Group A

FOIA/PA NO: 2015-0010

RECORDS BEING RELEASED IN THEIR ENTIRETY

No.	Date	Description/(Page Count)
1.	7/6/2011	Email: From: David Kenagy, To: Leah Smith. Subject: "FW: CNS - Responses to Questions on the U.S. National Report" (128 pages)
2.	7/6/2011	Email: From: David Kenagy, To: Leah Smith. Subject: "FW: CNS Responses to Post" (77 pages)

Smith, Leah A

From: Kenagy, W David
Sent: Wednesday, July 06, 2011 2:37 PM
To: Smith, Leah A
Subject: FW: CNS - Responses to Questions on the U.S. National Report
Attachments: Question and Answer Report table - consolidation of answers - final.docx

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From: Quinones, Lauren [mailto:Lauren.Quinones@nrc.gov]
Sent: Tuesday, March 01, 2011 3:04 PM
To: Kenagy, W David
Cc: Fladeboe, Jan P; Metz, Patricia J; Rodriguez, Veronica
Subject: CNS - Responses to Questions on the U.S. National Report

Good Afternoon David,

Per Veronica's email below, I am sending the responses to the questions on the U.S. National Report. There are 179 questions. If you have any questions or if you need help, please don't hesitate to contact us, you can contact me at Lauren.Quinones@nrc.gov and at 301-415-2007.

Thanks for your support,
Lauren

From: Kenagy, W David [mailto:KenagyWD@state.gov]
Sent: Sunday, February 27, 2011 8:13 PM
To: Rodriguez, Veronica
Cc: Fladeboe, Jan P; Metz, Patricia J; Quinones, Lauren
Subject: RE: CNS - Responses to Questions on the U.S. National Report

I should be able to support.

From: Rodriguez, Veronica [mailto:Veronica.Rodriguez@nrc.gov]
Sent: Friday, February 25, 2011 3:06 PM
To: Kenagy, W David
Cc: Fladeboe, Jan P; Metz, Patricia J; Quinones, Lauren
Subject: CNS - Responses to Questions on the U.S. National Report

Good Afternoon David –

I spoke to Patricia yesterday about the responses to the questions received on our CNS report. We wanted to inform you that we are planning to send the file on Tues or Wed. If possible, we would like to have all the responses posted in the CNS secured website by Friday. Giving the potential shutdown, we would like to get this out to IAEA as soon as possible. Patricia stated that this shouldn't be a problem. If DOS would need assistance from the NRC to upload the questions, please don't hesitate to contact us. We will make ourselves available.

I'll be out of the office next week; however, Lauren Quinones will be sending you the questions and following up on this action. Lauren can be contacted at Lauren.Quinones@nrc.gov and at 301-415-2007. If you need me, I'll be available via email.

'11 JUL 18 PM2:45

Thanks for your continued support,

A1

Veronica

Convention on Nuclear Safety
Questions Posted To United States of America in 2011

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 1			Country Canada	Article General	Ref. in National Report 36
Question/ Comment	(P) HR	8.1.5.2 and Knowledge management discussion on P. 36	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: Probabilistic Risk Analysis, Thermal Hydraulics – Numerics, Medical Physics and Medical Health Physics, Nuclear Analysis, Seismic Engineering, Thermal Hydraulics – Model Development, and Geotechnical Engineering, at the doctoral and post-doctoral level.				
Q. No 2			Country Canada	Article General	Ref. in National Report 38
Question/ Comment	(P) DLR	P. 38 and 89	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 US 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, ageing management of nuclear power plants, as in the context of license renewal of those plants, is important to the agency. Ensuring for 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 ageing 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 ageing management programs to incorporate lessons-learned from operating experience.				
Q. No 3			Country Canada	Article General	Ref. in National Report 18

<table>
<tr><td>Question number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Question/ Comment</td><td>(P) NRO</td><td>New Reactor Licensing P 18</td><td colspan="3">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.</td></tr>
<tr><td>Answer</td><td colspan="5">The appropriate word that should be used in each case is plant parameter envelope “approach”. The ESP application may specify a reactor design; however it is not required by the 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 envelope 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 Plant Parameter Envelope is a set of reactor and owner engineered parameters listed in the Early Site Permit (ESP) that are expected to bound the characteristics of a reactor that might later be deployed at the ESP site. A plant parameter envelope (PPE) sets forth postulated values of parameters that provide details to support the NRC staff's review of an ESP application.

Part 52 allows for approval of a site for future nuclear power plants as a separate licensing action well in advance of decisions on reactor technology and when to build. In those instances where 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 for 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 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.</td></tr>
<tr><td>Q. No 4</td><td></td><td></td><td>Country Canada</td><td>Article General</td><td>Ref. in National Report 35</td></tr>
<tr><td>Question/ Comment</td><td>(P) HR</td><td>Regulatory Effectiveness p. 35</td><td colspan="3">The Report under "Regulatory Effectiveness" states that the US NRC has grown from 3110 employees in 2004 to more than 4000 today. Please elaborate on measures implemented by the US NRC to meet the challenges of training new staff and maintaining the quality of inspections, evaluations, and investigations.</td></tr>
<tr><td>Answer</td><td colspan="5">During that time period, the agency 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.</td></tr>
</table>

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 5			Country Canada	Article General	Ref. in National Report 178
Question/ Comment	INPO	Part 3, Section 3	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 (CDE) system captures the data needed for the NRC's Reactor Oversight Process performance indicators, WANO's performance indicators, the NRC's Monthly Operating Report, additional indicators used by INPO members, and the Equipment Performance Indicator Exchange system (EPIX). These indicators measure performance in areas including generation, safety system performance, personnel safety, and equipment reliability.				
Q. No 6			Country Japan	Article General	Ref. in National Report p32
Question/ Comment	(P) NRO	Issuance of ESP and LWA p. 31 - 32	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 early site permit 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 that combined license applicants that reference an early site permit submit any new and significant information for environmental issues related to construction and operation of the facility that were resolved in the early site permit. Combined license 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 combined license. In addition, while an early site permit is in effect, the Commission may change or impose new site characteristics, design parameters, or terms and conditions on the early site permit 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 combined license who has filed an application referencing an early site permit is required to update the emergency preparedness information that was provided with the early site permit 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 early site permit if it determines that a modification is necessary based on the updated emergency preparedness information.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 7			Country Japan	Article General	Ref. in National Report Part 3, 7b, p188
Question/ Comment	INPO	Part 3, 7b	One of the previous challenges for the US 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 US industry uses candidates from the following areas as potential new employees: Nuclear Navy Navy Retirees Navy Commanding Officers Agricultural Industry Merchant Marines Automotive Industry Industry Suppliers Engineering Firms Recently, many utilities are participating with local high schools, technical schools and colleges to promote the nuclear industry as a career path and the opportunities it has to offer.				
Q. No 8			Country Pakistan	Article General	Ref. in National Report Introduction- "Power up rate"- Page 17
Question/ Comment	(P) DPR	"Power up rate"- Page 17	It is mentioned that Commission has approved EPUs (extended power up-rates) of up to 20 percent. Can the US provide information which is required from the licensee for approving uprates up to 20 %?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Review Standard for Extended Power Uprates (RS-001) was created for the NRC staff to use in its review and evaluation of 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. Since RS-001 is publicly available (ADAMS 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 sub-areas 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 systems; human performance, health physics, radiological consequences, risk evaluation and environmental assessment; and power ascension and testing plan. RS-001 has been used to review power uprate applications up to 20%, and there is no limit specified in RS-001 regarding how high an EPU the staff will consider.				
Q. No 9			Country Pakistan	Article General	Ref. in National Report "New Reactor Licensing" Page 18
Question/ Comment	(P) DORL	"New Reactor Licensing" Page 18	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. USA 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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	In a Commission Paper (SECY-07-0096) 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 SRM SECY-07-096 the Commission directed the staff to use the current licensing basis for Watts Bar Unit 1 as the reference basis for the review and licensing of Watts Bar Unit 2. Further, the Commission indicated that TVA and the NRC staff should review any exemptions, reliefs, and other actions, which were specifically granted for Watts Bar Unit 1, to determine whether the same allowance would be appropriate for Watts Bar Unit 2. Significant changes to this licensing approach would be allowed for cases where the existing Backfit Rule 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 CFR50.55a(2), which states that, "systems and components...must meet the requirements of the ASME Boiler and Pressure Vessel Code specified in...this section. Protection systems...must meet the requirements specified in...this section." 10 CFR50.55a (2) Systems and components of boiling and pressurized water-cooled nuclear power reactors must meet the requirements of the ASME Boiler and Pressure Vessel Code specified in paragraphs (b), (c), (d), (e), (f), and (g) 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 where the unirradiated state of Watts Bar Unit 2 makes the issue easier to resolve than at Watts Bar Unit 1.				
Q. No 10			Country Pakistan	Article General	Ref. in National Report "Moisture Effects ... Cables" Page 24
Question/ Comment	(P) DE	"Moisture Effects on Underground Cables" Page 24	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 USA describe what measures are being taken to develop and implement the cable testing program for plants operating under 40 years of design life?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC staff has provided guidance to nuclear power plant 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 1.218 (the draft version of this regulatory guide was issued as DG-1240, June 2010), "Condition Monitoring Program for Electric Cables Used in Nuclear Power Plants," in 2011. The purpose of this regulatory guide is to provide specific guidance for monitoring the performance of cables during their installed life. In particular, this regulatory guide 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 in 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 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, "Licensing of Production and Utilization Facilities," requires nuclear power plant licensees to establish a test program to ensure that all testing required to demonstrate that structures, systems, and components will perform satisfactorily in service is identified and performed. Paragraph (a)(1) of 10 CFR 50.65, 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 a SCC within the scope of the rule is being effectively controlled through preventive maintenance.				
Q. No 11			Country Pakistan	Article General	Ref. in National Report "Reactor Materials ..Issues" Page 28

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DCI	"Reactor Materials Degradation Issues" Page 28	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 USA describe how NRC has ensured that, in-spite of not taking mitigative measures for remaining four plants, these are safer?		
Answer	Each of 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 four (4) years. The four (4) year inspection interval is an increase in inspection frequency from the American Society of Mechanical Engineer's Boiler and Pressure Vessel Code requirement of inspection once every ten (10) years in order to address the aggressive crack growth rates of primary water stress corrosion cracking (PWSCC) in nickel alloys. The four (4) year inspection frequency was based on a conservative deterministic flaw assessment assuming 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 four (4) year interval would provide reasonable assurance of structural integrity of each weld of concern. Additional information is available in Regulatory Issue Summary 08-25, "Regulatory Approach for Primary Water Stress Corrosion Cracking of Dissimilar Metal Butt Welds in Pressurized Water Reactor Primary Coolant System Piping," and at the NRC public web site at the following web page link. http://www.nrc.gov/reactors/operating/ops-experience/pressure-boundary-integrity/weld-issues/index.html				
Q. No 12			Country Romania	Article General	Ref. in National Report Introduction, page 15
Question/ Comment	(P) NRO (S) RES		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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	In accordance with Nuclear Regulatory Commission (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 (LWR) nuclear power plants, 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 early in this decade. Following enactment of the United States (U.S.) Energy Policy Act of 2005 (EPAct), the NRC and U.S. Department of Energy (DOE) considered applying NUREG-1860 in the licensing strategy required by the EPAct for the Next Generation Nuclear Plant prototype—an HTGR prototype being developed by DOE. However, DOE and the NRC jointly determined that the NGNP licensing strategy would not apply 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 Staff Requirements Memorandum (SRM) on COMSECY-08-0018, 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 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 building, as a long-term objective, on the NRC reviews of small modular reactor (SMR) 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). 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 pre-application and license review of the NGNP prototype and long term plans for developing a new risk-informed regulatory framework for advanced reactors.				
Q. No 13			Country Switzerland	Article General	Ref. in National Report Introduction p. 18
Question/ Comment	(P) NRO	New Reactor Licensing, p. 18	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRO was established in 2006 and currently has a staff of approximately 500. The staffing level is expected to decrease to 475 in FY2012. 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.				
Q. No 14			Country Switzerland	Article General	Ref. in National Report Introduction p.18
Question/ Comment	(P) NRO	New Reactor Licensing, p. 18	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 U.S. 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, and 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 assure that these and other specific components are designed to enable inservice inspections be performed in accordance with regulations.				
Q. No 15			Country Canada	Article Article 6	Ref. in National Report 46
Question/ Comment	(P) DIRS	6.3.3	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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The latest results reported for the Industry Trends Program (ITP), including trends for all 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." This document provides both the ten-year trends and short term performance for the ITP performance indicators. As stated in SECY-10-0028, no statistically significant adverse trends were observed in the Industry Trends Program performance indicator data from the most recent 10 years (fiscal year (FY) 2000 to FY 2009). All ITP performance indicators continued to show an improving trend for this ten-year period.				
Q. No 16			Country Canada	Article Article 6	Ref. in National Report 47
Question/ Comment	(P) DIRS	6.3.3	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.		

<table>
<tr><td>Question number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Answer</td><td colspan="5">The events that are tracked in the first level (Tier 1) ITP Baseline Risk Index for Initiating Events are:

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

1. Loss of offsite power (LOOP)
2. Loss of vital AC bus (LOAC)
3. Loss of vital DC bus (LODC)
4. Loss of main feedwater (LOMFW)
5. Very small loss of coolant accident (VSLOCA)
6. PWR general transient (TRAN)
7. PWR loss of condenser heat sink (LOCHS)
8. PWR stuck open safety/relief valve (SORV)
9. PWR loss of instrument air (LOIA)
10. Steam generator tube rupture (SGTR)

<u>Boiling Water Reactors (BWRs)</u>
1. Loss of offsite power (LOOP)
2. Loss of vital AC bus (LOAC)
3. Loss of vital DC bus (LODC)
4. Loss of main feedwater (LOMFW)
5. Very small loss of coolant accident (VSLOCA)
6. BWR general transient (TRAN)
7. BWR loss of condenser heat sink (LOCHS)
8. BWR stuck open safety/relief valve (SORV)
9. BWR loss of instrument air (LOIA)

In general, these risk-significant initiating event types, cover approximately 60% of the internal event core damage risk (excluding internal flooding) from the operating commercial nuclear power plants in the United States. Also, these initiating events do not overlap.</td></tr>
<tr><td>Q. No
17</td><td></td><td></td><td>Country
Canada</td><td>Article
Article 6</td><td>Ref. in National Report
44</td></tr>
<tr><td>Question/ Comment</td><td>(P) NRO
(S) DORL</td><td>6.3.1</td><td colspan="3">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.</td></tr>
</table>

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	An early site permit (ESP) allows an applicant to attain finality and resolution of certain environmental and siting issues and, optionally, of emergency planning issues prior to receiving a combined license (COL) application. To the extent these issues are resolved, they are not subject to further review or hearing at the Construction permit (CP) or COL licensing proceeding stage. The degree of finality that can be achieved is dependent 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" (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 pre-construction activities which otherwise would have to await a construction permit or combined license. Certain pre-construction 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 structures, systems, or components would require an LWA.				
Q. No 18			Country Canada	Article Article 6	Ref. in National Report 45
Question/ Comment	(P) NRO (S) DIRS	6.3.2	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 NPP development these inspectors are assigned and role played by the Office of New Reactors in the transition from construction overseers to compliance oversight.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The 10 CFR part 52 licensing process has several specific milestones. The key points from an oversight aspect, are the issuance of a Limited Work Authorization (LWA), the issuance of a Combined Operating License (COL), and the 10 CFR part 52.103g decision. The LWA allows a licensee to do specific construction tasks that may be safety related prior to 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, a nuclear power plant (NPP). The conditions that must be met are primarily made up of the completion of all the 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 the Office of New Reactor (NRO) to the Office of Reactor Regulation (NRR). The transition of organizational responsibility from NRO to NRR will occur following the 103g decision. Although NRR will have the responsibility for oversight after the 103g decision, it is expected that NRO construction inspectors will remain onsite for an appropriate amount of time to ensure that a smooth transition occurs from NRO to NRR.				
Q. No 19			Country Canada	Article Article 6	Ref. in National Report 45
Question/ Comment	(P) DLR	Article 14, Sec 14.1.2.1, p. 115	Once revisions to the Standard Review Plan and the Generic Ageing Lessons Learned (GALL) Report are made will the lessons learned affect the recent licence renewals that have been issued?		
Answer	The revision 2 of the Standard Review Plan and the GALL Report were published in December, 2010. The lessons learned from these documents affect the license renewals in the following ways: (1) for license renewal applications that are currently under review, the NRC is requesting the applicants to demonstrate that their applications have incorporated the lessons learned from the revised documents; (2) for those plants who have already received renewed license, the agency is evaluating a range of options to ensure these plants take advantage of the lessons learned from the revised guidance documents. The options include, but are not limited to, issuance of generic communication to the plants highlighting the key aspects of the renewed ageing management guidance and methodology to renewed license holders, and inspecting the licensee's programs prior to entering the extended period of operation to verify that the plant's ageing management programs have been expanded to incorporate relevant operating experience.				
Q. No 20			Country China	Article Article 6	Ref. in National Report 6

<table>
<tr><td>Question number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Question/ Comment</td><td>(P) DIRS</td><td>6.3.3</td><td colspan="3">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 110-5 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.</td></tr>
<tr><td>Answer</td><td colspan="5">The quantification method used for formulating the related changes in CDF is given by a formula found in the Inspector Manual Chapter 0313, “Industry Trends Program,” Appendix D, Baseline Risk Index for Initiating Events (BRIIE), page D1 – 3. See the following link for BRIIE formulation:

http://adamswebsearch2.nrc.gov/idmws/DocContent.dll?library=PU_ADAMS^pbntad01&LogonID=f2fad323d823efdbf1dbcf05780cb739&id=081510084

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 industry-wide data to generate the “common industry current frequency” for each initiating event category.</td></tr>
<tr><td>Q. No 21</td><td></td><td></td><td>Country France</td><td>Article Article 6</td><td>Ref. in National Report § 6.3.2 - p.45</td></tr>
<tr><td>Question/ Comment</td><td>(P) DPR</td><td>6.3.2</td><td colspan="3">In the previous reports, the USA 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 USA 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?</td></tr>
<tr><td>Answer</td><td colspan="5">The United States of America Fifth National Report for the Convention on Nuclear Safety, 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 IAEA and Western European Nuclear Regulators’ Association periodic safety review guidance.

Specifically in Section 14.1.3.7, it is stated 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 re-examine nuclear power plant design assumptions absent new information.</td></tr>
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Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 22			Country France	Article Article 6	Ref. in National Report § 6.3.4 - p.47
Question/ Comment	(P) RES	6.3.4	"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	Calculations are not performed for all events reported in licensee event reports (LERs) and/or inspection reports During an initial screening performed by a 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% to 85% of all the 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.				
Q. No 23			Country France	Article Article 6	Ref. in National Report § 6.3.5 - p.49
Question/ Comment	(P) DIRS	6.3.5	"The US NRC screens carefully the operating experience of foreign facilities. Past events show the need of such a screening. Could the USA 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."		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC screens events from foreign facilities, primarily through review of reports submitted to the International Reporting System for Operating Experience (IRS) and through the International Nuclear and Radiological Event Scale (INES). Events which 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 determine the best method for applying the lessons learned. The Forsmark event was screened in for such evaluation. A presentation on the event causes and consequences was made to 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 on August 17, 2006 to inform industry and the public of the event and the information that was available at the time, and a supplement to the IN, 2006-18 supp. 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 the Kruemmel Nuclear Plant during a transformer fire in 2007, a scenario which 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 the Tihange Nuclear Station from 2007-2008 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.				
Q. No 24			Country France	Article Article 6	Ref. in National Report § 6.3.4 - p.48
Question/ Comment	(P) RES	3.6.4	"The present paragraph shows an improving trend according to the last three indicators. Could the US 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 Accident Sequence Precursor (ASP) remains alert for commonalities and would alert our NRR staff if we observed any. However, ASP is just one of many regulatory tools and would be much more sensitive to negative than positive trends. However, 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., FYs 2001–2003).				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 25			Country India	Article Article 6	Ref. in National Report 6.3.4 (Last bullet), Page 48
Question/ Comment	(P) RES	3.6.4	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. BWR precursor counts were examined, and no significant trend was observed.				
Q. No 26			Country Japan	Article Article 6	Ref. in National Report Sec.6.3.5, p49
Question/ Comment	(P) DIRS	3.6.5	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 the Office of Nuclear Reactor Regulation (NRR) and the Office of New Reactors (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, collections of generic communications and international reports, and 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 contain an analysis of the event, diagrams of systems involved, relevant pictures, and links to related operating experience. The Office of New Reactors (NRO) participates in the daily screening of operating experience. Any information from events examined by the operating experience branch which are determined to be of potential interest to NRO is forwarded to contacts established within NRO to ensure their awareness. In addition, NRO has 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 the Office of New Reactors stared posting OpE/ConE COMM reports to the Operating Experience COMM forum. NRO staff perform similar roles to that of NRR OpE staff, in terms of managing and processing OpE/ConE under the evaluation process titled "Issue for Resolution" (IFR).				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 27			Country Japan	Article Article 6	Ref. in National Report Sec.6.3.5, p48
Question/ Comment	(P) DIRS	6.3.5	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 NRC and the Institute of Nuclear Power Operations (I NPO) is established by a Memorandum of Agreement between the two organizations. The NRC operating experience branch maintains communication with the INPO groups analyzing operating experience. This communication occurs through bi-weekly phone calls to exchange information on events of interest or trends that have been noted and an annual meeting between the two groups to present ongoing projects and upcoming work. Communication with the World Association of Nuclear Operators (WANO) is conducted primarily through INPO. The NRC also receives INPO operating experience reports for consideration of the relevant operating experience.				
Q. No 28			Country Mexico	Article Article 6	Ref. in National Report Section 6.1, page 43
Question/ Comment	(P) DIRS	6.1	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 this Safety Measure 1 is a reflection of industry performance. According to the Congressional Budget Justification for Fiscal Year 2011, 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 nuclear power plants. Inspection results show that all of the nuclear power plants are operating safely. The fourth measure tracks the trends of several key indicators of nuclear power plant safety. This measure is the broadest measure of the safety of nuclear power plants, incorporating the performance results from all plants to determine industry average results.				
Q. No 29			Country Romania	Article Article 6	Ref. in National Report section 6.3.10 Reactor Safety Research P
Question/ Comment	(P) RES	6.3.10	Could you please provide some information on the status of the State-of-the-Art Reactor Consequence Analyses (SOARCA) project?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	As its name implies, the SOARCA research project is designed to develop realistic estimates of the potential public health effects, which might result from a nuclear power plant 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 CDF criterion of 10-7 (i.e., "one-in-ten-million") per year to select scenarios for analysis. NRC staff is currently addressing comments that have originated 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, 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 website for additional and updated information on the SOARCA Project: http://www.nrc.gov/about-nrc/regulatory/research/soar/overview.html				
Q. No 30			Country Russian Federation	Article Article 6	Ref. in National Report section 6.3.2, p. 45
Question/ Comment	(P) DRA		To what extent the risk monitoring technology is applied at U.S. NPPs?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Most risk monitoring technology for the day-to-day operation at plants is done to comply with 10 CFR 50.65 (a)(4) – the Maintenance Rule requirement for managing and assessing workweek risk. From what we've gathered, most all licensees use a software derived monitor. The most popular ones are EOOS (Equipment Out Of Service) and Safety Monitor. The lesser popular one is Paragon (formerly ORAM-Sentinel). These packages are used primary at the site Work Control Center and some licensees run them in the Control Room as well. The extent they're 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 something fails at times when workweek managers are unavailable to run the software to make an assessment on plant risk status. Currently, other than what we require as part of the maintenance rule, the vast majority of licensees have no need to continuously monitor changes in overall risk.				
Q. No 31			Country Spain	Article Article 6	Ref. in National Report Section 10.3.4, page 87
Question/ Comment	(P) DRA (S) NRO	Article 10, Sec. 10.3.4	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	In the context of licensing actions for current operating plants (i.e., those plants licensed under 10 CFR Part 50), the guidance related to the technical adequacy (quality) of the PRAs/PSAs used in risk-informed decision-making is provided in Regulatory Guide (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 regulatory guide was issued in early 2004 and addressed internal initiating events at full power operations. This regulatory guide has been revised as the PRA quality standard has been revised and expanded to incorporate external initiating events (e.g., fires, seismic). Prior to the initial standard being issued, the review of the quality of the licensee's PRA/PSA relied heavily on the expertise and knowledge of the individual staff members. These staff typically had decades of experience developing and utilizing plant-specific PRAs. For current operating plants, there is no overarching regulation that requires a PRA/PSA and thus there is no specific inspection program on PRA/PSA quality. Rather, PRA/PSA quality is addressed when licensees request risk-informed licensing actions. 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 Regulatory Guide: monitor PRA inputs and collect new information, ensure cumulative impact of pending plant changes are considered, maintain configuration control of the computer codes used in the PRA, identify when PRA needs to be updated based on new information or new models/techniques/tools, and ensure peer review is performed on PRA upgrades. All of these aspects are evaluated by the staff in the review of a licensee's risk-informed licensing action. New reactor applicants and licensees are subject to specific PRA requirements. Design certification or combined license applicants are required to provide a description of the design-specific or plant-specific PRA and its results (10 CFR 52.47 and 52.79, respectively). NRC staff reviews this documentation in accordance with Chapter 19 of the Standard Review Plan (NUREG-0800), which refers to RG 1.200. After a license is issued, a combined license holder is required to develop a Level 1 and 2 PRA no later than its scheduled date for initial loading of fuel (10 CFR 50.71). This PRA must cover initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to that scheduled date for initial loading of fuel. Additional requirements exist for maintaining the PRA and upgrading it to cover consensus standards endorsed beyond this point. As discussed above, RG 1.200 is the document in which the NRC staff endorses these consensus standards.				
Q. No 32			Country Spain	Article Article 6	Ref. in National Report Section 6.3.11, page 54
Question/ Comment	(P) DE (S) OGC	6.3.11	What training is used for inspectors to receive and treat concerns and allegations relating to safety issues?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Inspection Manual Chapter 1245 identifies the required training for all Operating Reactor Program inspectors and Appendix A, "Basic-Level Training and Qualification Journal" 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, annual web-based Allegations Refresher Training is required, for all NRC employees, so that they are prepared to deal with an allegation, if necessary.				
Q. No 33			Country Sweden	Article Article 6	Ref. in National Report 47
Question/ Comment	(P) RES	6.3.4	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 MOSC factors into the Accident Sequence Precursor (ASP) Program. However, if MOSC factors are observed at a nuclear power plant experiencing an operational event, they sometimes can be taken into account in the human reliability analysis (HRA) portion of ASP analysis. Some specific MOSC factors can be linked to performance shaping factors in our HRA analysis.				
Q. No 34			Country Ukraine	Article Article 6	Ref. in National Report page 45
Question/ Comment	(P) DIRS	6.3.2	It is stated that certain changes have been made in Reactor Oversight Process in 2009. What were the main reasons for the changes?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The 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, feedback received from internal and external stakeholders, and direction and insight contained in several Commission staff requirements memoranda (SRM). The staff analyzes the information from these various sources to gain insights regarding ROP effectiveness and potential areas for improvement. Based on each self-assessment, the staff develops a consolidated listing 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 the status of past commitments and provides a listing of new commitments in each annual ROP self-assessment. The staff's annual self-assessment for CY 2009 is publicly available (ref. ADAMS Accession No. ML100550404), and contains more discussion about the specific reasons for the more significant changes made to the ROP in 2009.				
Q. No 35			Country Ukraine	Article Article 6	Ref. in National Report Page 47
Question/ Comment	(P) RES	6.3.4	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 CLERP evaluations are not within the scope of the ASP program. However, NRC utilizes 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 effort to expand the SPAR models to beyond Level 1; however, we currently do not have the modeling capabilities to analyze events in relation to CLERP or large early-release frequency (LERF).				
Q. No 36			Country United Kingdom	Article Article 6	Ref. in National Report Page 50, Section 6.3.7

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<tr><td>Question number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Question/ Comment</td><td>(P) DPR</td><td>6.3.7</td><td colspan="3">The report says that "The Executive Director for Operations [EDO] is authorized to approve final rules that do not involve policy changes." Could the USA 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?</td></tr>
<tr><td>Answer</td><td colspan="5">As stated in existing 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:

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.</td></tr>
<tr><td>Q. No 37</td><td></td><td></td><td>Country Ukraine</td><td>Article Article 7.1</td><td>Ref. in National Report page 192</td></tr>
<tr><td>Question/ Comment</td><td>INPO</td><td>7.C.i</td><td colspan="3">What criteria are used to classify events under the following event categories:
• SOERs
• Significant Event Reports (SERs)
• Significant Event Notifications (SENs)</td></tr>
</table>

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The above non-NRC documents are used to report to the Institute of Nuclear Power Operations (INPO) significant events or significant trends. These report types have been replaced by INPO Event Reports (IERs) 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 sole criteria for assigning significance. Rather, the effect or possible effect on nuclear safety is the prime consideration, though effects of the event on reliability are also considered.				
Q. No 38			Country China	Article Article 7.2.1	Ref. in National Report 7.2.2
Question/ Comment	(P) OGC	7.2.2	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 Part 50, and not the one-step licensing process set forth in 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 Part 50 two-part licensing scheme, an applicant needs to acquire a construction permit before beginning construction of a nuclear power plant. The process is as follows. First, the applicant submits a preliminary safety analysis report (PSAR) along with its construction permit application. The PSAR includes technical information about the safety of the site and safety of the plant design. 10 C.F.R. Part 50.34(a) details what the applicant must put in its application and PSAR. The NRC will grant a construction permit 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. Under the Part 50 licensing scheme, however, a construction permit does not authorize actual operation. After construction, the applicant must submit a separate operating license application as well as 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. 10 C.F.R. Part 50.35 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.				
Q. No 39			Country Japan	Article Article 7.2.2	Ref. in National Report Sec.7.2.2, p57

