflect these responsibilities?
Answer	No. The ROP is used to evaluate each plant's performance individually. If there are indications that problems exist at more than one plant within the same corporate utility company, the Commission may request that each licensee within that utility company do an evaluation to determine if there is a common cause contributing to the problems.
Question No. 70	
Question/ Comment	It is a good practice that the regulatory body assesses its own safety culture.
Answer	The agency believes in the importance of focusing on the same underlying tenets that have been communicated externally by continuously improving its own safety culture to ensure that management and employees are dedicated to putting safety first. As discussed in the report, the NRC's OIG conducts an independent Safety Culture and Climate Survey every 3 years, the last one in May 2009. The NRC takes a combination of agencywide and office-specific actions to address the areas for improvement identified by the staff's analysis of the results of the survey. In addition to this periodic agencywide survey, the NRC undertakes many other improvement efforts throughout the agency on an ongoing basis, such as self-assessments, program reviews, and process evaluations. In order to ensure effective coordination, the staff supporting both internal and external safety culture activities work together closely and share information, experiences, and resources.
Question No. 71	
Question/ Comment	It is said that there are no regulatory requirements for licensees to perform safety culture assessments routinely. How do you evaluate the voluntary self-evaluation and the result performed by licensees? Will you require licensees to perform safety culture assessments under the regulation for the future?
Answer	The NRC does not have a requirement that licensees perform routine safety culture assessments. The agency has developed a Safety Culture Policy Statement that outlines the Commission's expectations that licensees foster a strong safety culture. The industry relies on INPO to advocate and develop tools for fostering this expectation. NRC inspectors have the option to review self- and independent assessments as needed per specific IPs. For example, IP 71152, "Problem Identification and Resolution," states the following:

	If the licensee conducted any periodic self-initiated assessments of safety culture during the review period, this assessment shall be included along with other non-safety culture self-assessments selected to review. If the licensee performed several assessments that collectively addressed safety culture issues, then those assessments combined should be considered as one assessment…. Inspectors should review the adequacy of the licensee's evaluation and actions to address the issues identified by the safety culture assessment. In addition, depending on the safety significance of plant performance issues or plant events or when there are longstanding and substantive cross-cutting issues at a plant, the NRC may request the performance of licensee safety culture assessments.
Question No. 72	
Question/ Comment	With reference to section 10.4.1 NRC Monitoring of Licensee Safety Culture, in the last paragraph on page 89 it is mentioned that the ongoing inspector training now includes safety culture topics. Could you please provide more information on the specific training provided to inspectors in the area of safety culture?
Answer	The NRC inspector qualification and requalification training manuals provide online training for inspectors in the area of safety culture and a safety-conscious work environment. Additionally, the root cause and incident response course required for inspector qualification uses the ROP safety culture components to allow the trainees to conduct mock root cause evaluations. As the NRC Safety Culture Policy Statement is implemented, the staff will assess current inspector training and suggest improvements if needed.
Question No. 73	
Question/ Comment	One of the 13 components important to safety culture addressed by the Enhanced Reactor Oversight Process, mentioned on page 88, refers to organizational change management. Could you please provide more information on the regulatory requirements imposed on the licensees and / or guidance available to licensees on the management of organizational change?
Answer	There are no regulatory requirements associated with the safety culture components. The Safety Culture Policy Statement will outline the Commission's expectations that licensees foster a healthy safety culture, but the NRC does not currently have regulations in this area. The NRC also does not have guidance on organizational change management other than the following definition in IMC 0310: Organizational change management -Management uses a systematic process for planning, coordinating, and evaluating the safety impacts of decisions related to major changes in organizational structures and functions, leadership, policies, programs, procedures, and resources. Management effectively communicates such changes to affected personnel.
Question No. 74	
Question/ Comment	The Report provides information on how probabilistic safety analysis results are used in the decision-making relevant to operation and regulation of nuclear plant

	safety. What are the main requirements to PSA being used as a substantiation of a risk-informed decision?
Answer	The general guidance related to the use of PRAs and PSAs in risk-informed decisionmaking in the context of licensing actions (e.g., relief requests or license amendments) is provided in RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." The guidance related to the technical adequacy of the PRAs and PSAs used in risk-informed decisionmaking is provided in RG 1.200. There is also application-specific guidance, such as RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications," RG 1.178, "An Approach for Plant-Specific, Risk-Informed Decisionmaking: Inservice Inspection of Piping," and RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," for a risk-informed categorization process for special treatment requirements. These application-specific guides provide additional guidance for the use of PRAs and PSAs for these applications. In addition, some risk-informed regulations (e.g., 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors"; 10 CFR 50.71(h)(1) and (h)(2); and 10 CFR 52.47) contain specific requirements for the PRAs and PSAs that are specific to those regulations.
Question No. 75	
Question/ Comment	The Report informs that licensees perform periodic self-assessments of safety culture. What safety culture indicators specifically are used in NPP self-assessments?
Answer	Typically, licensees will use INPO's "Principles for a Strong Nuclear Safety Culture," issued November 2004, for their self-assessments.
Question No. 76	
Question/ Comment	How many licensees have decided to implement the structure, system, and component (SSC) categorization based on this rule? Could you shortly describe the process of implementing the rule? Does it require detailed review and/or approval of the PRA model?
Answer	At this time no licensee has implemented the SSC categorization process based on 10 CFR 50.69. As a demonstration of the concept from which lessons were learned and incorporated into this rule, the South Texas Project did apply for and was granted an exemption to a number of the special treatment requirements. Currently, the licensee for the Vogtle Electric Generating Plant has recently requested to be a pilot application of this rulemaking. In 10 CFR 50.69(b)(2), the NRC identifies the information that a licensee must submit as part of a license application requesting to implement the rule, including a description of the quality of the plant-specific PRA and the results of the PRA review process. The technical adequacy of the plant-specific PRA is one of the major areas of the staff review for this application. As identified in 10 CFR 50.69(c)(1), the PRA must be of sufficient quality and level of detail to support the categorization process and must be subjected to a peer review process assessed against a standard endorsed by the NRC. The current PRA quality standard is ASME/ANS RA-Sa-2009, "Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications," issued February 2009, which is endorsed by RG 1.200. The companion NRC staff review guidance is Section 19.1 of the Standard Review Plan (NUREG-0800).
Question No. 77	

Question/ Comment	Could you describe an example of the use of ROP in the assessment of the safety culture of the licensee?
Answer	Woven into the structured framework of the ROP is the concept of the cross-cutting areas, which are certain aspects of licensee performance that could potentially impact more than one cornerstone of safety and multiple facets of plant operation. In the ROP, the cross-cutting areas are described in terms of nine components of safety culture, which are considered during both baseline and supplemental inspections. The cross-cutting components for the human performance area are decisionmaking, resources, work control, and work practices. The components for the problem identification and resolution area are the corrective action program, operating experience, and self/independent assessments. The components of the safety conscious work environment area are the environment for raising safety concerns and preventing, detecting, and mitigating perceptions of retaliation. The safety culture components are further broken down into various aspects, which are specific behaviors or characteristics that are examples of the component. Issues reflective of cross-cutting areas generally manifest themselves as the root causes of performance problems. When an NRC inspector identifies a finding, the NRC inspector will consider the causal information that is available. If the most significant contributor to an inspection finding is equivalent to one of the aspect descriptions, the NRC will assign that aspect to the inspection finding and document the aspect in the inspection report. The guidance for doing this is contained in IMC 0310 and IMC 0612, "Power Reactor Inspection Reports." The ROP was developed with the presumption that plants that had significant performance issues with cross-cutting areas would be revealed through the existence of safety-significant performance indicators or inspection findings. Accordingly, in identifying a substantive cross-cutting issue, there must be an NRC concern that the licensee has had multiple performance deficiencies that had commonality in the central cross-cutting aspects. The cross-cutting components and aspects are described in IMC 0310. Central cross-cutting aspects are assigned and substantive cross-cutting issues are issued on a per site basis; not on a per-unit basis. The NRC evaluates whether a substantive cross-cutting issue exists at each operating reactor twice a year; during the midcycle and end-of-cycle assessment meetings in accordance with IMC 0305, "Operating Reactor Assessment Program." If the NRC determines that a substantive cross-cutting issue exists at a given plant, the resultant midcycle and end-of-cycle assessment letters summarize the specific substantive cross-cutting issue to include the necessary actions to resolve the issue. The next midcycle or annual assessment letter will either state that the issue has been satisfactorily resolved or summarize the agency's assessment and the licensee's progress in addressing the issue.
Question No. 78	
Question/ Comment	How does (with which tools) inspector identify whether an aspect of safety culture component is a significant contributor to a finding?
Answer	The inspector applies the causal factors that were identified by the licensee in its root cause analysis to determine which (if any) aspect most closely applies.
Question No. 79	
Question/ Comment	From the last review meeting one of the NRC challenges was: "maintaining a positive and adequate safety culture". In your risk-informed oversight, would it be

	possible to quantify/measure safety culture, and if so; what would be an "adequate" level?
Answer	No, it is not possible to quantify safety culture or to define "adequate" levels because of the subjective nature of safety culture concepts.
Question No. 80	
Question/ Comment	It is stated that NRC has begun to evaluate the regulatory changes that may be necessary to ensure that its licensees can identify and mitigate neutron-absorber degradation before it challenges sub criticality safety. To what degree has the licensee such a responsibility already today, e.g. before any regulatory changes?
Answer	The licensees are responsible for operating their facility in accordance with their licensing basis, including maintaining subcriticality in the spent fuel pool. Licensees who have received NRC approval to credit neutron absorbers in the spent fuel pool to maintain subcriticality are required to ensure that degradation of these materials does not challenge assumptions in the criticality analysis. The NRC has initiated research to better understand whether current tools employed by licensees to monitor degradation are capable of accurately measuring existing degradation and predicting future degradation. Once this research is complete, the NRC will assess whether any regulatory changes, such as updates to NRC guidance documents, is warranted.
Question No. 81	
Question/ Comment	What kind of methodology/tools is used for evaluating safety culture? Is the 2009 addendum to "Principles for a Strong Nuclear Safety Culture" open for non INPO members?
Answer	<u>NRC Response</u>: Licensees may choose a number of ways to evaluate safety culture. The most common tool is the use of a survey instrument designed to gather data about how employees are feeling about the culture at the worksite. Coupled with a survey tool, licensees may use focus groups or individual interviews, which allow a researcher to gain a more in-depth look at organizational and cultural issues at a site. An evaluation team may also participate in behavioral observations to more fully assess how individuals conduct their day-to-day work activities. The information is available only to INPO and WANO members. <u>INPO Response</u>: Because safety culture is such a broad construct, in the United States there are three primary ways in which safety culture is assessed: (1) INPO evaluations/WANO peer reviews, (2) the nuclear safety culture assessment (NSCA), and (3) surveys. The assessment of safety culture during INPO evaluation/WANO peer review is described in Part 3.6 of "Principles for a Strong Nuclear Safety Culture": > Safety culture is thoroughly examined during each plant evaluation. Each evaluation team is expected to evaluate safety culture throughout the process, including during the pre-evaluation analysis of plant data and observations made at the plant. The results of this review are included in the summary on organizational effectiveness and may be documented as an area for improvement, as appropriate. The evaluation team discusses aspects of a plant's safety culture with the chief executive officer of

	the utility at each evaluation exit briefing. The NSCA is a special, week-long assessment conducted by a team of approximately 12 individuals. The team is typically composed of both plant and nonplant personal but may be all nonplant personnel, depending on the circumstance. The assessment mostly consists of interviews of individuals in most functions and at all levels, asking them questions related to “Principles for a Strong Nuclear Safety Culture.” Some work and meeting observations are conducted. Following the evaluation, a written report is delivered to the station management. The NSCA methodology is very similar to the IAEA Safety Culture Assessment Review Team methodology. Safety culture surveys are administered before both INPO evaluations and NSCAs. They are also administered by stations independently of both INPO evaluations and NSCAs. A value of surveys is that one can more quickly and easily obtain a reading on an entire station than by using interviews. However, surveys cannot provide the depth of information that is available through conducting interviews and observations. It is because of these strengths and weaknesses that both surveys and interviews are used during INPO evaluations and NSCAs.
Question No. 82	
Question/ Comment	The report says: “Similarly, given the NRC’s safety and security mission, the NRC recognizes the importance of maintaining its own strong safety culture (...). Actions include the following: The appointment of an agency Safety Culture Program Manager”. Can you describe the functional specification of the Safety Culture Program Manager?
Answer	The Safety Culture Program Manger serves as the staff lead for the agency’s internal safety culture activities. The Safety Culture Program Manager leads and coordinates efforts to develop, implement, and maintain polices and a framework for supporting a strong internal safety culture. The Safety Culture Program Manager conducts activities to monitor and continuously strengthen the agency’s internal safety culture, including serving in an advisory role for related initiatives, performing assessment and evaluation activities, implementing continuous improvement projects, developing training and learning products and opportunities, and supporting and advising managers and staff throughout the agency.

ARTICLE 11. FINANCIAL AND HUMAN RESOURCES

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

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

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

Question No. 83	
Question/ Comment	How is it determined that reactor operators must pay into a "retrospective premium pool" in maximum annual installments not to exceed \$15 million, up to a total of \$111.9 million each after an accident? How are the above figures adjusted for inflation?
Answer	The Price-Anderson Act of 1957, which became Section 170 of the Atomic Energy Act of 1954, as amended, establishes the financial and legal frameworks to compensate those who suffer bodily injury or property damage as a result of accidents at nuclear facilities covered by the law. The NRC regulations implementing the provisions of Section 170 for NRC licensees are codified in 10 CFR Part 140. The U.S. Congress amended the Price-Anderson Act in 2005 to require each licensee of a commercial reactor (one with a rated capacity of 100,000 electrical kilowatts or more) to pay into a retrospective premium pool, in maximum annual installments not to exceed \$17.5 million, up to a total of \$111.9 million each. The retrospective premium pool replaces the U.S. Government as the second provider of funds if the first layer of financial protection (liability insurance, now \$375 million per reactor) is exhausted. These insurance levels are subject to adjustments due to inflation at 5-year intervals. The last adjustment was made in August 2009.
Question No. 84	
Question/ Comment	What are the financial arrangements which U.S. NRC insists on to provide for decommissioning in case the plant is prematurely shutdown for decommissioning?
Answer	Decommissioning funding assurance for NPPs is governed by 10 CFR 50.33(k); 10 CFR 50.75, "Reporting and Recordkeeping for Decommissioning Planning"; and 10 CFR 50.82, "Termination of License," in a three-stage process. First, licensees and applicants are required to submit a report, including a certification, specifying how reasonable assurance will be provided that funds will be available to decommission the facility. Second, licensees are required to adjust annually the amount of decommissioning funding assurance, using an amount equal to or greater than that required under the formula in 10 CFR 50.75(c)(2), and report on the status of their decommissioning funds as provided by 10 CFR 50.75(f). Periodic adjustments to the funding amount should be made in coordination with a licensee's State-level rate regulator, if applicable, or by itself. Third, in

	accordance with 10 CFR 50.75(f), 5 years before permanent cessation of operations, a licensee must submit a preliminary decommissioning cost estimate that includes a plan to ensure that funds will be available when needed to cover the cost of decommissioning. By the time of submission of the postshutdown decommissioning activities report required in 10 CFR 50.82, licensees should have either (1) funds plus an estimate of expected earnings on the fund, or (2) a guarantee, insurance, or other funding assurance method for the total estimated decommissioning cost, as provided in 10 CFR 50.75(e). Final funding plans, and adjustments to them during any safe storage period, are also required as necessary. For those licensees that shut down their power plants prematurely (that is, before the scheduled end of their operating license term), 10 CFR 50.82 provides that the schedule for collecting any balance of funds estimated to be needed for decommissioning will be determined on a case-by-case basis.
Question No. 85	
Question/ Comment	Can U.S. describe the impact of economic deregulation of nuclear power Plants on safety in U.S.?
Answer	The NRC has not observed any negative impact on NPP safety as a result of the deregulation of the U.S. energy market in the early 1990s. Nuclear licensees must maintain plant safety regardless of the energy market regulatory scheme. The current NRC ROP continues to ensure the safety of U.S. NPPs.
Question No. 86	
Question/ Comment	What is the process for the nuclear plant decommissioning fund establishment and accumulation?
Answer	Please see the response to Question No. 84.
Question No. 87	
Question/ Comment	The report says that “Although there does not appear to be a consistent relationship between a licensee’s finances and operational safety, some evidence suggests that financial pressures have limited the resources devoted to corrective actions, plant improvements, and other safety-related expenditures.” Noting that the U.S. has taken measures to set rules (see page 103) for minimum staffing in control rooms, fire brigades and emergency response personnel, are there any plans to adopt rules that might require licensees to justify significant changes in the numbers of operations and management staff in other areas and departments at the nuclear power plants?
Answer	As suggested in Question No. 87 and assuming certain possibilities, it can be postulated that a licensee of a commercial NPP, under certain circumstances of financial difficulties, may resort to “limited resources devoted to corrective actions, plant improvements, and other safety-related expenditures.” However, this type of cause and effect is not completely correct. Assuming this type of cause and effect does not recognize the intermediate actions of management. Although intuitively it would seem that limited financial recourses would lead directly to fewer corrective actions, plant improvements, and other safety-related expenditures, this is not necessarily the case. The management of a commercial NPP is constantly reprioritizing actions at the plant to reflect business circumstances, financial resources, and safety regulations. Therefore, it is not an inevitable conclusion that limited financial recourses would lead directly to fewer corrective actions, plant improvements, and other safety-related expenditures, just as it is not an inevitable conclusion that having