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) OGC (S) NRO	7.2.2	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 what is the scope of the NRC's safety review of a combined license (COL) application which: (i) references a final design certification rule (DCR) but (ii) proposes to use a design approach in some limited aspect which is different from the DCR ("departing" from the DCR"). First, in a COL proceeding, the NRC reviews those portions of the proposed nuclear power plant'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, NRC reviews these site-specific design elements during the COL application proceeding. In addition, the DCR does not address non-design related NRC requirements (e.g., emergency preparedness; security programs, operational programs). Therefore, NRC also reviews the COL applicant's compliance with these non-design requirements in the COL application review. Second, any departures from the design of a referenced DCR which are proposed by the COL applicant must be reviewed by the NRC in 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 ITAAC in the DCR have been met, the NRC would determine whether it could make such a finding.				
Q. No 40			Country Sweden	Article Article 7.2.2	Ref. in National Report 57
Question/ Comment	(P) OGC (S) NRO	7.2.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	It is true that the NRC regulations contain two alternative ways of licensing nuclear power plants. The first approach, which NRC/AEC used for all currently operating nuclear power plants, is a "two-step" licensing process where the applicant first gets a construction permit, and then gets an operating license (the 10 CFR Part 50 process). The second approach, which involves early site permits, design certifications, combined licenses and manufacturing licenses, is in 10 CFR Part 52. Under the old Part 50 process, most design issues were not resolved until *after* construction began. The aim of the original Part 52 was both standardization of design and early resolution of design and site issues. The 2007 rulemaking to amend Part 52 addressed the concern that the overall regulatory relationship between Part 50 and Part 52 was not always clear. This rulemaking clarified whether Part 50's safety requirements apply to each of the licensing processes in Part 52 (those licensing processes include early site permitting, standard design approval, standard design certification, combined license, and manufacturing license). But the alternative licensing process in Part 50 was *not* amended in the part 52 update rulemaking. Specifically, the 2007 amendments to Part 52 clarified that plants licensed under Part 52 procedures must nonetheless comply with the generally applicable technical requirements from Part 50 (these applicable requirements are identified in Part 52, so there is no ambiguity as to what constitutes an "applicable requirement"). For example, Part 52 provides that the general design criteria in 10 CFR Part 50, Appendix A, applies to nuclear power plants licensed under Part 52. The 2007 amendments also clarified that plants licensed under the Part 52 process must comply with certain administrative requirements in Part 50. By identifying the specific Part 50 requirements which are applicable, the 2007 amendments removed the ambiguity of determining what requirements in Part 50 are "technically relevant" to nuclear power plants approved or licensed under the procedures of Part 52.				
Q. No 41			Country China	Article Article 7.2.3	Ref. in National Report 7.2.2
Question/ Comment	(P) DLR	Introduction, License Renewal, p.16	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Yes, all nuclear power plants to date have requested, and received 20-year license extensions (following NRC approval of their license renewal applications). As stated in NRC regulations (10 CFR 54.31), the renewal period cannot exceed 20 years. The precise language in the regulation is as follows: § 54.31 (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. A renewed license may be subsequently renewed in accordance with all applicable requirements.				
Q. No 42			Country Japan	Article Article 7.2.3	Ref. in National Report Sec.7.2.3, p58
Question/ Comment	(P) DIRS (S) OGC	7.2.3	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Resident and regional inspectors are assigned different inspection procedures in the NRC baseline inspection program. All baseline inspections which require completion are identified in Appendix A to Inspection Manual Chapter 2515, "Risk-Informed Baseline Inspection Program." A subset of these baseline inspections identified in Appendix A to IMC 2515 is normally completed by regional inspectors. These baseline inspections which are normally completed by regional inspectors are identified in paragraph 8.1 of IMC 2515, "Light-Water Reactor Inspection Program -- Operations Phase." An inspection plan consisting of approximately 15 months of activities (from the issuance of the annual assessment letter) is used to communicate what inspections 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). Proposed inspection plan is reviewed during the end-of-cycle and mid-cycle meetings which are attended by staff from both headquarter and regional offices (resident inspectors participate in these meetings as well). These inspections plans are included in our end-of-cycle and mid-cycle letters to the licensees and are also publically available on the NRC website. In addition Resident Inspectors and Regions Offices communicate on a daily basis on activities and plant performance. NRC headquarters and the Regions communicate regularly, and at least bi-weekly during counterpart phone calls.				
Q. No 43			Country Sweden	Article Article 7.2.3	Ref. in National Report 58
Question/ Comment	(P) DIRS (S) OGC	7.2.3	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 who are assigned to the site where a licensee is constructing a nuclear power plant under Title 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 Inspection Manual Chapter (IMC) 2503, "Construction Inspection Program: Inspection 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 at a timeframe (about 6 months to a year) before the NRC, specifically, the Commission, makes a decision on whether the acceptance criteria in the combined license were met (Title 10 CFR Part 52.103(g) finding). Assignment of Operational Resident Inspectors before the Commission makes their 52.103(g) finding ensures an orderly transition from construction to operational oversight.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 44			Country Euratom	Article Article 8.1	Ref. in National Report page 68
Question/ Comment	(P) OIP (S) DPR	8.1.4	"Since 1999, the NRC has participated in more than 20 Integrated Regulatory Review Teams or 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 US operating reactor program." Could the USA clarify how many of the high-level technical experts per year were involved in IRRS missions in EU Member States? How many IRRS missions have been carried out in the USA 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)?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The United States sent high-level technical experts to the IRRS missions and follow-up missions in France (2006, follow-up 2008, 1 expert), Germany (2008, 1 expert), Spain (2008, follow-up 2011, 2 experts), and the United Kingdom (2006, follow-up 2009, 1 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. As such, regulations pertaining to the entire U.S. fleet of 104 operating reactors were assessed. A complete list of U.S. operating power reactors can be found in the U.S. 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 had some involvement in preparing for and/or participating in the IRRS mission. Of those NRC staff who had involvement, it is estimated that approximately 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 EU member states including the Czech Republic, Finland (2 experts including 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%/year of the NRC's budget for 2 years. For senior NRC experts participating in foreign IRRS missions, the overall level of effort is two weeks of travel time for the mission (or one week for a follow-up mission), plus approximately one week of preparation (reading advance reference materials, formulating questions, consulting with NRC experts about the country's regulatory program, etc.).				
Q. No 45			Country Japan	Article Article 8.1	Ref. in National Report Sec.8.1.4, p68
Question/ Comment	(P) OIP	8.1.4	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC derives great benefit from participation in the IAEA Commission on Safety Standards (CSS), as well as 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 evaluate whether (1) 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) to identify any key differences between the IAEA document and NRC or other U.S. agency regulations and guidance documents. The gap analysis results are then used by the NRC staff 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 CSS. 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 agency-wide Knowledge Management database that is later consulted when a revision to an NRC regulation or regulatory guide is being considered, in order to address any potential gaps between the proposed NRC documents and the IAEA Safety Standards, as appropriate.				
Q. No 46			Country Japan	Article Article 8.1	Ref. in National Report Sec.8.1.5.2, p71
Question/ Comment	(P) HR	8.1.5.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 agency-wide human capital goals and strategies align with the agency's mission.				
Q. No 47			Country Japan	Article Article 8.1	Ref. in National Report Sec.8.1.7, p76
Question/ Comment	(P) DPR	8.1.7	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 teem in the NRC?		
Answer	NRC is considering each recommendation and suggestion contained in the IRRS mission report and will develop actions to address them, where appropriate. NRC will provide a summary of its actions to address the recommendations and suggestions to the follow-up IRRS mission team.				
Q. No 48			Country Japan	Article Article 8.1	Ref. in National Report Sec.8.1.5.2, p70

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) HR	8.1.5.2	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. We use 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.				
Q. No 49			Country Japan	Article Article 8.1	Ref. in National Report Sec.8.1.5.2, p71
Question/ Comment	(P) HR	8.1.5.2	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: expanded use of on-line 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 number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 50			Country Pakistan	Article Article 8.1	Ref. in National Report Section 8.1.5.2, Page 70
Question/ Comment	(P) HR	8.1.5.2	US 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 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 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 regarding their career goals and working with their supervisor to develop an executive development plan 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.				
Q. No 51			Country Romania	Article Article 8.1	Ref. in National Report Section 8.1.5.2 Human Resources
Question/ Comment	(P) HR	8.1.5.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 of area of practice rather than by strict alignment with agency offices or regions. This form provides the ability for staff to share knowledge across different organizations within NRC. Currently, access to the Knowledge Center is only available internal to 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.				
Q. No 52			Country Russian Federation	Article Article 8.1	Ref. in National Report section 8.1.5, p. 70
Question/ Comment	(P) CFO	8.1.5.1	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 full cost for NRC research activities in FY 2010 is $126.4 million.				
Q. No 53			Country Russian Federation	Article Article 8.1	Ref. in National Report section 8.1.7, p. 76
Question/ Comment	(P) DPR	8.1.7	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 procedure, Guidance for Integrated Regulatory Review Service dated 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. Since 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.				
Q. No 54			Country Spain	Article Article 8.1	Ref. in National Report Section 8.1.3.3.
Question/ Comment	(P) OI	8.1.3.3	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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, Maryland. OI is comprised of experienced Federal Criminal Investigators and a professional/specialized investigation support staff. OI develops and implements policies and 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 Department of Justice for prosecution consideration. OI keeps the Nuclear Regulatory Commission (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 Inspector General.				
Q. No 55			Country Spain	Article Article 8.1	Ref. in National Report Section 8.1.5
Question/ Comment	(P) HR	8.1.5.2	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 where 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.				
Q. No 56			Country Spain	Article Article 8.1	Ref. in National Report Section 8.1.5.2
Question/ Comment	(P) HR (S) OE	8.1.5.2	Human Resources Do you carry out annual surveys on working climate at NRC and staff perception of the organization?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 Office of the Inspector General (OIG). The NRC has been rated the best place to work in the Federal Government as a result of the two last 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, where 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, the 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 agency wide about enhancing the safety culture. The Task Force also benchmarked external organizations. These ideas have been taken forward in staff training and a number of internal programs.				
Q. No 57			Country Sweden	Article Article 8.1	Ref. in National Report 70
Question/ Comment	(P) CFO	8.1.5.1	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 US CNS national report the reported sums for FY 2005 and FY 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 three 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.				
Q. No 58			Country Ukraine	Article Article 8.1	Ref. in National Report Page 76
Question/ Comment	(P) DPR	8.1.7	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 53.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 59			Country United Kingdom	Article Article 8.1	Ref. in National Report Page 68, Section 8.1.4
Question/ Comment	(P) OIP	8.1.4	The report says that the USA "...intends to continue to plan for an OSART mission in the United States every 3 years." Noting that there is an extensive program of INPO evaluations at US reactor sites every two years (page 181), would the USA 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 USA) has invited one OSART mission per year, plus follow-up missions, in every year since 2002? Does the USA 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 OSART mission every three years to coincide with the three 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 Reactor Oversight Process (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, NRC believes that comparisons and discussions of whether one type of evaluations 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 NRC's decision nor can NRC require that these missions be accomplished on any periodicity, although, the NRC works with the U.S. nuclear industry to accomplish one OSART mission every three years. Considering the NRC ROP baseline inspection program that is in place, the INPO reviews, and the voluntary nature of OSARTs, NRC believes that the current goal of encouraging an OSART mission every three years is reasonable for U.S. power plants.				
Q. No 60			Country India	Article Article 9	Ref. in National Report 9.3, Para 2, Page 80

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) OE	9.3	NRC enforcement program allows for imposing civil penalties & 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 (nov)and/or Order (if applicable) and a proposed imposition of the civil penalty amount. The NOV 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, either denying the violation or showing 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 CY2007 and CY2009, the NRC issued 4 Orders that imposed civil penalties (all material licensees). Specific cases of which civil penalties were imposed are located within the NRC Office of Enforcement 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 Department of Justice (DOJ), cases involving investigations are provided for DOJ review and DOJ makes the determination to pursue a case for criminal action.				
Q. No 61			Country Japan	Article Article 9	Ref. in National Report Sec.9.3, p82
Question/ Comment	(P) OE	9.3	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Unlike the Operating Reactor Oversight Program, which focuses on monitoring and evaluating the performance of existing nuclear power plants, regulatory oversight for new reactors focuses on the construction of reactor facilities (that is, the period between licensing and initial operation). Additional information regarding 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 for issues not under the Reactor Oversight Process 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) programs and/or submitted documents, or through information provided to NRC by allegations or requests by members of the public. Any identified apparent violation(s) 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 by 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 by issuing a non-cited 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 by NRC. Additional information regarding the enforcement processes is located at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.				
Q. No 62			Country Japan	Article Article 9	Ref. in National Report Sec 9.1,9.2, p79
Question/ Comment	(P) DORL (S) OGC	9.1 and 9.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 U.S., the prime responsibility for safety is conveyed through the license, rather than through the Atomic Energy Act. 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).				
Q. No 63			Country Korea, Republic of	Article Article 9	Ref. in National Report p 79
Question/ Comment	(P) OGC	9.1	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 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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 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 we can do, however, is ensure that we are constantly evaluating past mistakes to ensure that those mistakes are not repeated in the future. And the NRC does this by constantly evaluating the "lessons learned" from past regulatory experiences, both good and bad.				
Q. No 64			Country Sweden	Article Article 9	Ref. in National Report 165
Question/ Comment	(P) DORL (S) NRO	19.2	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 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 technical specifications. The NRC would consider improved standard technical specifications (ITSB), but would not approve such a change with compliance with ITSB as the sole basis. The TS 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/systems. The TS generated for the new designs reflect the existing STS format and content, and become the generic TS (GTS) that are approved with the design certification rule. The GTS are required to be adopted by the new plants. The adoption of subsequent STS changes (TSTFs) will be optional, as are current TSTF changes to the existing STS.				
Q. No 65			Country Canada	Article Article 10	Ref. in National Report 90
Question/ Comment	(P) DIRS	10.4.1.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 with regard to the development of possible options for enhancing oversight of 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 plant. 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 a staff requirements memorandum (SRM) on SECY–04-0111 that included the following: 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, 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 inspection manual chapters (IMCs) and inspection procedures (IPs). The staff submitted to the Commission, SECY-06-0122, "Safety Culture Initiative Activities to Enhance the Reactor Oversight Process and Outcomes of the Initiative," 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 NRC Regulatory Issue Summary 2006-13, "Information on the Changes Made to the Reactor Oversight Process to More Fully Address Safety Culture" (ADAMS ML061880341) which provides a summary of these changes. The Office of Nuclear Reactor Regulation (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.				
Q. No 66			Country China	Article Article 10	Ref. in National Report 10

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DIRS	10.4.1.2	Which safety culture indicators used to monitor plant performance?		
Answer	The ROP safety culture cross-cutting components which are used to evaluate findings at licensed facilities can be found in Inspection Manual Chapter (IMC) 0310, and currently include: <u>Decision-Making</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 assure 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 (OE) 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 their activities and practices, as appropriate, to assess performance and identify areas for improvement. <u>Self- and Independent Assessments</u> - The licensee conducts self- and independent assessments of their 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 also describes four "Other" components which 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: <u>Accountability</u> - Management defines the line of authority and responsibility for nuclear safety. <u>Continuous learning environment</u> - The licensee ensures that a learning environment exists. <u>Organizational change management</u> -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. <u>Safety policies</u> - Safety policies and related training establish and reinforce that nuclear safety is an overriding priority.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 67			Country France	Article Article 10	Ref. in National Report § 10.3 p. 84
Question/ Comment	(P) DRA	10.3	"US NRC has developed a public website for the risk-informed and performance plan. Could USA indicate if this site is frequently consulted and give some feedback on this action? "		
Answer	The staff updates the information on this website as new information is made available and frequently uses the information in developing related briefing packages, plans, etc.. At a minimum, the website is updated about every six months since that is the frequency at which an update on the status of risk-informed activities has been provided to the Commissioners. The NRC does not maintain a count of website "hits" or frequency at which staff or members of the public visit the website.				
Q. No 68			Country France	Article Article 10	Ref. in National Report § 10.3.3 p. 85/86
Question/ Comment	(P) DRA	10.3.3	"Industry has developed 8 separate initiatives to improve existing technical specifications. How does the US NRC make sure that these initiatives have a positive effect on safety? "		
Answer	Each of the initiatives, as they are developed, were submitted to the Nuclear Regulatory Commission (NRC) by several industry organizations in the form of topical reports, industry methodology documents, and/or as specific proposed changes to the standard Technical Specifications. The NRC technical staff provided extensive review and comment, often resulting in requests for additional information (RAI) and follow-on submittals by the industry. In some cases, changes were made to the original proposed initiative. The final product(s) 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 a nuclear power plant requires a plant-specific license amendment, which also provides an opportunity for the NRC to assure plant safety is not adversely impacted and to assure that the initiative is being implemented on a plant-specific basis consistent with the NRC staff safety evaluation. After issuance of a plant-specific amendment, the inspection and reactor oversight process is used by regional NRC staff to ensure the licensee is properly applying the initiative.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 69			Country Germany	Article Article 10	Ref. in National Report page 88, paragraph 10.4.1.2, second para
Question/ Comment	(P) DIRS	10.4.1.2	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 Reactor Oversight Process is used to evaluate each plants' 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.				
Q. No 70			Country Germany	Article Article 10	Ref. in National Report page 90, para. 10.4.2
Question/ Comment	(P) OE	10.4.2	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 management and employees are dedicated to putting safety first. As discussed in the report, the NRC's Office of the Inspector General conducts an independent Safety Culture and Climate Survey every three years, with the last one in May 2009. The NRC takes a combination of Agency-wide 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 agency wide survey, the agency 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 number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 71			Country Japan	Article Article 10	Ref. in National Report Sec.10.4.1.2, p68
Question/ Comment	(P) DIRS	10.4.1.2, P. 88	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 which outlines the Commission's expectations that licensee's foster a strong safety culture. The industry relies on the Institute of Nuclear Power Operations to advocate and develop tools for fostering this expectation. NRC inspectors have the option to review self and independent assessments as needed per specific inspection procedures. For example, Inspection Procedure 71152, "Problem Identification and Resolution," states: *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 long standing and substantive cross-cutting issues at a plant, the NRC may request the performance of licensee safety culture assessments.				
Q. No 72			Country Romania	Article Article 10	Ref. in National Report section 10.4.1 NRC Monitoring of License
Question/ Comment	(P) DIRS	10.4.1.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC inspector qualification and re-qualification training manuals provide on-line training for the inspectors in the area of safety culture and 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 neede				
Q. No 73			Country Romania	Article Article 10	Ref. in National Report section 10.4.1 NRC Monitoring of License
Question/ Comment	(P) DIRS	10.4.1.2	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 definition and aspects located in IMC 0310 as follows: *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.*				
Q. No 74			Country Russian Federation	Article Article 10	Ref. in National Report Section 10.3, pp. 83 – 87
Question/ Comment	(P) DRA	10.3	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The general guidance related to the use of PRAs/PSAs in risk-informed decision-making, in the context of licensing actions (e.g., relief requests or license amendments) is provided in Regulatory Guide 1.174 and the guidance related to the technical adequacy of the PRAs/PSAs used in risk-informed decision-making is provided in Regulatory Guide 1.200. There are also application-specific guidance such as Regulatory Guide 1.177 for risk-informing technical specifications, Regulatory Guide 1.178 for risk-informing inservice inspections, and Regulatory Guide 1.201 for risk-informed categorization process for special treatment requirements. These application-specific guides provide additional guidance for the use of PRAs/PSAs for these applications. In addition, some risk-informed regulations (e.g., 10 CFR 50.69, 10 CFR 50.71(h)(1) and (h)(2) and 10 CFR 52.47) contain specific requirements for the PRA/PSA that are specific to those regulations.				
Q. No 75			Country Russian Federation	Article Article 10	Ref. in National Report section 10.4.1, p. 88
Question/ Comment	(P) DIRS	10.4.1.2	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" for their self-assessments.				
Q. No 76			Country Slovenia	Article Article 10	Ref. in National Report 10.3.1,p.84
Question/ Comment	(P) DRA	10.3.1	How many licensees have decided to implement the 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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 nuclear plant has recently requested to be a pilot application of this rulemaking. 10 CFR 50.69(b)(2) 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, which is endorsed by Regulatory Guide 1.200. The companion NRC staff review guidance is Section 19.1 of the Standard Review Plan (NUREG-0800).				
Q. No 77			Country Slovenia	Article Article 10	Ref. in National Report 10.4.1.2,p.88
Question/ Comment	(P) DIRS	10.4.1.2	Could you describe an example of the use of ROP in the assessment of the safety culture of the licensee?		

Questio n number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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: decision-making, 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 Inspection Manual Chapters (IMCs) 0310 and 0612. The ROP was developed with the presumption that plants which had significant performance issues with cross-cutting areas would be revealed through the existence of safety-significant performance indicators (PIs) or inspection findings. Accordingly, in identifying a Substantive Cross Cutting Issues (SCCI), there must be an NRC concern that the licensee has had multiple performance deficiencies that had commonality in the central cross-cutting aspects (CCAs). The cross-cutting components and aspects are described in IMC 0310, "Reactor Oversight Process Safety Culture Components and Aspects." CCAs are assigned and SCCIs 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 mid-cycle and end-of-cycle assessment meetings in accordance with IMC 0305. If the NRC determines that a substantive cross-cutting issue exists at a given plant, the resultant mid-cycle and end-of-cycle assessment letters summarize the specific substantive cross-cutting issue to include the necessary actions to resolve the issue. The next mid-cycle or annual assessment letter will either state that the issue has been satisfactorily resolved or summarize the agency's assessment and licensee's progress in addressing the issue.				
Q. No 78			Country Slovenia	Article Article 10	Ref. in National Report 10.4.1.2,p.88
Questio n/ Comme nt	(P) DIRS	10.4.1.2	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 number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 79			Country Sweden	Article Article 10	Ref. in National Report 87
Question/ Comment	(P) DIRS	Conclusions from the 4th Review Meeting, p. 19 and sec. 10.4.1	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 based on the subjective nature of safety culture concepts.				
Q. No 80			Country Sweden	Article Article 10	Ref. in National Report 22
Question/ Comment	(P) DCI	Reactor Material Degradation Issues, p. 20 – 22	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.				
Q. No 81			Country Sweden	Article Article 10	Ref. in National Report 87
Question/ Comment	(P) DIRS (P) INPO	10.4.1.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRC Response: 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 to only INPO and WANO members. Industry Response: Because safety culture is such a broad construct, in the US there are three primary ways in which safety culture is assessed – INPO evaluations/WANO Peer Reviews, Nuclear Safety Culture Assessment (NSCA), and surveys. The assessment of safety culture during INPO evaluation/WANO Peer Review is described in Part 3.6 of the "Principles for a Strong Nuclear Safety Culture" document where it states, "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 CEO 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 comprised of both plant and non-plant personal but may be all non-plant personnel, depending upon the circumstance. The assessment is mostly interviews of individuals in most functions and all levels, asking them questions related to the Principles for a Strong Nuclear Safety Culture. Some work and meeting observations are conducted. Following the evaluation, a report is written that is delivered to the station management. The NSCA methodology is very similar to the IAEA SCART methodology. Safety culture surveys are administered prior to 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 conducting interviews and observations It is because of these strengths and weaknesses, that both surveys and interviews are used during both INPO evaluations and NSCAs.				
Q. No 82			Country Switzerland	Article Article 10	Ref. in National Report 90 / 10.4.2

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) OE	10.4.2	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 (SC PM) serves as the staff lead for the agency's internal safety culture activities. The SC PM leads and coordinates efforts to develop, implement, and maintain polices and a framework for supporting a strong internal safety culture. The SC PM conducts activities to monitor and continuously strengthen the agency's internal safety culture, including serving 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.				
Q. No 83			Country China	Article Article 11.1	Ref. in National Report 11.1.3
Question/ Comment	(P) DPR	11.1.3	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, 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, "Financial Protection Requirements and Indemnity Agreements." 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 five year intervals. The last adjustment was made in August 2009.				
Q. No 84			Country India	Article Article 11.1	Ref. in National Report 11.1, Para 1, Page 95

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DPR	11.1	What are the financial arrangements which USNRC insists on to provide for decommissioning in case the plant is prematurely shutdown for decommissioning?		
Answer	Decommissioning funding assurance for nuclear power plants is governed by 10 CFR 50.33(k), 50.75, and 50.82 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 section 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 section 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 post-shutdown decommissioning activities report (PSDAR) required in section 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), section 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.				
Q. No 85			Country Pakistan	Article Article 11.1	Ref. in National Report Section 11.1, Page 95
Question/ Comment	(P) DPR	11.1	Can USA describe the impact of economic deregulation of nuclear power Plants on safety in USA?		
Answer	The NRC has not observed any negative impact on nuclear power plant (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 reactor oversight program continues to assure the safety of U.S. NPPs.				
Q. No 86			Country Russian Federation	Article Article 11.1	Ref. in National Report section 11.1.2, p. 97

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DPR	11.1.2	What is the process for the nuclear plant decommissioning fund establishment and accumulation?		
Answer	See response to question 84.				
Q. No 87			Country United Kingdom	Article Article 11.1	Ref. in National Report Page 95, Section 11.1
Question/ Comment	(P) DIRS (S) DPR	11.1 and 12.3.3	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 USA 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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	As suggested in Question 87 and assuming certain possibilities, it can be postulated that a licensee of a commercial nuclear power plant, under certain circumstances of financial difficulties, may lead 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. By assuming this type of cause and effect, the assumption 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. Management of a commercial nuclear power plant is constantly reprioritizing actions at a commercial nuclear power plant reflective of 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 in either circumstance of financial difficulties or financial surpluses, such 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 nuclear power plant, 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.				
Q. No 88			Country Japan	Article Article 11.2	Ref. in National Report Sec.11.2.1, p98
Question/ Comment	(P) DIRS	11.2.1	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Examination security is discussed by the NRC with facility licensees prior to the start of examination development. This is required in accordance with NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," Section ES-201, paragraph C.2.c, and 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, where adherence to proper examination security during examination development and administration is observed by the NRC. Any lapse in examination security self-identified by a facility licensee is required to be reported to the NRC. Regardless of whom discovers a lapse in examination security (NRC or the licensee), any such incident will be thoroughly reviewed for appropriate actions, which typically consists of replacing examination material prior to the examination, if examination material has potentially been compromised. In severe cases, regulatory action can be taken against a licensee, for violations of Title 10 of the *Code of Federal Regulations,* Part 55, Paragraph 55.49, "Integrity of examinations and tests."				
Q. No 89			Country Sweden	Article Article 11.2	Ref. in National Report 98
Question/ Comment	(P) HR		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 (ORISE) and the Labor Market Outlook for Health Physicists updated to 2010. Both confirmed that the available U.S. civilian labour supply of new nuclear engineering graduates and health physicists is substantially less than the number of job openings (Q 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 we anticipate some growth in new job positions. Yet, replacement positions may be reduced if workers choose to remain on the job rather than retire. However, 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.				
Q. No 90			Country China	Article Article 12	Ref. in National Report 12
Question/ Comment	(P) DIRS	12.2	What's the relationship between the Human Event Repository and Analysis system developed by NRC and the HFE Operation Experience Review referred in NUREG 0711?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Sources for the data in the Human Event Repository and Analysis system (HERA) include empirical and experimental data. Empirical data sources include operations and event reports, while 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 one while retaining positive features. So, there is no direct relationship between HERA and the Operating Experience Review in NUREG 0711. 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.				
Q. No 91			Country China	Article Article 12	Ref. in National Report 12
Question/ Comment	(P) DIRS	12.2	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 Human Event Repository and Analysis (HERA) system. The HERA system as described in NUREG/CR-6903, "Human Event Repository and Analysis (HERA) System, Overview," was to provide comprehensive, detail analyzed information of past events with rich human performance information for human performance analysts. The information is for improving understanding the behavior of nuclear power plant operators responding to plant malfunctions and the contributing factors to human performance. The human failures and successes of each event was 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 more focused 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 assessable from the world wide web. Login name and password are required from NRC to access the site.				
Q. No 92			Country China	Article Article 12	Ref. in National Report 12

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DIRS	12.3.1	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. nuclear power plants 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 HSIs and human performance, especially with professional operators. 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," (***which can be accessed through BNL's public website) was prepared for the NRC by Brookhaven National Laboratories. For researching this topic empirical research and operating experience were both reviewed. In addition, selected failure modes of the digital feedwater system of a PWR were analyzed. 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 for degradations of I&C subsystems include: 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 report states that it was determined 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 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. 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. This tasks and interfaces are key review points for the NRC.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 93			Country China	Article Article 12	Ref. in National Report 12
Question/ Comment	(P) NRO (S) DIRS	12.3.1 and 18.3.2.1	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 multi-module design certification applications have been submitted to the NRC for review. When the NRC does receive an application, it will use the current guidance in NUREGs 0800, 0700 and 0711 to evaluate that application's human factors engineering design. Since current regulations (10 CFR 50.54(m)) have deterministic staffing numbers that are not relevant to the new multi-module 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)." NUREG-1791 is a public document and can be found online at the NRC's online reading room.				
Q. No 94			Country France	Article Article 12	Ref. in National Report § 12 p.101
Question/ Comment	(P) DIRS	12.2	"The challenge of new technological development is mentioned. Could the USA clarify if the problem of a failure of a digital control room is considered, and in this case what are the proposed solutions?"		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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. nuclear power plants 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 instrumentation and control (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. A framework for linking digital I&C systems to human performance was developed as the initial phase of creating evaluation guidance. An I&C characterization was developed. In addition to reviewing the details of individual systems being proposed for advanced reactors, efforts to characterize modern, digital I&C systems were reviewed. Once a suitable I&C system characterization was developed, we sought to identify failure modes. The failure modes represent the set of degradation conditions whose effects on human performance we wish 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.				
Q. No 95			Country France	Article Article 12	Ref. in National Report § 12 p.101
Question/ Comment	(P) DIRS	12.2	"The USA develop the Human Performance Program including data collection. Could the USA 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.				
Q. No 96			Country India	Article Article 12	Ref. in National Report 12.3.1, Para 1 on Page 103

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DIRS	12.3.1	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 reactor=s 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 be dependent upon several factors. The time available and the time required to complete an action are the primary considerations as to whether crediting an operator action is acceptable; there is no set time under which any action couldn't 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 and what the communication requirements are for this data and how the operator will receive information to confirm 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 (stand, sit, squat, etc.) biomechanics, movements (lift, push, turn, pull, crank, etc.), and the forces needed to complete the action. The licensees must validate and verify that the tasks can be completed under the conditions which may exist including time restrictions.				
Q. No 97			Country Korea, Republic of	Article Article 12	Ref. in National Report Section 12.3.1
Question/ Comment	(P) DIRS (S) DE	12.3.1	According to the descriptions of paragraph 12.3.1, the staff published DI&C-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 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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Currently there is no change in our regulatory position concerning the time response to safety-related operator actions concerning the application of ANSI/ANS-58.8. The objective of the safety review is to verify that the applicant's HSI inventory and characterization accurately describes all HSI displays, controls, and related equipment that are within the defined scope of the Human Factors Engineering 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/sub-function 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 assure 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 AOO/PA using realistic assumptions, and the acceptance criteria of BTP 7-19. Guidance for performing this analysis, and criteria for acceptance, has been developed within Interim Staff Guidance DI&C-ISG-05. (Interim Staff Guidance DI&C-ISG-05, Rev 1)				
Q. No 98			Country Korea, Republic of	Article Article 12	Ref. in National Report Section 12.3.1
Question/ Comment	(P) DIRS	12.3.1	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 ESFAS 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.		

<table>
<tr><td>Question number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Answer</td><td colspan="5">The content of the safety evaluation concerning Human Factors include the assessment of the licensee replacing the reactor protection system (RPS) and Engineered Safeguards Protection System (ESPS) systems. A new failure mechanism was introduced, the software common mode failure (SWCMF). Should SWCMF occur with the new digital system, it is possible that:
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), and
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 staff found crediting the new operator actions acceptable, based on:
The operator actions are contained in existing plant procedures
The operator actions (and verifying their success) are prompted by control room indications and alarms which are diverse from the digital RPS/ESPS,
The operator actions are simple tasks and can be performed independently of the digital RPS/ESPS,
The operator actions have been time-validated on a sampling of operating crews using a properly modeled control room simulator,
The operator actions times are well within allowed times to meet acceptance criteria, and
The licensee has appropriate plans in-place to update plant procedures, operator training, and the control room simulator to reflect the new digital RPS/ESPS.

The review concluded based on the considerations discussed above, that the health and safety of the public will not be endangered by the additional manual actions associated with the digital upgrade.</td></tr>
<tr><td>Q. No 99</td><td></td><td></td><td>Country Korea, Republic of</td><td>Article Article 12</td><td>Ref. in National Report Section 12.3.6</td></tr>
<tr><td>Question/ Comment</td><td>(P) DIRS</td><td>12.3.6</td><td colspan="3">According the description of paragraph 12.3.6, NRC staff members with human factors expertise participate in an 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.</td></tr>
</table>

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The procedure adherence findings were identified by the inspectors on the 95003 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 website via this hyperlink: http://pbadupws.nrc.gov/docs/ML0803/ML080320562.pdf, and in this supplement to the inspection report: http://pbadupws.nrc.gov/docs/ML1025/ML102500671.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 being placed in the Multiple / Repetitive Degraded Cornerstone Column (Column IV) of the NRC Action Matrix and issues identified during independent assessments of the site's safety culture.				
Q. No 100			Country Russian Federation	Article Article 12	Ref. in National Report Section 12.3.1, p. 102
Question/ Comment	(P) DIRS	12.3.1	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 aren't typically associated with specific NRC evaluations.				
Q. No 101			Country Sweden	Article Article 12	Ref. in National Report 101
Question/ Comment	(P) DIRS (P) INPO	12.2	What measures have been/are taken by the licensees to address Human Factors? (Are there any specific industry network/group/ association addressing these issues?)		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRC Response: There are professional associations which often form tasks groups to address and dialogue with the NRC to address various aspects of Human Factors with regards to safety. The Nuclear Energy Institute (NEI) for example, has task groups on Digital I&C, Safety Culture, and Fatigue Management. The Institute of Nuclear Power Operations (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. Industry Response: The US industry doesn't have a human factors organization. However, in the 1990's, 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 and worked with EPRI on them. A recent Procedures Symposium attended addressed human factors issues when it comes to procedure format, development, and implementation.				
Q. No 102			Country Sweden	Article Article 12	Ref. in National Report 101
Question/ Comment	(P) DIRS	12.2	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 not any regulations; however, the 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, Operating Experience Review; Functional Requirements Analysis and Function Allocation, Task Analysis, Staffing, Human Reliability Analysis, Human-System Interface Design, Procedure Development, Training Program Development, Human Factors Verification and Validation, Design Implementation, and Human Performance Monitoring.				
Q. No 103			Country Sweden	Article Article 12	Ref. in National Report 104

Question number	Reviewer (P)Primary (S) Secondary	Report Section.	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DIRS	12.3.4	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 Congressmen expressed concern that low staffing levels and excessive overtime may present serious safety hazard at some commercial nuclear power plants. 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 nuclear power plant 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 have 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 the Regulatory Issue Summary (RIS) 2002–007, "Clarification of NRC Requirements Applicable to Worker Fatigue and Self- Declaration of Fitness-for-Duty." The NRC issued the RIS following several allegations made to the NRC regarding the appropriateness of licensee actions or policies related to individuals declaring 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.				
Q. No 104			Country China	Article Article 13	Ref. in National Report 13

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DE (S) NRO	13.2.3	Please give more information on how to use the ISO QA standards in NRC？		
Answer	The NRC does not require licensees to adopt the ISO Quality Management standard. Licensees are required to meet Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." NRC addressed ISO 9001 in SECY-03-0117 "Approaches for Adopting More Widely Accepted International Quality Standards." The NRC also endorses American Society of Mechanical Engineers (ASME) standard NQA-1 guidance through Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)."				
Q. No 105			Country Germany	Article Article 13	Ref. in National Report pages 108/109, para. 13.2.3
Question/ Comment	(P) DE (S) NRO	13.2.3	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 response to question 111.				
Q. No 106			Country Japan	Article Article 13	Ref. in National Report Sec.13.5.1, p110
Question/ Comment	(P) DE	13.5	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC periodically observes audits performed by the Nuclear Procurement Issues Committee (NUPIC). NUPIC is an organization that includes all domestic US 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 Inspection Procedure (IP) 43005, "NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements." As discussed in the inspection procedure, our findings would be documented and discussed at NUPIC meetings. IP43005 can be found on the NRC public website 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.				
Q. No 107			Country Japan	Article Article 13	Ref. in National Report Sec.13.5.1, p110
Question/ Comment	(P) DE	13.5.1	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 response to question 106.				
Q. No 108			Country Korea, Republic of	Article Article 13	Ref. in National Report p.108
Question/ Comment	(P) DE	13.2.2	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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC has a list of vendors that supply basic (safety-related) components to the US nuclear industry. Safety-related component is any system, structure, component (SSC) or service that would affect its safety function necessary to assure: (A) The integrity of the reactor coolant pressure boundary; (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (C) The capability to prevent or mitigate the consequences of accidents Inspections of vendors performed since 2005 is available on the NRC public website at: http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html				
Q. No 109			Country Sweden	Article Article 13	Ref. in National Report 110
Question/ Comment	(P) DE	13.5	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 of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," 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 quality assurance programs to ensure compliance with both NRC requirements as well as other international standards that may be required to allow the use of a component in other countries.				
Q. No 110			Country Sweden	Article Article 13	Ref. in National Report 110
Question/ Comment	(P) DE (S) NRO	13.4	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," are applied. Equipment that has been categorized as important to safety includes systems, structures and components that mitigate station blackout, anticipated transient without scram, fire protection, environmentally qualified equipment and pressurized thermal shock. Safety-related refers to any system, structure, component (SSC) or service that would affect the integrity of the reactor coolant system, the ability to shutdown and maintain the Reactor in a safe shutdown condition, or 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 program. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," 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, as well as important to safety equipment. In addition, regulatory guidance for augmented quality can be found in other documents such as Regulatory Guide 1.155 "Station Blackout;" Appendix A "Quality Assurance Guidance for Non-Safety Systems and Equipment." Section 17.5 of NUREG-0800 can be located on the NRC public website at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/ch17/ See Paragraph V.				
Q. No 111			Country Switzerland	Article Article 13	Ref. in National Report 108
Question/ Comment	(P) DE (S) NRO	13.2.3	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC addressed ISO 9001 in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards." Licensees are required to Meet Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." In the SECY-03-0117, the NRC provided a matrix of the significant differences between ISO 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 the SECY is ML031490421. A few key supplemental requirements in Appendix B that are not required by ISO 9001 include: Appendix B, Criterion X, inspections performed by individuals other than those who performed an activity; Appendix B, Criterion III, 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 Appendix B Criterion VII, suppliers to pass requirements consistent with Appendix B to sub-suppliers. The IAEA's GS-R-3 was not part of the review in 2003 because it had not been issued at the time. However, NRC does not specify requirements for or provide guidance on a management system to the level of GS-R-3, for licensees to follow.				
Q. No 112			Country Canada	Article Article 14.1	Ref. in National Report 114
Question/ Comment	(P) DLR	14.1.2.1	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.		

<table>
<tr><td>Question number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Answer</td><td colspan="5">The key measures that are in place to foster continuous improvements include, but are limited to,
(1) Operating Experience – The effective use of operating experience from domestic and international plants is crucial in enhancing safety and plant operations. The NRC has established and commits to a robust ongoing Operating Experience Program that collects, evaluates, communicates, and applies the operating experience to prevent significant events and inform NRC decision-making.
(2) Reactor Oversight Process – The Reactor Oversight Process (ROP) is the NRC's program to inspect, measure, and assess the safety performance of commercial nuclear power plants and to responds to any decline in performance. The objective of the ROP is to monitor plant's performance in three key areas: (i) reactor safety, (ii) radiation safety, (iii) safeguards.
(3) Generic upgrades – The NRC evaluates industry-wide safety significant issues that may require technical resolution. The agency issues generic communications (e.g., Generic Letters, Information Notices, etc.,) 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 assure an acceptable level of safety.
Incorporation of risk information into the regulatory activities – The NRC has embraced the concept of risk since the agency's inception. Examples range from (i) the Rasmussen Report (WASH-1400 or NUREG-75/014) in the 1970's, (ii) the IPE and IPEEE in the 1980's and early 1990's, (iii) use of risk insights in an alternate fire protection program to allow licensees voluntarily adopt and use the fire protection requirements of NFPA Standard 805, and (iv) use of risk insights in the revised Pressurized Thermal Shock (PTS) Rule (10 CFR 50.61) to ensure continued protection against PTS events.</td></tr>
<tr><td>Q. No 113</td><td></td><td></td><td>Country France</td><td>Article Article 14.1</td><td>Ref. in National Report § 14.1.3 - p.118</td></tr>
<tr><td>Question/ Comment</td><td>(P) OGC
(S) DRA</td><td>14.1.3.2</td><td colspan="3">"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 USA give some examples of the application of these "unnecessary burdens", proving that there is no safety reduction?"</td></tr>
</table>

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC infers from the question that the reference to the PSA (probabilistic safety assessment) is actually referring to the PRA (probabilistic risk assessment) Policy Statement (there is no PRA/PSA Rule that applies to current operating plants). The question clearly reflects a concern that using PSA/PRA and the "backfit rule," have the potential to reduce safety, especially if one of the NRC's aims is to "eliminate unnecessary burdens on licensees," as page 118 and also pages 17 and 165 of the National Report say. The question essentially is, Can you show that, using these approaches, you don't reduce safety when you reduce unnecessary burdens? Yes, we can show that, though of course a detailed showing would require discussion of a range of particular agency actions. But at a higher level, it should be clear from the 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. Page 165 in fact 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 isn't focused on the wrong things, help the agency allocate resources in ways that will not reduce safety – 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's worth pointing out that the agency's practice under the rule parallels government-wide practices overseen by the U.S. Office of Management and Budget.) Some examples are: 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 the overall safety resulting from the program). For risk-informed special treatment program (10 CFR 50.69), the licensee uses risk insights to identify those safety-related system, structures, and components (SSCs) that are not significant to safety (based on the plant-specific PRA) and as a result can reduce the special treatment requirements for these SSCs (burden reduction). At the same time, the risk insights are used to identify non-safety-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/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 the overall safety resulting from the program).				
Q. No 114			Country France	Article Article 14.1	Ref. in National Report § 14.1.3 - p. 121

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DLR	14.1.3	"USA 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 USA explain how and when are the PSAs updated? (for comment in case of Periodic Safety Reassessment, a PSA updating is a requirement)."		
Answer	For current operation plants (i.e., those plants licensed under 10 CFR Part 50), there is no overarching regulation that requires a PRA/PSA and thus there is no general regulation that specifies the periodicity for updating PRAs for use in risk-informed decision making for current operating plants. However, there are some risk-informed regulations, such as 10 CFR 50.69, that do contain specific PRA update periodicity requirements 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). Regulatory Guide (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 Regulatory Guide: monitor PRA inputs and collect new information, ensure cumulative impact of pending plant changes are considered, maintain configuration control of the computer codes used in the PRA, identify when PRA needs to be updated based on new information or new models/techniques/tools, and ensure peer review is performed on PRA upgrades. The PRA model used to support risk-informed decision making (e.g., using RG 1.174) is expected to reasonably reflect the as-built, as-operated plant. Therefore, it 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 (NUREG-0800, Standard Review Plan (SRP) 19.2, which is the companion staff guidance to RG 1.174), as well as the PRA technical adequacy staff review guidance (SRP 19.1, which is the companion staff guidance to RG 1.200).				
Q. No 115			Country France	Article Article 14.1	Ref. in National Report § 14.1.2 - p. 114
Question/ Comment	(P) DLR	14.1.2.1	"USA indicate, in the framework of licence renewal, that aging phenomena are readily manageable. Could USA 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....)? "		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	As delineated in 10 CFR 54.4, the focus of the license renewal review is to ensure the intended function of those long-lived passive structures, systems, and components (SSCs) (e.g., the reactor vessel, the reactor coolant system pressure boundary, steam generators, the pressurizer, piping, pump casings, valve bodies, etc.) will be maintained during the extended period of operation. For active components (e.g., motors, diesel generators, cooling fans, batteries, relays, and switches, etc.), normal surveillance and maintenance programs will continue throughout the period of extended operation and will ensure for 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 implication(s) of such replacement to the operating fleet is reviewed by the agency under Part 50 process, not Part 54. Regarding the topic of climate changes, this topic is discussed qualitatively in terms of greenhouse gas emissions in the supplemental Environmental Impact Statement as a part of the license renewal review.				
Q. No 116			Country India	Article Article 14.1	Ref. in National Report 14.1.1.2
Question/ Comment	(P) DORL (S) DRA	14.1.1.2	Is there any specified periodicity for updating PSAs/PRAs for use in risk-informed decision making process?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	For current operating plants (i.e., those plants licensed under 10 CFR Part 50), there is no overarching regulation that requires a PRA/PSA and thus there is no general regulation that specifies the periodicity for updating PRAs for use in risk-informed decision making for current operating plants. However, there are some risk-informed regulations, such as 10 CFR 50.69, that do contain specific PRA update periodicity requirements 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). Regulatory Guide (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 Regulatory Guide: monitor PRA inputs and collect new information, ensure cumulative impact of pending plant changes are considered, maintain configuration control of the computer codes used in the PRA, identify when PRA needs to be updated based on new information or new models/techniques/tools, and ensure peer review is performed on PRA upgrades. The PRA model used to support risk-informed decision making (e.g., using RG 1.174) is expected to reasonably reflect the as-built, as-operated plant. Therefore, it 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 (NUREG-0800, Standard Review Plan (SRP) 19.2, which is the companion staff guidance to RG 1.174), as well as the PRA technical adequacy staff review guidance (SRP 19.1, which is the companion staff guidance to RG 1.200).				
Q. No 117			Country India	Article Article 14.1	Ref. in National Report General
Question/ Comment	(P) NRO		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 Three Mile Island (TMI), the requirements for controlling combustible gas in non-inerted containments changed from 5% fuel clad coolant interaction to 75% in Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.44. This requirement was a backfit and still applies to operating plants. Future applicants were required to analyze the combustible gas released from the equivalent of 100% fuel clad coolant interaction. These requirements reflect the Commission's expectation that future designs achieve a higher standard of severe accident performance.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 118			Country Japan	Article Article 14.1	Ref. in National Report Sec.14.1.3, p117
Question/ Comment	(P) DPR	14.1.3	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 Integrated Regulatory Review Service (IRRS), the NRC identified that it could more systematically review findings from other regulator's 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 the IRRS mission recommendations and suggestions including this one and will develop actions for them, where appropriate. Currently, NRC actions are still being determined to address the recommendations and suggestions.				
Q. No 119			Country Slovenia	Article Article 14.1	Ref. in National Report 14.1.1.1,p.112
Question/ Comment	(P) DORL	14.1.1.1	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Licensees are not allowed to fully implement a modification that requires NRC approval prior to the approval being 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 to determine if prior NRC approval is required. If the licensee determines that prior NRC approval is not necessary, then they need to report that the change was screened against 10 CFR 50.59 in a periodic report. The resident inspections examine the 50.59 evaluations to determine if the licensee has correctly determined whether or not prior NRC approval were 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 report section 9.3) rather than the significance determination process 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 significance determination process.				
Q. No 120			Country Sweden	Article Article 14.1	Ref. in National Report 118
Question/ Comment	(P) DLR	14.1.3.3	How many of issues described in section 14.1.3.3 are still unresolved? Are they still considered significant?		
Answer	All of the 22 SEP issues have been addressed and resolved under Generic Issue (GI) 156, "Systematic Evaluation Program." NUREG-0933 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, three issues were addressed in resolution of other GIs, and one issue was resolved with no new requirement. None of the 22 SEP issues are considered significant anymore.				
Q. No 121			Country United Kingdom	Article Article 14.1	Ref. in National Report Page 116 et seq., Section 14.1.3

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DLR	14.1.3	The USA 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 USA agree that the introduction of a program of regular periodic safety reviews would further strengthen the many excellent practices already in force to maximise the safety of licensed sites?		
Answer	The NRC appreciates the safety that other nuclear regulators received from conducting PSRs 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 5th CNS National Report, the NRC continuously evaluates operating experience, considers upgrades and performs assessments annually. In an effort to further strengthen the safety practices in the U.S., the IAEA Integrated Regulatory Review Service (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 Strategic Plan Fiscal Years 2008 – 2013, 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, 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 they are soundly based and determine whether substantial safety improvement can be identified and incorporated domestically.				
Q. No 122			Country United Kingdom	Article Article 14.1	Ref. in National Report Page 118, Section 14.1.3.2
Question/ Comment	(P) DLR (S) OGC	14.1.3.2	Would the USA 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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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, NGOs, 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 the NRC's approach has, for, in order to implement such a requirement – in order to be able to say what reasonably practicable changes the licensee 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.				
Q. No 123			Country Germany	Article Article 14.2	Ref. in National Report page 115, 10 CFR Part 54
Question/ Comment	(P) DLR	14.1.2.1	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 licence renewal process in order to ensure a safe operation of the respective nuclear power plant during extended lifetime?		
Answer	The detrimental effects of ageing include, but are not limited to, embrittlement, loss of material due to different corrosion and erosion mechanisms, hardening/loss of strength, loss of heat transfer function due to accumulation of debris and other undesirable material(s), etc. These material degradation mechanisms may adversely prevent safety-related and certain non-safety related systems, structures, and components (SSCs) from fulfilling their safety functions. Thus they are the primary consideration in granting a license extension. 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 on-site audits and inspections of licensee's documents. The purpose of the NRC review is to determine if the applicant meets 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 ageing mechanisms and describe programs in place to manage aging.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 124			Country Russian Federation	Article Article 14.2	Ref. in National Report Section 14.2, p. 124
Question/ Comment	(P) DCI (S) DORL (S) DE	41.2	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 American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME Code), inspections of US nuclear power plant components are typically conducted based on a ten year interval between inspections. However, in some cases, inspection frequencies of less than every ten years may be required based on the degradation mechanism being inspected for. For example, inspection of nickel alloy welds in pressurized water reactors for evidence of primary water stress corrosion cracking (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 ten 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 degradation mechanism being inspected for, safety significance of the components, etc.) imposed by the ASME Code and/or NRC regulations.				
Q. No 125			Country Sweden	Article Article 14.2	Ref. in National Report 25
Question/ Comment	(P) DSS	NPSH for ECCS pump net positive suction head, p. 25	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 extended power uprate applications are not risk-informed. The existing Commission policy is for the staff to use the guidance in Standard Review Plan (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. ACRS position is that special circumstances are met when containment accident pressure is used to determine 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.				
Q. No 126			Country China	Article Article 15	Ref. in National Report 15.3
Question/ Comment	(P) DIRS (S) FSME	15.3	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, US 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, they are required to follow them. The dose limit for members of the public is specified in 10 CFR 20.1301, and it is 1 mSv (100 mrem) annually. This is a safety limit. To provide additional assurance the safety limit will not be challenged, the ALARA design objectives of 10 CFR 50 have been established. There are several design objectives listed in 10 CFR 50, Appendix I. One example design objective 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 includes the principal of ALARA to ensure that doses are maintained as low as is reasonably achievable.				
Q. No 127			Country China	Article Article 15	Ref. in National Report 15.4.1
Question/ Comment	(P) DIRS (S) FSME	15.4.1	How about the maximum radiation individual exposure of radiation workers in the recent years? Please give more information on how to use the ICRP newly standards in U.S. NPPs.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	In addition to the declining trend in collective dose at operating nuclear power plants, individual (both average and maximum) exposures have also declined. The latest occupational doses data compiled in NUREG-0713, Volume 31, 2009, indicates that 2009 was the first year on record where no individual received more than 2 rem (20 mSv) working at a US commercial light water reactor. The NRC is currently evaluating what changes to the US regulations are warranted in response to the recently revised ICRP recommendations in their Publication 103. Included in this evaluation is how the NRC should address the recommended 20 mSv average annual occupational dose limit.				
Q. No 128			Country China	Article Article 15	Ref. in National Report 15.4.1
Question/ Comment	(P) DIRS (S) FSME	15.4.1	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 1980's, for both PWR and BWRs. In the 1980 through 2000 dramatic reductions were achieved by these 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 the use of automated/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 their dedication of resources to research, such as through the Electric Power Research Institute (EPRI), and the individual licensee's commitment to operational excellence, as promoted by the Institute for Nuclear Power Operations (INPO).				
Q. No 129			Country Czech Republic	Article Article 15	Ref. in National Report Page 127
Question/ Comment	(P) NRO (S) DIRS	15.1	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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	In the context of Article 15, which deals with Radiation Protection, the assessment of benefits of a new use of radioactive material (for example, use in a new nuclear power plant) 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 (AEA): "...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 the radiological balancing described in Article 15 under the authority of the AEA, the U.S. National Policy for considering environmental values is stated in the National Environmental Policy Act of 1969, as amended (NEPA): "...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, alternative systems designs, etc.), 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, the Clean Air Act, etc.). In the end, while only the NRC can grant permission for the use of radioactive material for a new nuclear power plant, that is not the only permission that is needed to make a new nuclear power plant a reality.				
Q. No 130			Country France	Article Article 15	Ref. in National Report § 15.1 - p 128
Question/ Comment	(P) DIRS (S) FSME	15.1	"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 USA specify when the ICRP 103 will be implemented and what will be the main principles which will be adopted?"		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The NRC staff is currently engaged in an ongoing dialogue with stakeholders on 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 regarding implementation of ICRP Publication 103 recommendations, and the USA cannot specify any schedule for a change to the regulations. 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 program include requirements for licensees to reduce exposures As Low As Reasonably Achievable, and to limit exposures to occupationally exposed individuals, and members of the public.				
Q. No 131			Country France	Article Article 15	Ref. in National Report § 15.4.2 - p. 131
Question/ Comment	(P) DIRS (S) FSME	15.4.2	"Could USA 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 USA present a diagram which indicates the individual dose distribution for occupational workers? Could USA also give some elements about the intern effective dose for occupational workers?"		
Answer	See the answer to question number 128 above. Table 4.4 of NUREG-0713 provides the occupational dose distribution, by exposure ranges, for light water reactors. Although, consistent with ICRP 26 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 light water reactors actually receive measurable intakes of radio-nuclides. Licensees are required to use engineering controls (i.e., containment, and, or ventilation) to reduce airborne concentrations of radioactive materials, and use respiratory protection, or other means as appropriate, to limit intakes of workers in areas where the airborne concentrations can not be reduced to below what is considered an airborne radioactivity area.				
Q. No 132			Country France	Article Article 15	Ref. in National Report § 15.4.2 - p. 131
Question/ Comment	(P) DIRS (S) FSME	15.4.2	"Could USA give more details about the technical measures in order to reduce the gaseous and liquid release ? Could USA also give values of the effective dose for the critical group assessed with the level of discharges released ? "		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 10 CFR 50 Appendix I, and reported to the NRC on an annual basis. The most recent effluent reports for each operating US NPP can be found on the NRC web site at: http://www.nrc.gov/reactors/operating/ops-experience/tritium/plant-info.html				
Q. No 133			Country Germany	Article Article 15	Ref. in National Report page 127, section 15.1
Question/ Comment	(P) DIRS (S) FSME	15.1	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 129.				
Q. No 134			Country Germany	Article Article 15	Ref. in National Report page 130, section 15.3
Question/ Comment	(P) DIRS (S) FSME	15.3	Are dose limits defined for the occupational exposure of trainees, students and pregnant women?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRC regulations at 10 CFR 20.1207 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 § 20.1201. There are no special occupational dose limits for trainees, or students if they are 18 years of age or older. 10 CFR 20.1208, provides a limit of 0.5 rem (5 mSv) dose equivalent to the embryo/fetus, during the entire pregnancy, due to the occupational exposure of a declared pregnant woman. To the extent that this limit is met, the occupational dose limits in § 20.1201 (lens of the eye, skin, extremities, etc.) still apply to the declared pregnant woman. The limit applies when the woman has chosen to declare her pregnancy to the licensee. To the extent that this limit is met, the occupational dose limits in § 20.1201 (lens of the eye, skin, extremities, etc.) still apply to the declared pregnant woman.				
Q. No 135			Country India	Article Article 15	Ref. in National Report 15.4, Page 131
Question/ Comment	(P) DIRS (S) FSME (P) INPO	15.4	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRC Response: The Radiation Protection Manager (RPM) at NPPs is not an NRC licensed position. However, each NPP has a condition in their license (Technical Specification) specifying the RPM's qualifications (experience and training criteria in Regulatory Guide 1.8). In addition each operating plant has committed to implement the guidance in Regulatory Guide 8.8 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 a NPP is authorized under the provisions of 10 CFR 19 and 10 CFR 21 to report safety issues directly to the NRC. Industry Response: Most Radiation Protection Managers 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 person may contact the NRC directly to report a safety concern. The number of people and organizational structure of the RP 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 Radiation Protection manager must meet minimum requirements of the position. The requirements vary somewhat based on when the plant was licensed and their commitment to the NRC. Typical requirements are: 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 a nuclear power plant Some standards specify additional requirements for experience with refueling outages and at power operation (> 20 percent power) Training as necessary to fill in any knowledge gaps General Employee Training				
Q. No 136			Country Japan	Article Article 15	Ref. in National Report Sec.15.1, p128
Question/ Comment	(P) DIRS (S) FSME	15.1	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)?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	The USA, and in particular the Nuclear Regulatory Commission, is 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 Administrative Procedure Act of the United States, 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 entering, or not entering, 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 US also considers other points of reference, including 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.				
Q. No 137			Country Korea, Republic of	Article Article 15	Ref. in National Report p.128
Question/ Comment	(P) DIRS (S) FSME	15.1	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 136.				
Q. No 138			Country Korea, Republic of	Article Article 15	Ref. in National Report p.128
Question/ Comment	(P) DIRS (S) FSME	15.1	If the dose assessment system is improved in accordance with ICRP103, is the 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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	As noted in the answer to question 136, the changes to 10 CFR 50 Appendix I necessary to adopt ICRP 103 are still being evaluated by the staff. It is not clear if a separate constraint on the release of radio-iodine and particulates, as provided in the current Appendix I, would be warranted. Presumably if C-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 than the current requirement to meet the ICRP 2 based design criteria in Appendix I.				
Q. No 139			Country Russian Federation	Article Article 15	Ref. in National Report Section 15.4.1, Annex 2 (pp. 239-240)
Question/ Comment	(P) DIRS (S) FSME	15.4.1	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 129.				
Q. No 140			Country Spain	Article Article 15	Ref. in National Report Section 15.4.1 Page 131
Question/ Comment	(P) DIRS (S) FSME	15.4.1	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	10 CFR 20 requires the licensees to have a program (e.g., procedures and engineering controls) to maintain doses ALARA. 10 CFR 20 does not require each individual dose to be as low as possible. The NRC Reactor Oversight Process (ROP) uses collective dose to assess the effectiveness of these programs. Specifically 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), respectively. 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. 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 (TEDE) to an individual.				
Q. No 141			Country Sweden	Article Article 15	Ref. in National Report 131