	surplus financial resources will directly lead to additional corrective actions, plant improvements, and other safety-related expenditures. (Financial resources can be diverted from elective actions, or profits; and financial resources can be increased through higher revenue.) The NRC has not seen a strong enough correlation to conclude, for either financial difficulties or financial surpluses, that there is an immediate need for concern. However, when and if warranted, it is the policy of the NRC to review the financial qualifications of each licensee of a commercial NPP on a case-by-case basis. Financial qualifications reviews can be initiated by license amendments, petitions, or staff initiatives. Currently there are no plans to require licensees to make staffing justifications in any areas that are not covered under current regulations.
Question No. 88	
Question/ Comment	The report states: "Licensees that elect to prepare their own examinations are required to establish procedures to control examination security and integrity…The NRC reviews the facility-prepared examinations…administers all operating tests." How do you review the licensees' obedience of this procedure, especially in terms of security?
Answer	The NRC discusses examination security with facility licensees before the start of examination development. This is required in accordance with NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," issued July 2004, Section ES-201, paragraph C.2.c; Attachment 1 to ES-201 provides detailed guidance. Throughout the examination process, facility licensees are required to adhere to proper examination security practices per NUREG-1021 and the licensee's own procedures, and the NRC observes adherence to proper examination security during examination development and administration. Any lapse in examination security self-identified by a facility licensee is required to be reported to the NRC. Regardless of whether the NRC or the licensee discovers a lapse in examination security, the NRC will thoroughly review any such incident for appropriate actions, which typically consist of replacing examination material before the examination if examination material has potentially been compromised. In severe cases, regulatory action can be taken against a licensee for violations of 10 CFR 55.49, "Integrity of Examinations and Tests."
Question No. 89	
Question/ Comment	In response to a question on supply of suitable candidates (nuclear engineers, health physicists) in 2008, U.S. informed about the Labor Market Trends for nuclear engineers through 2010 by Oak Ridge Institute for Science and Education and the Labor Market Outlook for Health Physicists updated to 2010. Both confirmed that the available U.S. civilian labor supply of new nuclear engineering graduates and health physicists is substantially less than the number of job openings (Question No. 87). Has any significant changes emerged since these forecasts were made?
Answer	More recent studies prepared by the Oak Ridge Institute for Science and Education indicate that the current slow and uneven economic recovery and resulting uncertainty as to when stronger economic growth will begin increases the difficulties already inherent in estimating the outlook for the nuclear engineering labor market for 2010 through 2014. Most economic outlooks for 2010 and beyond are factoring in only a small probability of a double-dip

	recession. As a result, the demand for nuclear engineers has decreased, but the NRC anticipates some growth in new job positions. Yet replacement positions may be reduced if workers choose to remain on the job rather than retire. The outlook, at least after 2010, is for a continuation of somewhat more job openings than there are new nuclear engineering graduates becoming available in the U.S. civilian labor force. On the supply side, when compared to 2010 levels, the number of new nuclear engineering graduates is likely to increase by approximately 30 percent by 2014.

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 (HFE) issues, (2) emergency operating procedures and plant procedures, (3) working hours and staffing, (4) fitness for duty, (5) the Human Factors Information System, (6) support to event investigations and for-cause inspections, and (7) training.

Question No. 90	
Question/ Comment	What's the relationship between the Human Event Repository and Analysis system developed by NRC and the human factors engineering (HFE) Operation Experience Review referred in NUREG 0711?
Answer	Sources for the data in the Human Event Repository and Analysis (HERA) system include empirical and experimental data. Empirical data sources include operations and event reports, and experimental data include human performance studies such as those conducted in control room simulators. The main purpose of conducting an operating experience review (OER) is to identify HFE-related safety issues. The OER should provide information on the past performance of predecessor designs. The objective of this review is to verify that the applicant has identified and analyzed HFE-related problems and issues in previous designs that are similar to the current design under review. In this way, negative features associated with predecessor designs may be avoided in the current design while retaining positive features. There is no direct relationship between HERA and the OER in NUREG-0711, "Human Factors Engineering Program Review Model," issued February 2004. There may be a system under review as a part of an OER that has an event that was noted in an event report and therefore could be included as data in HERA.
Question No. 91	
Question/ Comment	Please explain the regulatory measures of Human Event Repository and Analysis system. For example, what's the scope of the system user? How to analyze the data? How to track and feed back the results of analysis?
Answer	There are no regulatory measures or specific regulatory requirements associated with the HERA system. The HERA system, as described in NUREG/CR-6903, "Human Event Repository and Analysis (HERA) System, Overview," issued July 2006, was to provide comprehensive, detailed analyzed information about past events with rich human performance information for human performance analysts. The information is for improving the understanding of the behavior of NPP operators in responding to plant malfunctions and of the contributing factors to human performance. The human failures and successes of each event were identified. For each key human failure, the failure types and contributing factors were identified. Factors analysis has been performed to identify the correlations among the performance contributing factors and between the performance contributing factors and human failures. Current work on human performance data collection has focused more

	on data generated from routine simulator training and examinations. The prospective users are the analysts and method developers of human reliability analysis. The HERA events and analysis information as described in NUREG/CR-6903 were stored in a database accessible from the worldwide Web. A login name and password are required from the NRC to access the site.
Question No. 92	
Question/ Comment	Since NRC should be prepared to review safety issues for human-system interfaces resulting from Digital I&C, please introduce more research details or results on the research of the ergonomics issues in digital I&C systems;such as the effects of Digital I&C on human cognitive ability, human error/reliability and system safety, task complexity measures? What's the key review point on human-system interfaces for NRC?
Answer	Digital control systems provide the capability to implement more advanced control algorithms than those that have been used in U.S. NPPs to date. Current plants rely primarily on single-input, single-output, classical control schemes to automate individual control loops. There has been limited research on the effect of I&C subsystem degradation on human-system interfaces (HSIs) and human performance, especially with professional operators. Brookhaven National Laboratory prepared the technical report, "The Effects of Degraded Digital Instrumentation and Control Systems on Human-System Interfaces and Operator Performance: HFE Review Guidance and Technical Basis," Technical Report BNL-91047-2010 dated February 2010 (http://www.ntis.gov/search/product.aspx?ABBR=DE20111013463) for the NRC (the report can be accessed through Brookhaven National Laboratory's public Web site). Researchers reviewed both empirical research and operating experience and analyzed selected failure modes of the digital feedwater system of a PWR. I&C degradations were prevalent in plants employing digital systems, and the overall effects on plant behavior can be significant, such as causing a reactor trip or causing equipment to operate unexpectedly. Examples of operator performance affected by degradations of I&C subsystems include the following: • poor situation awareness due to deterioration of the sensor and monitoring subsystems • poor situation awareness and response planning on the loss of automatic systems • unstable control and errors in performance due to delays in the communication subsystem • effects on teamwork and shifts in the concept of operations due to loss of computer-based HSIs The above technical report states that plant designs may not consider the effect of I&C degradation on the operation of the plant and the performance of personnel to the extent that they probably should. Important degradations may not be alarmed, and operators may have insufficient information at their HSIs, in procedures, and in training to deal with them.

	The NRC is currently developing guidance to address this issue. The NRC reviews how nuclear plant operators perform primary tasks, including monitoring plant parameters, following procedures, responding to alarms, starting pumps, and aligning valves. In a computer-based control room, personnel must successfully perform secondary tasks or "interface management tasks" so that they can complete their primary tasks. Under these conditions, those secondary tasks include navigating or accessing information at workstations and arranging various pieces of information on the screen. In part, these tasks are necessary because operators view only a small amount of information at any one time through the workstation displays. Therefore, they must undertake interface management to retrieve and arrange the information. These tasks and interfaces are key review points for the NRC.
Question No. 93	
Question/ Comment	Since there are already some multi-module reactor projects (one integrated MCR) in progress now, please provide NRC's consideration about the HFE design and safety or regulation development.
Answer	Currently no multimodule DC applications have been submitted to the NRC for review. When the NRC does receive an application, it will use the current guidance in NUREG-0800, -0700, and -0711 to evaluate that application's HFE design. Because current regulations (10 CFR 50.54(m)) have deterministic staffing numbers that are not relevant to the new multimodule designs, the NRC will evaluate a proposed staffing exemption request based on guidance found 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. NUREG-1791 is a public document and can be found in the NRC's online library.
Question No. 94	
Question/ Comment	The challenge of new technological development is mentioned. Could the U.S. clarify if the problem of a failure of a digital control room is considered, and in this case what are the proposed solutions?
Answer	The I&C system is the primary means by which personnel monitor and control the plant; its degradation will have a significant impact on the operator's ability to monitor plant conditions, detect disturbances, assess the plant status, and take actions in response to unfolding conditions. Digital control systems provide the capability to implement more advanced control algorithms than those that have been used in U.S. NPPs to date. Current plants rely primarily on single-input, single-output, classical control schemes to automate individual control loops. New and advanced reactors will use integrated digital I&C systems to support operators in their monitoring and control functions. Even though digital systems are typically highly reliable, their potential for degradation or failure could significantly affect operator situation awareness and performance and, consequently, impact plant safety. The NRC initiated a research project to investigate the effects of degraded I&C systems on human performance and plant operations. Researchers developed a framework for linking digital I&C systems to human performance as the initial phase of creating evaluation guidance, as well as an I&C characterization. In addition to reviewing the details of individual systems

	being proposed for advanced reactors, researchers reviewed efforts to characterize modern digital I&C systems. Once a suitable I&C system characterization was developed, the NRC sought to identify failure modes. The failure modes represent the set of degradation conditions whose effects on human performance the agency wishes to determine. How the licensee addresses these issues is a key review point for the NRC, and the NRC is currently developing guidance to address this issue.
Question No. 95	
Question/ Comment	The U.S. develop the Human Performance Program including data collection. Could the U.S. indicate if data collected include data issued from simulator results (especially with the objective of human reliability assessment)?
Answer	Yes, the data collection includes simulator results.
Question No. 96	
Question/ Comment	The NRC reviews licensees' requests that involve aspects of human factors engineering. Examples include crediting operator manual actions in amendments to plant technical specifications, transferring facility operating licenses, and increasing the reactors authorized power level (i.e., power uprates). What is the minimum time considered for operator to take action in case of any transient or emergency conditions?
Answer	The minimum time considered for an operator action in case of a transient or emergency condition would depend on several factors. The time available and the time required to complete an action are the primary considerations for whether crediting an operator action is acceptable; there is no set time under which any action could not be taken. Inputs to the times associated with the actions must take into account how the operator will receive information that the action needs to be performed, what the communication requirements are for these data, and how the operator will receive information to confirm that the actions they are performing are addressing the issue. Other important considerations include the type of action to be taken, task frequency, tolerance and accuracy required, temporal constraints (task ordering), physical position (e.g., stand, sit, squat), biomechanics, movements (e.g., lift, push, turn, pull, crank), and the forces needed to complete the action. The licensees must validate and verify that the tasks can be completed under the conditions that may exist, including time restrictions.
Question No. 97	
Question/ Comment	According to the descriptions of paragraph 12.3.1, the staff published digital instrumentation and control (DI&C)-interim staff guidance (ISG)-05 to make some of the current human factors guidance clearer relevant to the digital operation environment. As stated in DI&C-ISG-05, the time response of safety-related operator actions might be different between in operation environment of the hardware-based human-system interfaces (HSIs) (i.e. in the traditional main control room(MCR)) and in computer-based HSIs (i.e. in the advanced MCR). In the application of American National Standards Institute (ANSI)/ANS-58.8 published in 1994 to determine the time response for the safety-related operator actions, it might be inappropriate to the digital operational environment. Please explain the details of your regulatory position or direction for this issue when you perform safety review for new plants.
Answer	Currently, there is no change in the NRC's regulatory position on the time

	response to safety-related operator actions concerning the application of American National Standards Institute (ANSI)/ANS-58.8, "Time Response Design Criteria for Safety-Related Operator Actions." The objective of the safety review is to verify that the applicant's HSI inventory and characterization accurately describe all HSI displays, controls, and related equipment that are within the defined scope of the HFE program. The review should verify that the applicant developed an inventory of all HSI components associated with the personnel tasks based on the identified operational conditions. The inventory should include aspects of the HSI that are used for interface management, such as navigation and display retrieval, in addition to those that control the plant. A minimal set of information for the characterization includes the associated personnel functions/subfunction and the type of HSI component (computer-based control and/or computer-based display). Given the available HSI inventory, NRC guidance recommends that an analysis be performed to ensure that the time available to perform the required manual actions is greater than the time required for the operator(s) to perform the actions, and that the operator(s) can perform the actions correctly and reliably in the time available. The time available to perform the actions should be based on analysis of the plant response to the anticipated operational occurrence and postulated accident using realistic assumptions, and on the acceptance criteria of Branch Technical Position 7-19, "Guidance for Evaluation of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems," of NUREG-0800. Guidance for performing this analysis and criteria for acceptance has been developed within Interim Staff Guidance DI&C-ISG-05, "Highly Integrated Control Rooms – Human Factors," Revision 1, November 3, 2008.
Question No. 98	
Question/ Comment	According the description of paragraph 12.3.1, the Oconee Units 1 and 2 proposed changes to manual operator actions as a result of digital upgrade of a RPS and the engineered safety features actuation system and the NRC reviewed the amendment of the licensees' request. Related to the safety-related operator manual actions, please briefly explain the main contents of the safety review on HFE aspects for the licensees' request.
Answer	The content of the safety evaluation concerning human factors includes the assessment of the licensee replacing the RPS and Engineered Safeguards Protection System (ESPS). A new failure mechanism was introduced, the software common-mode failure (SWCMF). Should SWCMF occur with the new digital system, the following are possible: • An automatic reactor trip will not occur when a reactor trip setpoint is reached (RPS failure). • Automatic actuations associated with ESPS will not occur when the actuation setpoint(s) are reached (ESPS failure). • RPS and ESPS failures will occur simultaneously. To account for the potential for SWCMF, the licensee examined in their analysis the capability to withstand a hypothetical SWCMF for a spectrum of initiating

	events. The licensee assumed that the SWCMF results in simultaneous RPS and ESPS failures. For each of these initiating events, a total failure of RPS to automatically actuate is assumed, as is a total failure of ESPS to automatically actuate. The capability to manually actuate both RPS and ESPS remains functional. Primary or backup protection is provided for most events and is either an automatic safety-related system or automatic control system. The licensee in part still relied on operator actions. The NRC review included an in depth evaluation of the credited operator actions. The NRC staff found crediting the new operator actions to be acceptable, based on the following: • The operator actions are contained in existing plant procedures. • The operator actions (and verifying their success) are prompted by control room indications and alarms that are diverse from the digital RPS and ESPS. • The operator actions are simple tasks and can be performed independently of the digital RPS and ESPS. • The operator actions have been time-validated on a sampling of operating crews using a properly modeled control room simulator. • The operator action times are well within allowed times to meet acceptance criteria. • The licensee has appropriate plans in place to update plant procedures, operator training, and the control room simulator to reflect the new digital RPS and ESPS. Based on these considerations, the review concluded that the health and safety of the public will not be endangered by the additional manual actions associated with the digital upgrade.
Question No. 99	
Question/ Comment	According the description of paragraph 12.3.6, NRC staff members with human factors expertise participate in an inspection procedure (IP) 95003 inspection at Palo Verde to assess human performance and the inspectors found some deficiencies related to procedure adherence. Please explain the details of these findings and Palo Verde's post actions to resolve these issues.
Answer	The procedure adherence findings were identified by the inspectors on the IP 95003, “Supplemental Inspection for Repetitive Degraded Cornerstones, Multiple Degraded Cornerstones, Multiple Yellow Inputs or One Red Input,” team other than the human factors personnel. The details of the procedure adherence findings are described in the inspection report, available from the NRC public Web site via this hyperlink: http://pbadupws.nrc.gov/docs/ML0803/ML080320562.pdf. In response to the issues identified by the inspection team, the site developed a site integrated improvement plan (SIIP). The SIIP contained key improvement actions that corporate management committed to take to address the causes of

	the decline in performance at the site, including actions to address the issues that led to Palo Verde Nuclear Generating Station being placed in the multiple/repetitive degraded cornerstone column (Column IV) of the NRC action matrix and to address the issues identified during independent assessments of the site's safety culture.
Question No. 100	
Question/ Comment	Please provide specific examples of Main Control Room improvements that have been implemented as a result of NRC evaluations performed.
Answer	Changes to main control rooms occur over time with updates to the plant technology and emerging technologies and are not typically associated with specific NRC evaluations.
Question No. 101	
Question/ Comment	What measures have been/are taken by the licensees to address Human Factors? (Are there any specific industry network/group/ association addressing these issues?)
Answer	<u>NRC Response</u>: Professional associations often form tasks groups to address and dialogue with the NRC to address various aspects of human factors with regard to safety. The Nuclear Energy Institute, for example, has task groups on digital I&C, safety culture, and fatigue management. INPO also has issued significant operating event reports to communicate lessons learned and best practices throughout the nuclear power industry. These reports cover various operational issues, including human factors. <u>INPO Response</u>: The U.S. industry does not have a human factors organization. However, in the 1990s, the industry did control room design studies that looked at human factors issues. These resulted in control room design modifications. The University of West Florida has performed human factors studies, working with the Electric Power Research Institute. A recent procedures symposium addressed human factors issues related to procedure format, development, and implementation.
Question No. 102	
Question/ Comment	Are there any regulations that require the licensees to regularly analyse from human factor perspective: events and faults identified at the plants; organization and management; safety culture; procedures; etc.?
Answer	There are no regulations; however, evaluations are regularly performed and use the guidance in NUREG-0711 to verify that accepted HFE practices and guidelines are incorporated into the applicant's HFE program. The review methodology provides a basis for performing reviews that address the twelve elements of an HFE program: HFE program management, OER; functional requirements analysis and function allocation, task analysis, staffing, human reliability analysis, HSI design, procedure development, training program development, human factors verification and validation, design implementation, and human performance monitoring.
Question No. 103	
Question/ Comment	On March 31, 2008, the NRC published a rule that included new regulation in 10 CFR Part 26 Subpart I, "Managing Fatigue". The NRC required licensees to implement the requirements by October 1, 2009 with an 18-month period to hire and train new staffs.

	What were the main concerns and the basis of this new rule-making? Has fatigue been established as root-cause for incidents and lacking performance? Was there a trend of non-compliance with work hour control requirements?
Answer	The NRC's ''Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors'' which was first published on February 18, 1982, requested licensees to revise the administrative section of their technical specifications to ensure that plant administrative procedures were consistent with the work-hour guidelines. In 1999, members of Congress expressed concern that low staffing levels and excessive overtime may present a serious safety hazard at some commercial NPPs. Also in 1999, the NRC received a petition for rulemaking to establish clear and enforceable work-hour limits to mitigate the effects of fatigue for NPP personnel performing safety-related work. During the development of the fatigue management requirements, the NRC observed an increase in concerns (e.g., allegations, media and public stakeholder reports) related to the workload and fatigue of security personnel following the terrorist attacks of September 11, 2001. The NRC determined that an integrated approach is necessary to effectively manage worker fatigue because individuals experience fatigue for many reasons, including long work hours, inadequate rest, and stressful or strenuous working conditions. Shift-work, home-life demands, and sleep disorders can all contribute to inadequate sleep and excessive fatigue. Reviews of industry control of work hours identified practices that were inconsistent with the NRC's policy on worker fatigue, including excessive use of extended work weeks and the overuse of work-hour limit deviations. In addition to excessive work hours and work-hour guidelines deviations, the NRC has recently identified other concerns related to licensee policies and practices applicable to worker fatigue. On May 10, 2002, the NRC issued RIS 2002-007, ''Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-for-Duty.'' The NRC issued the RIS following several allegations made to the NRC about the appropriateness of licensee actions or policies related to individuals declaring that they are not fit due to fatigue. These concerns indicate a need to ensure that individuals and licensees clearly understand their responsibilities with respect to self-declarations of worker fatigue.

ARTICLE 13. QUALITY ASSURANCE

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

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

Question No. 104	
Question/ Comment	Please give more information on how to use the ISO QA standards in NRC
Answer	The NRC does not require licensees to adopt the International Organization for Standardization (ISO) quality management standard. Licensees are required to meet Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50. The NRC addressed ISO 9001, "Quality Management Systems—Requirements," in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards," dated July 9, 2003. The NRC also endorses the guidance in ASME standard NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," through RG 1.28, "Quality Assurance Program Criteria (Design and Construction)."
Question No. 105	
Question/ Comment	It is stated that the NRC "continues to assess how various national and international quality standards comport with NRC regulations in an ongoing effort to seek convergence of standards." Does NRC also plan to require the licensees to implement a management system according to the IAEA Safety Requirement GS-R-3?
Answer	See the response to Question No. 111.
Question No. 106	
Question/ Comment	It is said that Appendix B to 10 CFR Part 50 requires licensees who 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. How do you evaluate audits performed by licensees including joint audits? How do you utilize the result of the audits in the regulatory process?
Answer	The NRC periodically observes audits performed by the Nuclear Procurement Issues Committee (NUPIC). NUPIC is an organization that includes all domestic U.S. nuclear utilities and several international members. The audit responsibilities are shared and the reports are provided to all members. Staff guidance on how to conduct the observations is provided in IP 43005, "NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements." As discussed in the IP, the findings would be documented and discussed at NUPIC meetings. IP 43005 can be found on the NRC's public Web site at

	http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/index.html. Should there be a significant problem with an observed vendor during a NUPIC audit, the NRC staff may take action by issuing a generic communication to the industry. In addition, the NRC may determine that an NRC inspection of the vendor is necessary to follow up on the NUPIC audit findings. NUPIC also has a process to notify affected utilities of a significant problem that was identified during an audit.
Question No. 107	
Question/ Comment	The report states: "10 CFR Part 50 requires licensees who procure material, equipment, or services from contractors or subcontractors to perform audits." How do you audit the licensees' implementation of this requirement?
Answer	See the response to Question No. 106.
Question No. 108	
Question/ Comment	It is stated that the NRC staff performs inspections at vendors who supply basic components to the nuclear industry. Please describe in detail which vendors (or which items) are inspected by the NRC.
Answer	The NRC has a list of vendors that supply basic (safety-related) components to the U.S. nuclear industry. A safety-related component is any SSC or service that would affect its safety function necessary to ensure any of the following: • the integrity of the reactor coolant pressure boundary • the capability to shut down the reactor and maintain it in a safe shutdown condition • the capability to prevent or mitigate the consequences of accidents Inspections of vendors performed since 2005 are available on the NRC public Web site at http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html
Question No. 109	
Question/ Comment	Are external audits required by NRC regulations? Do the licensees use outside experts in their internal auditing teams? Are any particular standards (ISO-standards or similar) used voluntarily by the industry in their quality work?
Answer	Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50 requires audits to be performed in order to provide objective evidence of quality furnished by a vendor. Licensees sometimes seek outside experts to conduct internal audits. This action may be taken to enhance the independence of the audit or to incorporate enhanced experience. Some vendors have voluntarily used ISO standards in conjunction with their required Appendix B to 10 CFR Part 50 quality assurance programs to ensure compliance with both NRC requirements and other international standards that may be required to allow the use of a component in other countries.

Question No. 110	
Question/ Comment	What are the main differences between the quality assurance controls specified by the NRC for equipment classified as nonsafety-related and yet still important to safety, and the requirements in 10 CFR Part 50, Appendix B?
Answer	Essentially, the difference between equipment that is important to safety and equipment that is safety-related is the degree to which the requirements of Appendix B to 10 CFR Part 50 are applied. Equipment that has been categorized as important to safety includes SSCs that mitigate station blackout, anticipated transient without scram, fire protection, environmentally qualified equipment, and pressurized thermal shock. Safety-related refers to any SSC or service that would affect the integrity of the reactor coolant system, the ability to shut down and maintain the reactor in a safe shutdown condition, or the ability to mitigate the consequences of an accident. The NRC requires that licensees address augmented quality control for equipment that is important to safety in their quality assurance programs. NUREG-0800, Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants," establishes the criteria that the NRC uses to evaluate whether a licensee meets the NRC's regulations for safety-related and important-to-safety equipment. In addition, regulatory guidance for augmented quality can be found in other documents, such as Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," to RG 1.155, "Station Blackout." See paragraph V of Section 17.5 of NUREG-0800, located on the NRC public Web site at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ch17/. .
Question No. 111	
Question/ Comment	The report says: "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 10 CFR Part 50, Appendix B. 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". Which are these supplemental quality requirements? Are the IAEA Safety Requirements stated in GS-R-3 also considered?
Answer	The NRC addressed ISO 9001 in SECY-03-0117. Licensees are required to meet the criteria in Appendix B to 10 CFR Part 50. In SECY-03-0117, the NRC provided a matrix of the significant differences between ISO 9001 and Appendix B to 10 CFR Part 50. The matrix was an attachment to the SECY. The ADAMS Accession No. for the matrix attachment is ML031490463. The ADAMS Accession No. for SECY-03-0117 is ML031490421. A few key supplemental requirements in Appendix B to 10 CFR Part 50 that are not required by ISO 9001 include (1) Criterion X, "Inspections," on inspections performed by individuals other than those who performed an activity being inspected, (2) Criterion III, "Design Control," on measures for independently

	verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculations, or by a suitable testing program, and (3) Criterion VII, on suppliers required to pass requirements consistent with Appendix B to 10 CFR Part 50 to subsuppliers. The IAEA's GS-R-3 was not part of the review in 2003 because it had not been issued at the time. However, the NRC does not specify requirements for or provide guidance on a management system to the level of GS-R-3 for licensees to follow.

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 the period of extended operation. It focuses on assessments performed to maintain the licensing basis of a nuclear installation. Finally, this section explains verification of the physical state and operation of the nuclear installation by analysis, surveillance, testing, and inspection.

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. 112	
Question/ Comment	Please elaborate on the measures in place to foster continuous improvement of licensee programs and safety performance (e.g., by adapting to modern standards), given the 40 year licence period.
Answer	The key measures that are in place to foster continuous improvements include, but are not limited to, the following: (1) Operating Experience—The effective use of operating experience from domestic and international plants is crucial to enhancing safety and plant operations. The NRC has established and commits to a robust ongoing Operating Experience Program that collects, evaluates, communicates, and applies operating experience to prevent significant events and inform NRC decisionmaking. (2) Reactor Oversight Process—The ROP is the NRC's program to inspect, measure, and assess the safety performance of commercial NPPs and to respond to any decline in performance. The objective of the ROP is to monitor a plant's performance in three key areas: (1) reactor safety, (2) radiation safety, and (3) safeguards. (3) Generic Upgrades—The NRC evaluates industrywide safety-significant issues that may require technical resolution. The agency issues generic communications (e.g., generic letters, information notices) to alert licensees to issues and upgrade requirements, as necessary. (4) Regulatory Changes—As new technical information develops, the NRC

	reviews the potential safety concerns and may conclude that existing programs or regulations may merit revision to ensure an acceptable level of safety. (5) Incorporation of Risk Information into Regulatory Activities—The NRC has embraced the concept of risk since the agency's inception. Examples range from (1) the Rasmussen Report (WASH-1400 or NUREG-75/014, "Reactor Safety Study: An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants") in October 1975, (2) the individual plant examination and individual plant examination of external events in the 1980s and early 1990s, (3) the use of risk insights in an alternate fire protection program to allow licensees to voluntarily adopt and use the fire protection requirements of National Fire Protection Association Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," and (4) the use of risk insights in the revised Pressurized Thermal Shock Rule (10 CFR 50.61, "Fracture Toughness Requirements for Protection against Pressurized Thermal Shock Events") to ensure continued protection against pressurized thermal shock events.
Question No. 113	
Question/ Comment	In the backfitting process and in the PSA Rule a particular objective is to reduce unnecessary burden for the licensees. This point is sometimes considered as a possible reduced safety level. Could the U.S. give some examples of the application of these "unnecessary burdens", proving that there is no safety reduction?
Answer	The NRC infers from the question that the reference to the PSA is actually referring to the PRA Policy Statement (there is no PRA/PSA Rule that applies to currently operating plants). The question clearly reflects a concern that using PSA, PRA, and the Backfit Rule (10 CFR 50.109) has the potential to reduce safety, especially if one of the NRC's aims is to "eliminate unnecessary burdens on licensees," as the Fifth National Report says (page 118, also pages 17 and 165). The question essentially is this: "Can you show that, using these approaches, you do not reduce safety when you reduce unnecessary burdens?" Yes, the NRC can show that it does not reduce safety when it reduces unnecessary burdens, although of course a detailed showing would require discussion of a range of particular agency actions. At a higher level, it should be clear from the Fifth National Report that the agency's aim is to prioritize the use of resources—the NRC's and licensees'—to maintain and improve safety, not reduce it. In fact, page 165 of the Fifth National Report says just that. The reason behind this policy is simple: too much time and money spent on small matters reduces the time and money available for more important matters. PSA, PRA, and the Backfit Rule, because they help ensure that the agency is not focused on the wrong things, help the agency allocate resources in ways that will not reduce safety—and in ways that will impose burdens that are necessary to maintain or increase safety. The Backfit Rule in particular, by its very nature, has nothing to do with reducing safety or reducing unnecessary burdens. Its aim is to ensure that *increased* requirements can be justified under a cost-benefit analysis. (It is worth pointing out that the agency's practice under the rule parallels governmentwide practices overseen by the U.S. Office of Management and

	Budget.) The following are some examples of how the NRC uses its risk-informed approaches. For the risk-informed inservice inspection program, the licensee uses risk insights in selecting the proper welds to inspect, as opposed to the current inservice inspection program that does not use risk insights in determining the amount and locations of inspections. Through the risk-informed program, the licensee will typically identify fewer welds to inspect (burden reduction), while focusing those inspections on the more risk-significant/potential locations (improving overall safety as a result of the program). For the risk-informed special treatment program (under 10 CFR 50.69), the licensee uses risk insights to identify those safety-related SSCs that are not significant to safety (based on the plant-specific PRA), and, as a result, the licensee can reduce the special treatment requirements for these SSCs (burden reduction). At the same time, the licensee uses risk insights to identify nonsafety-related SSCs that are significant to safety or safety-related SSCs that are significant to safety for beyond-design-basis conditions and, as a result, must establish processes and programs to maintain and control the performance and reliability of these SSCs (improved safety). Through this risk-informed program, the licensee will typically identify a large number of SSCs that can have their special treatment requirements reduced (burden reduction), while focusing the need for treatment on those SSCs and functions that are identified as significant contributors to safety (improving overall safety as a result of the program).
Question No. 114	
Question/ Comment	U.S. explain that there are no formal periodic safety reviews, but a continuous safety assessment, using (among others) Risk informed decisions. This approach needs the existence of a quality PSA updated as appropriate to support decision making. Could U.S. explain how and when are the PSAs updated? (for comment in case of Periodic Safety Reassessment, a PSA updating is a requirement).
Answer	For currently operating plants (i.e., those plants licensed under 10 CFR Part 50), there is no overarching regulation that requires a PRA and PSA; therefore, there is no general regulation that specifies the periodicity for updating PRAs for use in risk-informed decisionmaking for currently operating plants. However, there are some risk-informed regulations, such as 10 CFR 50.69, that do contain specific requirements for the periodicity of PRA updates for licensees that implement them. Additionally, new reactors licensed under 10 CFR Part 52 have explicit PRA update periodicity requirements (10 CFR 50.71(h)(1) and (2)). RG 1.200, which endorses the ASME/ANS PRA standards, provides guidance on what an acceptable program to maintain and upgrade the PRA should include. An acceptable process for maintaining and upgrading the PRA is expected to include the following characteristics and attributes, as listed in the RG: (1) monitor PRA inputs and collect new information, (2) ensure that the cumulative impact of pending plant changes is considered, (3) maintain configuration control of the computer codes used in the PRA, (4) identify when the PRA needs to be updated based on new information or new models, techniques, or tools, and (5) ensure that peer review is performed on PRA upgrades.