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DIRS (S) FSME	15.4.1	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. It must be recognized, however, 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 BRAC (BWR Radiation and Control) 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.				
Q. No 142			Country United Kingdom	Article Article 15	Ref. in National Report Page 128, Section 15.1
Question/ Comment	(P) DIRS (S) FSME	15.1	The USA is to be commended for starting an "active dialogue with all segments of the licensed community in the US" 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 USA indicate when rule changes might come into force that would align the USA more closely with the current ICRP recommendations that form the basis of national legislation in most other countries?		
Answer	See the answer to question 136.				
Q. No 143			Country China	Article Article 16.1	Ref. in National Report 16.5
Question/ Comment	(P) NSIR	16.5	How does the NRC ensure the emergency exercise effectiveness of the NPPs? And what's the criterion of evaluation?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRC regulations require NPP licensees to conduct an exercise of its onsite emergency plans every two years (biennially). Offsite plans for each site are also required to be exercises biennially with full participation by each offsite authority having a role under the radiological response plan within the site's 10-mile Plume Exposure Pathway Emergency Planning Zone (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 Inspection Procedure (IP) 71114.01. Similarly, a 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 their 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 decision making, and plant system repair and corrective actions) to ensure that adequate emergency response capabilities are maintained. The NRC utilizes the Reactor Oversight Process (ROP) to ensure the EP program maintains the skills of the licensee's Emergency Response Organization (ERO). As such, licensees are required by regulation to critique the ERO performance in all drills and exercises and to correct weaknesses. The ERO 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.				
Q. No 144			Country Germany	Article Article 16.1	Ref. in National Report 16.4, page 138
Question/ Comment	(P) NSIR	16.4	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 U.S., concerning thyroid blocking by stable iodine, the intervention level is 5 REM child thyroid-dose for administration of potassium iodide (KI), where applicable. KI tablets are maintained and distributed through State/County/local arrangements. This many include the pre-distribution or stockpiling of tablets.				
Q. No 145			Country Sweden	Article Article 16.1	Ref. in National Report 138

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) NSIR	16.5	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 offsite response organizations (OROs), every two years. The NRC also requires its licensee, when requested, to provide for the participation of any State or local OROs in other scheduled drills. Although, the NRC is cognizant that the involvement of State and local OROs can increase the demand on communications, cooperation, and coordination. The NRC believes that requiring licensees and State and local OROs to participate in a full participation exercise every two years provides a reasonable basis for ensuring continued performance without the potentially excessive demands on State and local resources for 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.				
Q. No 146			Country Switzerland	Article Article 16.1	Ref. in National Report 135 / 16.1
Question/ Comment	(P) NSIR	16.1	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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," and summarized in Section 1, of NUREG-0654. Although a number of accident sequences, including core melt accidents analyzed in WASH-1400, "Reactor Safety Study," 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 emergency preparedness as a matter of prudence rather than in response to a quantitative analysis of accident probabilities. NUREG-0396 also recommended two emergency planning zones (EPZ) in which detailed planning would be required: a plume exposure pathway EPZ of 10-miles (16 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 Federal Emergency Management Agency (FEMA) regulations and supporting guidance, which were issued in 1980, shortly after the Three Mile Island 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 about 30 minutes; and The source term is not larger than that used to set the 10 mile emergency planning zone. The NRC is currently studying this issue to determine if a spectrum of scenarios can be identified for EP regulatory purposes.				
Q. No 147			Country Switzerland	Article Article 16.1	Ref. in National Report 135 / 16.1
Question/ Comment	(P) NSIR	16.1	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	NRC staff has concluded that the emergency planning requirements remain the same for advanced large light water reactor designs (e.g., AP1000, etc.). Emergency planning requirements have not yet been prepared for small modular reactor designs.				
Q. No 148			Country China	Article Article 16.2	Ref. in National Report 16.4
Question/ Comment	(P) NSIR	16.4	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 impacts off-site, 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 locals) 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." This document embodies guidance from EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions For Nuclear Incidents." 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.				
Q. No 149			Country Germany	Article Article 16.2	Ref. in National Report 16.4
Question/ Comment	(P) NSIR	16.4	Which provisions for information of the public in the vicinity of a NPP as part of emergency planning are required?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	10 CFR 50.47(b)(7) 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, "Criteria for Preparation and Evaluation of radiological Emergency response Plans and Preparedness in Support of Nuclear Power Plants." Additional guidance related to all-hazards risk communication is available through the U.S. Department of Homeland Security.				
Q. No 150			Country Germany	Article Article 16.2	Ref. in National Report 16.2, page 137
Question/ Comment	(P) NSIR	16.2	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 emergency preparedness 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.				
Q. No 151			Country Spain	Article Article 16.3	Ref. in National Report Section 16.7
Question/ Comment	(P) NSIR (S) OIP	16.7	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?		

<table>
<tr><td>Questio n number</td><td>Reviewer (P)Primary (S) Secondary</td><td>Report Section</td><td>Country</td><td>CNS Article</td><td>Page of the National Report</td></tr>
<tr><td>Answer</td><td colspan="5">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 which 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 (HOO) 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, 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 US International Borders. In general (not limited to incident response), the NRC meets regularly with both the Canadians and Mexicans. 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 Boiling Water Reactors, operator licensing, new reactor licensing, the NRC's reactor operating program, and various NRC codes. The CNSNS 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.</td></tr>
<tr><td>Q. No 152</td><td></td><td></td><td>Country France</td><td>Article Article 17.1</td><td>Ref. in National Report § 17.1 - p. 146</td></tr>
<tr><td>Questio n/ Comme nt</td><td>(P) NRO</td><td>17.1</td><td colspan="3">""""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 USA give details about the reasons why some applications for siting were not retained?"</td></tr>
</table>

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Since starting up in 2006, the NRC Office of New Reactors took several steps to ensure success in the staffing area for new reactor licensing include: 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 design certification and combined license 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 design certification and multiple combined license 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 combined licenses and 6 applications for early site permit. 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 combined license applications, the reviews were subsequently suspended 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 COLAs requested that the reviews be suspended while they reconsider the GEH ESBWR reactor technology, which was the basis for the COLA.				
Q. No 153			Country Germany	Article Article 17.1	Ref. in National Report page 146-148, Sect. 17.2
Question/ Comment	(P) NRO	17.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	As explained in Section 17.2 of NUREG-1650 all siting factors, including those cited above, 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 consider societal and demographic factors, manmade hazards (such as airports and dams), and 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 early site permit, a combined license, a construction permit, or an operating license on or after January 10, 1997. RGs 1.27, Revision 2, "Ultimate Heat Sink for Nuclear Power Plants," dated January 1976; RG 1.59, Revision 2, "Design Basis Floods for Nuclear Power Plants," dated August 1977; RG 1.102, Revision 1, "Flood Protection for Nuclear Power Plants," dated September 1976; and RG 1.208, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion," dated March 2007, describe methods acceptable to 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 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, RG1.194, 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 to conduct the review of the site safety content in these reports. Therefore, all the factors cited above are to be assessed for new sites, and re-evaluated, as appropriate, for existing sites.				
Q. No 154			Country Germany	Article Article 17.1	Ref. in National Report page 145 ff.
Question/ Comment	(P) NRO	17.1	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)?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 the mean annual frequency of occurrence is calculated to be is less than 10^{-7}. For wind and external flooding hazards, the assessment is deterministic, which is in conformance with General Design Criterion 2 of Appendix A to 10 CFR Part 50. There is a long history of use of deterministic criteria in the USA 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 Probabilistic Risk Analysis (PRA) requirements for new reactor licensing (see regulation citation below). **Citation for PRA-based regulation:** For design certification: 10 CFR 52.47(a)(27) - A description of the design-specific probabilistic risk assessment (PRA) and its results. For combined operating license: 10 CFR 52.79(a)(46) - A description of the plant-specific PRA and its results.				
Q. No 155			Country Germany	Article Article 17.1	Ref. in National Report page 147, sect. 17.2.2
Question/ Comment	(P) NRO	17.2.2	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 (SHHAC) level depends on seismic sources, for example, SSHAC Level 3 analysis is used for the sources in Central and Eastern US, for a relatively well understood source, such as the Charleston, South Carolina source, a SHHAC Level 2 analysis is acceptable.				
Q. No 156			Country India	Article Article 17.1	Ref. in National Report 17.1 Page 145 & 17.2.2 Page 147
Question/ Comment	(P) NRO	17.1 and 17.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Methodology in RG 1.208 is applied to both early site permit (ESP) and combined operating license (COL) applications. Should there be 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. RG 1.208 methodology is to be applied regardless of the reactor design. The ESP or the COL review process establishes all the site characteristics that are to be later matched with the reactor design site parameters. The product of the RG 1.208 is the site-specific ground motion response spectra that constitute only one element of the site characteristics.				
Q. No 157			Country Slovenia	Article Article 17.2	Ref. in National Report p.148
Question/ Comment	(P) NRO	17.2.3	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)?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	A very short answer is yes, as indicated in the excerpts from NUREG 1465 and RG 1.183 provided below. There is an important point to raise here. The sole purpose of an Early Site Permit (ESP) application is to get approval on a postulated envelope of a set of site parameters for all 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 its 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 Light Water Reactors (LWRs). Current LWR licensees may voluntarily propose applications based upon it. These will be reviewed by the NRC staff. Introduction 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.				
Q. No 158			Country India	Article Article 17.3	Ref. in National Report 17.2.2 , Para 4, Page 147
Question/ Comment	(P) NRO	17.2.2	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	This is a three part question and the answers are provided in sequence. No, operating NPPs are not re-evaluated periodically. Continued safety of nuclear plants and adequate protection of a licensed NPP is imperative. If there is a significant change in any hazard to an already licensed nuclear plant, then the NRC will determine whether a back fit 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 US is one such issue, designated as Generic Issue (GI) 199. 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 shutdown due to high seismic hazard. On the issue of seismic requalification, this is hardly necessary, when data bases are available for equipment already qualified or tested to fragility levels, and the IEEE Standard 344 provides various criteria to determine the appropriate level of ruggedness. The plant owner decides whether or not particular equipment is to be re-qualified 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.				
Q. No 159			Country Canada	Article Article 18.1	Ref. in National Report 154
Question/ Comment	(P) NRO	18.1.1	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.		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Article 18, Section 18.1, paragraph 6, refers to the NRC staff's environmental reviews as required by 10 CFR 51. 10 CFR 51.45(e) 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 requires that NRC staff independently evaluate and be responsible for the reliability of all information used. The staff uses NUREG-1555, "Standard Review Plan for Environmental Reviews for Nuclear Power Plants" 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 a 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 as to when independent analyses are necessary. As prescribed by NUREG-1555, examples of "safety and environmental matters" which the staff has performed independent analyses are identified below: **Geographic Information:** 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. **Meteorological Input to Individual Dose Assessment** 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 Regulatory Guide 1.111. **Cooling System Components:** 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)				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
	Spray system performance and Discharge system performance (e.g., flow velocity) **Transportation of Radioactive Material** 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. **Hydrologic Alteration:** 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. **Thermal Description and Physical Impacts:** Base analysis 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 Regulatory Guides 4.4, *Reporting Procedure for Mathematical Models Selected to Predict Heated Effluent Dispersion in Natural Water Bodies* (NRC 1974) and 1.125, Rev. 1, *Physical Models for Design and Operation of Hydraulic Structures and Systems for Nuclear Power Plants* (NRC 1978), to analyze the applicant's mathematical or physical models. If the NRC staff reviewer'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. **Heat Dissipation to the Atmosphere:** 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.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
	Chemical Monitoring The NRC staff reviewer should independently evaluate the applicant's description of the methodologies used for data collection, analysis, and interpretation of result. The staff is required to make a finding regarding 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. **Severe Accident Mitigation Alternatives (SAMA)** 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 SAMA. **Description of Power System:** Affected States and/or regions are expected to prepare a need-for-power evaluation. 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 acceptable, no additional independent review by 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 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.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
	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 as to 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.				
Q. No 160			Country Canada	Article Article 18.1	Ref. in National Report 155
Question/ Comment	(P) NRO	18.1.1	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	The description in Section 18.1.1 of the US report states: The new inspection program revises the 10 CFR Part 50 Construction Inspection Program. It incorporates inspections, tests, analyses, and acceptance criteria (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 (Regulatory Guide 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 prior to final installation (e.g., at the fabrication location offsite). Several companies have developed or are developing manufacturing capabilities in the U.S. 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 assure compliance with quality assurance requirements in 10 CFR Part 50, Appendix B (e.g., the NRC could treat the modular fabrication or an integral reactor vessel similar to onsite construction activities). The NRC staff is also evaluating the potential use of the manufacturing license provisions defined in Subpart F to 10 CFR Part 52. 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 number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 161			Country China	Article Article 18.1	Ref. in National Report Part 1 introduction
Question/ Comment	(P) DSS	Containment Pressure Credit for ECCS Pump NPSH	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," available on the NRC public web site, describes the substantial base of knowledge that has been amassed as a result of the research on boiling-water reactor (BWR) suction-strainer and pressurized-water reactor (PWR) sump-screen clogging issues. Section 4 of the 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 since some of that info is relevant to the PWR evaluations. 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 (PWROG) to provide guidance for the evaluation of the potential for sump strainer bypassed debris to affect core cooling. The WCAP 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 the fuel cladding temperature would not exceed 800 °F. The NRC staff has not yet completed the review of WCAP-16793-NP, Revision 1.				
Q. No 162			Country France	Article Article 18.1	Ref. in National Report § 18.1.1 - p. 154

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) NRO	18.1.1	"""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 authorisation, do the USA ask for an updating process of the Final Safety Analysis Report after authorisation to begin construction and before the commissioning of the reactor?"		
Answer	Yes, the NRC requires the applicant to revise the final safety analysis report (FSAR) to account for changes during the review process prior to issuance of the combined license so that the FSAR is the up-to-date licensing basis for the combined license. Also, after issuance of the combined license, the licensee is required to periodically 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 FSAR as required by 10 CFR 50.71(e) and some changes may be allowed through the 10 CFR 50.59 process.				
Q. No 163			Country Romania	Article Article 18.1	Ref. in National Report section 18.1.2.2 Design Certifications
Question/ Comment	(P) NRO	18.1.2.2	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 design certification 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 final safety evaluation report activities such as rulemaking, etc.				
Q. No 164			Country Slovakia	Article Article 18.1	Ref. in National Report 155
Question/ Comment	(P) NRO	18.1.1	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 USA? Slovakia would welcome the list of inspections for vendors(dated 27 April 2010).		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 10 CFR Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and 10 CFR Part 21, "Reporting of Defects and Noncompliance," as required under vendor procurement contracts with applicants or licensees. Vendor inspections can be conducted at vendor shops in and outside of the US. 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 utilizing 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 our inspections are publically available on our website at www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html.				
Q. No 165			Country Slovenia	Article Article 18.1	Ref. in National Report 18.1.1,p.155
Question/ Comment	(P) NRO	18.1.1	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 inspections and tests specified in the inspections, tests, analysis, and acceptance criteria (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 have been completed. When the licensee notifies the NRC that an ITAAC is complete, they 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.				
Q. No 166			Country Ukraine	Article Article 18.1	Ref. in National Report Para 18.4. page 161
Question/ Comment	(P) NRO	18.4	Do other counties have an access to the ConE database and what are the conditions of such access?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
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 non-public 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 Webpage is accessible on the Internet at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/. Additionally, the NRC staff submits non safeguards-related reports and information in the ConE database to the CNRA/WGRNR construction database.				
Q. No 167			Country India	Article Article 18.2	Ref. in National Report 18.2, Page 157
Question/ Comment	(P) NRO	18.1.2.2 and 18.2	USNRC 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 Economic Simplified Boiling Water Reactor (ESBWR) Design Certification review is nearing completion. All technical and regulatory issues have been resolved and the Advisory Committee for Reactor Safeguards (ACRS) review was completed in October 2010. The staff expects to issue the final safety evaluation report 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 boiling water reactors (BWRs) and the results were found to be acceptable. The staff also evaluated initiating events such as inadvertent actuation of the isolation condenser system since 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 light water reactor (LWR) designs. However, the Office of New Reactors (NRO) Advanced Reactor Project Office (ARP) is preparing to review smaller LWR and non-LWR reactor designs that use unique or passive design features. The NRC discussions related to these designs is, however, preliminary and as not yet identified specific postulated initiating events to be included in design basis or beyond design basis evaluations.				
Q. No 168			Country China	Article Article 18.3	Ref. in National Report 18

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) NSIR (S) NRO (S) CSO	18.3.2.3	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 SSEP functions. Do SSEP functions include non-safety instrumentation and control system? If not, shall cyber security for those systems which are non SSEP functions related be assured？After submitting the cyber security program, when and how will cyber security design be verified? Will it be included in ITAAC?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	(1) Yes. Systems that perform security and emergency preparedness functions are non-safety instrumentation and control systems. Within the scope of 10 CFR 73.54, licensees are also required to protect those systems "associated with" 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 Regulatory Guide 5.71 "Cyber Security Programs for Nuclear Facility," provides a method that a licensee can use to determine which digital computer, communication systems and networks in operation at a nuclear power plant perform SSEP functions, and are within the scope of 10 CFR 73.54. Regulatory Guide 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 a nuclear power plant 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 the requirements of 10 CFR 73.54. According to 10 CFR 73.54 (e) the cyber security plan must include the following: (a) Description of how the requirements of 10 CFR 73.54 will be implemented and account for site-specific conditions that affect implementation; (b) Measures for incident response and recovery from cyber attacks; and; (c) Description of how the licensee will: - Maintain the capability for timely detection and response to cyber attacks; - Mitigate the consequences of cyber attacks; - Correct exploited vulnerabilities; and - 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 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 both requirements contained in 10 CFR 73,10 CFR 50, and 10 CFR 52. According to 10 CFR 50 and 10 CFR 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 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.				

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
	(4) COL applicants are required to comply with requirements contained in both 10 CFR 52 and 10 CFR 73. Under 10 CFR 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.				
Q. No 169			Country France	Article Article 19.1	Ref. in National Report § 19.1 p. 164
Question/ Comment	(P) NRO (S) DORL	19.1	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	We agree with including a listing of the current design certifications under review in this section. The certifications are: Westinghouse AP1000 design certification amendment, GE ESBWR, Mitsubishi US APWR, Toshiba ABWR renewal, and GE-Hitachi ABWR renewal.				
Q. No 170			Country France	Article Article 19.1	Ref. in National Report § 19.6 - p.167
Question/ Comment	(P) DIRS (S) DORL (S) NSIR	19.6	Could USA specify the number of events reported by the operators to the US NRC and could develop the main lessons learnt from these events?		
Answer	2008 – There were 870 event notifications received by the Operations Center. 2009 – There were 856 event notifications received by the Operations Center. 2010 – There were 915 event notifications received by the Operations Center. 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 number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 171			Country Slovakia	Article Article 19.1	Ref. in National Report 163
Question/ Comment	(P) NRO (S) DORL	19.1	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 combined license is initially issued for 40 years, the same as an operating license in the 2 step process. The combined license may reference a certified design but it is not required. A combined license may reference an early site permit, a certified design, or neither.				
Q. No 172			Country Sweden	Article Article 19.2	Ref. in National Report 165
Question/ Comment	(P) DE (S) DORL (S) NRO	19.2	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, and to assure 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 subject to the electromagnetic (EMI/FRI) conditions that would be present within a nuclear power plant control building, as well as seismic and vibratory motion appropriate to its location. Guidance has been developed by the NRC staff (Regulatory Guide 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 regarding 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.				
Q. No 173			Country France	Article Article 19.6	Ref. in National Report "§ 19.6 - p. 167

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Question/ Comment	(P) DIRS (S) DORL (S) NSIR	19.6	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 Reports (LER), are required to be submitted within 60 days. However, most of the events which meet the requirement for an LER also met the requirements for reporting in accordance with 10 CFR 50.72, Event Notification, which requires events to be reported within 1, 4, or 8 hours. 10 CFR 50.72 event notification requirements cover important events for which the NRC should be notified quickly such as emergency declarations or reactor trips.				
Q. No 174			Country Korea, Republic of	Article Article 19.6	Ref. in National Report Section 19.6
Question/ Comment	(P) DIRS (S) DORL (S) NSIR	19.6	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, FSME for materials, NMSS for fuel cycle and transportation, and NSIR for security) review the event reports to determine if any of the events exceed the threshold for exceeding Level 2 on the INES scale. For reactors events, of which there are approximately 500 per year, NRR rates every reactor event, and that rating is kept in a database of event notifications. Out of approximately 500 reactor events per year, NRR has had 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 (ERF) which is reviewed by their 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) are not included in the NRC Event Reports, nor are they posted on the NRC public website.				
Q. No 175			Country Sweden	Article Article 19.6	Ref. in National Report 167
Question/ Comment	(P) DIRS (S) DORL (S) NSIR	19.6	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Only the NRC classifies events based on the International Nuclear and Radiological Event Scale and transmits events to the IAEA. Neither NRC licensees nor Agreement States licensees are required by regulations to classify their events according to the INES scale. However, U.S. licensees have been made aware of the scale via issuance of NRC Information Notice 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 correspondence 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 scale and of the benefits of communicating the safety significance of events to the public.				
Q. No 176			Country Russian Federation	Article Article 19.7	Ref. in National Report Section 19.7, pp. 167-168
Question/ Comment	(P) DIRS	19.7	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 Inspection Procedure (IP) 71152, "Identification and Resolution of Problems." In addition to quarterly, semi-annual, and annual sampling requirements performed as part of the baseline inspection process, on a biennial sampling basis, IP 71152 requires inspectors to perform an in-depth review of corrective action reports and trending of plant issues and problems from the previous five 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 inspection procedures including IP 71111.21, "Component Design Basis Inspection," for items specific to the inspectable area. Inspectors review performance indicators throughout the year and ensure that thresholds exceeded are addressed, and 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 number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Q. No 177			Country Ukraine	Article Article 19.7	Ref. in National Report Page 168
Question/ Comment	(P) DIRS	19.7	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 licensee event reports 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.				
Q. No 178			Country Sweden	Article Article 19.8	Ref. in National Report 170
Question/ Comment	(P) NMSS (S) FSME	19.8	How many years are the existing temporary spent nuclear fuel storages, predicted to last?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	Recently, NRC reviewed current information supporting the storage of spent nuclear fuel. 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. Studies performed to date also 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 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 81032; December 23, 2010). Since 1999, 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 structures, systems, and components important to safety. 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 Federal Register 81068; December 23, 2010). Based on available information, 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, NRC has confidence that at least 120 years of storage would be safe and without environmental significance (75 Federal Register 81032; December 23, 2010).				
Q. No 179			Country Switzerland	Article Article 19.8	Ref. in National Report 169
Question/ Comment	(P) NMSS (S) FSME (S) NRO	19.8	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?		

Question number	Reviewer (P)Primary (S) Secondary	Report Section	Country	CNS Article	Page of the National Report
Answer	For several decades, the NRC has proceeded with the licensing of new nuclear power plants 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 nuclear power plants, 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, 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 Federal Register 34688; August 31, 1984). NRC also concluded 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 Federal Register 38474; September 18, 1990; 64 Federal Register 68005; December 6, 1999; 75 Federal Register 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 Federal Register 81069; December 23, 2010.) This assurance was developed assuming that the proposed repository at Yucca Mountain, Nevada, was not constructed as planned. Consideration of available information allows 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 Department of Energy 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 Federal Register 81063; December 23, 2010).				

Smith, Leah A

From: Kenagy, W David
Sent: Wednesday, July 06, 2011 9:48 PM
To: Smith, Leah A
Subject: FW: CNS Responses to Post
Attachments: CNS Responses to Post - Part 1.doc

-----Original Message-----
From: Theresa Valentine [mailto:TXV@nrc.gov]
Sent: Monday, March 28, 2005 7:48 AM
To: BurrowsRA@state.gov; KenagyWD@state.gov
Cc: Thomas Hiltz
Subject: CNS Responses to Post

Good morning,

I have attached NRC's responses for 234 of the 266 questions we were asked for the Convention on Nuclear Safety. The table in Word format includes the "Seq. No", article, and question to help you line the responses up with the right questions. Please post these answers to the CNS website as soon as you can. We plan to send you the rest of the responses by the end of the week. Thank you for your help, and please let me know if you have any questions.

--
Theresa Valentine
Nuclear Safety Professional Development Program U.S. Nuclear Regulatory Commission
txv@nrc.gov / 301.415.2290

>>> "Burrows, Ronald A" <BurrowsRA@state.gov> 03/24/05 05:53PM >>>
Tom,

It should be in Word. Please make David your POC since I will be departing State shortly.

Regards,

Ron

Ronald A. Burrows
Office/Senior Coordinator for Nuclear Safety US Department of State
2201 C St. NW
Room 3310A
Washington, DC 20520
202-647-6109
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burrowsra@state.gov

-----Original Message-----
From: Thomas Hiltz [mailto:TGH@nrc.gov]
Sent: Thursday, March 24, 2005 3:19 PM
To: Burrowsra@state.gov
Cc: Elizabeth Doroshuk; Theresa Valentine
Subject: Q's and A's

A2

You should be getting the first round of answers tomorrow.

Can you cut and paste from a .pdf file or does it need to be in Word?

Tom

Seq No	Country	Article	Question	Response
1	China	General	What criteria is used when use risk-informed methodology to modify technical specification (T.S.)? For example, how much risk probability is allowed to modify T.S.?	Risk-informed changes to technical specifications (TS) are approved in accordance with guidelines set forth in Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment (PRA) in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," and RG 1.177, "An Approach for Plant-Specific, Risk-Informed Decision-making: Technical Specifications." RG 1.174 provides guidelines in evaluating risk probability regarding plant specific TS changes, which includes the use of the five principles in implementing risk-informed decision-making. These principles are:1) The proposed change meets the current regulations unless it is explicitly related to a requested exemption or rule change, i.e., a "specific exemption" under 10 CFR 50.12 or a "petition for rulemaking" under 10 CFR 2.802, 2) The proposed change is consistent with the defense-in-depth philosophy, 3) The proposed change maintains sufficient safety margins, 4) When proposed changes result in an increase in core damage frequency or risk, the increases should be small and consistent with the intent of the Commission's Safety Goal Policy Statement, 5) The impact of the proposed change should be monitored using performance measurement strategies. RG 1.177 provides the risk acceptance criteria in making plant specific TS changes, which include the following guidelines: 1) The licensee must demonstrate that the TS AOT (allowed outage time; also known as TS completion time) change has only a small quantitative impact on plant risk. An ICCDP (Incremental Conditional Core Damage Probability) of less than 5.0 E-7 is considered small for a single TS AOT change. An ICLERP (Incremental Conditional Large Early Release Probability) of 5.0 E-8 or less is also considered small. Also, ICCDP contribution should be distributed in time such that any increase associated with conditional risk is small and within normal operating background (risk fluctuations) of the plant. [Known as Tier 1 constraints.] 2) The licensee must demonstrate that there are appropriate restrictions on dominant risk-significant configurations associated with the change. This includes actions to minimize the likelihood of initiating events and actions to mitigate the risk of the risk significant configuration should an initiating event occur. [Known as Tier 2 constraints.] 3) The licensee must implement a risk-informed plant configuration control program, including procedures to utilize, maintain, and control such a program. [Known as a Tier 3 constraint.] Additional information on RG 1.174 can be found on the following link on the NRC public website, which is: http://www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/active/01-174/index.html . Additional information on RG 1.177 can be found at: http://www.nrc.gov/reading-rm/doc-collections/reg-guides/power-reactors/active/01-177/index.html
2	China	General	Design application and construction application are separated for new installation. How to deal with site-related safety analysis? When the plant get the approval for design and construction applications separately, if the combined license is still need?	Although separate applications for design certification and construction authorization may be submitted under the alternative licensing processes in 10 CFR Part 52, that approach is not required. If an application for a combined license references a certified design, the site-related safety analysis may be provided in the combined license application or an application for an early site permit. Also, a combined license application, which requests construction authorization, is still needed whether or not a previously certified design is referenced. The combined license application includes applicant qualifications and a description of operational programs.
3	China	General	How to deal with reactor vessel head penetration defects in Davis-Besse plant?	The Davis-Besse licensee replaced the reactor pressure vessel top head with an unused head from a canceled nuclear power plant. Inspection of the new head is subject to requirements issued by NRC Order. Alloy 600 material is used for the control rod drive mechanism (CRDM) penetrations in the new head. The licensee is planning another head replacement in the future with alloy 690 CRDM penetrations.
4	China	General	Please give a brief introduction on what measures have been taken to prevent blockage of containment sump by the plants in USA.	The NRC has issued Bulletin 2003-01, "Potential Impact of Debris Blockage on Emergency Sump Recirculation at Pressurized-Water Reactors," in which PWR licensees were asked to either confirm their compliance with existing regulatory requirements or describe interim compensatory measures they would put in place to reduce potential risks associated with sump performance.
5	China	General	It is mentioned that the grid reliability decreases. What measures have been taken by the plants in USA to improve the reliability of internal power supply?	While the NRC staff is not currently working on additional measures regarding on-site power (emergency diesel generators), recent studies indicate that the reliability of on-site power sources has improved. The reliability of on-site power is governed by plant technical specifications and plant compliance with the NRC regulations 10 CFR 50.63, "Loss of all alternating current power," 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," and 10 CFR Part 50, Appendix A, "General Design Criteria," General Design Criterion 17, "Electric Power Systems." During the summer of 2004, the NRC staff assessed the licensees' readiness to manage any degraded or losses of offsite power through inspections using Temporary Instruction (TI) 2515/156, "Offsite Power System Operational Readiness." The NRC also raised awareness of the significance of grid reliability by issuing Regulatory Issue Summary (RIS) 2004-05, "Grid Reliability and the Impact on Plant Risk and the Operability of Offsite Power." The staff is currently working with the organizations that have the primary responsibility for grid reliability to address issues related to safe nuclear plant operations.