	The PRA model used to support risk-informed decisionmaking (e.g., using RG 1.174) is expected to reasonably reflect the as-built, as-operated plant. Therefore, the model must be reasonably up to date when the licensee submits the PRA results to be used to support a certain risk-informed decision as part of a risk-informed licensing action. This is a specific area of the staff review of risk-informed licensing actions, which is discussed in both the risk-informed application staff review guidance (SRP Section 19.2, which is the companion staff guidance to RG 1.174), and the PRA technical adequacy staff review guidance (SRP Section 19.1, which is the companion staff guidance to RG 1.200).
Question No. 115	
Question/ Comment	U.S. indicate, in the framework of license renewal, that aging phenomena are readily manageable. Could U.S. give some precision about the treatment of important changes due to new technology for replacing obsolete equipment or more general context evolution (introduction of digital I&C, climatic changes….)?
Answer	As delineated in 10 CFR 54.4, "Scope," the focus of the license renewal review is to ensure that the intended function of those long-lived passive SSCs (e.g., the reactor vessel, the reactor coolant system pressure boundary, steam generators, the pressurizer, piping, pump casings, valve bodies) will be maintained during the extended period of operation. For active components (e.g., motors, diesel generators, cooling fans, batteries, relays, switches), normal surveillance and maintenance programs will continue throughout the period of extended operation and will ensure timely repair and/or replacement. Replacement of obsolete equipment by new technology (e.g., introduction of digital I&C) is controlled by the normal license amendment process. The potential safety implications of such replacements to the operating fleet are reviewed by the agency under the 10 CFR Part 50 process, not under 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants." The topic of climate changes is discussed qualitatively in terms of greenhouse gas emissions in the supplemental environmental impact statement as a part of the license renewal review.
Question No. 116	
Question/ Comment	Is there any specified periodicity for updating PSAs/PRAs for use in risk-informed decision making process?
Answer	For currently operating plants (i.e., those plants licensed under 10 CFR Part 50), there is no overarching regulation that requires a PRA or PSA; therefore, there is no general regulation that specifies the periodicity for updating PRAs for use in risk-informed decisionmaking for currently operating plants. However, there are some risk-informed regulations, such as 10 CFR 50.69, that do contain specific requirements about PRA update periodicity for licensees that implement them, and new reactors licensed under 10 CFR Part 52 have explicit PRA update periodicity requirements (10 CFR 50.71(h)(1) and (2)). RG 1.200, which endorses the ASME/ANS PRA standards, provides guidance on what an acceptable program to maintain and upgrade the PRA should include. An acceptable process for maintaining and upgrading the PRA is expected to include the following characteristics and attributes, as listed in the RG: (1) monitor PRA

	inputs and collect new information, (2) ensure that the cumulative impact of pending plant changes is considered, (3) maintain configuration control of the computer codes used in the PRA, (4) identify when the PRA needs to be updated based on new information or new models, techniques, or tools, and (5) ensure that peer review is performed on PRA upgrades. The PRA model used to support risk-informed decisionmaking (e.g., using RG 1.174) is expected to reasonably reflect the as-built, as-operated plant. Therefore, the model must be reasonably up to date when the licensee submits the PRA results to be used to support a certain risk-informed decision as part of a risk-informed licensing action. This is a specific area of the staff review of risk-informed licensing actions, which is discussed in both the risk-informed application staff review guidance (SRP Section 19.2, which is the companion staff guidance to RG 1.174), and the PRA technical adequacy staff review guidance (SRP Section 19.1, which is the companion staff guidance to RG 1.200).
Question No. 117	
Question/ Comment	BWRs having Mark III type containments and PWRs with ice condenser containments must have the capability for controlling combustible gas generated from metal water reaction involving 75% of the fuel cladding surrounding the active fuel region so that there is no loss of containment structural integrity. Whereas for new licenses the capability should exist for 100%. Can you please clarify the difference?
Answer	In 1985, following the accident at TMI, the requirements for controlling combustible gas in noninerted containments changed from 5-percent fuel clad coolant interaction to 75 percent in 10 CFR 50.44, "Combustible Gas Control for Nuclear Power Plants." This requirement was a backfit and still applies to operating plants. The NRC required future applicants to analyze the combustible gas released from the equivalent of 100-percent fuel clad coolant interaction. These requirements reflect the Commission's expectation that future designs will achieve a higher standard of severe accident performance.
Question No. 118	
Question/ Comment	It is said that the NRC license renewal process are considered equally adequate and acceptable. On the other hand, according to the IAEA press release of IRRS implemented last October, the IRRS review team made suggestion that the NRC should incorporate lessons learned by the practice of other nations using licensee-conducted periodic safety reviews. How do you implement to this suggestion for the future?
Answer	From the self-assessment performed in preparation for the IRRS, the NRC identified that it could more systematically review findings from other regulators' assessments of periodic safety reviews to continue to verify that international experience is fully evaluated for potential applicability to U.S. licensees. The IRRS mission team agreed with the proposed action and made a suggestion to that effect. The NRC is reviewing all of the IRRS mission recommendations and suggestions, including this one, and will develop actions for them where appropriate. Currently, the NRC is still determining what actions it will take to address the recommendations and suggestions.

Question No. 119	
Question/ Comment	Is a licensee allowed to start with the implementation of the modification, for which the NRC approval or even a license amendment is required, before the NRC authorizes the change? If not, did NRC have any experience with the violation of this rule? If yes, how does NRC deal with the violations?
Answer	Licensees are not allowed to fully implement a modification that requires NRC approval before the approval is given. They may be allowed to perform certain preparatory activities, such as assembling parts or raising scaffolding, but they may not affect any areas that would require prior NRC approval. Licensees are expected to screen any potential changes against the criteria in 10 CFR 50.59, "Changes, Tests and Experiments," to determine if prior NRC approval is required. If the licensee determines that prior NRC approval is not necessary, then it needs to report that the change was screened against 10 CFR 50.59 in a periodic report. The resident inspections examine the evaluations under 10 CFR 50.59 to determine if the licensee has correctly determined whether or not prior NRC approval was needed. If the licensee had determined that prior NRC approval was not needed and implemented the modification, and the resident inspection determines that prior NRC approval should have been obtained, then this is considered a potential violation of 10 CFR 50.59. The NRC does have experience with violations of 10 CFR 50.59. Potential violations of 10 CFR 50.59 are handled under the traditional enforcement process (see Section 9.3 of the U.S. CNS National Report) rather than the SDP because they are considered to be potential violations that could impact or impede the regulatory processes. The underlying technical issue of the change itself is evaluated under the SDP.
Question No. 120	
Question/ Comment	How many of issues described in section 14.1.3.3 are still unresolved? Are they still considered significant?
Answer	All of the 22 systematic evaluation program (SEP) issues have been addressed and resolved under Generic Issue (GI)-156, "Systematic Evaluation Program." NUREG-0933, "Resolution of Generic Safety Issues," issued August 2010, provides a description of the historical background, prioritization process, and final disposition for each one of these issues. As discussed in NUREG-0933, 18 issues under GI-156 were dropped from further consideration, 3 issues were addressed in the resolution of other GIs, and 1 issue was resolved with no new requirement. None of the 22 SEP issues are considered significant any longer.
Question No. 121	
Question/ Comment	The U.S. is to be commended on the extensive and detailed arrangements for gathering and tracking safety performance indicators described in various parts of the report and, in particular, under Article 6 on pages 46 – 49. Section 14.1.3.1 of the report (page 117) states that "The NRC carries out many regulatory activities that, when considered together, constitute a process providing ongoing assurance that the licensing bases of nuclear power plants provide an acceptable level of safety." Does the U.S. agree that the introduction of a program of regular periodic

	safety reviews would further strengthen the many excellent practices already in force to maximize the safety of licensed sites?
Answer	The NRC appreciates the safety that other nuclear regulators received from conducting periodic safety reviews at the facilities they regulate and regards the process of standing back and performing a holistic, in-depth evaluation of each plant at a regular interval to be beneficial. As stated in the Fifth National Report to the CNS, the NRC continuously evaluates operating experience, considers upgrades, and performs assessments annually. In an effort to further strengthen the safety practices in the United States, the IAEA IRRS mission made the following suggestion in its report on the U.S. reactor program in October 2010: "NRC should incorporate lessons learned from Periodic Safety Reviews performed in other countries as an input to the NRC's assessment processes." The NRC, as part of its preparation for the IRRS mission, identified this suggestion as part of its self-assessment. As stated in the NRC's "Strategic Plan: Fiscal Years 2008–2013" (NUREG-1614, Volume 4, issued February 2008), the agency's safety goal is to ensure adequate protection of public health and safety and the environment. The plan also states that the NRC "works closely with international counterparts to enhance nuclear safety." Additionally, the NRC analyzes domestic and international operating experience and other events of national interest for lessons learned and best practices. The NRC also participates in the development and evaluation of international standards to ensure that they are soundly based and to determine whether substantial safety improvement can be identified and incorporated domestically.
Question No. 122	
Question/ Comment	Would the U.S. agree that a requirement for the licensee, as a part of a regular periodic safety review, to identify and to implement any reasonably practicable changes to the plant to improve its safety, would be wholly consistent with the principle in Article 9 of the CNS that the prime responsibility for the safety of a nuclear installation rests with the licensee? Would this not be more consistent with the intent of Article 9 than the current NRC backfitting process that seems to place the onus on NRC to identify "staff-proposed backfits" to improve the safety of the plant?
Answer	A requirement that the licensee, as part of a regular periodic—or continuing—safety review, identify and implement reasonably practicable changes to improve safety would be consistent with Article 9 of the CNS. But it is to be doubted whether such a requirement would be "more consistent" with Article 9 than the NRC's approach would be. First, under the Backfit Rule, the onus is not on the NRC to identify backfits. Licensees, nongovernmental organizations, and the NRC have all been sources of suggestions for improving safety. Second, the requirement the question suggests may, in fact, have the same practical impact that the NRC's approach has because, in order to implement such a requirement (i.e., in order to be able to say what reasonably practicable changes the licensee has overlooked), the regulator must be able to independently assess what such changes exist; in other words, the regulator must be able to self-identify such changes. In addition, it is doubtful that Article 9 is to be read as urging that *every* reasonably practicable change be carried out. The emphasis in Article 9, and in its more explicit reflection in Requirements 5 and 6 of GS-R-1 and the

	commentary there, is on *compliance*, namely, compliance across a wide range of facilities, activities, and persons—not on self-imposed backfitting—as demonstration of the licensee's prime responsibility.
Question No. 123	
Question/ Comment	It is said that license renewal requirements are based on two key principles. According to the first principle there are possible exceptions to "the regulatory process being adequate to ensure that the licensing basis … provides an acceptable level of safety": "Detrimental effects of aging on certain SSCs, and possibly on a few other issues applying to safety only during the period of extended operation". What are the effects and issues? And how does the NRC deal with these effects and issues during the license renewal process in order to ensure a safe operation of the respective nuclear power plant during extended lifetime?
Answer	The detrimental effects of aging include, but are not limited to, embrittlement, loss of material due to different corrosion and erosion mechanisms, hardening and loss of strength, and loss of heat transfer function due to accumulation of debris and other undesirable materials. These material degradation mechanisms may adversely prevent safety-related and certain nonsafety-related SSCs from fulfilling their safety functions. Thus, they are the primary consideration in granting a license extension. The NRC deals with these effects and issues during the license renewal process by conducting a safety review of the applicant's license renewal application and supporting documents. This review includes onsite audits and inspections of the licensee's documents. The purpose of the NRC review is to determine if the applicant meets the NRC's technical and regulatory requirements. Specifically, the application must identify those SSCs that are within the scope of license renewal and subject to an aging management review and must also identify applicable aging mechanisms and describe programs in place to manage aging.
Question No. 124	
Question/ Comment	Is there any justification of the scope and frequency of inspections of reactor materials and structures condition with both ageing process rates and inspection representativeness taken into account?
Answer	Yes, both the frequency and scope of inspections may depend on the potential degradation mechanism for which the inspections are being conducted. Consistent with the requirements of the ASME Code, inspections of U.S. NPP components are typically conducted based on a 10-year interval between inspections. However, in some cases, inspection frequencies of less than every 10 years may be required based on the degradation mechanism being inspected for. For example, inspection of nickel-alloy welds in PWRs for evidence of PWSCC has been linked to the operating temperature to which the welds are exposed. Higher operating temperatures are believed to promote the initiation and growth of PWSCC and, as a result, a licensee may be required to inspect certain nickel-alloy welds (e.g., those of the reactor vessel upper head, pressurizer, and/or the reactor coolant system hot leg) more frequently than every 10 years. In terms of inspection scope, licensee inspection programs may involve the

	inspection of 100 percent or less than 100 percent (i.e., a sampling-based inspection program) of like components depending on the requirements (based on the degradation mechanism being inspected for, the safety significance of the components, and so forth) imposed by the ASME Code or NRC regulations.
Question No. 125	
Question/ Comment	It is said that "As part of the re-examining of the issue of NPSH after a loss of coolant accident, NRC will also be evaluated whether this issue raises a policy question regarding the use of PRA in deterministic regulatory decision-making and defence-in-depth." What is the reason for the questioning?
Answer	The PRA question is a difference in the recommended approach of the NRC's Advisory Committee on Reactor Safeguards (ACRS) and the staff's interpretation of the direction from the NRC Commission. Licensee submittals, such as EPU applications, are not risk informed. The existing Commission policy is for the staff to use the guidance in SRP Section 19.2, Appendix D. According to this guidance, the staff may only ask for risk analyses for nonrisk-informed applications if "special circumstances" (defined in the SRP) are met. ACRS recommends that plant-specific PRAs be done for each application of containment accident pressure. The ACRS position is that special circumstances are met when containment accident pressure is used to determine net positive suction head (NPSH) margin. However, the staff does not believe that the use of containment accident pressure to determine NPSH margin results in special circumstances and, therefore, cannot request plant-specific PRAs.

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. Article 17 of this report discusses radiological assessments that apply to licensing and facility changes.

Question No. 126	
Question/ Comment	How to establish the management targets based on the regulations for individual dose and radioactive discharge control in the U.S. NPPs?
Answer	For control of occupational exposures, U.S. licensees set lower, "administrative" dose limits for their workers. These administrative dose limits are not required by regulation. However, a condition to each NPP license requires that procedures necessary to ensure compliance with NRC regulation be established and implemented. Therefore, if a licensee establishes administrative limits in plant radiation protection procedures, it is required to follow them. The dose limit for members of the public is specified in 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," and is 1 millisievert (mSv) (100 millirem (mrem)) annually. This is a safety limit. To provide additional assurance that the safety limit will not be challenged, the as low as is reasonably achievable (ALARA) design objectives of 10 CFR Part 50 have been established. Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation To Meet the Criterion "As Low as Is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50 lists several design objectives. One example of these design objectives is that the total body dose to members of the public in an unrestricted area will not exceed 0.03 mSv (3 mrem) annually. These are system operational design and control limits, and they are set to a small fraction of the safety limit. In addition to the numerical design objectives, the NRC regulations include the principle of ALARA to ensure that doses are maintained as low as is reasonably achievable.
Question No. 127	
Question/ Comment	How about the maximum radiation individual exposure of radiation workers in the recent years? Please give more information on how to use the International Commission on Radiological Protection (ICRP) newly standards in U.S. NPPs.
Answer	In addition to the declining trend in collective dose at operating NPPs, individual (both average and maximum) exposures have also declined. The latest occupational doses data compiled in NUREG-0713, Volume 31, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2009: Forty-Second Annual Report," issued May 2011, indicates that 2009 was the first year on record in which no individual received more than 20 mSv (2 rem) working at a U.S. commercial LWR. The NRC is currently evaluating what changes to the U.S. regulations are warranted in response to the recently revised

	International Commission on Radiological Protection (ICRP) recommendations in ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection." Included in this evaluation is how the NRC should address the recommended 20-mSv average annual occupational dose limit.
Question No. 128	
Question/ Comment	From the national report, we know the average doses for both PWRs and BWRs have been steadily declining in the recent years. What's the key measure adopted to reduce exposure?
Answer	Average collective doses have actually been declining since the early 1980s for both PWRs and BWRs. From 1980 through 2000, dramatic reductions were achieved by reactor licensees through optimized work (outage) planning, and radiation source term reduction (including efforts to remove cobalt bearing components from the plants, improved decontamination techniques, improved reactor fuel integrity, and improved reactor water chemistry controls), as well as through the use of automated and robotic devices for high-dose routine surveillance and maintenance activities. In recent years, the industry has maintained this declining trend partly due to improved plant component reliability, but also through the continued vigilance of the radiation protection and ALARA staff to identify and implement dose reduction techniques (such as zinc and noble metal injection reactor water chemistry), coupled with a strong utility management commitment to maintaining doses ALARA. Although NRC oversight has contributed to this declining trend, much of the industry's success can be attributed to its dedication of resources to research, such as through the Electric Power Research Institute, and the individual licensees' commitment to operational excellence, as promoted by INPO.
Question No. 129	
Question/ Comment	Please provide further details of the justification of new reactor as a high-level assessment of whether the benefits of building new nuclear plants outweigh the detriments (the justification of a practice). Which part of the new reactor licensing could be identified as justification and who could be regarded as the supreme justification authority?
Answer	In the context of Article 15, which deals with radiation protection, the assessment of the benefits of a new use of radioactive material (for example, use in a new NPP) must demonstrate that the use would result in some "public good"; otherwise, it could not be justified and, consequently, would not be authorized. The U.S. national policy on use of radioactive material is stated in the Atomic Energy Act of 1954, as amended: "the development, use, and control of atomic energy shall be directed so as to make the maximum contribution to the general welfare, subject at all times to the paramount objective of making the maximum contribution to the common defense and security." From a radiological health, safety, and security perspective, NRC decisions balance radiation exposure (a "cost" to individuals and to society as a whole, no matter how negligible) and public welfare (a "benefit" to the quality-of-life experience from, for example, the availability of energy) while ensuring security, which is not subject to balancing. Apart from certain authorities granted to the States by other statutes (such as low-level waste management) or authority delegated to the States by the NRC (as part of the Agreement States program), prospective users of radioactive material must seek approval from the NRC. The approval is in the form of a grant of

	permission (i.e., a permit, a license, or an authorization), and the ultimate balancing of societal risk and benefits is the responsibility of the NRC. In addition to the radiological balancing described in Article 15 under the authority of the Atomic Energy Act of 1954, as amended, the U.S. national policy for considering environmental values is stated in the National Environmental Policy Act of 1969, as amended: "encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation." This is addressed in Article 17 as part of the regulatory actions related to siting new facilities. The NRC's grant of permission for use must be informed by an assessment of the environmental effects of the regulatory action, the alternatives to the action (such as alternative energy sources, alternative sites, and alternative systems designs), and the weighing and balancing of costs (potential degradation of the human environment, such as land disturbing activities) and benefits (including an assessment of the "need for power" in the particular region in a particular timeframe). In addition to an approval from the NRC, other agencies (such as the U.S. Army Corps of Engineers or the U.S. Environmental Protection Agency) may have to determine whether or not they should grant permission to affect or use environmental resources; these authorities exist under other environmental statutes (such as the Rivers and Harbors Act, the Clean Water Act, and the Clean Air Act). In the end, although only the NRC can grant permission for the use of radioactive material for a new NPP, that is not the only permission that is needed to make a new NPP a reality.
Question No. 130	
Question/ Comment	The report states that there is a staff initiating stakeholder dialogue and technical basis development to explore the benefits and effects of increasing alignment with ICRP 103. Could U.S. specify when the ICRP 103 will be implemented and what will be the main principles which will be adopted?
Answer	The NRC staff is currently engaged in an ongoing dialogue with stakeholders on the options, implications, and impacts of possible changes to the NRC regulatory framework to increase alignment with international recommendations. The NRC staff is currently expected to provide recommendations to the Commission in late 2011 on key issues. When the Commission gives its direction, the staff will continue its work, as necessary. No decisions have been made on implementation of ICRP Publication 103 recommendations, and the United States cannot specify any schedule for a change to the regulations. The NRC's regulations are currently designed to ensure adequate protection of public health and safety, and this will continue to be the case. The NRC's licensing and inspection programs include requirements for licensees to reduce exposures ALARA and to limit exposures to occupationally exposed individuals and to members of the public.
Question No. 131	
Question/ Comment	Could U.S. give some more details about the technical measures which are or will be implemented in order to reduce the effective individual and collective dose (per type of reactor: PWR and BWR)? Could U.S. present a diagram which indicates the individual dose distribution for

	occupational workers? Could U.S. also give some elements about the intern effective dose for occupational workers?
Answer	See the answer to Question No. 128 above. Table 4.4 of NUREG-0713 provides the occupational dose distribution, by exposure ranges, for LWRs. Although, consistent with ICRP 26, "Recommendations of the ICRP," recommendations, the NRC total effective dose equivalent (TEDE) dose limit is based on the sum of the external and internal dose, very few individuals at commercial LWRs reactors actually receive measurable intakes of radionuclides. Licensees are required to use engineering controls (i.e., containment and/or ventilation) to reduce airborne concentrations of radioactive materials and to use respiratory protection, or other means as appropriate, to limit intakes of workers in areas where the airborne concentrations cannot be reduced to below what is considered to be an airborne radioactivity area.
Question No. 132	
Question/ Comment	Could U.S. give more details about the technical measures in order to reduce the gaseous and liquid release? Could U.S. also give values of the effective dose for the critical group assessed with the level of discharges released?
Answer	The most significant factor that contributed to these reductions in effluents has been the improvements in reactor fuel pin integrity performance. Particularly for BWRs, but to some extent for PWRs as well, radioactive gasses released from fuel pin defects directly contribute to plant gaseous effluents. In addition, improved integrity of plant components, such as steam generator tube leaks in PWRs and main condenser tube leaks in BWRs, has minimized the contamination of systems that ultimately contribute to plant effluents. The NRC does not use the "critical group" for assessing the impact of radioactive releases in plant effluents. Licensees are required to monitor all effluent releases and calculate the expected dose to the maximum exposed member of the public using standard models and methods. These effluent dose results are compared to the design criteria in Appendix I to 10 CFR Part 50 and reported to the NRC on an annual basis. The most recent effluent reports for each operating U.S. NPP can be found on the NRC Web site at http://www.nrc.gov/reactors/operating/ops-experience/tritium/plant-info.html
Question No. 133	
Question/ Comment	How is determined whether "the overall benefit to society [of an application] is outweighed by the risk of the radiation exposure associated with the activity?"
Answer	See the answer to Question No. 129.
Question No. 134	
Question/ Comment	Are dose limits defined for the occupational exposure of trainees, students and pregnant women?
Answer	NRC regulations at 10 CFR 20.1207, "Occupational Dose Limits for Minors," limit the annual occupational dose for minors (individual less than 18 years of age) to 10 percent of the annual dose limits specified for adult workers in 10 CFR 20.1201, "Occupational Dose Limits for Adults." There are no special

	occupational dose limits for trainees, or for students if they are 18 years of age or older. In 10 CFR 20.1208, “Does Equivalent to an Embryo/Fetus,” the NRC provides a limit of 5 mSv (0.5 rem) dose equivalent to the embryo/fetus during the entire pregnancy as a result of the occupational exposure of a declared pregnant woman. To the extent that this limit is met, the occupational dose limits in 10 CFR 20.1201 (to the lens of the eye, skin, extremities) still apply to the declared pregnant woman. <u>The limit applies when the woman has chosen to declare her pregnancy to the licensee</u>.
Question No. 135	
Question/ Comment	What is the organizational hierarchy of the Radiation Protection group at the NPPs? Is the Head of Radiation Protection group Licensed / authorized by NRC. Does this group have the mandate or authority to report directly to NRC?
Answer	<u>NRC Response</u> The radiation protection manager (RPM) at NPPs is not an NRC-licensed position. However, each NPP has a condition in its license (technical specification) specifying the RPM’s qualifications (the experience and training criteria are in RG 1.8, “Qualification and Training of Personnel for Nuclear Power Plants”). In addition, each operating plant has committed to implementing the guidance in RG 8.8, “Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable,” that specifies that the RPM should be independent of plant operations and maintenance organizations (e.g., report directly to the plant manager). Any individual at an NPP is authorized under the provisions of 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” and 10 CFR Part 21, “Reporting of Defects and Noncompliance,” to report safety issues directly to the NRC. <u>INPO Response</u> Most RPMs report to the plant manager. Some report to another senior manager, such as a director of safety. Even if they are in the line organization for operations, they may independently take concerns directly to the site vice president. Any plant personnel may contact the NRC directly to report a safety concern. The number of people and organizational structure of the radiation protection departments vary but are generally composed of a technical staff and field operations personnel, including supervisors and technicians. The number of people ranges from about 20 to 70 depending on the number of units and the distribution of responsibilities. Supplemental personnel are brought in to support outages. The RPM must meet the minimum requirements of the position. The requirements vary somewhat based on when the plant was licensed and its commitment to the NRC. The following are typical requirements: • a bachelor’s degree or equivalent in science or engineering • 5 years of professional experience in applied radiation protection with at least 3 of those years at a nuclear facility with radiological problems similar to those found in an NPP

	• some standards specify additional requirements for experience with refueling outages and at-power operation (greater than 20-percent power) • training as necessary to fill in any knowledge gaps • general employee training
Question No. 136	
Question/ Comment	It is stated that the U.S. regulations were founded on older (rather than the most recent) ICRP recommendations. How does the NRC adapt and adopt international standards in the area of radiation protection? How do you consider the ICRP recommendations in particular the new ICRP recommendation (ICRP publication 103)?
Answer	The United States and, in particular, the NRC are currently engaged in a public stakeholder process to explore the benefits and impacts of possible changes to increase alignment with international recommendations. No decisions have been made at this time regarding adoption or adjustment of particular standards or recommendations. The NRC uses a regulatory development process, consistent with the United State's Administrative Procedure Act, which includes development of a proposed rulemaking package supported by technical analysis, regulatory analysis, and environmental analysis; solicitation of public comment on the proposed regulatory action; and development of a final action based on public comment. The NRC has not yet made any decision on whether or not to enter into specific rulemaking actions for possible changes for radiation protection. Actions of other U.S. Federal agencies with responsibilities in the area of radiation protection are subject to similar administrative procedures. The NRC and other Federal agencies pursue close cooperation and information exchange through the Interagency Steering Committee on Radiation Standards. This committee also includes participation by representatives from State organizations that have specific responsibilities for some types of radiation sources in their jurisdictions. The international recommendations, including those of the ICRP, form one reference for possible changes. The United States also considers other points of reference, including the recommendations of the U.S. National Council on Radiation Protection and Measurements, provisions of other international standards and recommendations, and international and national consensus standards.
Question No. 137	
Question/ Comment	It is understood that you consider to apply ICRP103. When it is applied, does NRC have a plan to revise your design objective stipulated in 10CFR50 App.I? If yes, what is the direction?
Answer	See the answer to Question No. 136.
Question No. 138	
Question/	If the dose assessment system is improved in accordance with ICRP103, is the

Comment	assessment of each nuclide (i.e. Iodine, C-14) unnecessary under effective dose system? If yes, please provide information on whether the assessment of Iodine and C-14 be separated or performed in the effective dose assessment system.
Answer	As noted in the answer to Question No. 136, the changes to Appendix I to 10 CFR Part 50 necessary to adopt ICRP 103, “The 2007 Recommendations of the International Commission on Radiological Protection,” are still being evaluated by the staff. It is not clear if a separate constraint on the release of radioiodine and particulates, as provided in the current Appendix I to 10 CFR Part 50, would be warranted. Presumably, if carbon-14 is a principle contributor to public dose from plant effluents, it will have to be considered in demonstrating compliance with any effective dose-based constraint. This is no different from the current requirement to meet the design criteria based on ICRP 2, “Permissible dose for internal radiation,” in Appendix I to 10 CFR Part 50.
Question No. 139	
Question/ Comment	Annex 2 to the Report shows trends in the performance indicator “Collective Radiation Exposure” for units with BWR and PWR reactors. One can see from these diagrams that this indicator has a trend towards improvement over several recent years. By what means such an improvement has been achieved?
Answer	See the answer to Question No. 129.
Question No. 140	
Question/ Comment	Apart from the collective doses, Does the NRC assess the effectiveness of other aspects of the ALARA concept as control the spread of contamination, or individual doses below the limits that do not always affect the collective doses?
Answer	In 10 CFR Part 20, “Standards for Protection Against Radiation,” the NRC requires licensees to have a program (e.g., procedures and engineering controls) to maintain doses ALARA. The regulation in 10 CFR Part 20 does not require each individual dose to be as low as possible. The NRC ROP uses collective dose to assess the effectiveness of these programs. Specifically, the ROP compares the collective dose actually expended for individual work activities with the collective dose that the licensee determined was ALARA for each (during work planning). The control of doses received by individuals in the plant is evaluated to assess the implementation of required procedures to ensure that doses are within the dose limits. The ROP does not have a performance indicator associated with the spread of contamination. Radioactive contamination, surface or airborne, is considered if it contributed to unplanned or unintended dose to an individual.
Question No. 141	
Question/ Comment	In light water reactors, the source term (mainly 60Co) is influenced by optimised water chemistry and measures to minimize the build-up of radioactive nuclides in the primary circuits. Are the prevailing ambient dose rates officially used as indicators on the effectiveness of the ALARA work of the licensees?
Answer	Although prevailing ambient dose rates are part of the basis for determining if ALARA is effective, it is neither the exclusive nor the primary indicator of the adequacy of the ALARA program. For example, a licensee may experience an operational condition that is not associated with a deficiency (e.g., it is beyond the control of the licensee) that results in elevated dose rates. In this case, the fact that dose rates are elevated would not be the basis for determining the effectiveness of the ALARA program.

	However, it must be recognized that, when evaluating the programmatic elements of the licensee's shutdown chemistry control program, the dose rates on selected key components (e.g., the steam generator bowl) may be used. These selected key components are often referred to as BWR radiation and control (BRAC) points. Although initially associated with BWRs, the selection of these BRAC points has been standardized for the particular type of reactor (BWRs or PWRs) in the United States. In general, if the licensee experiences a typical, routine fuel cycle and executes an effective shutdown chemistry control program, the dose rates at the BRAC points would ideally decrease but, in any case, would not be expected to increase significantly.
Question No. 142	
Question/ Comment	The U.S. is to be commended for starting an "active dialogue with all segments of the licensed community in the U.S." on the possibility of "increasing alignment with ICRP." The text of this section of the report appears to be quietly optimistic that there may be a possibility of a change on the horizon. Could the U.S. indicate when rule changes might come into force that would align the U.S. more closely with the current ICRP recommendations that form the basis of national legislation in most other countries?
Answer	Please see the answer to Question No. 136.

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) emergency planning and emergency planning zones (EPZs), (2) offsite emergency planning and preparedness, (3) emergency classification system and action levels, (4) recommendations for protection in severe accidents, (5) inspection practices and regulatory oversight, (6) response to an emergency, and (7) international arrangements.

Question No. 143	
Question/ Comment	How does the NRC ensure the emergency exercise effectiveness of the NPPs? And what's the criterion of evaluation?
Answer	NRC regulations require NPP licensees to conduct an exercise of their onsite emergency plans every 2 years (biennially). Offsite plans for each site are also required to be biennial exercises, with full participation by each offsite authority having a role under the radiological response plan within the site's 10-mile plume exposure pathway EPZ. An NRC inspection team evaluates the licensee's ability to effectively (1) conduct a biennial exercise that tests the adequacy and content of implementing procedures and methods, test emergency equipment and communications networks, test the public notification system, and ensure that emergency response personnel are familiar with their duties, and (2) identify and correct weaknesses. Criteria for this evaluation are contained in NRC IP 71114.01, "Exercise Evaluation." Similarly, a U.S. Federal Emergency Management Agency (FEMA) inspection team evaluates the performance of the State and local government offsite response organizations (OROs) and would handle the resolution of any identified offsite deficiencies in accordance with its Radiological Emergency Preparedness Program Manual. Between biennial exercises, licensees are required to conduct drills that test principal functional areas of emergency response (such as management and coordination of emergency response, accident assessment, protective action decisionmaking, and plant system repair and corrective actions) to ensure that

	adequate emergency response capabilities are maintained. The NRC uses the ROP to ensure that the EP program maintains the skills of the licensee's emergency response organization (ERO). Licensees are required by regulation to critique the ERO's performance in all drills and exercises and to correct weaknesses. The ERO's performance in these drills and exercises in the key functions of emergency classifications, notifications, and protective action are tracked by the licensee and reported quarterly to the NRC. Degrading trends in EP are addressed by escalated regulatory oversight.
Question No. 144	
Question/ Comment	Concerning thyroid-blocking by stable iodine, what is the intervention level for applying this measure? Are the tablets usually pre-distributed to the households and if yes, up to which distance to the plant?
Answer	As a standard in the United States for thyroid blocking by stable iodine, the intervention level is 5 rem child thyroid-dose for administration of potassium iodide, where applicable. Potassium iodide tablets are maintained and distributed through State, county, or local arrangements. This many include the predistribution or stockpiling of tablets.
Question No. 145	
Question/ Comment	It is mentioned that one performance indicator is drill and exercise performance. One experience from Sweden is the added difficulty, by an increase in demands on communication, co-operation and co-ordination, in exercises where several actors are trained simultaneously. Are such exercises, where on- and off-site parties are exercised simultaneously, arranged in the U.S.? Is the experience (feed-back and results) of such exercises given higher weight (in evaluations and otherwise)?
Answer	The NRC requires the conduct of a full-participation exercise, including participation of State and local OROs, every 2 years. The NRC also requires its licensee, when requested, to provide for the participation of any State or local OROs in other scheduled drills. The NRC is cognizant that the involvement of State and local OROs can increase the demand on communications, cooperation, and coordination, but the NRC believes that requiring licensees and State and local OROs to participate in a full-participation exercise every 2 years provides a reasonable basis for ensuring continued performance without the potentially excessive demands on State and local resources from more frequent participation. The NRC also has a periodic audit requirement in which licensees are specifically directed to evaluate the adequacy of interfaces with State and local governments. The NRC does not give higher weight to such exercises but evaluates the overall effectiveness of the EP program.
Question No. 146	
Question/ Comment	What are the source term characteristics (noble gases, iodine, aerosols) released to the environment, duration of release, time of release after onset of accident) of the scenarios used for emergency planning? What is the probability of an accident source term leading to health consequences to the public larger than those associated with the scenarios used for emergency planning?
Answer	The requested source term characteristics are documented in NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants," issued November 1978, and are summarized in Section 1 of NUREG-0654,