6	China	General	Please give a brief introduction on the measures or plans established by NRC in order to deal with new challenges on new license application, significant operation event and significant terror event.	If a significant event happens prior to or during the review of a new license application, the NRC will require the applicant to describe how their plant addresses the new safety concern and either resolve the concern on a plant-specific basis or apply the generic resolution to that application if it is available prior to completion of the review.
7	China	General	Please give a brief introduction on the measures or plans established by NRC in order to deal with new challenges on new license application, significant operation event and significant terror event. (REPEAT - IGNORE)	No response required.
8	France	General	The reports reviewed by France in view of the third peer-review meeting were all examined according to a standard list of issues derived from the obligations of the Convention. If an issue appeared to be covered in an incomplete way by the report of a Contracting Party, this led to a question or comment. However France recognizes that the corresponding information may be available in other existing documents.	No response required.
9	Germany	General	The U.S. National Report for the Convention on Nuclear Safety gives comprehensive answers with regard to the articles of the Convention. The questions posted by Germany are mostly related to specific details.	No response required.
10	Korea, Republic of	General	IN the Appendix A, NRC major management challenges for the future, P A-4, in your report, you refer to 'Managing human capital'. It is stated that NRC has developed a set of strategic human capital management initiatives to mitigate the expected loss of personnel . This is believed as a desirable approach to prepare for the future of NRC. What are the licensees' general strategy or programs to maintain competent employees who possess the skills and experience needed to ensure the safety of nuclear power plants ?	While the NRC has a set of strategic human capital management initiatives to mitigate the expected loss of personnel, the NRC does not directly monitor licensee strategies to maintain competent employees needed to ensure continued safe operation of the facility. However, the NRC does monitor the National Academy for Nuclear Training process to accredit training programs. The accreditation process assists National Academy for Nuclear Training members in establishing and maintaining training programs that produce competent nuclear professionals who can safely operate and maintain nuclear power plants. The National Academy for Nuclear Training integrates the training-related activities of all nuclear operating companies, the Institute of Nuclear Power Operations (INPO), and the independent National Nuclear Accrediting Board (NNAB). INPO develops the accreditation objectives, criteria; and supporting guidance; assists in development, implementation, and maintenance of job performance-based training programs; and evaluates the quality and effectiveness of industry training programs. Licensee seek accreditation of training and qualification programs for personnel responsible for operating and maintaining equipment important to safe and reliable nuclear power plant operation. Personnel who perform these duties participate in 12 accredited training programs. Accreditation is awarded at each nuclear plant location by training program i.e., each facility has 12 accredited training programs. NRC monitors the accreditation process by observing INPO-led accreditation team visits and NNAB meetings to provide assurance that training programs accredited and implemented in accordance with the NANT objectives will be in compliance with the SAT requirements contained in 10 CFR 50.120 and 10 CFR Part 55.
11	Korea, Republic of	General	What's your basic strategy for securing public understanding and confidence in nuclear regulation and safety? Do you have a program for enhancing perceived safety other than engineering safety?	Ensuring openness in our regulatory processes is one of our goals and ways of achieving this goal is spelled out in our strategic plan (Found at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v3/sr1614v3.pdf.) Over the next several years, the public's interest in the safety and security of nuclear facilities is expected to increase because of emerging issues, such as the increase in the number of applications to extend the operating life of reactors and the possible submittal of applications for reactor facilities. As a result of the terrorist attacks on September 11, 2001, both security and emergency planning issues have become increasingly important to both the public and government officials. The NRC must, therefore, concentrate its efforts on assuring the public that its rigorous oversight and "defense-in-depth" approach ensures that the public is adequately protected, and that emergency plans surrounding the facility are well conceived and will work. In light of increased terrorist activity worldwide, the agency has had to reexamine its traditional practice of releasing almost all documents to the public. While most important safety information would not be useful to potential terrorists and can be shared with the public, that is not true for an increasing amount of security information. The NRC will adopt policies relating to sensitive security information consistent with those at the Department of Homeland Security and other agencies. Although the NRC will withhold a relatively

				small amount of information that could assist potential terrorists, the agency will continue to make as much information as possible available to the public. The focus on security has emerged at a time of renewed interest in nuclear power. Some utilities are applying to the NRC for early site permits for new reactors, and existing plants are extending their licenses so they can operate for an additional 20 years. As the NRC processes these requests, it will need to address public concerns about vulnerability to many different types of terrorist attacks without disclosing information that could aid terrorists. The NRC believes in the importance of transparency in its communications, as well as early and meaningful public involvement in the regulatory process. The agency is committed to keeping the public informed and believes that a responsible and effective regulatory process includes an involved public that is well informed. STRATEGIES AND MEANS The NRC will employ the following strategies to ensure openness in its regulatory processes. (1) Provide accurate and timely information to the public about the uses of and risks associated with radioactive materials. (2) Enhance the awareness of the NRC's independent role in protecting public health and safety and the environment. (3) Provide accurate and timely information about the safety performance of the licensees regulated by the NRC. (4) Provide a fair and timely process to allow public involvement in NRC decision-making in matters not involving sensitive unclassified, safeguards, classified, or proprietary information. (5) Provide a fair and timely process to allow authorized (appropriately cleared with a need to know) stakeholders involvement in NRC decision-making in matters involving sensitive unclassified, safeguards, classified, or proprietary information. (6) Obtain early public involvement on issues most likely to generate substantial interest and promote two-way communication to enhance public confidence in the NRC's regulatory processes. MEANS TO SUPPORT OPENNESS STRATEGIES The NRC conducts a number of programs and initiatives to ensure openness in the agency's regulatory process. Activities include the following examples: • Enhance the NRC's communications both within the agency and with the public, the media, and Congress. [Supports Strategies 1, 2, 3, 4, 5, and 6] • Actively engage the public, particularly potentially affected local individuals, before actions are taken. [Supports Strategies 1, 4, and 6] • Hold annual public meetings (such as the Regulatory Information Conference and the Nuclear Safety Research Conference) to bring together diverse groups of stakeholders to discuss the latest trends in industry performance and cutting-edge research. [Supports Strategies 1, 3, 4, and 5] • Improve communications about licensee operating events and their significance using easily understood risk comparisons, plant features,and regulatory controls to put situations into their proper context. Develop and implement agency-wide guidelines that will improve the NRC's ability to communicate with stakeholders regarding risk insights and other health and safety issues. [Supports Strategy 3] • Develop communication plans for key program activities. [Supports Strategies 1 and 4] • Maintain and update the NRC's external Web site with timely, user-friendly information and continue to make site enhancements based on input from Web user satisfaction measurement. [Supports Strategies 1, 3, and 4] • Identify areas that require additional public engagement and dialogue. This may be achieved through independent surveys or other measurement instruments. [Supports Strategy 2].

12	Korea, Republic of	General	Concerning Davis Besse situation, was there any actual charge or punishment to the personnel involved within USNRC? Was there any program prepared and implemented to renew working attitude or approach in the USNRC related to the Davis Besse case?	1) This information on personnel charges or punishments is protected by law and cannot be disclosed. 2) After extensive degradation was discovered in the reactor pressure vessel (RPV) head at the Davis-Bessie Nuclear Power Station, the NRC Executive Director of Operations (EDO) established a lessons learned task force to evaluate NRC regulatory processes for ensuring RPV head integrity and to recommend improvements for either the NRC or the nuclear industry. On September 30, 2002, the task force reported its findings to a senior management review team, including 51 recommendations for the NRC to take to address factors that contributed to the Davis-Besse event. In its report of November 26, 2002 , the senior management review team endorsed all but two task force's recommendations. The approved recommendations were placed into four categories: (1) assessment of stress corrosion cracking; (2) assessment of operating experience, integration of operating experience into training, and review of program effectiveness; (3) evaluation of inspection, assessment, and project management guidance; and (4) assessment of barrier integrity requirements. The review team assigned each recommendation a priority and directed that the highest priority items be addressed by action plans. All other items were to be integrated into the operational planning activities of the lead offices. On January 3, 2003, the EDO issued a tasking memorandum to the directors of the Offices of Nuclear Reactor Regulation (NRR) and Nuclear Regulatory Research (RES), instructing them to develop a plan for accomplishing the actions recommended by the review team. RES and NRR issued the plan on March 7, 2003. See http://www.nrc.gov/reactors/operating/ops-experience/vessel-head-degradation/lessons-learned.html for more information.
13	Mexico	General	The National Report (Introduction) in page xvi, indicates that the NRC staff is also actively reviewing pre-application issues concerning two additional designs and has four other designs in various stages of pre-application review. Please name these designs under review	The NRC is actively reviewing pre-application issues for the ESBWR and ACR-700 designs. The other designs in various stages of pre-application review are EPR, IRIS, PBMR, and SWR-1000.
14	Pakistan	General	It is mentioned that the blackout in the eastern United States and Canada on August 14, 2003, highlighted the need to further consider the impact of grid reliability on nuclear power plants, primarily because of its long duration. Although plants are designed for these occurrences with backup power supplied by emergency diesel generators, a loss of offsite power would reduce a plant's safety margin. In this context following points may please be elaborated: • What measures have been taken in terms of grid reliability? • Has NRC suggested additional measures regarding reliability of on-site power (diesels) for long duration operation? • Is the feasibility of plant operation at house load to maintain the plant safety margin in case of loss of offsite power is being looked into?	(1) During the summer of 2004, the NRC staff assessed the licensees' readiness to manage any degraded or losses of offsite power through inspections using Temporary Instruction (TI) 2515/156, "Offsite Power System Operational Readiness." The NRC also raised awareness of the significance of grid reliability by issuing Regulatory Issue Summary (RIS) 2004-05, "Grid Reliability and the Impact on Plant Risk and the Operability of Offsite Power." The staff is currently working with the organizations that have the primary responsibility for grid reliability to address issues related to safe nuclear plant operations. The North American Electric Reliability Council (NERC) revised its reliability standards and they were approved by its Board of Trustees on February 8, 2005. The new reliability standards take effect on April 1, 2005. (2) While the NRC staff is not currently working on additional measures regarding on-site power (emergency diesel generators), recent studies indicate that the reliability of on-site power sources has improved. The reliability of on-site power is governed by plant technical specifications and plant compliance with the NRC regulations 10 CFR 50.63, "Loss of all alternating current power," 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," and 10 CFR Part 50, Appendix A, "General Design Criteria," General Design Criterion 17, "Electric Power Systems." During the summer of 2004, the NRC staff assessed the licensees' readiness to manage any degraded or losses of offsite power through inspections using Temporary Instruction (TI) 2515/156, "Offsite Power System Operational Readiness." The NRC also raised awareness of the significance of grid reliability by issuing Regulatory Issue Summary (RIS) 2004-05, "Grid Reliability and the Impact on Plant Risk and the Operability of Offsite Power." The staff is currently working with the organizations that have the primary responsibility for grid reliability to address issues related to safe nuclear plant operations. (3) The US plants are not designed to switch power to house loads on loss of main load. It is possible to come to house load only during a controlled shutdown.
15	Pakistan	General	It is written that "In October 2001, NRC amended 10CFR 55 to permit applicants for operator and senior operator licenses to fulfill a part of experience prerequisites by manipulating a plant-referenced simulator as an alternative to manipulating the controls of an actual nuclear power plant. This change takes advantage of improvements in simulator technology and reduces unnecessary regulatory burden on licensees." What are the bases for changing the experience pre requisite by plant–referenced simulator manipulation?	As stated in the Federal Register (66 FR 52657, dated October 17, 2001), "...technology has allowed advances in the simulators' computing capability, model complexity, and fidelity. Consequently, the Commission has fewer concerns regarding the equivalence of experience gained on simulation facilities and that obtained on the actual plant." 10 CFR 55.31(a)(5) requires applicants for operator and senior operator licenses perform five significant control manipulations that affect reactivity or power level. The manipulations are to be performed on either the actual plant or on a plant-referenced simulator meeting the regulatory criteria of 10 CFR 55.46(c).
16	Russian Federation	General	In the Introduction to the Report (section entitled "Power Uprate Program") and also in the Section 6.2.11 it is stated that extensive efforts are in progress in the USA to	While a power uprate program will produce an increase in core average thermal power, it may not result in an increase in the peak rod linear heat generation rate (LHGR) above historic values. During the past two decades, changes in fuel assembly design and fuel management techniques have yielded reductions in peak LHGR. For example, PWR fuel assembly designs have

			increase thermal power of reactors in the range of 15-20%. It is noted that as of August 2004 NRC has approved more than 100 power uprates. Since during reactor thermal power increase linear loads on the fuel rods become higher while the thermal and reliability margins decrease, some points need to be clarified here. 1) Which factors has allowed to improve fuel assembly power and increase linear loads on the fuel rods? 2) If power uprate was being achieved through reducing safety margins while preserving the maximum permissible value of linear loads, then could it have resulted in the degradation of safety level in the fuel performance? 3) If the safety margins remained unchanged, and the maximum permissible linear load was increased, then did you make modifications to the fuel assemblies or did you use new kind of fuel?	significantly increased the linear feet of fuel in the core by replacing poison rods (e.g. B4C shims) with fuel rods doped with integral burnable absorbers (e.g. gadolinium). This design change results in a decrease in the core average LHGR. Fuel management techniques (e.g. radial U235 enrichment zoning) have flattened the radial power distribution across an assembly and promoted a reduction in peak LHGR. Analytical improvements (e.g. best-estimate LOCA models) have been employed to increase LHGR and DNB thermal margins. Fuel design improvements (e.g. mid-span mixing vanes) have also been employed to increase fuel design margins. As a result of these improvements, power uprates have not diminished safety margins. The U.S. nuclear industry is committed to preserving a high level of fuel reliability. Continuing improvements in fuel design, fuel manufacturing, and plant operations maintain this level of fuel performance . NRC staff monitors fuel performance and maintains involvement in the design and licensing of fuel design changes.
17	Russian Federation	General	The Report fails to give an assessment of reactor uprating impact on the risk of core damage. What is the effect of US reactors uprating on the probability of severe accidents at these reactors?	Small power uprates are not expected to have an appreciable impact on risk. Extended power uprates (i.e., uprates greater than about 5%) can have a slight impact on the calculation of core damage frequency. The main impact observed during reviews conducted to date from extended power uprates is a slight reduction in the timing associated with performing operator actions. However, due to conservatisms in many current PRAs related to timing of events (and thus conservatively high estimates of human error probabilities), the impact from extended power uprates is either already bounded by the current PRA results or only slightly increased.
18	Russian Federation	General	Section "Electric Grid Reliability" of the Introduction notes that the blackout event in the eastern US and Canada that occurred on 14 August 2003 highlighted the need to improve grid reliability since this may have an impact on the availability of off-site power and on NPP safe operation. However, it is not mentioned in the Report, what changes have occurred in NPP operation regimes and in the interactions with the grids. 1) Are NPPs involved in the load following operation? 2) If so, please indicate the ranges of frequency and power change? 3) Are NPPs involved in daily and weekly load following operation in the grid? 4) What corrective actions have been implemented to improve grid reliability and prevent the events similar to that of 14 August 2003 in the eastern US and Canada?	(1) The nuclear power plants in the U.S. are base loaded and do not load follow. (2) Not applicable. (3) United States NPPs do not typically load follow on a daily or weekly basis; however, there have been cases where plants have maintained a steady, reduced load for several days in response to excess generating capacity on the grid. (4) The Nuclear Regulatory Commission (NRC) staff raised awareness of the concerns by developing and issuing a Regulatory Issue Summary (RIS) 2004-05, "Grid Reliability and the Impact on Plant Risk and the Operability of Offsite Power," highlighting the significance of grid reliability with respect to the operability of the offsite power system for nuclear power plants. In addition, during the summer of 2004, the NRC staff assessed the licensees' readiness to manage any degraded or losses of offsite power through inspections using Temporary Instruction (TI) 2515/156, "Offsite Power System Operational Readiness." The staff is currently working with the organizations that have the primary responsibility for grid reliability to address issues related to safe nuclear plant operations. The North American Electric Reliability Council (NERC) revised its reliability standards and they were approved by its Board of Trustees on February 8, 2005. The new reliability standards take effect on April 1, 2005.
19	Russian Federation	General	The existing situation in the countries with nuclear power programs is characterized by the need for more frequent upgrading of control systems as compared to NPP major process equipment since the lifetimes of automation features and process equipment differ by the factor of 3-5. Besides, fast progressing development of automation features does not allow to perform adequate replacement of the obsolete automatic controls with new, up-to-date ones. The appearance of programmable automation features with new capabilities to perform information and control functions is currently not quite properly substantiated in terms of reliable functioning, and this is noted in the IAEA and IEC documents. In this situation it is essential to have a well-reasoned concept of control systems upgrading that could be performed with no breach of NPP safe operation standards and regulations.	The NRC agrees that control systems are upgraded more frequently than major process equipment, but has not had a problem with this in the past. There are several parts to the question above, and each will be answered separably. A. " Fast progressing development of automation features does not allow to perform adequate replacement of the obsolete automatic controls with new, up-to-date ones". We have not found that fast program development has prevented adequate replacement of obsolete control systems with new, up-to-date equipment. The equipment used for replacement of control and safety equipment is required to be highly reliable and of high quality. It is inherent in the nature of high quality and reliability equipment that it is seldom on the cutting edge of the technology, but uses equipment and technology which has been proven to be of the required high quality and reliability. B. "The appearance of programmable automation features with new capabilities to perform information and control functions is currently not quite properly substantiated in terms of reliable functioning, and this is noted in the IAEA and IEC documents. In this situation it is essential to have a well-reasoned concept of control systems upgrading that could be performed with no breach of NPP safe operation standards and regulations". The NRC has not found this to be true. While new capabilities are generally available in more modern digital equipment, the

			Do you have a concept of upgrading NPP safety-related control systems for all operating nuclear plants?	required safety functions remain the same. NRC requires that each new safety system demonstrate that is has adequate reliability commensurate with the safety function it performs. It is also required that the licensees demonstrate that any new capabilities will not interfere with the required safety functions. If these requirements can not be proven, the equipment will not be approved for use in a NPP. C. "Do you have a concept of upgrading NPP safety-related control systems for all operating nuclear plants?" The NRC has extensive guidance for the upgrading of safety related equipment which is applicable for all operating nuclear plants. These include Regulatory Guides endorsing standards to be used when designing, testing, installing and using safety related digital equipment, Chapter 7 of the Standard Review Plan (NUREG-0800), and numerous topical reports by industry associations, owners groups, and vendors which NRC has reviewed and found acceptable to meet NRC regulations. If the licensee decides to retain the existing equipment, and if that existing equipment continues to meet the safety requirements, NRC will not require its replacement. NRC does not, however, require upgrading safety related control system at operating nuclear plants unless the proposed change meets the requirements of the NRC's backfit rule, 10 CFR 50.109.
20	Russian Federation	General	Widespread use of programmable automation means to substitute human action at NPPs eventually results in a situation where these means are being offered and applied to implement safety-related functions, in particular, reactor emergency protections. As is known, reliability of programmable automation means cannot be estimated quantitatively, while the qualitative justification can always be admitted as incomplete, which is noted in the IAEA and IEC documents. In this connection a question arises as to the need for justifying/demonstrating the applicability of programmable automation means for these purposes as well as availability of positive experience with their use. Do you have good experience with justifying the applicability and actual use of digital programmable safety-related protection systems made under IAEA and IEC recommendations at operating NPPs?	There are several parts to the question, and each will be answered separably. A. "Widespread use of programmable automation means to substitute human action at NPPs eventually results in a situation where these means are being offered and applied to implement safety-related functions, in particular, reactor emergency protections." NRC does not believe that programable automation in safety-related systems will necessarily replace human action. In general, upgrades to digital safety systems substitutes one automatic action for a previous automatic action. We know of no instance where the ability of manual action is eliminated in a digital upgrade, and particular care is taken to assure that the manual action is still possible if the digital system fails. There are some instances in non-safety control systems where actions which previously required manual action are now done automatically, but in these instances there is still the possibility for manual override of the automatic function. B. "As is known, reliability of programmable automation means cannot be estimated quantitatively, while the qualitative justification can always be admitted as incomplete, which is noted in the IAEA and IEC documents." The NRC also believes that it is not currently possible to determine an accurate value for the reliability and failure probability of a programmable digital system. For this reason, safety-related digital systems are evaluated on a deterministic basis, not on a risk-informed basis. In addition, due to the complexity of modern digital systems, qualitative justification may be incomplete. Because of this, the NRC requires diversity and defense-in-depth in required safety functions. C. "Do you have good experience with justifying the applicability and actual use of digital programmable safety-related protection systems made under IAEA and IEC recommendations at operating NPPs?" The NRC, while permitting use of IAEA and IEC standards and recommendations, does not require their use, and U.S. licensees seldom use IAEA and IEC standards and recommendations. For this reason, NRC does not have either good or bad experience with justifying the applicability and actual use of digital programmable safety-related protection systems made under IAEA and IEC recommendations. NRC has good experience with the actual use of digital programmable safety-related protection systems approved under 10 CFR Part 50, and the various Regulatory Guides, industry standards, and topical reports previously mentioned. NRC has found that safety-related digital equipment that was designed, tested, and used in accordance with the proper requirements has functioned very well at NPPs.
21	Russian Federation	General	Subsection (paragraph) "Electronic Maintenance and Submission of Information" of the Introduction says that the licensees and members of the public may use electronic means (such as CD-ROM, E-mail or fax) to exchange information with the agency. Can licensee submit to NRC safety case documentation in electronic form and how is the approval of the final version of the justification documents assured in this case?	NRC's Electronic Information Exchange (EIE) allows NRC to exchange material related to official agency business with its customers (including licensees) and other Federal agencies across the Internet. The *EIE system* uses a public key infrastructure and digital signaturing technology to authenticate documents and validate the person submitting the information. That is, the system ensures that the exchanged material is secure and that the person submitting the material is, in fact, who is indicated. More information may be found on the NRC web site at http://www.nrc.gov/site-help/eie.htm

22	Slovenia	General	The report presents an overview of various NRC activities for control of NPP operation and design changes as well of some programs that exist in NPPs. However, reviews of either NRC or the NPPs by an international mission were not mentioned neither their findings or recommendations. The approach of those missions may be different from NRC's and would give different insight into NPPs' safety and operation. Could you present a list of these missions and their recommendations.	The US strongly supports the operational safety program of the IAEA, of which the OSART program is a very important part. We see participation in this program as a further indication to the IAEA and member states that all countries can learn from independent safety reviews of their nuclear power plants. Similarly, the US believes that IRRT missions provide a valuable and useful independent review of regulatory authorities. The IAEA has conducted four OSART missions in the US: at Calvert Cliffs (1987), Byron (1989), Grand Gulf (1992) and North Anna (1999) nuclear power plants. Next month, May 2005, the IAEA will conduct an OSART mission to the Brunswick nuclear power plant in Southport, North Carolina. The US is seeking to schedule an OSART mission to a US nuclear power plant at least once every 3 years. The North Anna OSART Report, with its conclusions and recommendations, is available publically through the NRC's ADAMS document management system. The North Anna OSART's ADAMS accession number is ML010470115. Because the Calvert Cliffs, Byron and Grand Gulf OSART reports are over 12 years old, the reports pre-date the implementation of ADAMS and they are not readily available. The US has not hosted an IRRT. However, the NRC will complete a targeted IRRT self-assessment, focusing on reactor-related areas, prior to the Fourth National Report Review. At the conclusion of the self-assessment NRC will consider the scheduling of an IRRT. At the Fourth National Report Review Meeting, the United States will either discuss the results of its self assessment and/or make available the results of the IRRT mission to the United States.
23	Switzerland	General	The report is well structured, clear and discusses all relevant aspects of nuclear and radiation safety from both the regulatory and the operators' side in depth.	No response required.
24	Switzerland	General	All US-nuclear power plants have implemented Severe Accident Management Guidance (SAMG). Are there any periodic emergency exercises / drills which require the use of SAMG?	There are no periodic exercises or drills which require the use of Severe Accident Management Guidance (SAMG), however all licensees have implemented SAMG. Licensees develop scenarios for emergency exercises/drills that do require the use of the SAMGs, but this is not required for the exercises/drills. Industry practice is to periodically perform self-evaluation of the licensee's severe accident response capability to ensure its feasibility and usefulness. Upon creation of the plant-specific SAMG, an initial evaluation may be performed to ensure the process has been integrated into the licensee's emergency response capability. Periodic table-top and/or inter-facility drills may be used to ensure personnel are familiar with the use of SAMGs, with the objective of training, testing, and improving severe accident management response capability.
25	Australia	6	Australia notes with interested the level of public involvement in the rule making process. Does the Nuclear Regulatory Commission provide a similar opportunity when it considers an application for a licence or for renewal or extension of licence?	Public Involvement in Licensing Actions The public can become involved in the licensing of a facility, and can make their views known to the Commission at various stages in the process. In the pre-licensing stage, the public is notified through the Federal Register, press releases, and local advertisements that an application has been received. Notices regarding opportunities for hearings or public comment on all reactor licensing actions, including amendments to a facility's operating license, or license renewal proceedings are published in the Federal Register. If local interest is strong, the NRC may hold public meetings in the vicinity of a proposed facility. Notices of meetings may be mailed to citizens' groups and civic and government leaders in the community and may be advertised in local newspapers. For nuclear power plants, individuals who are directly affected by the proceeding may participate in a formal hearing. However, for materials licensees and fuel facilities, most hearings are informal. Information on opportunities and requesting a hearing for major licensing and regulatory actions involving nuclear power reactors can be found. Hearing requests and intervention petitions ordinarily must be filed within sixty (60) days of the date of Federal Register publications of the "Notice of Opportunity for Hearing" 10 CFR 2.309. Involvement in Environmental Impact Review NRC considers impacts on the environment while reviewing any proposals for new, major facilities, or other major actions. An Environmental Assessment is usually prepared, which describes the need for a proposed action and a list of the agencies and experts consulted. If the assessment indicates the proposed facility or action will have a significant effect on the environment, an Environmental Impact Statement is also developed by the NRC staff. The Environmental Impact Statement includes information on the physical characteristics of the area - geology, water, and air - the ability of the transportation systems to support the facility, and local population data. Scoping meetings are held in the vicinity of the affected community to provide a forum for members of the public to express their opinion and provide information for the environmental review. These meetings are often held to help NRC identify issues

				to be addressed in an environmental impact statement and typically involve state and local agencies, Indian Tribes, or other interested people who request participation. Public Involvement in Reactor License Renewal As with any licensing activity, the public has an opportunity to participate in NRC's decision making process with regard to license renewal. Guidance for the review process is based not only on NRC views, but on industry experience as well. Furthermore, the expertise of technical organizations and professional societies was used, as appropriate, during the development of the license renewal process. The public, in general, is also encouraged to participate in the process through public meetings, and public comment periods on rules, renewal guidance, and other documents. In addition, the public has an opportunity to request a formal adjudicatory hearing if that party would be adversely affected by the renewal.
26	China	6	How to establish the thresholds for performance indicators when NRC evaluates the licensee's performance indicator data?	For the Initiating Events PIs and the Safety System Functional Failures PI, the green-white thresholds were established to identify outliers from industry performance. The staff collected historical data from 1995 to 1997 for each plant for each PI. Then the staff determined the values of that PI for every calculational interval during the three years from 1995 to 1997. The highest value for each plant was then plotted on a histogram and a line drawn that would place about 5 percent of the plants above that line. This became the green-white threshold. For each of the above PIs except the Safety System Functional Failure PI, which is not risk-significant and therefore has only a green-white threshold, the white-yellow and yellow-red thresholds were established using about a dozen generic probabilistic risk assessment (PRA) models. The measured parameter was increased until the change in the PRA value exceeded 10-5 for the white yellow threshold and 10-4 for the yellow-red threshold. All the Safety System Unavailability PI thresholds were established using generic PRAs as described above, with the green-white threshold set at a change in the PRA value of 10-6. The Barrier Integrity thresholds were set at 50 percent of the technical specification (TS) limit for the green-white threshold and 100 percent of the TS limit for the white-yellow threshold. There is no yellow-red threshold because plants are required to shut down if they exceed the TS limit. The thresholds for the Emergency Preparedness, Occupational Radiation Safety, Public Radiation Safety, and Physical Protection cornerstones were all set by expert panels. None of these cornerstones have yellow-red thresholds because none of these programs can be allowed to be unacceptable; the NRC would step in to ensure their continued viability.
27	China	6	What measures have been taken by plants in USA to prevent Davis-Besse event of boric acid corrosion at control rod driving mechanism penetration of reactor vessel head recurrent?	Plants have performed inspections of the control rod drive mechanism penetrations. Also, some have replaced or are planning to replace their reactor pressure vessel heads. Alloy 690 material, instead of alloy 600, is often used for the new reactor vessel head CRDM penetrations. The inspections were guided by NRC bulletins and Orders. Following discovery of the corrosion, the NRC issued two bulletins, Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity" and Bulletin 2002-02, "Reactor Pressure Vessel Head and Vessel Head Penetration Nozzle Inspection Programs." Additionally in 2003, the NRC issued an Order modifying licenses establishing inspection requirements for reactor pressure vessel heads at pressurized water reactors. A revised Order was issued in 2004 and superceded the original Order. An ASME Code case is being developed concerning reactor pressure vessel head inspection requirements.
28	China	6	Why the trend of precursor occurrence rate in 1999~ 2001 is increasing in Figure 3? How about the trend of 2002 and 2003?	The NRC has not determined the basis for changes in occurrence rates during these time periods. We are planning to initiate an evaluation of the accident sequence precursor (ASP) data to determine whether there is an explanation for the relatively low number of precursors between 1997 and 1998; assess the increasing number of potential precursors in 2000-2002; and identify any engineering insights that can be applied in the NRC's regulatory programs. Data for 2003 is not yet available.
29	Czech Republic	6	In article No.6 Power Uprates extended power uprate among others are described. The document "Review Standard for Extend Power Uprates " to guide licensees has been mentioned. What are basic criteria that the unit has to fulfill for Extended Power Uprate?	Facility operating licenses and technical specifications specify the maximum power level at which commercial nuclear power plants may be operated. The U.S. Nuclear Regulatory Commission (NRC) approval is required for any changes to facility operating licenses or technical specifications. The process for making changes to facility operating licenses and technical specifications is governed by Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities." Licensees have to provide sufficient documentation in a power uprate application to allow the NRC to reach the following conclusions: (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public. For extended power uprates the NRC uses the review standard for extended power uprates (EPU) as guidance to reach the above conclusions.

				The review standard establishes standardized review guidance and acceptance criteria for the NRC reviews of EPU applications to enhance the consistency, quality, and completeness of reviews. It provides detailed references to various NRC documents containing information related to the specific areas of review. It serves as a tool for the NRC staff to process EPU applications in a more effective (i.e., complete) and efficient manner. The review standard also informs licensees of the guidance documents the NRC staff will use when reviewing EPU applications. This will help licensees prepare EPU applications that address those topics necessary for a complete application. By addressing the areas in the review standard, a licensee could prepare and submit a more complete application and thus minimize the NRC staff's need for requests for additional information (RAIs). This would improve the efficiency of the NRC staff's reviews. The development of this review standard included an evaluation of NUREG-0800, "Standard Review Plan [SRP] for the Review of Safety Analysis Reports for Nuclear Power Plants," to determine the applicability and adequacy of the various SRP sections to the review of EPU applications and development/revision of guidance, as necessary. During this evaluation, the NRC staff considered the versions of the SRP sections identified in the matrices in Section 2 of this review standard. To determine the need for guidance beyond that in the SRP, the NRC staff reviewed: (1) safety evaluations for previously approved power uprates, (2) previously approved topical reports for EPUs, (3) various reports related to lessons learned from the Maine Yankee experience (e.g., Report of the Maine Yankee Lessons Learned Task Group, dated December 1996), and (4) generic communications. The NRC staff also considered feedback from internal and external stakeholders. In addition, the NRC staff reviewed RAIs issued for recent EPU applications to ensure that the review standard adequately addresses areas where repeat RAIs have been issued. The NRC staff reviewed NRC procedural guidance documents to identify those applicable to processing EPU applications. The review of these documents also included consideration of the recommendations in various reports related to the Maine Yankee experience and the feedback received from internal and external stakeholders.
30	Czech Republic	6	According NRC that monitors experience at plants that have implemented power uprates, steam dryer cracking and flow-induced vibration damage on components and support for the main steam and feedwater lines have been observed. Have you modified your criteria in results of this experiences? Are you sure that this type of Power Uprates does will not influence nuclear safety in negative sense?	The NRC has not modified its criteria for the structural integrity of nuclear power plants. While the requirements for structural integrity depend upon the safety classification of the components, all components are expected to maintain their integrity during normal operation. Unfortunately, while the effects of increased flow were evaluated for safety-related components, such as reactor vessel and internals, control rod drive mechanisms, main steam piping and supports, safety/relief valves, and power-operated valves, in some cases the evaluation of non-safety-related components, such as steam dryers, was inadequate. The staff considers the integrity of non-safety-related components to be important, especially if failure of the component can effect a safety-related component. In response to industry experience, the NRC has increased its attention to the flow induced vibration of safety-related and non-safety-related components. The NRC is monitoring the corrective actions of those plants that have experienced problems due to flow induced vibration. The NRC has issued generic correspondence to alert licensees to this issue, and the NRC has issued RS-001, "Review Standard for Extended Power Uprates," to ensure that the impacts of increased flow rates are adequately addressed in future uprate requests. NRC and industry are taking steps to ensure that the structural integrity of all components is maintained such that there is no reduction in nuclear safety.
31	France	6	The chapter 6 devoted to power uprate explains clearly the safety problems encountered by the operators who have performed extended power uprate on their BWR units. This reported information is a proof of a good level of transparency reached in the USA by both the operators and the regulator and is of great interest for regulators in charge of controlling BWR units world-wide. However it is unclear whether the regulatory position in this text is given by the regulator or by the operators. What is the opinion of the US regulator relating to the acceptability of extended power uprate causing flow induced vibrations leading to cracking and failures in the steam dryers? In addition, as power uprate is an operation leading to reduce significantly the safety margins, the safety basis on which US/NRC allows such power output increase doesn't appear obvious. Could US/NRC develop the assumptions made or regulation relaxation necessary for acceptance of power uprate?	There was no regulatory relaxation for power uprates and power uprates are not intended to result in equipment failures or a reduction in plant safety with respect to component structural integrity, though the uprate can reduce the plant's safety margin. That is, the plant may come closer to the limits that establish what the NRC has determined is safe enough while still remaining within these limits. In this manner, the NRC ensures adequate protection of the public is maintained with the power uprate. NRC reviews EPU requests against the design bases for the specific nuclear plant. After equipment failures attributable to power uprates were identified, the NRC issued generic communications and strengthened its review guidance. RS-001, "Review Standard for Extended Power Uprates," discusses the issue of flow induced vibration in the steam dryers, steam lines, and feedwater lines, and states that the NRC will review the licensee's analyses of the impact of increased flow on vibration of these components.
32	France	6	The third United States of America report gives examples	These inspection procedures attempt to focus the inspector on risk-significant design and modification issues, not minor ones

			of significant findings resulting fro the implementation of the Reactor Oversight Process. Answers to the questions related to the previous report explain that the regulatory process is as efficient as PSR to upgrade NPPs when necessary. However, could the United States of America clarify whether ROP covers the design conformity check of the installation to the original /recent requirements? For example, does ROP aim at detection of minor or non-identified modifications implemented since units start up?	that have little impact on plant safety. IP 71111.21, "Safety System Design and Performance Capability", verifies that design bases have been correctly implemented to insure that systems can be relied upon to meet functional requirements. IP 71111.17, "Permanent Plant Modifications", and IP 71111.23, "Temporary Plant Modifications", verify that design bases, licensing bases, and performance capability have not been degraded through modifications. IP 71111.15, "Operability Evaluations", review operability evaluations to ensure that operability is properly justified and the component or system remains available such that there is no unrecognized increase in risk.
33	France	6	The industry trends program concludes that "no statistically significant adverse industry trends have been identified" through the years under review. However, some significant incidents are mentioned in the report (Davis Besse, South Texas). Are the indicators used in the industry trends program really fit for identifying such safety issues?	The industry trend program provides a means to assess overall industry performance using industry-level indicators. The program does so using indicators of known conditions and issues that are compiled from the best available data. The NRC staff monitors a comprehensive set of indicators; however, the staff recognizes that there are limits on what can be tracked and trended by the program. It is noted that one of the industry trend indicators is the number of "significant events." If a trend is identified in the number of significant events occurring industry wide, the industry trends program would analyze the trend and take any necessary actions using established programs (such as generic communications or generic safety issues program). In addition, individual plant issues would be addressed in the reactor oversight program.
34	France	6	In the corresponding chapter, the report describes the probabilistic analysis of events (Precursor Programme) and gives examples of events corresponding to a significant conditional Core Damage Frequency. A distribution of the number of precursor events versus time is also given. To complete this interesting information, could the United States of America clarify the following points: - Are ageing effects highlighted by the results? - Are the ASP results compared to the INES scaling of the events? - For long lasting events (unavailability existing for several years), how is this duration accounted for in the results? (to be more specific: is the conditional Core Damage Frequency multiplied by the number of years of the unavailability, and by the number of plants affected by the problem?)	1) No ageing effects are highlighted by the results at this time, but this is the part of ASP insights study that is planned to for 2005. 2) Because the INES is not a risk-based scale, the ASP results cannot directly be compared to the INES scaling of events. 3) For long-lasting events a maximum of one year is defined in ASP program. The one year is chosen in ASP analysis to compare the risk of all power plants on a yearly basis. The ASP program analyzes risk on an individual plant basis.
35	France	6	The significant findings resulting from inspections on the US NPPs and presented in the report and the detection of trends from screening the operating experience are practises that improve the safety. Nevertheless, could the United States of America indicate if main other lessons drawn from international experience are also used?	The NRC uses the Accident Sequence Precursor Program (Section 6.2.4 of the National Report) to analyze events using probabilistic risk assessment techniques to determine conditional core damage probabilities. Only United States operating experience is considered in this program. In addition to the Accident Sequence Precursor program, the NRC established an operating experience staff to perform gathering, screening, and communication functions (see Sec 19.7 of the National Report and Sec 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession Number ML033350063)). The operating experience staff reviews foreign experience as well as United States experience. For those issues deemed generic, the staff performs a number of actions, including communications of lessons drawn to internal stakeholders, issuing generic communications to external stakeholders, and identifying needs for specific inspections.
36	Germany	6	In the Accident Sequence Precursor Program, the precursor occurrence rate is used as a performance indicator. Considering their use as performance indicators, and that some precursors may be more significant than others, is there a weighting factor applied to account for their safety or risk significance?	The trend in the occurrence rate of Accident Precursors Analysis is used as a performance goal in the NRC's annual performance and accountability report NUREG-1542, "Performance and Accountability Report." This report can be found on the NRC's public website at: (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1542/). At present, we do not use a weighting factor to account for the different types of accident precursors. However, it should be noted that in FY2004, the NRC had a performance goal of no more than one event per year identified as a significant precursor of a nuclear accident (defined as those events that have a probability of 1 in 1,000 or greater of leading to substantial damage to the reactor fuel). In FY2005, the annual performance goal has been reduced to no significant accident precursor events. Additionally, the NRC bins accident precursors according to their risk significance and annually reports trends in this data to the Commission.
37	Hungary	6	This chapter presents the NRC's Accident Sequence Precursor Program. Does this program help to identify generic safety issues? What practical advantages does this program have comparing with traditional event investigation methodologies?	Several programs are involved with the identification of generic safety issues. Events reported by nuclear power plant operators are reviewed daily for generic implications and communicated by the NRC Operating Experience Clearinghouse to groups within the NRC for action and for information. One such action may result in issuing an information notice to power plant operators (see www.nrc.gov/what-we-do/regulatory/event-assess.html). NRC staff, including inspectors and risk analysts, can report potential generic safety issues to the NRC Generic Safety Issue Program (see www.nrc.gov/what-we-do/regulatory/gen-

				issues.html). Results of ASP Program analyses have been used to support the resolution of generic safety issues. In 2000, the NRC implemented the Reactor Oversight Process (ROP) that uses a risk-informed approach for monitoring safety. As part of the ROP, inspection findings are evaluated using the significance determination process (SDP), which uses risk assessment methods based on those used in the ASP Program. The NRC Incident Investigation Program also uses risk assessment methods and models largely developed from the ASP Program to determine the risk significance of events.
38	Japan	6	The reactor licensing process provides for the review and approval of changes after initial licensing. These provisions addressamendments to the operating license to support plant changes, license renewal, changes of ownership and license transfer, exemptions and relief from NRC regulations, and increasing the reactor power level ("power uprates"). Licensees have been implementing power uprates since the 1970s to increase the power output of their plants. The staff has completed more than 100 reviews for power uprates. As of August 2004, the staff had approved measurement uncertainty recapture power uprates for 34 units, stretch power uprates for 55 units, and extended power uprates for 12 units. Q/Your answer to the question regarding review requirements for license renewal and power uprates would be appreciated. We would address power uprates as an example. NRC has been reviewing of power uprates application since the 1970s for a long period and will continue to review in future. From the viewpoint of feedback of new requirements for power uprates, is it required for the already approved plants to comply with newly introduced requirements? If so, by what kinds of procedure does NRC confirm its compliance?	The NRC reviews power uprate applications against a licensee's current design and licensing bases. The NRC does not intend to impose new criteria or requirements in the review of power uprate applications on plants whose design and licensing bases do not include the criteria or requirements contained in NRC review guidance. No backfitting is intended or approved in connection with the issuance of power uprate license amendments. The NRC will evaluate the licensee's proposed changes to the power plant in the power uprate application against the current NRC rules and regulations. However, the NRC will impose new requirements on operating reactors when it determines there is a substantial increase in the overall protection of the public health and safety or the common defense and security. The regulation used to control new requirements is 10 CFR 50.109, "Backfitting." The regulation ensures that backfitting of a nuclear power reactor is appropriately justified and documented.
39	Japan	6	On January 31, 2002, NRC issued Regulatory Information Summary (RIS) 2002-03, "Guidance on the Content of Measurement Uncertainty Recapture Power Uprate Applications." In addition, on December 24, 2003, NRC issued Review Standard (RS)-001, "Review Standard for Extended Power Uprates." Q/What document guides NRC staff in reviewing stretch power uprate applications and provides the information that helps licensees prepare stretch power uprate applications? Have operating the experiences with extended power uprate (e.g. failure of steam dryer due to increased flow rate) been already reflected in RS-001 that provides review standard for extended power uprates, or will be reflected? If yes, what kind of items to be evaluated and reviewed should be newly added through operating experience feedback?	1) The NRC staff has been reviewing stretch power uprate applications since the 1970s and has completed reviews of stretch power uprate applications for over 50 units. The review process for stretch power uprates is well established. Every 6 months the NRC conducts an audit of the nuclear industry to determine the number and types of power uprates applications which will be submitted to the NRC for review and approval. The last survey was completed in January 2005. The survey indicated that over the next 4 years the number of stretch power uprates to be submitted to the NRC for review and approval would be minimal and the need for formal guidance for stretch power uprates is not necessary. 2) Yes. In the development of RS-001, the NRC changed the review standard to reflect experience with steam dryer failures in boiling water reactors and identify focus of staff review in relation to this experience. As indicated in NRC Inspection Notice (IN) 2002-26 and Supplement 1 to IN 2002-26, steam dryers and other plant components recently failed at Quad Cities, Units 1 and 2 during operation under EPU conditions. The failures occurred as a result of high-cycle fatigue caused by increased flow-induced vibrations at EPU conditions. The NRC review of the reactor internals as part of EPU requests will include detailed analyses of flow-induced vibration and acoustically-induced vibration (where applicable) on reactor internal components such as steam dryers and separators, and the jet pump sensing lines that are affected by the increased steam and feedwater flow for EPU conditions. In addition, the NRC staff is evaluating the need to address potential adverse effects on other plant components from the increased steam and feedwater flow under EPU conditions and will revise RS-001 accordingly.
40	Japan	6	For each safety cornerstone, NRC develops findings from inspections, evaluates those findings for safety significance using a significance determination process and compares performance indicator data collected by licensees against prescribed thresholds. NRC then assesses the resulting information in accordance with the Action Matrix (Table 3) to determine whether further regulatory action is required. Q/When the color assessed from inspection findings for	The Reactor Oversight Process (ROP) was developed with the following principles in mind: 1) Both the performance indicators and the results of inspections used to assess a cornerstone will have risk-informed (not risk-based) thresholds. 2) Crossing a performance indicator threshold and inspection threshold will have the same meaning with respect to safety significance and directly define the level of NRC involvement and action. Inspection finding and performance indicator thresholds were developed utilizing expert judgement with significant input from internal and external stakeholders. The expert panels developed the significance determination process (SDP), which uses generic and plant-specific risk information, to assess most inspection findings for risk significance within the appropriate

			one performance using a significance determination process is the same color of the performance indicator for the other performance, how does NRC ensure that the both performance have the equivalent safety significance? The same color code means the same safety significance, even if performance indicators or inspection items belong to different cornerstones?	cornerstone. The performance indicator thresholds were developed by expert panels using appropriate risk insights and deterministic criteria for each cornerstone. The NRC has continuously solicited feedback on this subject through the self-assessment process and adjusts individual thresholds, as appropriate.
41	Mexico	6	The National Report (6.2.1.1) indicates that NRC is closely monitoring the unexpected small differences in power level indications that have been observed at Braidwood and Byron. Please provide information on the magnitude of these differences	The differences in power levels observed at each of the units at Byron and Braidwood resulted from problems with the installation and operation of the ultrasonic flow meters used to measure main feedwater flow rates to the steam generators. Feedwater flow is a major factor used in the calculation of reactor thermal power. As a consequence of an investigation and testing conducted by the licensee, it was determined that Byron, Unit 1 exceeded its licensed power by as much as 2.6 percent. Comparable overpower values for the other units were estimated to be 1.9 percent for Byron, Unit 2, 1.1 percent for Braidwood, Unit 1, and 1.2 percent for Braidwood, Unit 2. While the overpower situations were a violation of the respective licenses and will be addressed through inspection program, they were not considered safety significant. For accident analyses NRC regulations require that plants be analyzed at 102 percent reactor thermal power to account for instrument uncertainties. In addition, there are assumptions inherent in the models that result in additional conservatisms in the calculations.
42	Mexico	6	Regarding to the Inspections and Performance Indicators (Section 6.2.2.3) and specifically to the 36 baseline inspections areas. Are inspections to supporting organizations such as fuel vendors, engineering analysis companies, etc. included? Have you ever made inspections to foreign companies that give technical support to the nuclear installations that are under your regulation?	No. We do not perform inspections of supporting organizations such as fuel vendors, engineering analysis companies, etc. under the reactor oversight process (ROP). We rely on licensees' programs to identify and correct potential performance issues in this area. However, on a routine basis, using ROP baseline procedures, NRC inspectors verify the effectiveness of the licensee's corrective action program. We have a vendor inspection program to establish general requirements for the review and inspection of nuclear steam system suppliers, architect engineering firms, suppliers of products and/or services, independent testing laboratories performing equipment qualification tests, and holders of NRC licenses (construction permit holders and operating licenses) in vendor-related areas. This program also provides guidance for the review and inspection of licensees/applicants and their vendors, as applicable, for an effective system for reporting defects under 10 CFR Part 21, 10 CFR Part 50.73, and 10 CFR Part 50.55(e). Presently, this program is implemented on an as needed basis. In addition, we also conduct vendor inspections to verify concerns received through NRC's Allegations Process.
43	Mexico	6	It seems to be an error in the reference to used for the inspection performed by Davis-Besse on February 16, 2002 (NRC Bulletin 2002-01 was emitted on March 18, 2002). Was not instead Bulletin 2001-01, which deals with the same topic? Davis-Besse was performed based on the operational experience at other nuclear installations from your discussion in this section on the analysis of this event Please describe areas for improvement of your Reactor Oversight Process	The inspections performed at Davis-Besse were performed pursuant to NRC Bulletin 2001-01, "Circumferential Cracking of Reactor Pressure Vessel Head Penetration Nozzles," not NRC Bulletin 2002-01. As a result of the Davis-Besse Lessons Learned Task Force's (DBLLTF's) recommendations, the NRC made several changes to the Reactor Oversight Process (ROP). The staff made these changes to enhance the NRC's ability to detect declining plant performance, including the specific issues that were identified at the Davis-Besse plant. The changes completed include modifying the inspection program to help identify negative equipment performance trends, enhancing inspector training, and better tracking and managing resident inspector staffing. The DBLLTF's recommendations resulted in several changes to the Baseline Inspection Program. First, the staff made significant changes to Inspection Procedure (IP) 71152, "Identification and Resolution of Problems." Specifically, these changes include establishing a semiannual trend review, performed by the resident inspectors, which will focus on declining equipment performance trends. Second, the staff added a requirement to require mandatory screening of all items in the licensee's corrective action program. Third, the staff issued a temporary instruction to review licensees' inspection activities related to the Reactor Pressure Vessel (RPV) head and vessel head penetration nozzles. In addition, the staff increased inspection focus on outage activities and modifications deferred by the licensee. The staff also developed a new Web-based "read-and-sign" training process to provide a vehicle for more timely dissemination of information to the inspection staff. For example, one module concerned the effects of boric acid corrosion, another was associated with the importance of maintaining a questioning attitude toward safety. Procedure changes also included revisions to (1) Inspection Procedure (IP) 71111.08, "Inservice Inspection Activities," to add periodic inspection requirements and guidance for boric acid corrosion control, (2) Manual Chapter 0305, "Operating Reactor Assessment Program," to include consideration of independent assessment of licensee performance during mid-cycle and end-of-cycle assessment preparations, (3) IP 71111.20, "Refueling and Other Outage Activities," to include containment walkdowns and consideration of walkdowns in other restricted areas, and (4) several procedures to verify licensees have programs and processes in place to detect, monitor, and take corrective actions for adverse trends of reactor coolant system leakage. The staff also developed and issued a site staffing metric to monitor gaps in permanent resident and senior resident staffing at reactor sites. Further details on specific DBLLTF recommendations are included in the relevant program area discussions. The status of the

				DBLLTF recommendations is also included in the Director's Status Report to ensure continued management attention (reference ADAMS Accession Number ML043480034).
44	Pakistan	6	It is mentioned that as of August 2004, the NRC has completed more than 100 reviews of power uprates which has contributed 1000 MWe to the national grid and more than 25 power uprates are expected to be submitted to NRC within the next five years. While NRC has monitored the operating experience of plants with power uprates, and steam dryer cracking and flow induced vibration damage on components and supports for the main steam and feedwater lines have been observed at these plants. How does NRC view its decision regarding allowing large scale power uprates when operating experience indicates evidence of steam dryer cracking & flow induced damage of steam/feedwater components?	The NRC does not intend a reduction in safety with respect to component structural integrity to achieve a power uprate, though the uprate can reduce the plant's safety margin. That is, the plant may come closer to the limits that establish what the NRC has determined is safe enough while still remaining within these limits. In this manner, the NRC ensures adequate protection of the public is maintained with the power uprate. The higher flow rates at power uprate conditions have been evaluated for their effect on major, safety-related components. Unfortunately, the evaluation of non-safety related components, and some safety-related components at the subsystem level, such as vent and drain lines and valve sub-components, was not always evaluated thoroughly. The NRC staff is closely monitoring the licensee corrective actions at nuclear power plants that have experienced adverse flow effects from power uprates. The NRC staff is also carefully reviewing new uprate requests for the effects of increased flow.
45	Pakistan	6	It is stated that "some stakeholders raised concern about the complexity and subjectivity of the Significance Determination process, the effectiveness of the performance indicator program, a perceived lack of NRC responsiveness to stakeholder comments, and other areas where improvements have been suggested." In addition to the above mentioned concerns of stakeholders, are some other important factors being considered in improvements of Reactor Oversight Process to enhance regulatory effectiveness?	Absolutely. The three concerns specifically mentioned are some examples of potential areas for improvement within the ROP. These suggestions, along with numerous others, continue to be evaluated by the NRC. The NRC staff assesses the ROP on a continual basis to identify and implement potential program improvements per its self-assessment program (reference IMC 0307). The staff reports the results of its self-assessment on an annual basis, and is in the process of completing its self-assessment for CY 2004. The results of the previous annual assessment were presented in SECY-04-0053, dated April 6, 2004.
46	Russian Federation	6	1) Cracks have been found in reactor vessel head penetrations at Davis Besse NPP. What corrective actions have been taken to preclude the recurrence of such incidents and prevent the occurrence of new cracks? 2) What corrective actions have been taken to deal with the problem of Davis Besse containment sump clogging? 3) What corrective actions have been taken to resolve the problem of auxiliary feedwater pumps' recirculation lines fouling at Point Beach-2 NPP? 4) What corrective actions have been taken to address the problem of the fouling/clogging in the system that supplies cooling water to the heat exchangers of emergency diesel generators at D.C.Cook NPP? 5) Does the trend towards an increase in the number of accident precursors in 1998-2001 indicate safety level degradation at US NPPs? 6) What are the recent trends in the numbers of US NPP accident precursors (2001-2003)?	1) Plants have performed inspections of the control rod drive mechanism penetrations. Also, some have replaced or are planning to replace their reactor pressure vessel heads. Alloy 690 material, instead of alloy 600, is often used for the new reactor vessel head CRDM penetrations. The inspections were guided by NRC bulletins and Orders. Following discovery of the corrosion, the NRC issued two bulletins, Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity" and Bulletin 2002-02, "Reactor Pressure Vessel Head and Vessel Head Penetration Nozzle Inspection Programs." Additionally in 2003, the NRC issued an Order modifying licenses establishing inspection requirements for reactor pressure vessel heads at pressurized water reactors. A revised Order was issued in 2004 and superceded the original Order. An ASME Code case is being developed concerning reactor pressure vessel head inspection requirements. 2) The licensee installed a larger containment sump screen to better handle post-accident debris and repainted inside containment to ensure all coatings were qualified. Additionally, the licensee modified the high pressure injection/recirculation pumps to handle post-accident debris. 3) Immediate actions included briefings and procedure changes to ensure that minimum recirculation flow was maintained or the pumps would be secured from operation. Subsequently a design change was made and new recirculation line orifices were installed that were not susceptible to clogging from service water debris. 4) A debris intrusion event occurred at Donald C. Cook Nuclear Plant on August 29, 2001. A failed essential service water (ESW) strainer basket, caused by inadequate strainer basket installation instructions, permitted debris to bypass the strainer and enter the ESW system, resulting in fouling of most of the heat exchangers dependent upon ESW, including the Unit 1 and Unit 2 emergency diesel generator (EDG) heat exchangers. The event is described in Licensee Event Report (LER) 316/2001-003-01, "Degraded ESW Flow Renders Both Unit 2 Emergency Diesel Generators Inoperable," dated March 12, 2002 (ML020730082), and in NRC Special Inspection Report 50-315 and 316/01-17, dated June 10, 2002 (ML021610713). The root cause was determined to be incorrect installation of a strainer basket during basket replacement activities that occurred in the 1989 time frame. The failure to adjust the height of the basket to align the top edge of the basket with the lip of the strainer body allowed the basket to be placed in compression when the approximately 700 pound strainer lid was reinstalled. The compressive force exerted by the lid caused the basket mesh to tear in the area of the weld on the basket's vertical support bracket and was the initiating event for the resultant damage and eventual failure of the basket. Weaknesses in the preventive

				maintenance program and strainer inspection procedure permitted the failed condition of the basket to go undetected for an extended period of time. The failure of the basket, combined with the design of the ESW system and the way in which it was operated, led to silt intrusion. The silt intrusion was a common mode failure mechanism that affected all four EDGs (two per unit). The licensee's corrective actions included: - All of the Unit 1 and Unit 2 strainers were inspected and their associated baskets were replaced with baskets having stronger bracket support welds. - Non-destructive examinations of the replacement baskets were performed to ensure critical parameters and welds were satisfactory. - The ESW maintenance procedure for the ESW strainers was revised to ensure the strainers are properly assembled and installed. - Additional revisions to the ESW maintenance procedure for the ESW strainers were implemented to ensure the proper critical parameters are monitored during subsequent disassembly and to ensure proper repair criteria are in place. - Commercial grade dedication and/or receipt inspection practices were upgraded to ensure the critical basket design attributes are inspected. The NRC determined the event to be of low to moderate safety significance, as documented in the final significance determination and notice of violation to the licensee dated October 3, 2002 (ML022760571). Followup inspections of the licensee's corrective actions were conducted as documented in NRC Inspection Report 50-315 and 316/03-04, dated April 15, 2003 (ML031050539) and NRC Inspection Report 50-315 and 316/03-09, dated July 15, 2003 (ML031970694). 5) The NRC Industry Trends Program performs statistical analysis of long term trends. From 1993 through 2002, no statistically significant adverse trends have been observed in the accident sequence precursor data. Although no statistically significant trend was identified in the precursor occurrence rate, the NRC staff plans to initiate an evaluation of the ASP data in 2005 to determine whether there is an explanation for the relatively low number of precursors between 1997 and 1998; assess the increasing number of potential precursors in 2000-2002; and identify any engineering insights that can be applied to the NRC's regulatory programs. 6) The most recent ASP trend data (through 2002) is discussed in SECY 04-0210, "Status of the Accident Sequence Precursor (ASP) Program and the Development of Standardized Plant Analysis Risk (SPAR) Models." This paper can be found on the NRC's Public Website at: http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2004/secy2004-0210/2004-0210scy.html
47	Russian Federation	6	The Report lacks information on the storage of radwaste and spent nuclear fuel (SNF) at US NPP sites. For how long will the existing capacities for radwaste and SNF storage be sufficient at US NPP sites?	NRC considers spent fuel to be out of the scope of the CNS. It plans to include the inventory of spent fuel at nuclear plants in its next National Report for the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, unless sensitive information screen requirements change. The Commission's waste confidence decision found reasonable assurance that, if necessary, spent fuel generated in a reactor can be stored safely and without significant environmental impacts for at least 30 years beyond the licensed life for operations (which may include the term of a revised or renewed license) of that reactor at its spent fuel storage basin or at either onsite or offsite independent spent fuel storage installations.
48	Russian Federation	6	The Report gives no information on US NPP safety performance indicators. What are the US NPP indicators on: the number of NPP operational events; the number of cases of the breach of limiting conditions of operation; the number of scram actuations; the number of failures of safety systems and normal operation systems; number of personnel errors, cases of poor safety culture; radioactivity releases into environment; event ratings by INES levels?	1. NPP operational events are captured in the Initiating Events cornerstone by the Unplanned Scrams per 7,000 Critical Hours, the Unplanned Scrams with Loss of Normal Heat Removal, and the Unplanned Power Changes per 7,000 Critical Hours performance indicators. See NEI 99-02, Revision 2, pages 11 through 22. 2. Breaches of limiting conditions of operation are not directly reported in the PIs. They would be included only when such breaches result in conditions reportable under other PIs, such as an unplanned scram, an unplanned power change, safety system unavailable hours, a safety system functional failure, or increased reactor coolant system activity or leakage. 3. Every scram actuation is included in the Unplanned Scrams per 7,000 critical hours PI. 4. Failures of certain safety systems are captured in the Safety System Functional Failures PI as well as the Safety System Unavailability PI. Failures of normal operation systems are included only for the power conversion systems (circulating water, condensate, feedwater, main steam. 5. Personnel performance and safety culture are not included in our PIs. 6. Radioactivity releases to the environment that exceed specified dose rates are included in the Radiological Effluent Occurrences PI. 7. Event Ratings by INES levels are not included in our PIs.
49	Russian Federation	6	Section 6.2.5 of the Report "Program for Resolving Generic Issues" mentions the document NUREG-0933 "A Prioritization of Generic Safety Issues". At the same time, there is a document in NRC on the non-resolved safety issues.	All unresolved (and resolved) safety issues are documented in NUREG-0933. Beginning in 1983, the priority rankings were HIGH, MEDIUM, LOW, and DROP (see the Introduction of NUREG-0933). The resolution of those generic issues that were ranked HIGH and MEDIUM was pursued. In 2001, the priority categories were changed to CONTINUE and DROP. Only those generic issues in the CONTINUE category were pursued. NUREG-0933 includes: (1) generic issues that were prioritized HIGH and MEDIUM and were subsequently resolved; (2) generic issues that were prioritized LOW or DROP and whose