	"Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (FEMA-REP-1)." Although a number of accident sequences, including core melt accidents analyzed in WASH-1400, were considered in the development of the planning basis, no single accident sequence or even a limited number of sequences were established. The task force developing the planning basis determined that no single accident sequence should be isolated because each accident could have different consequences in nature and degree. Instead, the emergency planning basis is independent of any specific accident sequence. The stated objective of emergency planning is to provide dose savings for a spectrum of accidents that could produce public doses in excess of established protective action guides (i.e., intervention levels). Since the planning basis is not predicated on a single accident sequence, there is similarly no single probability value. The NRC requires EP as a matter of prudence rather than in response to a quantitative analysis of accident probabilities. NUREG-0396 also recommended two EPZs in which detailed planning would be required: a plume exposure pathway EPZ of 10 miles (16 kilometers (km)) and an ingestion pathway EPZ of 50 miles (80 km) for which detailed response planning would be performed. The sizes of the two EPZs, which are described in NUREG-0396, were selected, in part, on the fact that protective action guides would not be exceeded outside of the EPZ for most core melt accidents, and on the belief that detailed planning within 10 miles would provide a substantial base for expanding response efforts in the event of the worst core melt sequences. This planning basis was used in the development of the NRC and FEMA regulations and supporting guidance, which were issued in 1980 shortly after the TMI accident. Following the terrorist events of September 11, 2001, the current EP planning basis was reviewed and found to be adequate, although many enhancements were required to better respond to terrorist events. That basis can be summarized as follows: • Serious nuclear accidents are very unlikely. • A significant release will not occur more quickly than in about 30 minutes. • The source term is not larger than that used to set the 10-mile EPZ. The NRC is currently studying this issue to determine if a spectrum of scenarios can be identified for EP regulatory purposes.
Question No. 147	
Question/ Comment	How are new plant designs with improved safety features impacting the selection of accident scenarios for emergency planning? Is a reduction of emergency planning zones considered for new plant designs?
Answer	The NRC staff has concluded that the emergency planning requirements remain the same for advanced large LWR designs (e.g., AP1000). Emergency planning requirements have not yet been prepared for small modular reactor designs.
Question No. 148	
Question/ Comment	When nuclear accident which might impact off-site happens, how does license-holder make the protective action recommendation to the off-site public? What's

	the base to refer when making such recommendation?
Answer	If a nuclear accident should occur that has offsite impacts, the plant operator (licensee) notifies the responsible State and/or local authorities of the need to take protective actions and provides a specific protective action recommendation. The responsible offsite authorities (State and/or local) review the licensee's recommendation and make a protective action decision. The responsible offsite authority would then activate the public alert and notification system, generally a siren system and radio/TV announcements, respectively. The technical basis for protective action recommendations and decisions is contained in NUREG-0654/FEMA-REP-1, Supplement 3, "Criteria for Protective Action Recommendations for Severe Accidents," issued July 1996. This document embodies guidance from U.S. Environmental Protection Agency (EPA) 400-R-92-001, "Manual of Protective Action Guides and Protective Actions For Nuclear Incidents," issued in 1992. NRC guidance is that, if a plant has declared a General Emergency classification, a minimum protective action recommendation shall be made to State and local authorities, irrespective of actual offsite impact (i.e., whether a radioactive release is in progress or not). These actions are demonstrated for Federal inspectors as part of the biennial exercise requirement, and licensee performance is tracked under the ROP drill and exercise performance indicator.
Question No. 149	
Question/ Comment	Which provisions for information of the public in the vicinity of a NPP as part of emergency planning are required?
Answer	In 10 CFR 50.47(b)(7), the NRC requires that licensees make information available on a periodic basis to populations living in the 10-mile EPZ regarding emergency response actions. Guidance related to this regulatory planning standard is provided in Section II.G ("Public Education and Information") of NUREG-0654/FEMA-REP-1. Additional guidance related to all-hazards risk communication is available through the U.S. Department of Homeland Security.
Question No. 150	
Question/ Comment	Though there is no requirement to involve members of the public in any of the emergency preparedness exercises, has such an involvement taken place so far?
Answer	Although there is no regulatory requirement to involve members of the public as part of the required demonstration of response capabilities (i.e., evacuation of schools) during EP exercises, limited public involvement has taken place at the discretion of State and local officials. This participation has been on a limited basis to demonstrate certain aspects of emergency planning and is not a regular occurrence.
Question No. 151	
Question/ Comment	International Arrangements The NRC has agreements with its neighbors, principally Canada and Mexico, and commitments to IAEA Could you put some examples of the kind of topics tackled under these bilateral agreements to your neighbouring countries? How frequent do you keep meetings under these bilateral agreements?
Answer	The NRC's trilateral agreements with Mexico and Canada include NRC

	commitments and information exchanges that are outside the responsibility of the Incident Response Program. However, the NRC's Incident Response Program does have very specific commitments that are implemented on an as-needed basis. Per the trilateral agreements, the NRC has agreed to provide early notification to Mexico and Canada of (1) any serious nuclear operating incidents along the border States with these countries, or (2) the loss of radioactive materials along the border States with these countries. Most of the interactions under the trilateral agreement encompass notifications under the category of item (2). These notifications can be generalized as primarily involving lost or stolen nuclear material—usually in the form of radioactive material in nuclear density gauges that have been stolen from construction or engineering firms. For radioactive-material-loss notifications received from these countries, the Headquarters Operations Officer will make a logbook entry and forward the notifications to the responsible NRC parties. For reports of lost or stolen radioactive material from border States, the NRC will fax or e-mail an advance copy of the event report to the designated country contact. Reports of serious nuclear incidents under the trilateral agreement are very rare. The NRC would notify the Canadian or Mexican Government under the trilateral agreement for any notification classified as an Alert or above if it were to occur in the proximity of the U.S. international borders. In general (not limited to incident response), the NRC meets regularly with representatives of both Canada and Mexico. Interactions with Canada are perhaps more frequent, owing to the size of the Canadian nuclear program. Meetings are held upon request, not on an established schedule, so the frequency varies. Examples of recent subjects discussed with Mexico include steam dryer issues related to BWRs, operator licensing, new reactor licensing, the NRC's ROP, and various NRC codes. The Comisión Nacional de Seguridad Nuclear y Salvaguardias also recently sent two regulators to two different NRC training courses, one on risk assessment and one on accident progression analysis. Examples of recent discussions with Canada include regulatory organizational structure, monitoring strategies for assessing radionuclide releases from nuclear facilities (i.e., tritium), and IRRS planning.

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 EP. First, this section discusses the regulations applying to site safety and their implementation, emphasizing regulations applying to seismic, geological, hydrological, meteorological, and radiological assessments. Next, it explains environmental protection. Article 16 of this report discusses EP and international arrangements, which would apply to contracting parties in Obligation (iv) above.

Question No. 152	
Question/ Comment	The NRC received an unprecedented number of applications that require siting evaluations under the combined license application provisions of 10 CFR Part 52. Could NRC give more details about its organisation in order to carry out the evaluation of all applications submitted (human resources, working methods)? Among the applications for siting, how many cases were accepted? Could U.S. give details about the reasons why some applications for siting were not retained?"
Answer	Since starting up in 2006, the NRC's NRO took several steps to ensure success in staffing for new reactor licensing, including increasing and enhancing recruitment activities, pursuing direct hire authority, continuing to rehire retired employees with critical skills, and using the provisions of the Energy Policy Act of 2005 to provide enhanced recruitment and retention incentives to employees. The staffing of the office is complete, with a total of approximately 500 staff on board. The Commission will continuously evaluate and adjust its human capital strategies as market conditions change. In addition, in the environmental review area, which is part of the siting evaluation, the staff relies significantly on contractors to perform parts of the review. To effectively review the large number of applications under very demanding

	schedules, the staff developed a "design-centered approach" for its DC and COL reviews. This approach will use a "one issue-one review-one position" strategy in order to optimize the review effort and resources needed. The staff conducts one technical review for each reactor design issue, and this one decision will support the DC and multiple COL applications. These efficiencies cannot be realized in the siting evaluations, however, as each site is unique. For this reason, the staff relies on contractors to conduct portions of the evaluations. The NRC has received 18 applications for COLs and 6 applications for ESPs. All of these require a siting evaluation, and all applications were accepted for review. The purpose of the staff's acceptance review is to ensure that the applicant has submitted all of the information required by the applicable regulations, such that the staff can begin its more detailed technical review. After accepting five of the COL applications, the staff subsequently suspended the reviews at the request of the applicants due to changes in the applicants' business strategy. For example, the applicant for the River Bend Station, Unit 3 and the Grand Gulf Nuclear Station, Unit 3 COL applications requested that the reviews be suspended while it reconsiders the General Electric (GE)-Hitachi Nuclear Energy economic simplified boiling-water reactor (ESBWR) technology, which was the basis for the COL application.
Question No. 153	
Question/ Comment	Sect. 17.2 addresses seismic / geological aspects of siting, flooding issues, and the assessment of radiological consequences. Almost no information has been provided on the assessment of other external hazards (e.g. meteorological hazards and man-made hazards) during the siting process. Which hazards will be considered for the evaluation of new sites and the re-evaluation of existing sites where new reactors are to be built?
Answer	As explained in Section 17.2 of NUREG-1650, all siting factors, including those noted in the question, are to be addressed. This section explains the safety elements of siting. After providing a short background, it explains seismic and geological assessments. Finally, it discusses radiological assessments performed for initial licensing, as a result of facility changes, and according to regulatory developments since the licensing of all U.S. operating plants. In addition, Section 17.2.1, "Background," explains the NRC's site-safety regulations considering societal and demographic factors, manmade hazards (such as airports and dams), and the physical characteristics of the site (such as hydrological, seismic, and meteorological factors) that could affect the design of the plant. The requirements are specified in 10 CFR Part 100, "Reactor Site Criteria," Appendix A, "Seismic and Geologic Siting Criteria for Nuclear Power Plants"; 10 CFR Part 100, Subpart B, "Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997"; and 10 CFR 100.23, "Geologic and Seismic Siting Criteria." The requirements in 10 CFR 100.23 apply to applicants for an ESP, a COL, a CP, or an operating license on or after January 10, 1997. RG 1.27, Revision 2, "Ultimate Heat Sink for Nuclear Power Plants," issued January 1976; RG 1.59, Revision 2, "Design Basis Floods for Nuclear Power Plants," issued August 1977; RG 1.102, Revision 1, "Flood Protection for Nuclear Power Plants," issued September 1976; and RG 1.208, "A Performance-Based Approach To Define the Site-Specific Earthquake Ground

	Motion," issued March 2007, describe methods acceptable to the NRC staff for implementing those requirements. For additional guidance and information on reactor siting, please note that 10 CFR 100.20, "Factors To Be Considered When Evaluating Sites," and 10 CFR 100.21, "Non-Seismic Siting Criteria," determine the acceptability of the site for stationary power reactors. As addressed in NUREG-1650, Section 17.2.1, a number of RGs (such as RG 1.23, RG 1.27, RG 1.76, RG 1.78, RG 1.91, RG 1.145, RG 1.194, and RG 1.206) provide guidance on issues of site safety that the applicant needs to address in the safety analysis reports, and NUREG-0800 provides guidance to the staff on conducting the review of the site-safety content in these reports. Therefore, all of the factors cited above are to be assessed for new sites and reevaluated, as appropriate, for existing sites.
Question No. 154	
Question/ Comment	How will the design basis be derived from the results of the site evaluation / hazard assessment (e.g. determination of the most severe event possible at the site or estimation of the intensity of an impact for a pre-defined exceedance probability)?
Answer	The design basis for assessment of a site-specific hazard is primarily derived from the mean annual frequency of exceedance. This assessment is described in Chapter 2 of the NRC's Standard Review Plan (NUREG-0800). Some hazards, such as proximity hazards and missiles, can be excluded when the consequence of the hazard results in projected radiation doses less than the 10 CFR Part 100 limits or when the mean annual frequency of occurrence is calculated to be is less than 1×10^{-7}. For wind and external flooding hazards, the assessment is deterministic, which is in conformance with General Design Criterion 2, "Design Bases for Protection against Natural Phenomena," of Appendix A to 10 CFR Part 50. There is a long history of use of deterministic criteria in the United States and, combined with the sufficient margin requirement also discussed in the general design criteria, these assessments have withstood the test of time. Although some of the acceptance criteria are frequency based and others are deterministic, all site hazard evaluations are reviewed and examined under the PRA requirements for new reactor licensing: • for DC, 10 CFR 52.47(a)(27)—a description of the design-specific PRA and its results • for COL, 10 CFR 52.79(a)(46)—a description of the plant-specific PRA and its results
Question No. 155	
Question/ Comment	The evaluation of the site specific seismic hazard RG 1.208 will be applied (17.2.2). The assessments performed according to this RG seem to follow the SSHAC guideline (NUREG/CR-6372). What study level (c.f. NUREG/CR-6372, Tab. 3-1) will be applied for the seismic hazard analyses for new reactors?
Answer	The choice of Senior Seismic Hazard Analysis Committee level depends on seismic sources; for example, Level 3 analysis is used for the sources in the

	Central and Eastern United States, but for a relatively well-understood source, such as the Charleston, SC source, a Level 2 analysis is acceptable.
Question No. 156	
Question/ Comment	What are the differences in siting considerations for "early site permit" and a "combined license". Is the methodology of RG 1.208 applicable to an early site permit when the details of the reactor design may not be fully available?
Answer	The methodology in RG 1.208 is applied to both ESP and COL applications. Should there be a significant time difference between the two and the perception of seismic hazard changes significantly, the COL applicant may need to assess the impact. In that case, the NRC would need to justify the reason for the update. The RG 1.208 methodology is to be applied regardless of the reactor design. The ESP or the COL review process establishes all of the <u>site characteristics</u> that are to be later matched with the reactor design <u>site parameters</u>. The product of the RG 1.208 method are the site-specific ground motion response spectra that constitute only one element of the site characteristics.
Question No. 157	
Question/ Comment	Please confirm if true: So now if an applicant wants to apply for the Early Site Permit, instead of, for instance, using guidance of the RG 1.4, one can use the guidance made by the RG 1.183 (together with NUREG-1465)?
Answer	A very short answer is yes, as indicated in the excerpts from NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," issued February 1995, and RG 1.183, "Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors," provided below. There is an important point to raise here. The sole purpose of an ESP application is to get approval on a postulated envelope of a set of site parameters for all of the reactor designs, including radiological source terms, that can be considered at the site in the future by establishing the site characteristics of the ESP site. As long as a chosen reactor design, to be selected in the future, has site parameters that fall within the characteristic parameters of the site, including radiological source terms, the site will be acceptable for the chosen reactor design. It should be noted that non-LWR reactor designs can also be acceptable, provided the site parameters of the design are within those of the ESP site. It is the responsibility of the ESP holder to choose a design suitable for the ESP site. Abstract of NUREG-1465: In 1962 The U.S. Atomic Energy Commission published TLD-14844, "Calculation of Distance Factors for Power and Test Reactors" which specified a release of fission products from the core to the reactor containment in the event of a postulated accident involving a "substantial meltdown of the core." This "source term," the basis for the NRC's Regulatory guides 1.3 and 1.4, has been used to determine compliance with the NRC's reactor site criteria, 10 CFR Part 100, and to evaluate other important plant performance requirements. During the past 30 years substantial additional information on fission product releases has been developed based on significant severe accident research. This document utilizes this research by providing more realistic estimates of the "source term"

	release into containment, in terms of timing, nuclide types, quantities, and chemical form, given a severe core-melt accident. This revised “source term” is to be applied to the design of future LWRs. Current LWR licensees may voluntarily propose applications based upon it. These will be reviewed by the NRC staff. Introductory paragraph of RG 1.183: This guide provides guidance to licensees of operating power reactors on acceptable applications of alternative source terms; the scope, nature, and documentation of associated analyses and evaluations; consideration of impacts on analyzed risk; and content of submittals. This guide establishes an acceptable alternative source term (AST) and identifies the significant attributes of other ASTs that may be found acceptable by the NRC staff. This guide also identifies acceptable radiological analysis assumptions for use in conjunction with the accepted AST.
Question No. 158	
Question/ Comment	Are the site related factors of the NPPs re-evaluated periodically to ensure the continued acceptability of the safety of the nuclear installations? Presently NRC requires a plant level seismic margin of 1.67 times the design basis safe shut down earth quake for the advanced reactor design. In line with these requirements whether seismic re-qualification of the existing reactors is carried out?
Answer	No, operating NPPs are not re-evaluated periodically. The continued safety of nuclear plants and the adequate protection of a licensed NPP are imperative. If there is a significant change in any hazard to an already licensed nuclear plant, then the NRC will determine whether a backfit action under 10 CFR 50.109 is necessary. The NRC will always require the backfitting of an NPP if it determines that such regulatory action is necessary to ensure that the NPP provides adequate protection to the health and safety of the public and is in accord with the common defense and security, Change in the perception of seismic hazard in the Central and Eastern United States is one such issue, designated as GI 199, “Implications of Updated Probabilistic Seismic Hazard Estimates in Central and Eastern United States on Existing Plants.” The implementation process uses the GI evaluation criteria that examine the risk impact on facilities subject to implementation, and then cost beneficial improvements are identified for implementation. However, the NRC can order the shutdown of a plant where an imminent safety concern is identified. In the past, at least one NPP and another reactor facility have been shut down because of high seismic hazard. Seismic requalification is hardly necessary when databases are available for equipment already qualified or tested to fragility levels, and Institute of Electrical and Electronics Engineers (IEEE) Standard 344, “IEEE Recommended Practice for Seismic Qualification of Class 1E Equipment for Nuclear Power Generating Stations,” provides various criteria to determine the appropriate level of ruggedness. The plant owner decides whether or not particular equipment is to be requalified or replaced. A regulatory authority does not impose the choice. Other means, such as redundant paths or plant operating procedures, are all appropriate to consider.

ARTICLE 18. DESIGN AND CONSTRUCTION

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

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

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

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

This section explains the defense-in-depth philosophy and how it is embodied in the general design criteria of U.S. regulations. It explains how applicants meet the defense-in-depth goals and how the NRC reviews applications and conducts inspections before issuing licenses to ensure that this philosophy is implemented in practice. Next, this section discusses measures for ensuring that the applications of technologies are proven by experience or qualified by testing or analysis. Finally, this section discusses requirements for reliable, stable, and easily manageable operation, specifically considering human factors and the man-machine interface. Article 12 of this report also provided information on these obligations.

Question No. 159	
Question/ Comment	Governing Documents and Processes, Paragraph 6. Please give examples of the “safety and environmental matters” which have independent studies done, and the rationale used to determine the topics.
Answer	Article 18, Section 18.1, paragraph 6 refers to the NRC staff’s environmental reviews as required by 10 CFR Part 51. In 10 CFR 51.45(e), the NRC requires applicants to provide the information that the Commission needs in its development of independent analysis of environmental impacts. In addition, 10 CFR 51.70, “Draft Environmental Impact Statement—General,” requires that the NRC staff independently evaluate and be responsible for the reliability of all information used. The staff uses NUREG-1555, “Standard Review Plans for Environmental Reviews for Nuclear Power Plants: Environmental Standard Review Plan,” to conduct its environmental reviews. Where an analysis procedure, as outlined in NUREG-1555, has been conducted by an applicant and reported in the applicant’s environmental report, the applicant’s work is evaluated by an NRC staff reviewer in sufficient depth to permit independent verification of the analysis and its results. The NRC reviewer may conduct independent analyses, if necessary. NUREG-1555 provides the NRC staff with rationale for when independent analyses are necessary. The following are examples of “safety and environmental matters” for which the staff has performed independent analyses as prescribed by NUREG-1555.

	<u>Geographic Information</u> The NRC staff reviewer should verify, both by site visit and by independent review of geographical information, that the descriptive material is correct and sufficiently detailed for environmental analysis. <u>Meteorological Input to Individual Dose Assessment</u> The NRC staff reviewer should evaluate estimates of relative concentration (including consideration of radioactive decay during transport and depletion of radioiodines and particulates) and relative deposition (including the effects of wet deposition) used by the applicant for assessing the individual doses resulting from routine releases of radioactive effluent to the atmosphere to verify that these estimates are complete and appropriate to local conditions. Depending on the level of confidence in the applicant's model and considering the extent, applicability, and representative nature of the available meteorological data, the NRC staff reviewer may make an independent analysis of relative concentration and relative deposition values at each receptor, using the transport and dispersion models described in RG 1.111, "Methods for Estimating Atmospheric Transport and Dispersion of Gaseous Effluents in Routine Releases from Light-Water-Cooled Reactors." <u>Cooling System Components</u> The NRC staff reviewer should verify all significant performance characteristics and, if necessary, conduct independent analyses to ensure that performance characteristics are accurately described. The following are examples of such analyses: • intake system flow rates, flow velocities, and velocity distributions • cooling tower performance (e.g., approach to wet-bulb temperature, drift rate and droplet size, noise-level contours) • cooling pond performance (e.g., capacity, mean temperature) • spray system performance • discharge system performance (e.g., flow velocity) <u>Transportation of Radioactive Material</u> Applicants are to provide a description of the transportation of radioactive materials and an evaluation of transportation relative to the criteria associated with Table S-4 of 10 CFR 51.52(c). Section 7.4 of NUREG-1555 provides the NRC staff reviewer with a description of postulated accidents associated with transportation of radioactive materials and an evaluation of the transport relative to the criteria associated with Table S-4 of 10 CFR 51.52(c). If an independent analysis of the impacts of transportation accidents is required, the NRC staff review should ensure that sufficient information to support an independent analysis of these impacts is provided. <u>Hydrologic Alteration</u>

	The NRC staff reviewer's analysis of construction impacts on water use should be coordinated with the hydrologic alteration descriptions provided by the environmental review. This coordination should ensure that the environmental factors most likely to be impacted by hydrologic alterations are described in sufficient detail to permit assessment of the predicted impacts. The NRC staff reviewer should independently identify and analyze those construction activities expected to affect the quality of receiving water bodies. <u>Thermal Description and Physical Impacts</u> Base analyses of the hydrothermal data on the applicant's mathematical and/or physical models and on field or tracer studies are performed by the applicant. The NRC staff reviewer should consult RG 4.4, "Reporting Procedure for Mathematical Models Selected To Predict Heated Effluent Dispersion in Natural Water Bodies," issued May 1974, and RG 1.125, Revision 1, "Physical Models for Design and Operation of Hydraulic Structures and Systems for Nuclear Power Plants," issued October 1978, to analyze the applicant's mathematical or physical models. If the NRC staff's evaluation of these data verifies the validity of the applicant's approach and results, this should constitute an adequate independent analysis. If the reviewer is unable to verify the applicant's results by this method, then the NRC staff reviewer should perform an independent assessment, using the methods described in NUREG-1555. <u>Heat Dissipation to the Atmosphere</u> The NRC staff reviewer should perform independent analysis of additional hours of ground-level fogging, icing, drift, humidity increase, and deposition of pollutants generated by offsite sources. The need for this analysis will depend on the level of the potential impact, the level of confidence in the applicant's model, and the extent, applicability, and representative nature of the available meteorological data and observational experience at operating stations. <u>Chemical Monitoring</u> The NRC staff reviewer should independently evaluate the applicant's description of the methodologies used for data collection, analysis, and interpretation of the result. The staff is required to make a finding on the validity and adequacy of the preapplication, site preparation and construction, and preoperational monitoring programs for water quality to evaluate the impacts of the plant construction and operation on the water quality of the affected environment. <u>Severe Accident Mitigation Alternatives</u> The NRC staff reviewer should independently evaluate the applicant's basis for estimating the degree to which various alternatives would reduce risk (expressed as a reduction in core damage frequency or in terms of person-rem averted). In performing its independent assessment, the NRC staff reviewer may make bounding assumptions to determine the magnitude of the potential risk reduction for each severe accident mitigation alternative. <u>Description of Power System</u> Affected States and/or regions are expected to prepare a need-for-power evaluation. The NRC will review the evaluation and determine if it is (1) systematic, (2) comprehensive, (3) subject to confirmation, and (4) responsive

	to forecasting uncertainty. If the need-for-power evaluation is found to be acceptable, no additional independent review by the NRC is needed.
	Power and Energy Requirements The scope of the review directed by this plan should include a detailed analysis and evaluation of the applicant's treatment of these projections and, where needed, an independent assessment of forecasts of the service area growth in electricity consumption and peakload demand. Affected States and/or regions continue to prepare need-for-power evaluations for proposed energy facilities. The NRC will review the evaluation and determine if it is (1) systematic, (2) comprehensive, (3) subject to confirmation, and (4) responsive to forecasting uncertainty. Forecasts should include demand scenarios for midrange, high, low, 75th percentile, and 25th percentile conditions. If the need-for-power evaluation is found to be acceptable, no additional independent review by the NRC is needed. Benefits NUREG-1555 directs the staff's identification and tabulation of the benefits resulting from proposed project construction and operation. The reviewer may rely on an independent analysis of benefits by State or regional authorities, the applicant's analysis, or prepare an independent assessment. Costs NUREG-1555 directs the staff's identification and evaluation of the internal and external costs of construction and operation of the proposed project. The reviewer may rely on an independent analysis of benefits by State or regional authorities or the applicant's analysis. An independent assessment may also be prepared. Summary NUREG-1555 directs the staff's analysis, evaluation, and balancing of the benefits and costs of the proposed project, leading to a final decision on the acceptability of the project (1) as proposed by the applicant or (2) as proposed by the applicant with modifications identified by the staff. The reviewer may rely on an independent analysis of benefits by State or regional authorities, rely on the applicant's analysis, or prepare an independent assessment.
Question No. 160	
Question/ Comment	Governing Documents and Processes, Paragraph 8. Does the consideration of modular construction at remote locations include small reactors? If not, what is the NRC's approach to small reactors?
Answer	Section 18.1.1 of the Fifth National Report states the following: > The new inspection program revises the 10 CFR Part 50 Construction Inspection Program. It incorporates ITAAC from 10 CFR Part 52, as well as lessons learned from the inspection program used in the previous construction era (1970–1980). It also considers modular construction at remote locations. In the context of the report, modular construction is the fabrication of some structures, systems (or subsystems), and components for final assembly at the construction site. The NRC guidance (RG 1.215, "Guidance for ITAAC Closure

	Under 10 CFR Part 52") acknowledges that it may be impractical to perform some inspections and testing after installation in the plant. In such cases, it may be appropriate, where it is technically justifiable, to perform inspections or tests before final installation (e.g., at the fabrication location offsite). Several companies have developed or are developing manufacturing capabilities in the United States to fabricate piping systems or other subsystems to support an increased use of modular construction techniques for those plants currently undergoing a design or licensing review. The NRC staff is currently evaluating the evolution of modular construction concepts that are envisioned for small and medium-sized reactors (also referred to as small modular reactors). The extension of modular construction to encompass most or all of the nuclear steam supply system, containments, and other systems important to safety may lead the NRC to revise its construction inspection program beyond the typical examinations to ensure compliance with quality assurance requirements in Appendix B to 10 CFR Part 50 (e.g., the NRC could treat the modular fabrication or an integral reactor vessel as similar to onsite construction activities). The NRC staff is also evaluating the potential use of the manufacturing license provisions defined in 10 CFR Part 52, Subpart F, "Manufacturing Licenses." The manufacturing license provisions were developed to support concepts such as offshore power systems and may not be consistent with the fabrication and construction processes being discussed for the small modular reactors currently being developed.
Question No. 161	
Question/ Comment	Is there any detail documents such as NUREG, NER series document to guide the engineering design for the transportation fractions different type of debris with regard to debris transportation issues meeting the requirement of RG1.82 ? Is there a detail document such as NUREG, NER series document to guide the engineering design for the reactor core interactions with debris, especially in the area of core heat transfer with regard to the potential reactor core interactions with debris that passes through the sump strainer? Please give more information.
Answer	NUREG/CR-6808, "Knowledge Base for the Effect of Debris on Pressurized Water Reactor Emergency Core Cooling Sump Performance," issued February 2003, available on the NRC public Web site, describes the substantial base of knowledge that has been amassed as a result of the research on BWR suction-strainer and PWR sump-screen clogging issues. Section 4 of NUREG/CR-6808 discusses airborne and washdown debris transport, and Section 5 discusses transport in the sump pool. Each section has references for transport-related studies that apply to that part of the transport process. Many of the documents are referenced by both sections. The references date back to studies that were also done for the BWRs because some of that information is relevant to the PWR evaluations. The NRC has not issued or approved a NUREG or similar document that addresses reactor core interactions with debris that passes through the sump strainer. On June 4, 2007, Topical Report WCAP-16793-NP, "Evaluation of Long-Term Cooling Considering Particulate, Fibrous, and Chemical Debris in the Recirculating Fluid," was submitted to the NRC by the Pressurized Water Reactor Owners Group to provide guidance for the evaluation of the potential for sump strainer bypassed debris to affect core cooling. The topical report includes

	numerical analyses that show that, during the long-term core cooling period, the bypassed debris expected to be present in the emergency core cooling system of a typical PWR plant would not result in the formation of deposits on fuel rods exceeding acceptable limits, and that the fuel cladding temperature would not exceed 800 degrees Fahrenheit. The NRC staff has not yet completed the review of WCAP-16793-NP, Revision 1.
Question No. 162	
Question/ Comment	A significant difference in the 10 CFR Part 52 process is that the final safety analysis report must be submitted before authorization is granted to begin construction. In order to take into account the potential design changes occurred during the process of authorization, do the U.S. ask for an updating process of the Final Safety Analysis Report after authorization to begin construction and before the commissioning of the reactor?
Answer	Yes, the NRC requires the applicant to revise the FSAR to account for changes during the review process before the NRC issues the COL, so that the FSAR is the up-to-date licensing basis for the COL. Also, after issuance of the COL, the licensee is required to update the FSAR on an annual basis up to the authorization to operate, in accordance with 10 CFR 50.71(e). After the nuclear reactor is operational, licensees are required to update their FSARs as required by 10 CFR 50.71(e); some changes may be allowed through the 10 CFR 50.59 process.
Question No. 163	
Question/ Comment	Could you please provide information on the average size (no. of staff members) of a team involved in the regulatory technical review for design certification of a new reactor (including the performance of independent safety analyses and the production of the Final Safety Evaluation Report (FSER))?
Answer	Based on experience, the size of a team involved in the new reactor regulatory technical review for a DC application consists of a team of about 33 technical specialties. On average, the review takes about 115,000 man hours over 4 years. This estimate does not include any post-FSAR activities, such as rulemaking.
Question No. 164	
Question/ Comment	The NRC interacts with manufactures and suppliers of safety related components. How this provision is implemented in case of foreign suppliers when the shops are outside of U.S.? Slovakia would welcome the list of inspections for vendors (dated 27 April 2010).
Answer	The NRC is responsible for performing routine vendor inspections to verify effective implementation of a supplier's quality assurance program used to furnish safety-related components or services to the nuclear industry in compliance with Appendix B to 10 CFR Part 50 and 10 CFR Part 21, as required under vendor procurement contracts with applicants or licensees. Vendor inspections can be conducted at vendor shops in and outside of the United States. The selection criteria for inspection is based on the significance to safety of the equipment or product supplied, the frequency and safety significance of problems identified with the equipment, the number of licensees using the vendor, the performance history of the vendor, and other various information. The NRC does not provide a list of suppliers that will be inspected. However, the results of the agency's inspections are publically available on the NRC Web site at

	www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html.
Question No. 165	
Question/ Comment	During construction, inspectors sample the spectrum of the applicant's activities related to the ITAAC in the design-basis document. Who performs ITAAC?
Answer	The licensee performs the ITAAC. The licensee has the responsibility to inform the NRC by letter when it has completed each ITAAC. The NRC will verify that a sample of the ITAAC has been completed. When the licensee notifies the NRC that an ITAAC is complete, it will also identify the bases for the ITAAC completion. The NRC reviews the licensee's ITAAC documentation, as well as any NRC inspection related to that ITAAC, and will determine if the licensee's ITAAC completion letter and associated bases are satisfactory.
Question No. 166	
Question/ Comment	Do other counties have an access to the ConE database and what are the conditions of such access?
Answer	The ConE database is only accessible by the NRC staff and it is not available to other countries. The NRC has not made this database publically available because it contains nonpublic or proprietary information from domestic and international sources. The NRC staff, however, communicates generic construction experience information and lessons learned with external stakeholders, including the international community, by publishing various forms of generic communications, such as information notices. The NRC's generic communications Web page is accessible at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additionally, the NRC staff submits nonsafeguards-related reports and information in the ConE database to the Committee on Nuclear Regulated Activities/Working Group on the Regulation of New Reactors construction database.
Question No. 167	
Question/ Comment	U.S.NRC is currently performing design certification review of ESBWR (page 17, new reactor licensing). Are there any additional PIEs which are being considered for reactors with natural circulation such as ESBWR?
Answer	The ESBWR DC review is nearing completion. All technical and regulatory issues have been resolved, and the ACRS review was completed in October 2010. The staff expects to issue the FSAR in February 2011. The proposed rulemaking package is now with the Commission for review, and the staff expects to issue the final rule in late 2011. During the review of the ESBWR design, the staff evaluated initiating events unique to the passive ESBWR design features. For example, the staff considered potential thermal-hydraulic instabilities due to natural circulation design; however, the phenomena are not different than in operating BWRs and the results were found to be acceptable. The staff also evaluated initiating events such as inadvertent actuation of the isolation condenser system because that is a unique passive safety feature for the ESBWR. The results were found to meet relevant acceptance criteria. The staff is not aware of any planned future applications for certification of large passive LWR designs. However, the NRO Advanced Reactor Project Office is preparing to review smaller LWR and non-LWR reactor designs that use unique or

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<tr><td></td><td>passive design features. The NRC discussions related to these designs is, however, preliminary and has not yet identified specific postulated initiating events to be included in design-basis or beyond-design-basis evaluations.</td></tr>
<tr><td colspan="2">Question No. 168</td></tr>
<tr><td>Question/ Comment</td><td>10 CFR 73.54 requires licensees to provide high assurance that nuclear power plants' safety, safety-related, security, and emergency preparedness functions are protected from cyber attacks up to and including the design-basis threat. Please give some instances of safety, security and emergency preparedness (SSEP) functions. Do safety, SSEP functions include non-safety instrumentation and control system? If not, shall cyber security for those systems which are non SSEP functions related be ensured? After submitting the cyber security program, when and how will cyber security design be verified? Will it be included in ITAAC?</td></tr>
<tr><td>Answer</td><td>(1) Yes. Systems that perform security and emergency preparedness functions are nonsafety instrumentation and control systems. Within the scope of 10 CFR 73.54, "Protection of Digital Computer and Communication Systems and Networks," licensees are also required to protect those systems "associated with" safety, security, and emergency preparedness (SSEP) functions, including those that provide a pathway (direct or indirect) to systems that perform, or are relied upon, for SSEP functions. Section 3.1.3 of RG 5.71, "Cyber Security Programs for Nuclear Facilities," provides a method that a licensee can use to determine which digital computer, communication systems, and networks in operation at an NPP perform SSEP functions and are within the scope of 10 CFR 73.54. RG 5.71 was published in January 2010 and is publicly available.