			1) Do you mean to say that in Section 6.2.5 this very document is actually meant? 2) Is it possible to have a look at this document? 3) When compiling and prioritizing safety issues, do you use the results of reviews/evaluations conducted by NRC? 4) What priorities have been actually set?	resolution was not pursued; and (3) generic issues that are currently in the resolution process (CONTINUE). NUREG-0933 is accessible on the NRC webpage: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0933/ . All relevant sources of information, including reviews/evaluations conducted by the NRC, are used in the screening analysis that determines the priority of an issue.
50	Slovakia	6	It seems that the U.S. Licence Renewal Procedure is much less demanding (with the exception of the Environmental Report, where clearly opposite is true) than international practice – the Periodic Safety Review. Could you defend your procedure against such a statement?	The US license renewal process is not meant to be equivalent to the generally understood periodic safety review process. While there have been some international efforts to establish common guidance and standards for periodic safety reviews, we understand that the periodic safety review process is implemented differently and for different purposes in many countries consistent with each country's regulatory structure. Consequently, we believe that the focus should be on the rigor and independence of the regulatory infrastructure as a whole and not just on an isolated element such a periodic safety reviews. Periodic safety reviews thoroughly and comprehensively implemented and considered in the context of a country's regulatory framework can be an effective, even a necessary, element in ensuring continued power plant safety. However, PSRs are not the only way to ensure continued plant safety. NRC's approach for continuing to ensure plant safety differs from the historically deterministic focus of PSRs. The transition to a more risk-informed regulatory framework, the Reactor Oversight Process, and other safety-focused aspects of the US regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, or process improvements and provides confidence that the US civil nuclear power plants can continue to be operated safely. When considering the US regulatory infrastructure in the aggregate, we believe that the US regulatory process is as demanding and as rigorous as other Contracting Parties regulatory processes in ensuring safety.
51	Slovakia	6	Have already all license renewal applicants evaluated pressurised thermal shock (PTS) events according to the new PRA methodology?	The pressurized thermal shock (PTS) methodology development activities are still under way and are not reflected in license renewal activities, which is primarily focused on aging phenomena.
52	Slovakia	6	How the introduction of the risk-informed baseline inspection program influenced and improved overall safety of NPPs? Can you provide some quantitative information?	NRC's implementation of the baseline and supplemental inspection programs verifies that nuclear power plants are operating at an acceptable level of safety. The baseline inspection program is extensive and inspects the licensee's major programs. The supplemental inspection program is used to ensure that identified licensee performance deficiencies, which are evaluated as greater than green through our significance determination process, are adequately corrected in a timely manner. Additionally, the NRC staff implemented the Industry Trend Program in 2001 and has continued to develop the program as a means to confirm that the nuclear industry is maintaining the safety of operating power plants and to increase public confidence in the efficacy of the NRC's processes. The NRC uses industry-level indicators to identify adverse trends. Adverse trends are assessed for safety significance and the NRC responds as necessary to any safety issues identified. The results of this program, along with any actions taken or planned, are reviewed annually during the Agency Action Review Meeting (AARM) and reported to the NRC Commission.
53	Slovenia	6	The last paragraph of the subsection mentions that the Reactor Oversight Process (ROP) uses both plant-level performance indicators and inspections to provide plant-specific oversight of safety performance, whereas the industry trends program (ITP) provides a means to assess overall industry performance using industry-level indicators. It is mentioned that the Reactor Oversight Process (ROP) uses both plant-level performance indicators and inspections to provide plant-specific oversight of safety performance, whereas the industry trends program (ITP) provides a means to assess overall industry performance using industry-level indicators. ROP and ITP indicators are complementary in presenting an overview of a NPP. ROP indicators are presented in Table 1. Could we also have the ITP indicators presented?	The ITP indicators are updated and reported to the Commission annually. As discussed in Section 6.2.3.2 of NUREG 1650, Revision 1, the FY 2003 industry indicators are published in SECY-04-0052. This SECY paper is available on the NRC's public Web site in the electronic reading room. The ITP indicators can also be found on the Industry Trends page on the NRC's public Web site (http://www.nrc.gov/reactors/operating/oversight/industry-trends.html).
54	Slovenia	6	It is mentiones that the Accident sequence precursor	In addition to the Accident Sequence Precursor program, the NRC established an operating experience staff to perform

			program views US NPP operating experience from a perspective of safety significance. How NRC deals with operating experiences from foreign countries, specifically for US design NPPs (where findings could also be considered as generic issues)?	gathering, screening, and communication functions (see Sec 19.7 of the National Report and Sec 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession Number ML033350063)). The operating experience staff reviews foreign experience as well as United States experience. For those issues deemed generic, such as for foreign events involving nuclear power plant designs used in the United States, the staff performs a number of actions, including communications to internal stakeholders, issuing generic communications to external stakeholders, and identifying needs for specific inspections. In recent years, the NRC issued several information notices (INs) dealing with foreign experience (available at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/): IN 2004-11, "Cracking in Pressurizer Safety and Relief Nozzles and in Surge Line Nozzle (Tsuruga Power Plant Unit 2, Japan)," IN 2004-04, "Fuel Damage During Cleaning at a Foreign Pressurized Water Reactor," and IN 2002-15, "Hydrogen Combustion Events in Foreign BWR Piping."
56	Sweden	6	Integrity of Barriers to Release of Radioactivity is one of the seven cornerstones. The containment is one of the barriers, however there is no performance indicator addressing containment integrity. Sweden, as several other countries, has experienced problems with containment leakage. How justified is such a performance indicator in the US point of view?	A containment leakage indicator was tested in our pilot program; however, it was deleted for several reasons. Licensees perform leak rate testing primarily during refueling outages; they are allowed to choose one of two options for performing those tests, only one of which requires them to record as-found leakage. For licensees who choose that option, the as-found leakage would only represent the end-of-cycle condition of containment, which might or might not be indicative of the worst-case leakage during the cycle. For licensees who choose the other option, there would be little or no as-found leakage data. Regardless of the results of the tests, licensees are required to ensure leak rates are within limits in order to start up, which means that the test data provides only a backward look at containment integrity. Because (1) there is a lack of uniformity in leak rate testing methodology, (2) at best, such tests could only provide an estimate of worst-case leakage during the last cycle, and (3) leak rates are restored to within acceptable limits prior to restart, this indicator was deleted before full implementation of the NRC's Reactor Oversight Process. Nevertheless, there may be some value in this PI if it encourages licensees to become more uniform in their test methodology. In addition, even a backward look at containment integrity could be of value by identifying recurrent issues. For these reasons, the NRC has been evaluating whether to use a containment leakage PI.
57	Sweden	6	It is mentioned that the efficacy of the Reactor Oversight Process is assessed annually by the NRC itself as well as by stakeholders. What methods are used in the NRC self-assessment? Although many improvements have been made, further improvement is expected. What is seen today as weak points subject to potential improvement?	The NRC's self-assessment process is described in Inspection Manual Chapter (IMC) 0307, "Reactor Oversight Process Self-Assessment Program." The staff conducts numerous activities and obtains data from many diverse sources to ensure that a comprehensive and robust self-assessment is performed. Data sources include the ROP self-assessment metrics described in IMC 0307, recommendations from independent evaluations, comments from external stakeholders in response to a Federal Register notice (FRN), insights from internal stakeholders based on survey results, the ROP internal feedback process, and feedback received from stakeholders at various meetings, workshops, and conferences. The staff reports the results of its self-assessment on an annual basis, and is in the process of completing its self-assessment for CY 2004. The results of the previous annual assessment were presented in SECY-04-0053, dated April 6, 2004.
58	Ukraine	6	Could more detailed information be obtained on the one-step process of NPP sites licensing?	The discussion in Section 6.2.1 of the U.S. National Report, which states that 10 CFR Part 52 is a new streamlined one-step process, is not correct. The NRC does not have a one-step process for licensing new nuclear power plants. An explanation of the additional licensing processes in 10 CFR Part 52 is provided in Section 19.1.1 of the U.S. National Report. A more detailed explanation can be found in NUREG/BR-0298, Rev. 2, "Nuclear Power Plant Licensing Process."
59	Ukraine	6	What is the procedure to update a current licence?	The license amendment procedures are contained in the publicly available document, Office Instruction LIC-101 "License Amendment Review Procedures." ML040060258.
60	Ukraine	6	Are there formalised requirements for application of the risk-screening assessment method?	We believe the question refers to the method for assigning risk significance to inspection findings related to operation of commercial nuclear reactors, a process referred to as the Significance Determination Process (SDP). The SDP uses two approaches to risk-inform the significance of inspection findings. The first is more deterministic in nature. This approach is used for inspection findings related to licensed operator re-qualification, emergency preparedness, radiation safety, and physical security. The second approach is more probabilistically based and uses probabilistic risk assessment tools to determine significance. This approach is used for inspection findings related to power operation (both at-power and shutdown), steam generator tube integrity, fire protection, and containment integrity. The methodologies for each of these areas was developed with the cooperation of internal and external stakeholders with fundamental attributes including: -Objective. The risk decision framework is such that when different individuals use a given SDP tool and associated decision logic, they will arrive at the same result when using the same input assumptions and conditions. -Scrutable. In a manner that the SDP framework facilitates communication of each significance determination and its basis among technically knowledgeable stakeholders giving them a common understanding of SDP decision bases. All SDP procedures are described in Inspection Manual Chapter (IMC) 0609, and associated appendices and in the Reactor Oversight Process Basis Document, IMC 0308. All SDP procedures, excluding the SDP for physical security, are available on the NRC public website, http://www.nrc.gov
61	United Kingdom	6	The performance goal measure to report annually to Congress that there are "no statistically adverse industry trends in safety performance" is surprising. Given that the industry's safety performance is generally good, the	Performance measures are high level goals that demonstrate how the NRC is maintaining safety and are used in the NRC's performance and budgeting process. One performance measure is related to adverse industry trends. The NRC monitors a set of industry level indicators and uses statistically determined long term trending to ensure any trend is not due to "noise." All indicators are monitored for trends and improving and declining trends are reported to the Commission annually. Statistically

			statistics must be subject to some degree of "noise", some trends apparently getting better, others getting worse. Could this performance goal tend to make some staff within NRC reluctant to report events upwards if these would have the effect of worsening the statistical trend? Should the goal not be changed to one of simply making an annual report to Congress, telling Congress whether trends are getting better or worse? Would the statistical trend for the occurrence rate shown in Figure 3 (Page 6-22) not have shown a significant rise if the 1993 reporting year had been omitted?	significant adverse trends are monitored as a performance goal and reported to Congress. The NRC staff is focused on maintaining safety and the industry level indicators are a method to verify that safety is being maintained. The staff is focused on trying to identify trends, as this would allow actions to be taken to correct any cause(s) of adverse trends. In addition, the industry level indicators are objective measures, such as the number of automatic scrams, that are reported to the NRC by licensees. Although no statistically significant trend was identified in the precursor occurrence rate (as shown in Figure 3), the NRC staff will initiate a detailed evaluation of the ASP data to investigate the nature of trends, determine whether there is an explanation for the relatively low number of precursors between 1997 and 1998 and the increasing number of potential precursors in 2000-2002, and identify any engineering insights that can be applied to the NRC's regulatory programs.
62	Australia	7	Australia appreciates the overview of laws applicable to commercial nuclear installations in the United States. Based on the overview, it appears that a nuclear installation is prohibited from operating without a licence – is this correct at law?	Yes. Moreover, a license is legally required for the construction of nuclear reactors or production facilities.
63	Korea, Republic of	7	What is the exact criteria which you use to distinguish power reactor and research reactor ? What's the difference in licensing procedure, technical safety standards and regulatory inspection between the two?	The regulations in Title 10 of the Code of Federal Regulations define research and power reactors. Power reactor means a nuclear reactor designed to produce electrical or heat energy licensed by the Commission under the authority of section 103 or subsection 104b of the Act and pursuant to the provisions of § 50.21(b) or § 50.22 of this chapter. Reactors that are not power reactors are referred to as non-power reactors in the regulations. Non-power reactors include research reactors and test reactors (called testing facility in some regulations). Non-power reactor means a research or test reactor licensed under §§ 50.21(c) or 50.22 of this part for research and development. Research reactor means a nuclear reactor licensed by the Commission under the authority of subsection 104c of the Act and pursuant to the provisions of § 50.21(c) of this chapter for operation at a thermal power level of 10 megawatts or less, and which is not a testing facility as defined by paragraph (m) of this section. Testing facility means a nuclear reactor which is of a type described in § 50.21(c) of this part and for which an application has been filed for a license authorizing operation at: (1) A thermal power level in excess of 10 megawatts; or (2) A thermal power level in excess of 1 megawatt, if the reactor is to contain: (i) A circulating loop through the core in which the applicant proposes to conduct fuel experiments; or (ii) A liquid fuel loading; or (iii) An experimental facility in the core in excess of 16 square inches in cross-section. NRC's regulations have been specifically established to consider the lower risk of research and test reactors compared to power reactors to ensure an acceptable level of safety for all NRC-licensed activities. These licenses include authorization for operation, and possession of radioactive material. Licensing actions include license renewals, extensions, authorizations for decommissioning, license terminations after completion of decommissioning, conversions to low-enriched uranium fuel, and power upgrades. Test reactors, with their higher power levels follow a more complex licensing process than research reactors. For example, for the initial licensing of a test reactor and a power reactor, the staff is required by the regulations to prepare an environmental impact statement. An environmental impact statement is not required for research reactors. Technical safety standards follow a graded approach. Many of the technical safety standards that are applied to power reactors are not applicable to research and test reactors because of the difference in operating parameters. For example, 10 CFR 50.60, "Acceptance criteria for fracture prevention measures for lightwater nuclear power reactors for normal operation," does not apply to research and test reactors because these reactors run at low pressures and temperatures which do not challenge the coolant pressure boundary. NUREG-1537 discusses the applicability of some of the regulations to research and test reactors. The regulatory process and technical safety standards that research and test reactors follow are outlined in NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" (available at the NRC website under accession numbers ML042430048 and ML042430055). The regulatory approach to research and test reactors

				uses a graded approach where the complexity of the licensing process, technical safety standards and regulatory inspection process increases from research reactor, to test reactor, to power reactor as the risk the reactor poses increases. The NRC also uses a graded approach in its inspection program. Because they pose a lower risk than power reactors, inspections at research and test reactors occur less frequently than inspections at power reactors. The inspection program for operating research and test reactors includes review of operational activities, design control, review and audit functions, radiation and environmental protection, operator requalification, maintenance and surveillance activities, fuel handling, experiments, procedural controls, emergency preparedness, transportation, security, and material control and accounting. The inspection program also encompasses a review of organizational structure and qualifications and responsibilities of reactor personnel. If the inspection program identifies violations of requirements, the NRC takes appropriate enforcement action. The NRC Inspection Manual Chapter 2545 contains the guidance which the NRC uses to administer the Research and Test Reactor Inspection Process. Manual Chapter 2545 and research and test reactor inspection procedures can be found on the NRC's public web site. Similar areas are inspected at operating power reactors as described in Manual Chapter 2515 which is also available on NRC's public web site.
64	Ukraine	7	What is the mechanism to review and settle any disputable matters if a licensee (legal entity) or a person does not agree with NRC charges?	At the request of the charged party, a hearing is available to resolve disputes.
65	Ukraine	7	What is the procedure for hearings of disputes, who conducts/leads them, is participation of lawyers obligatory in hearings?	Written statements, oral argument and some trial-like procedures are available depending on the circumstances. See 10 C.F.R. Part 2. Nearly all disputed licensing matters are initiated before a 3-person Atomic Safety and Licensing Board. A party may seek review by the Commission, which it grants at its discretion based the papers presented. Some requests for a staff action may be heard by a Staff Director, whose decision will be reviewed by the Commission only on its own motion. The final decision of the agency is reviewable in the United States Courts of Appealsl. Participation by lawyers is not obligatory, but is most usual. However, participation by non-lawyers on their own behalf or on behalf of organizations to which they belong is not infrequent.
66	Turkey	7.2.2	More information would be appreciated regarding the final status of the design approval process for AP1000?	The NRC issued a Final Design Approval for AP1000 and NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," in September 2004. The proposed rule for certification of the AP1000 design is expected to be issued by April 2005.
67	Hungary	8	The IAEA IRRT mission is a group of international experts to perform independent review of all authority areas of a national regulatory body. Due to its independence and the high level of expertise of the selected review team members, such mission is generally accepted as a useful tool for identifying areas for further improvement. What are the views of the NRC on accepting an IRRT mission?	The United States believes that IRRT missions provide a valuable and useful independent review of regulatory authorities. The NRC will complete a targeted IRRT self-assessment, focusing on reactor-related areas, prior to the Fourth National Report Review. At the conclusion of the self-assessment NRC will consider the scheduling of an IRRT. At the Fourth National Report Review Meeting, the United States will either discuss the results of its self assessment and/or make available the results of the IRRT mission to the United States.
68	Korea, Republic of	8	1. Have you ever conducted in-depth evaluation on the pros and cons of your regulatory system, independent regulatory commission? If yes, what's the evaluation result? 2. Is there any concern that the active communication between NRC and NEI may develop a pressure exerted on regulatory body to induce biased decisions that conflict with public interest? Is there any mechanism to prevent it?	1) No. NRC has never received funds appropriated for this purpose. Congress has decided that the independent regulatory commission is the proper system for nuclear regulation. Both houses of Congress maintain continuous oversight over any and all aspects of the operations of the Commission and not infrequently seek review on a specified subject from the GAO (Government Accountability Office, formerly entitled Government Accounting Office. The NRC also is called upon to provide written answers to Congressional questions and to provide oral testimony at Committee Hearings in both houses. 2) Yes. Such concerns have been expressed by some public groups, often avowedly antinuclear organizations, who are concerned that NRC may be "too close" with the nuclear industry. There are many mechanisms that protect against such conflicts in interest, beginning with the appointment process which requires confirmation by the Senate. There are also rules avoiding any financial interests by the Commissioners or agency working staff in any licensees, prohibiting any contacts from non-agency persons on the decisionmakers on any matters before them. Neither the Commissioners nor agency staff may receive gifts or favors from anyone or any organization with an interest in a matter before the agency. Most importantly, Commission decisions are made on the public record and contain the reasons for the decisions. The decisions may be challenged in court if the reasons are not supported in the record or are insufficient to support the result. This listing is not exclusive, in many ways the agency constantly reminds everyone of the overriding importance of maintaining the integrity of the work, which in essence requires complete impartiality.
69	Slovakia	8	How the results of inspections in NPPs are evaluated and reviewed?	The NRC's assessment program collects information from inspections and performance indicators (PIs) in order to enable the agency to arrive at objective conclusions about the licensee's safety performance. Based on this assessment information, the NRC determines the appropriate level of agency response, including supplemental inspection and pertinent regulatory actions ranging from management meetings up to and including orders for plant shutdown. These actions, which are dictated by the

				Action Matrix, are graded based upon licensee safety performance. The assessment information and agency response are then communicated to the public. Follow-up agency actions, as applicable, are conducted to ensure that the corrective actions designed to address performance weaknesses were effective.
70	Slovakia	8	Do your inspectors work with complex analytical tools and programs to evaluate specific events?	Field inspectors do not use complex analytical tools and programs to evaluate specific events. Staff analysts and Senior Reactor Analysts (SRAs) use these tools to assess the risk significance of events. The NRC uses two programs that assess the risk significance of events. These are the Accident Sequence Precursor (ASP) Program and the event response evaluation process, as defined in Management Directive 8.3, "NRC Incident Investigation Program." The ASP Program assesses the significance of a broad range of operating experiences at all U.S. nuclear power plants to identify, document, and rank the operating events that are most likely to lead to inadequate core cooling and severe core damage (precursors), if additional failures occur. The ASP Program defines a "significant" precursor as an event through specified criteria. Because of the broad objectives of the ASP Program, ASP analyses provide a more detailed evaluation of events, including uncertainty and sensitivity analyses. The Standardized Plant Analysis Risk (SPAR) model is a standardized risk analysis tool that staff analysts use in many regulatory activities, including the ASP Program and event response evaluation process. The SPAR models comprise a standardized, plant-specific set of PRA-based risk models that use the event tree/fault tree linking methodology. The SPAR models include the capability to perform uncertainty analysis through the propagation of uncertainty distributions at the equipment and human performance levels.
71	Slovakia	8	What is the role of inspectors in preparation of regulations? Are the inspectors involved in drafting regulations and to which extent?	The process of developing regulations is called rulemaking. The inspectors do not take part in the rulemaking process. The NRC's headquarters technical staff usually initiates a proposed rule or a change to a rule because of new information related to power plant operations. However, any member of the public may petition the NRC to develop, change, or rescind a rule. For more information on rulemaking, visit the NRC Rulemaking-RuleForum web page at http://www.nrc.gov/what-we-do/regulatory/rulemaking.html.
72	Slovakia	8	What is the reason behind such a huge "Net Appropriated—S&E" increase of expenditure for FY 2004 shown in Table 8.1?	NRC's net appropriation increases by approximately $22 million in FY 2004, compared to FY 2003. The net appropriation includes two amounts: (1) the funding from the Nuclear Waste Fund for NRC's High-Level Waste program, and (2) the percentage of NRC's budget authority for its other programs which is not recovered through fees. The percentage of NRC's budget that is recovered through fees was defined in the Omnibus Budget Reconciliation Act of 1990, as amended. In FY 2004, NRC's budget was based on 92-percent fee recovery (with the exception of the High-Level Waste program). NRC's FY 2003 budget was based on 94-percent fee recovery. Therefore, the percentage of NRC's budget (excepting the High-Level Waste program) reflected in the net appropriation increased by 2 percent in FY 2004, to 8 percent. The amount of the net appropriation was also affected by overall growth in the NRC's budget. Funding for NRC's High-Level Waste program increased by approximately $8 million in FY 2004. This increase was related to the expected review of the Department of Energy's license application for a high-level waste repository at Yucca Mountain, Nevada.
73	Switzerland	8	All the relevant aspects of Quality Assurance and Quality Management are thoroughly discussed, but there is no discussion on the developments of a Quality Management System in the authority.	The Office of Nuclear Reactor Regulation (the authority) conducts its work activities using a comprehensive set of quality assurance and quality management elements. All work products are produced in accordance with work instructions. These work instructions include the process description, roles and responsibilities, and performance measures. In addition, the authority conducts various audits and assessments of its work processes and maintains a process improvement/corrective actions program. Recently, the authority has created an Organizational Effectiveness Branch which provides a centralized focal point on quality practices, roles and responsibilities, centralized work planning and human capital issues. Specific to quality practices, this new branch has assumed the lead for the corrective actions program and serves as a central point for planning, performance and documentation of the audit and assessment activities.
74	France	8.1	The inspector general is presented as enjoying a large degree of independence inside NRC. By whom is he or she nominated and appointed, and to whom does he or she report?	The Inspector General is appointed by the President of the United States and must be confirmed by the United States Senate. The Inspector General reports to and is under the general supervision of the Chairman of the Commission or, if the Chairman so delegates, a member of the Commission, but none other. Although the Inspector General reports to one of these officials, neither of them would have the authority to prevent or prohibit him from initiating or carrying out any audit or investigation. An Inspector General may be removed from office by the President; however he must advise both Houses of Congress of the reasons for any such removal. See generally, Inspector General Act of 1978, as Amended , 5 USC Appendix.
75	Germany	8.1	International Research Programs are very useful to make national research activities efficient and save resources. From a general point of view, what experience feedback did you receive from the projects mentioned, e.g. in comparison with research projects organised and co-ordinated by international organisations like the IAEA and the OECD? If possible, please include information	The benefits of bilateral and multilateral research programs conducted outside the auspices of international organizations such as IAEA and OECD stem primarily from more direct and closer interaction between the staff of the NRC's Office of Nuclear Regulatory Research and the staff of the participating organization. The formal and informal exchange of information and data is facilitated by this interaction. The programs can often be organized to specifically address issues of interest to the participating organizations without the additional complexity and costs associated with addressing broader interests that may be represented by the international organizations.

			about the International Collaboration Research Initiative Addressing Safety Aspects of Advanced Instrumentation and Control initiated by NRC.	With regard to the International Collaboration Research Initiative Addressing Safety Aspects of Advanced Instrumentation and Control initiative, the NRC has terminated this activity because there was not a sufficient level of interest in an international program. The NRC staff continues to be interested in collaborating with international peers in this area, and will do so through less formal interactions.
76	Hungary	8.1	How are the benefits utilized in the NRC activities gained from the cooperative research projects like CSARP, CAMP, COOPRA and SGTIP?	Both CAMP (thermal-Hydraulics) and CSARP (severe accidents) are programs through which international agreements on code applications and maintenance exist between the U.S. Nuclear Regulatory Commission and its counterpart at approximately 22 Countries These programs exchange of information in the form of technical reports, experimental data, correspondence, newsletters, visits, joint meetings, and such other means as the parties agree. The NRC provides NRC-developed reactor systems simulation codes including: MELCOR, TRACE, RELAP5/MOD3, TRAC-B, TRAC-P, the Symbolic Nuclear Analysis Package (SNAP), and the Nuclear Plant Analyzer (NPA) in exchange for a combination of cash and in-kind (data, assessment reports) contributions. These exchanges promote worldwide code usage feedback on code attributes which provides enhancements to the codes and facilitates code validation and verification through shared data. These programs contribute significantly to NRC's knowledge base. COOPRA is used to improve probabilistic risk assessment (PRA) technology through the timely sharing of research information, and optimizes member resources through coordinated and cooperative research projects. Information shared in COOPRA activities provides insights in the decision making on risk-informed regulatory activities. Input from COOPRA activities also assists in the overall implementation of the phased approach to PRA quality The results from the Steam Generator Tube Integrity Program contribute to addressing technical issues regarding the safe regulation of steam generator tubes. The results and analysis contribute to the development of regulatory policies and practices and enhance NRC's knowledge base.
77	Japan	8.1	NRC's mission is to ensure that the civilian uses of nuclear energy and materials in the United States are conducted with proper regard for public health and safety, national security, environmental concerns, and (in the case of the initial licensing of nuclear power plants) the antitrust laws. Q/Regarding scope of NRC's responsibility, does NRC take responsibility of protecting the workers from impacts of accidents that have no radiation risk in nuclear power plant, such as the secondary pipe rapture in PWR, electric shock accident, and toxic gas releases accident. If yes, which specific regulations are implemented for this purpose?	In general, the U.S. Occupational Safety and Health Administration will apply its standards to working conditions involving non-radiological hazards, the NRC will apply its standards to working conditions involving radiological hazards, and both agencies will apply their standards to conditions involving a combination of hazards. OSHA standards cover employee exposures from any radiation source not regulated by the NRC, a source such as an X-ray machine. Because it is not always practical to sharply identify boundaries between the nuclear and radiological safety the NRC regulates and the industrial safety OSHA regulates, a coordinated interagency effort insures against gaps in the protection of workers and at the same time avoids duplication of effort. This effort is under formal memoranda of understanding between the two agencies. Although the NRC does not conduct inspections of industrial safety, in the course of inspections of radiological and nuclear safety NRC personnel may identify industrial safety problems. If they are significant, the NRC will inform OSHA. Similarly, OSHA will inform the NRC of any significant radiological and nuclear safety problems OSHA may identify during its inspections of industrial safety. The NRC and OSHA conduct joint inspections of some chemical and nuclear operational safety hazards. To enhance the ability of NRC personnel to recognize industrial safety problems during NRC inspections of nuclear and radiological safety, OSHA provides NRC personnel with basic training in chemical and industrial safety and OSHA safety standards. Similarly, the NRC provides OSHA personnel basic training in radiation safety and NRC standards.
78	Japan	8	NRC also participates in the Commission on Safety Standards and safety standards committees. Q/The report says in the Section, International Organizations and Associations that the NRC participates in the IAEA Commission on Safety Standards and safety standards committees. By what mechanism does the NRC take IAEA safety standards in the US regulatory framework? Are there any specific organizations or system for that purpose?	New or revised IAEA safety standards are typically reviewed by the NRC staff. However, IAEA safety standards are not formally incorporated or adopted into the US regulatory framework. The United States gives due consideration to IAEA standards when it develops new standards or revises existing standards and endeavors to be consistent with IAEA standards where appropriate for the specific circumstances and permitted by law. The review of IAEA safety standards is typically assigned to the NRC organization with the appropriate technical expertise.
79	Japan	8.1	The section discusses the budget and funding of NRC, its human resources, and financial management. Q/The Report mainly concerns financial resources in the Section 8.1.4. How does the NRC assure human resources? Please show some examples of effective practices to maintain human resources in the NRC.	NRC has developed a FY 2004-2009 Strategic Human Capital Plan, and is developing a companion document – the Human Capital Action Plan – which outlines specific activities, milestones and metrics for achieving human capital goals. Key focus areas of the Human Capital Action Plan are: * Critical Skills Staffing * Training & Development * Knowledge Management