(2) NRC regulatory jurisdiction only extends to digital computer, communication systems, and networks in use at an NPP that fall within the scope of 10 CFR 73.54.

(3) Licensees are required to submit a cyber security plan to the NRC for review and approval that addresses all of the requirements of 10 CFR 73.54. According to 10 CFR 73.54(e), the cyber security plan must include the following:

• description of how the requirements of 10 CFR 73.54 will be implemented and account for site-specific conditions that affect implementation

• measures for incident response and recovery from cyber attacks and a description of how the licensee will do the following:

– Maintain the capability for timely detection and response to cyber attacks.

– Mitigate the consequences of cyber attacks.

– Correct exploited vulnerabilities.

– Restore affected systems, networks, and/or equipment affected by cyber attacks.

Once the NRC reviews and approves the submitted cyber security plan, the plan becomes a condition of the NRC-issued license. The cyber security programs</td></tr>
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	established and implemented by licensees are subject to verification through NRC inspection and oversight activities. As part of inspection and oversight activities, the NRC will verify that licensees have established, implemented, and maintained cyber security programs as described in their respective NRC-approved cyber security plans and may include a review of defensive architectures and the implementation of security controls. The timeframes in which inspection activities occur will vary by site based on implementation schedules submitted by licensees to the NRC along with the licensees' cyber security plans. Finally, licensees are required to comply with all NRC regulations. Licensees must comply with the requirements contained in 10 CFR Part 73, "Physical Protection of Plants and Materials," 10 CFR Part 50, and 10 CFR Part 52. According to 10 CFR Part 50 and 10 CFR Part 52 requirements, any cyber security design feature included as part of a safety system for the purposes of complying with 10 CFR 73.54 will be reviewed by the NRC to ensure that there is no associated impact on the reliable performance of a safety function. Whether cyber security features meet the commitments made in a licensee's cyber security plan is verified during an inspection of the licensee's cyber security program. (4) COL applicants are required to comply with requirements contained in both 10 CFR Part 52 and 10 CFR Part 73. Under 10 CFR Part 52, any cyber security design features included as part of a safety system for the purposes of complying with 10 CFR 73.54 will be reviewed as part of ITAAC to ensure that their inclusion would not impact the reliable performance of the safety function. However, no evaluation of the adequacy of those cyber security features should be made as part of the licensing review. The adequacy of cyber security features will be verified as part of the NRC's inspection and oversight activities of COL applicants' cyber security programs implemented in accordance with their NRC-approved cyber security plans under 10 CFR 73.54.

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, “Energy,” 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.

Question No. 169	
Question/ Comment	Certifications currently in progress are listed in the introduction of the report. It would be appreciated to find this point in the present chapter.
Answer	The NRC agrees with including a list of the current DCs under review in this section. The certifications are for the following: Westinghouse AP1000 DC amendment, GE-Hitachi ESBWR, Mitsubishi U.S. advanced pressurized-water reactor, Toshiba advanced boiling-water reactor (ABWR) renewal, and GE-Hitachi ABWR renewal.

Question No. 170	
Question/ Comment	Could U.S. specify the number of events reported by the operators to the U.S. NRC and could develop the main lessons learnt from these events?
Answer	2008—The NRC Operations Center received 870 event notifications. 2009—The NRC Operations Center received 856 event notifications. 2010—The NRC Operations Center received 915 event notifications. Event notifications include reactor, materials, and medical events. The NRC evaluates these events and determines whether to establish its response organization. These events have been evaluated to determine if any corrective actions were warranted. None of the events rose to the level of needing to be entered into a corrective action program; as such, there were no lessons learned from these events.
Question No. 171	
Question/ Comment	It is understood that both the two step and the combined license process are possible and the licensee decides which way to go. Does the combined licence is limited in terms of operating licences (e. g. 10 years)? It seems that the combined licence is mainly applicable to already certified designs.
Answer	A COL is initially issued for 40 years, the same as for an operating license in the two-step process. The COL may reference a certified design but it is not required to do so. A COL may reference an ESP, a certified design, or neither.
Question No. 172	
Question/ Comment	Have there been any specific concerns regarding operational limits and conditions for digital equipment?
Answer	As part of its review of proposed implementations of digital safety systems, the NRC staff evaluates a license applicant's description of the environment into which the digital system is to be installed to ensure that the equipment is suitably qualified to function continuously within that environment. In addition to mild environmental conditions, it is anticipated that the digital safety system will be subjected to the electromagnetic (EMI/FRI) conditions that would be present within an NPP control building, as well as the seismic and vibratory motion appropriate to its location. The NRC staff developed guidance (RG 1.209, "Guidelines for Environmental Qualification of Safety-Related Computer-Based Instrumentation and Control Systems in Nuclear Power Plants") for licensees to follow when assessing and assuring the capabilities of the proposed digital safety equipment. This guidance provides clarifications and NRC staff positions on compliance of the system design with IEEE Standard 323-2003, "IEEE Standard for Qualifying Class 1E Equipment for Nuclear Power Generating Stations," and discusses the appropriate use of other U.S. industry documents that licensees could apply when qualifying their proposed digital safety equipment for mild environmental conditions.
Question No. 173	
Question/ Comment	Sixty days seems to be a long time to report an event, particularly if the event is of major importance.
Answer	Reports made in accordance with 10 CFR 50.73, "Licensee Event Report System," are required to be submitted within 60 days. However, most of the events that meet the requirement for an LER also met the requirements for reporting in accordance with 10 CFR 50.72, "Immediate Notification Requirements

	for Operating Nuclear Power Reactors," which requires events to be reported within 1, 4, or 8 hours. Event notification requirements under 10 CFR 50.72 cover important events about which the NRC should be notified quickly, such as emergency declarations or reactor trips.
Question No. 174	
Question/ Comment	The section 19.6 describes that NRC reviewed each reported reactor-related event and assigned a rating of 1 to 7 on INES. 1) Please explain the event rating procedures in the NRC. What department takes charge of the event rating? 2) Does the NRC communicate the rating results of all events with the public?
Answer	(1) NRC program offices (NRR for reactors, the Office of Federal and State Materials and Environmental Management Programs (FSME) for materials, the Office of Nuclear Materials Safety and Safeguards for fuel cycle and transportation, and the Office of Nuclear Security and Incident Response (NSIR) for security) review the event reports to determine if any of the events exceed the threshold for exceeding Level 2 on the INES. NRR rates every event, and that rating is kept in a database of event notifications. Out of approximately 500 reactor events per year, NRR rated eight Level 1 events and one Level 2 event in 2010. If any of the events are expected to be a Level 2 or higher, the program office drafts an INES event notification form, which is reviewed by the program office management and the U.S. National Officer (who resides in NSIR) and is then transmitted to IAEA within 48 business hours by the Headquarters Operations officers. (2) The INES rating of events transmitted to IAEA (Level 2 and above) is not included in the NRC event reports, nor are they posted on the NRC's public Web site.
Question No. 175	
Question/ Comment	Are the licensees required to classify the events according to the International Nuclear and Radiological Event Scale, or is this classification only performed by the NRC?
Answer	Only the NRC classifies events based on the INES and transmits information on these events to IAEA. Neither NRC licensees nor Agreement States licensees are required by regulations to classify their events according to the INES. However, U.S. licensees have been made aware of the scale via issuance of NRC IN 2009-27, "Revised International and Nuclear Event Scale User's Manual," dated November 13, 2009. Agreement and Non-Agreement State licensees have been notified of INES via FSME-10-027, "Revised International Nuclear and Radiological Event Scale (INES) User's Manual," dated March 15, 2010, asking the Agreement States to share IN 2009-27 with all of their license holders in each state. In this way, the approximately 23,000 U.S. licensees have been made aware of the INES and of the benefits of communicating the safety significance of events to the public.
Question No. 176	
Question/ Comment	The Report says that the effectiveness of licensee operating experience programs is subject to NRC inspection. Could you please give details of particular criteria for effectiveness evaluation of these programs?
Answer	The effectiveness of licensee operating experience programs and application of NRC communications is subject to NRC inspection under IP 71152, "Problem

	Identification and Resolution." In addition to quarterly, semiannual, and annual sampling requirements performed as part of the baseline inspection process, IP 71152 requires inspectors to perform on a biennial sampling basis an in-depth review of corrective action reports and trending of plant issues and problems from the previous 5 years. As part of the routine baseline review, inspectors verify items entered into the corrective action program against the actions taken to address the issue for completeness and effectiveness. The corrective action program is also reviewed using other baseline IPs, including IP 71111.21, "Component Design Bases Inspection," for items specific to the inspectable area. Inspectors review performance indicators throughout the year and ensure that thresholds exceeded are addressed, and that any corrective actions taken are appropriate in order to prevent recurrence. Supplemental inspections (IP 95001, IP 95002, and IP 95003) are conducted to verify the adequacy of a licensee's corrective actions taken in response to inspection findings that have been determined to be greater-than-Green in accordance with IMC 0609, "Significance Determination Process," or to performance indicators that have crossed their Green-to-White thresholds. Reactive inspections chartered in response to specific events are conducted per IP 93800, "Augmented Inspection Team," or IP 93812, "Special Inspection," include a review of licensee corrective action program entries to determine if an ineffective review or application of operating experience contributed to the event. Operating Experience Smart Samples, available as a voluntary tool for inspectors to review specific systems and programs, contain relevant operating experience that can be referenced by the inspector for verification of the adequacy of licensee actions.
Question No. 177	
Question/ Comment	Do Utilities have access to the NRC's event database?
Answer	All event notifications made to the NRC in accordance with 10 CFR 50.72 are publicly available on the NRC Web site, as are all LERs made in accordance with 10 CFR 50.73. Utilities also have access to NRC generic communications and inspection reports, which are also available on the public Web site.
Question No. 178	
Question/ Comment	How many years are the existing temporary spent nuclear fuel storages, predicted to last?
Answer	Recently, the NRC reviewed current information supporting the storage of spent nuclear fuel. The NRC found continued support for safe spent fuel pool storage in the extensive studies that have occurred since 1990, and in the continued regulatory oversight of operating plants. Operating experience to date has shown that there have not been any safety problems during dry storage. Also, studies performed to date have not identified any major issues with long-term use of dry storage. The inherent robustness and passive nature of dry cask storage, coupled with decades of operating experience and research, allows the NRC to conclude that spent fuel can be safely stored in dry casks for a period of at least 60 years after the licensed life of reactor operations without significant environmental impacts (75 *Federal Register* (FR) 81032; December 23, 2010). Since 1999, the NRC has granted regulatory exemptions to allow a 40-year renewal period for four independent spent fuel storage installations after the staff

	reviewed the applicants' evaluations of aging effects on the SSCs important to safety. The NRC determined that the evaluations, supplemented by the licensees' aging management programs, provide reasonable assurance of continued safe storage of spent fuel in these installations (75 FR 81068; December 23, 2010). Based on available information, the NRC remains confident that, if necessary, spent fuel generated in any reactor can be stored safely and without significant environmental impacts for at least 60 years beyond the licensed life for operation (which may include the term of a revised or renewed license) of that reactor in a combination of storage in its spent fuel storage basin and either onsite or offsite independent spent fuel storage installations. Thus, if the original 40-year reactor operating license was renewed for an additional 20 years, the NRC has confidence that at least 120 years of storage would be safe and without environmental significance (75 FR 81032; December 23, 2010).
Question No. 179	
Question/ Comment	The report says: "The U.S. Government addresses in detail the spent fuel and radioactive waste programs ..." The NRC has received 18 combined license applications for 28 new light-water reactor units. The Blue Ribbon Commission will provide recommendations to the disposal of radioactive waste not before 2012. Is the licensing of new NPPs independent from the aspects of waste disposal, and as such, from the recommendations of the commission?
Answer	For several decades, the NRC has proceeded with the licensing of new NPPs based on an independent determination that waste could be stored safely and without significant environmental impact until disposal occurred. This determination arose, in part, from a 1979 ruling by the U.S. Court of Appeals for the D.C. Circuit. In the licensing of new NPPs, the Court held that the NRC needed to have reasonable assurance that a solution to the problem of waste storage and disposal would be available when needed, and that this assurance could be made with generic rulemaking (State of Minnesota vs. NRC, 602 F.2d 412 (1979)). In response, the NRC reviewed available information and determined that the licensed storage of spent nuclear fuel for 30 years after the reactor operating license had expired, either at or away from the reactor site, was feasible, safe, and would not result in a significant impact on the environment (49 FR 34688; August 31, 1984). The NRC also concluded that safe disposal in a geologic repository was technically feasible and that spent fuel would be managed safely until sufficient disposal capacity was available. Additional reviews in 1990, 1999, and 2010 confirmed this confidence in safe storage until geologic disposal is available (55 FR 38474; September 18, 1990; 64 FR 68005; December 6, 1999; 75 FR 81032; December 23, 2010). Because of the complex political and societal factors influencing development of a national repository, the NRC cannot predict the year when a geologic repository will become available. However, the NRC has reasonable assurance that a geologic repository will become available when necessary, and that spent nuclear fuel and high-level waste can be stored safely and without significant environmental impacts for at least 60 years after the licensed life of operation for

	any reactor (75 FR 81069; December 23, 2010). This assurance was developed assuming that the proposed repository at Yucca Mountain, NV, was not constructed as planned. Consideration of available information allows the NRC to have reasonable assurance that a geologic repository could be licensed and in operation within 25–35 years of a Federal decision to begin a repository program. Given the ongoing activities of the DOE Blue Ribbon Commission, events in other countries, the viability of safe long-term storage for at least 60 years (and perhaps longer) after reactor licenses expire, and the Federal Government's statutory obligation to develop a high-level waste repository, the NRC has confidence that a repository will be made available well before any safety or environmental concerns arise from the extended storage of spent nuclear fuel and high-level waste (75 FR 81063; December 23, 2010).

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This report is an addendum to NUREG-1650, Revision 3

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 “Fifth National Report” for peer review in September 2010 (NUREG-1650, “The United States of America National Report for the Convention on Nuclear Safety: Fifth National Report, September 2010,” Revision 3). Addendum 3 to NUREG-1650 documents the answers to questions raised by contracting parties during their peer reviews of the U.S. national report. Specifically, the questions and answers resulting from the peer reviews concern the safety of existing nuclear installations, the legislative and regulatory framework, the 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, and operation. The Fifth Review Meeting of the CNS was held at the International Atomic Energy Agency in Vienna, Austria, in April 2011.

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