				* Results-Oriented Performance Culture * Succession Planning for key positions To guide the NRC's program for the strategic management of human capital, the agency has developed a human capital vision: A diverse, high performing workforce with the skills needed to achieve the agency's mission and goals. The Atomic Energy Act permits NRC to appoint and compensate employees outside of normal civil service laws. For example, NRC has used this flexibility to create special pay ranges for Resident Inspectors, Entry-Level engineers/scientists, and Students.
80	Japan	8.1	The President assigned FEMA the lead responsibility for offsite emergency planning and response at nuclear power plants. NRC remained responsible for evaluating onsite planning, and for making the overall finding regarding whether a plant can operate "without undue risk to public health and safety." In fulfilling its obligation to the common defense and security, the agency (NRC) regulates security at nuclear facilities and the protection of radioactive materials. The new U.S. Department of Homeland Security was established in 2003 to lead a unified national effort to prevent terrorist attacks, reduce vulnerability to terrorism, and coordinate the Federal government's response to terrorist attacks and natural disasters. Q/Which agency(FEMA or NRC) has overall or total responsibility for emergency planning and response activities at nuclear power plants? Regarding responsibility for emergency planning and response at nuclear facilities other than a nuclear power plant, the basic principle of responsibility for the other nuclear facilities is same as for a nuclear power plant described in page 8-11? Which agency has the ultimate authority to establish generally applicable regulatory requirements that are applied in regulation against terrorist attacks and natural disasters to regulate security at nuclear facilities and the protection of radioactive materials?	The NRC has the responsibility for emergency planning and response activities, including those involving terrorist attacks or natural disasters, at civilnuclear power plants. FEMA has the responsibility to oversee the emergency preparedness activities related to State and local government decision making with regard to public health and safety. This would include evaluation of offsite activities related to emergency planning and response. This relationship is mandated by a Presidential order and is maintained by a Memorandum of Understanding between NRC and FEMA. The NRC has the authority to regulate radioactive materials and emergency planning at facilities other than nuclear power plants which are licensed by NRC or an agreement state. The Department of Defense (DOD) or the Department of Energy (DOE) have authority over emergencies at nuclear facilities owned or operated by DOD or DOE.
81	Mexico	8.1	Regarding the Section 8.1.3.2 Component Offices of the Commission - Office of Investigations. Please describe in a general way the technical profile and skills of the personnel of this office?	The Office of Investigations does not hire at the entry level; all agents have prior investigative experience. Currently, the average number of years of experience of an agent is 16 years. The job code of an agent (GS-1811, "Criminal Investigating Series") is the same as that for agents of the Secret Service, Drug Enforcement Administration, and the Bureau of Alcohol, Tobacco, and Firearms. This series includes positions that involve planning and conducting investigations relating to alleged or suspected violations of criminal laws. These positions require primarily a knowledge of investigative techniques and a knowledge of the laws of evidence, the rules of criminal procedure, and precedent court decisions concerning admissibility of evidence, constitutional rights, search and seizure and related issues; the ability to recognize, develop and present evidence that reconstructs events, sequences, and time elements, and establishes relationships, responsibilities, legal liabilities, conflicts of interest, in a manner that meets requirements for presentation in various legal hearings and court proceedings; and skill in applying the techniques required in performing such duties as maintaining surveillance, performing undercover work, and advising and assisting the U.S. Attorney in and out of court. Refs: http://www.opm.gov/fedclass/text/gs-1800.htm; Management Directive 9.8
82	Mexico	8.1	Regarding the Section 8.1.4 Financial and Human Resources. Are NRC's fees (license, inspection and annual) directly administered by the NRC or do they go to another government institution?	The NRC directly administers its fee collection requirements by assessing and collecting its license, inspection and annual fees. However, the NRC then sends these funds to the U.S. Department of the Treasury. It does not keep these funds, because it has already received its funding directly from Congress for that year. At the end of the Fiscal Year, the NRC sends to the Treasury the fees it has collected for that year in order to reimburse the Treasury for the funding it already received for that year.
83	Romania	8.1	What are the plans for management of its human and financial resources in case a situation like the one described in "NRC Major Changes for the Future" under "significant Operating Incident" occurs, taking into	Taken in context, the situation that is described (on page xxvii of the September 2004 Report) is an example of a significant external factor beyond the control of NRC that could affect the agency's ability to achieve its strategic outcome goals. Ensuring the protection of public health and safety and the environment continues to be the NRC's primary goal. Accordingly, safety is NRC's most important consideration and in the event of a significant safety incident, it is possible that output goals such as the

			account the existing large number of renewal licence request and the increasing number of new reactor licence request?	timeliness of reactor license renewals and/or future licensing milestones could be compromised. The NRC uses its Planning, Budgeting, and Performance Management (PBPM) process for forecasting, monitoring, and managing resources. The planning and budgeting elements of the NRC's PBPM process provide for the strategic allocation of estimated resources to key programs and planned activities. For example, within NRC's inspection program resources are budgeted for supplemental, reactive, and generic safety issue inspections that address areas of emerging concern or areas requiring increased emphasis. Several processes monitor and manage emergent issues as the budget moves to the execution phase. The first is the process by which new work not previously identified in the budget process is evaluated and added while other, lower priority work is stopped or delayed as a result. New work can result from unanticipated changes in external factors such as emerging technical issues including plant events. The regulatory effectiveness template, a prioritized ranking of the planned work relative to its contribution to the agency's five outcome goals, provides the basis for the decisionmaking process in evaluating newly identified work. In those instances where emergent issues cause lower priority work to be stopped or delayed, the appropriate stakeholder - depending on the source of the displaced work - would be briefed to ensure that expectations are clear.
84	Romania	8.1	It stated in the report that NRC is working to better understand the changes in grid performance to develop an appropriate response to ensure continued operation of nuclear power plants in a deregulated electricity market. Could NRC provide additional information about the main factors taken into account and foreseen changes on legal requirements in this respect?	The NRC is concerned with the reliability of offsite power to the Nation's nuclear power plants. The grid is now being used in ways for which it was not designed, and there has been a significant increase in the number and complexity of transactions on the transmission system. Users and operators of the system who used to cooperate voluntarily on reliability matters are now competitors with little incentive to cooperate with each other or to comply with voluntary reliability rules. The August 14, 2003, blackout raised questions regarding whether the existing scheme of voluntary compliance with North American Electric Reliability Council (NERC) reliability rules is still adequate for today's competitive electricity market. In response to this, NERC revised its reliability standards and they were approved by its Board of Trustees on February 8, 2005. The new reliability standards take effect on April 1, 2005. In addition, NERC is promoting the development of a new mandatory system of reliability standards and compliance. However, Federal legislation would be required to provide the statutory authority to enforce compliance with reliability standards. The final report of the U.S.-Canada Power System Outage Task Force found that the single most important thing Congress can do to ensure reliability is to pass legislation that would make NERC rules mandatory and enforceable.
85	South Africa	8.1	The USNRC was created as an independent regulatory agency in January 1975 with the passage of the Energy Reorganisation Act of 1974 but the basic charter for the USNRC regulatory responsibilities is the Atomic Energy Act of 1954 through which congress created a national policy of developing the peaceful uses of atomic energy. Does the Atomic Energy Act of 1954 contains elements related to promotional aspects of the development of peaceful uses of atomic energy or has it been updated to only reflect the regulatory responsibilities of the USNRC? If not are the regulatory responsibilities of the USNRC clearly dissociated / separated from those related to the development of atomic energy in the Act?	The Energy Reorganization Act of 1974, as amended, divided the government's role in the nuclear energy field. The regulatory role was given to the NRC and the promotional aspects of the development of nuclear power are assigned to the Department of Energy. The Atomic Energy Act was amended to recognize the division and contains separate provisions applicable to only NRC or the Department of Energy, as appropriate.
86	South Africa	8.1	Regional Offices: The responsibilities of the NRC's four regional offices are indicated by what are the powers and authority of regional offices in terms of these responsibilities e.g. has the Regional Administration authority to approve changes to licenses, issue operator licenses, request the shutdown of a nuclear power plant, etc.....	No response required.
87	South Africa	8.1	Advisory Committees: What is the appointment process e.g. how and by whom, of the various members of the advisory Committees and Licensing Boards? Are these members appointed on a permanent or short term basis?What are these Committees reporting lines/ executive authority and their funding?	Under the Atomic Energy Act (42 U.S.C. 2039)), the Advisory Committee On Reactor Safeguards is a permanent statutory advisory committee consisting of a maximum of fifteen members appointed by the Commission for terms of four years each. The Commission also has general authority to establish advisory boards for which the Commission must issue regulations setting forth the scope, procedure and limitation of the authority of each such board. 42 U.S.C. 2201. Advisory Committees are as their name implies solely advisory in nature and have no executive authority. They are funded by NRC out of its general appropriations from the Congress.
88	South Africa	8.1	Financial and Human resources: What is the process followed by the USNRC to establish the two types of fees indicated in this section. For example do the licensees participate in this process of establishment of fees through notice and comment rulemaking and if yes should there be some disagreement what is the process followed to	The NRC establishes its fees through notice and comment rulemaking each year. Because the NRC is required to recover its current year budget each year prior to September 30, the NRC must resolve any issues with the proposed rule, and issue a final rule, within a period of a few months. Licensees and any other members of the public are welcome to participate in this process by reviewing the NRC's proposed rule and sending comments to the NRC. The NRC carefully considers the comments it receives and either incorporates the

			resolve the disagreement?	requested changes or explains in the preamble of the rule why it did not make these changes. If licensees or other members of the public disagree with the NRC's final rule, they may continue to communicate with the NRC on these matters, or ultimately, they may seek legal action against the NRC through the judicial system.
89	Spain	8.1	In the section on research Programmes, under international responsibilities and activities, four Research Programmes are announced, none of which is specific to ageing or radioactive waste issues. It would, therefore, appear to be the case that the real problems have no explicit research programme, while the four programmes mentioned, which deal with potential aspects, do. Why this strategic approach?	The NRC's research effort addresses a broad range of topics, some of which deal with potential future issues and the development of analysis capabilities while others deal directly with operating plant issues. The international collaborative efforts cited in the report are examples of this range of topics. The Steam Generator Tube Integrity Program for example, deals directly with service-induced degradation of steam generator tubes and the ability to inspect tubes for this degradation, which are very real problems for many nuclear power plants around the world. Another example of a collaborative programs that is addressing operating plant issues include the Program for the Inspection of Nickel Alloy Components. While the efforts addressing operating plant issues are an important part of NRC's research program, a larger part of the program does, in fact, address potential issues. The underlying strategy is to develop the data and analysis capabilities so that the regulatory staff can address issues before safety is compromised. Other organizations, such as the Electric Power Research Institute, deal more directly with day-to-day plant operation and maintenance activities.
90	Spain	8.1	The section highlighted is dedicated to the "Office Commission Appellate Adjudication". In order to be able to evaluate the importance of this Office, might it be possible to illustrate any case in which its role has been a determining factor, as well as its workload?	The Office of Commission Appellate Adjudication (OCAA) participates in every adjudicatory matter that is appealed to the Commission. OCAA analyses the petitions for appellate review and advises the Commission on whether they have met the legal standards and what factual and policy issues are raised. If the Commission decides to accept review, OCAA assists the Commission in framing any questions that might need to be addressed and assists the Commission with the legal analysis of the briefs that are presented. With the Commission's policy guidance, OCAA prepares draft decisions for the Commission's review and adoption as modified by the Commission. In that light, we could not appropriately point to any single case. The office comprises no fewer than 4 full-time attorneys who report to the Office director.
91	Japan	8.2	The Commission's status as an independent regulatory agency within the Executive Branch of the Federal Government means that its regulatory decision cannot ordinarily be directed by the President. (By law, however, the U.S. Office of Management and Budget reviews the proposed NRC budget.) Q/The report(Section 8.1.2.3) says that The Commission's regulatory decisions cannot be ordinarily be directed by the President and the Congress cannot override the Commission's decision and The US Office of Management and Budget(OMB) reviews the proposed NRC budget. After the OMB reviewing, if the OMB opposes the NRC proposed budget, how does the NRC maintain its independency in its budget? Does the NRC have any means to confront the OMB in order to assure the financial independency?	The President submits the NRC budget to the Congress and thus, the NRC does not have independence on budgetary matters. If Congress disagrees with the President's proposed appropriation to the NRC, it can, and occasionally does, specify an amount in the annual Appropriations Acts other than that recommended by the President.
92	South Africa	8.2	Although it is not stated in the document we understand that some of the USNRC research programmes in support of their regulatory activities are receiving financial support from the DOE.In these specific instances does this situation present issues in terms of the USNRC mandate and how is the independence of the USNRC ensured?	NRC is authorized under law to engage in research and on a reimbursable basis provide interagency assistance to another federal agency to meet the needs of that agency. However, research arrangements are also reviewed for compliance with NRC's Conflict of Interests statute and its implementing regulation.
93	Mexico	9	Regarding to NRC Enforcement Program (Section 9.3), could you provide an estimated number, if any, of the petitions for review challenging NRC licensing decisions or regulations for significant enforcement actions to operating power reactors, during FY 2003? Additionally, what is the rate of success for these petitions?	In FY 2003, there were four lawsuits challenging NRC licensing decisions. None of the suits was successful. Under the NRC's Enforcement Policy a civil penalty is first proposed and a licensee has an opportunity to respond before the NRC imposes the civil penalty by order. This process is not a "petition" process. The public may petition the NRC to take enforcment action under 10 CFR 2.206. NRR should be consulted on any 10 CFR 2.206 questions. During FY 2003, no proposed civil penalties to operating power reactors were challenged. There was one lawsuit challenging an NRC 2.206 enforcement petition, but it was not successful. During FY 2003, two proposed civil penalty actions to materials licensees were challenged by licensees. In each case, the NRC reviewed the licensee's response and found no new information to change our position. In both cases the NRC concluded that a violation had occurred as stated and that there was not a significant basis for withdrawing the violation or modifying or rescinding the civil penalty. Orders imposing the full civil penalties were issued. The NRC posts its Enforcement Program annual reports on the public web site.

94	South Africa	9	Good Practice:Safety of commercial nuclear power reactor operations is the responsibility of the licensee by law.Steps in place to ensure licence holder meets its responsibility. Good Practice:Violations are subject to civil enforcement action and may also be subject to criminal prosecution.The regulator identifies violations through inspections and investigations. Steps in place are: Licensing process Reactor oversight program Enforcement process	No response required.
95	South Africa	9	The article is covered comprehensively with examples cited to illustrate the implementation of the enforcement process.The use of safety indicators is commendable. The oversight process seems, however, to be outcome orientated i.e. to focus on problems that have already occurred rather than on shortcomings of the licensees processes and organisational aspects relating to risk, which can provide advance warning of weaknesses which can have a direct bearing on risk. The cross-cutting areas help in this respect, but may not be sufficient to highlight quality / process / organisational type deficiencies. In South Africa our indicators point toward deficiencies in document configuration control, competencies, over-reliance on operator response. A safety indicator system that does not indicate such deficiencies can be counterproductive if safety significance tends to be skewed. However difficult it to take such factors into account in an objective and consistent way, they have to be considered, and the indicators must reflect them. It is acknowledged that the NRC has a difficult task in terms of the number of licensees and plants it has to regulate.	Thank you for your comments. The Commission recently directed the staff to enhance the treatment of Safety Culture in the Reactor Oversight Process (ROP). Safety Culture can be a leading indicator of poor performance and is therefore an important regulatory element. The challenge is in how to incorporate a relatively subjective area into the ROP, a program that is largely built on objective criteria.
97	Bulgaria	10	Integration of the risk aspects into the processes of complex decisions taking has been under development for a long time in the USA. With regard to this, could you provide more information on how the predictability of the regulatory measures is maintained?	Regulatory Guide 1.174 provides guidance for risk-informed decisionmaking, including a provision for performance monitoring. The primary goal for performance monitoring in risk-informed decisionmaking is to ensure that no adverse safety degradation occurs because of the changes to the licensing basis. The NRC's principal concern is the possibility that the aggregate impact of changes that affect a large class of structures, systems, and components could lead to an unacceptable increase in the number of failures from unanticipated degradation, including possible increases in common cause mechanisms. Therefore, an implementation and monitoring plan should be developed to ensure that the engineering evaluation conducted to examine the impact of the proposed changes continues to reflect the actual reliability and availability of structures, systems, and components that have been evaluated. This will ensure that the conclusions that have been drawn from the evaluation remain valid.
98	Finland	10	How is it guaranteed that the Risk Informed Decision making is based on adequate and qualified risk insights?	Regulatory Guide 1.174 provides guidance on risk-informed decisionmaking. Further, Regulatory Guide 1.200 endorses, with appropriate clarifications and qualifications, an industry standard on PRA technical adequacy for risk-informed activities.
99	Finland	10	What is an adequate set of PRA quality attributes that has to be fulfilled for decision making and various PRA applications?	The level of detail required of the PRA model is determined ultimately by the application. However, a minimal level of detail is necessary to ensure that the impact of dependencies is correctly captured and the PRA represents the as-built, as-operated plant. This minimal level of detail is implicit in the technical characteristics and attributes discussed in Regulatory Guide 1.200.
100	Finland	10	Is NRC staff using any PRA software to gain insights from up-to-date PRA models and applications (e.g. RI-IST, RI-ISI, RI-TechSpecs)?	The NRC can run standardized plant analysis risk (SPAR) PRA models of the licensed plants using the SAPHIRE software. The NRC also has the capability of running software programs typically used by the industry (e.g., NUPRA, CAFTA).
101	Finland	10	Has NRC staff full access to licensees' PRA computer models?	Generally, licensees have not been required to submit/docket PRA models. However, the NRC can have full access to the licensee's PRA model in the context of a license application review involving a site audit of the PRA model.
102	Finland	10	Are there any requirements related to for example - PRA quality management in general	Guidance (not requirements) for the cited examples is addressed in Regulatory Guide 1.200 and/or the application-specific risk-informed Regulatory Guides 1.174, 1.175, and 1.177. In addition, Regulatory Guide 1.200 is being pilot tested at a number of plants to gain additional insights into the adequacy and transparency of peer reviews, licensee self-assessment reviews,

			- up-to-date models - scope of PRA - transparency of documentation and analyses - peer reviews and other reviews - regulatory review?	documentation, model maintenance and management, and model scope. Finally, in risk-informed rules (e.g., 10 CFR 50.69), requirements are explicitly included in the regulation covering these areas.
103	France	10	The Risk-Informed approach is presented, and it is mentioned that the implementation of this approach is far from completed. On several specific difficult aspects, could the United States of America give some comments and indicate if some research is in progress: - Generally some parts of the PRA are treated with more simplified assumptions, due to a lack of knowledge and uncertainties, and these simplifications lead generally to more conservative results. For example it is often the case of low power and Shutdown PSA. When using PSA results for decision-making this effect could result in inappropriate decisions. Is there some research in this field? - How were treated the effects of ageing? Is ageing introduced at the level of component failure rates (especially components which cannot be replaced)? Is ageing considered at the level of initiating events frequency? Is ageing management introduced: effect of testing, inspections, and maintenance? - In case of replacement of equipment with new technologies (I&C for example), what is the approach? - The pipes failure frequency (medium and large LOCA) could have an important impact on decision-making: does USA performs some studies for the assessment of these low probability events?	The industry, including selected NRC staff members, is involved in the development of a standard for low power and shutdown PRAs. Aging effects are typically treated by aging management programs to ensure important structures, systems, and components are not susceptible to aging impacts. Thus, aging effects are not typically addressed in PRAs. There is currently under NRC review a topical report on digital I&C. There is on-going expert elicitation effort within the NRC Office of Nuclear Regulatory Research on the initiating event frequency of loss of coolant accidents.
104	France	10	A risk-informed inservice inspection program was elaborated. Does it take into account only probabilistic considerations calculated ex ante, or also experience feedback from recent incidents (Davis Besse, South Texas)?	A licensee's risk informed inspection program for piping does take industry experiences into consideration. However, a full recalculation of the probabilistic risk assessment is not always needed. Licensee's may use their expert panel to add additional inspections or justify why certain issues are not applicable for their plant. Risk informed inspection programs are considered living programs and new industry experiences are required to be evaluated and addressed in a timely manner.
105	France	10	Could the United States of America indicate if, in the case of standardized technical specifications changes, each individual licence holder shall apply for an authorisation? Or is a change approved by NRC systematically extended to others licence holders?	The United States does not require individual licensees to apply for changes to their plant-specific Technical Specifications (TS) after changes are approved by the NRC to the Standard Technical Specification (STS). However, plants of a given type (BWR or PWR) work jointly with the NRC to develop the STS changes, so that the plants can apply for the TS changes applicable to that type. The adoption of any plant-specific TS changes using STS are voluntarily made by the licensees, however the applicability of the STS changes have to be technically justified by each licensee. This includes evaluating each of the units' design basis as defined in the Final Safety Analysis Report (FSAR) for each plant. The review of a proposed generic change to STS is a multi-staged process designed to ensure that each STS remains internally consistent, maintains coherence among the various vendors' STS, and incorporates the knowledge and operating experience of the industry and the NRC. Changes to STS NUREGs, which are potentially applicable to multiple plants, are proposed to the NRC by the Technical Specifications Task Force (TSTF) through publically available submittals. The TSTF consists of representatives from the four U. S. commercial nuclear power plant owners groups (GE, Westinghouse, B&W, and CE). The NRC staff reviews the changes to the STS proposed by the TSTF and will accept, modify, or reject them. Individual licensees may propose to adopt TSTF changes during a license amendment application.
108	Hungary	10	In Chapters 10.2 and 10.3 the report presents the NRC's PRA policy and application of PRA. Playing a leading role in this area the NRC accumulated lots of experiences	1 and 2) The intent of this section is to provide a summary of various activities involving the use of PRA models. As such, it is not possible to provide the requested level of detail, though the current text provides a number of examples in which insights from PRAs are being used.

			during the past years. Therefore a summary would have been highly appreciated about - positive examples on the use of risk-informed tools/applications, - important regulatory decisions when insights from PRA were taken into consideration, - licensees' wide opinion on the NRC's risk-informed approach, - how experiences were integrated back into the PRA policy and - unforeseen difficulties arising during the implementation of the PRA policy.	3) Most licensees have embraced the risk-informed approach, as evidenced by the fact that nearly every licensee has implemented some risk-informed licensing basis change, especially risk-informed inservice inspection, for which the NEI expects 86 plants to implement. 4) Experiences are not integrated into the PRA policy, i.e., the policy statement does not change. This statement is described in more detail in the previous U.S. National Report. 5) We have not experienced difficulty implementing the PRA policy, but within specific applications there are always issues that must be addressed, including: areas not modeled or modeled simplistically in the PRA, modeling uncertainties, impact of uncertainties and model assumptions, etc.
109	Japan	10	NRC is also continuing a program to develop additional changes to the specific technical requirements in the body of 10 CFR Part 50, including the general design criteria. This program provides a framework for risk-informing deterministic requirements. Q/In the process of changing the specific technical requirements in the body of 10 CFR 50 into the risk-informed approach, what kinds of general principles are considered in the development process of risk-informed deterministic requirements?	The risk-informed approach to regulation enhances and extends the traditional deterministic approach. It is an extension and enhancement of traditional regulation. Principles employed to risk-inform NRC regulations include: (a) being consistent with the defense-in-depth philosophy; (b) maintaining sufficient safety margins; (c) allowing only changes that result in no more than a small increase in risk; and, (d) incorporating monitoring and performance measurement strategies. In addition, the Commission's safety goals for nuclear power reactors and subsidiary numerical objectives should be used with appropriate consideration of uncertainties.
110	Japan	10	NRC also engages in cooperative activities with industry (such as pilot programs for 10 CFR 50.69 and Regulatory Guide 1.200) and in activities that assess risk in determining plant-specific changes to the licensing basis. Q/Regarding the pilot program for the 10 CFR 50.69 and Reg. Guide 1.200 in cooperation with industry, your answer to the following questions would be appreciated. 1) What plants are participating in the pilot program? 2) What is the objectives and scope of the pilot program? 3) What is the status of the program?	The overall objectives of Regulatory Guide (RG) 1.200 and the associated Standard Review Plan (SRP) Section 19.1 are to: (a) provide the staff with the confidence that the base PRA (and therefore the PRA results used to support the application) is adequate for making the decision required by the application, (b) improve the focus and consistency of staff reviews, (c) increase public confidence in the adequacy of the licensee's base PRA (and therefore the PRA results used to support the application) and the associated staff reviews, and (d) reduce the overall depth of the staff review of the licensee's PRA. As such, the purpose of the RG 1.200 and SRP 19.1 trial application phase is to determine whether the guidance for implementation of RG 1.200 and SRP 19.1 will achieve the above objectives. Thus, the goal of the trial application phase is to: (a) provide assistance in clarifying aspects of the RG 1.200 and SRP 19.1 guidance, including interpretations of the ASME PRA Standard and the NEI guidance on peer reviews, (b) assess the licensee's self-assessment approaches, findings, and resolution to ensure that the base PRA is properly evaluated, and (c) develop industry and NRC lessons learned and identify specific improvements to RG 1.200, SRP 19.1, the ASME Standard, and the NEI guidance. In addition, the trial application phase will support improving the PRA technical adequacy guidance in the application-specific regulatory guides and associated SRP sections by providing guidance on the scope, elements, and level of detail on PRA technical adequacy in licensee application-specific submittals and associated staff reviews. The trial application phase involves five actual plant-specific risk-informed license applications that require a finding by the staff on the technical adequacy of the PRA for the specific application. The five plants involved in the trial application are: Columbia Generating Station, Limerick Generating Station, South Texas Project, San Onofre Nuclear Generating Station, and Surry. Only one trial remains to be conducted, which will be performed in early March 2005.
111	Japan	10	As a result, NRC established a subsidiary objective of a core damage frequency of 1 x 10-4 per reactor-year. In addition, NRC approved a conditional containment failure probability of 0.1 (one-tenth) for evolutionary light water reactor designs. Q/How the subsidiary objectives (i.e., a core damage frequency of 1x10-4 per reactor-year and a conditional containment failure probability of 0.1) were derived from the safety goal?	The derivation of the subsidiary objectives is presented in Appendix B to Attachment 1 of SECY-05-006.
112	Japan	10	The Risk-Informed Regulation Implementation Plan discusses NRC's actions to risk-inform its regulatory activities and specifically describes each of the activities identified as supporting the goals and objectives of the agency's Strategic Plan and the Probabilistic Risk Analysis Policy Statement.	In the latest version of the risk-informed regulation implementation plan (SECY-04-0197), this section has been revised such that it is generally applicable to all arenas.

			Q/In the RIR implementation plan (e.g., SECY-04-0068), the guideline for selecting candidates are briefly described. The guideline for selecting was developed not for the reactor safety arena, but for the material and waste arenas. Has the NRC already developed the guidance to be applied to the reactor safety arena? What is the reason why it is possible to apply the guideline for the material and waste arenas to the reactor safety arena.	
113	Japan	10	In addition, NRC is developing a database entitled Human Event Repository and Analyses for use in both human factors and human reliability analysis. This activity includes developing a structure for collecting information suitable for the needs of human reliability analysis and quantitative approaches using Bayesian frameworks to quantify human failure events. Q/Regarding a database entitled Human Event Repository and Analyses, your answer to the following questions would be appreciated. -Is the database for the *first generation* Human Reliability Analysis (HRA), or for the second generation HRA? -Is the data for the database constructed by consolidating existing data, or by collecting a new data? -Please explain the method of data collection, characteristics of the data to be collected, and the data collection period. -Is the database already in the stage of the practical usages for PRA?	1) HERA being built to support both 1st and 2nd generation HRA methods. The current structure is driven by the ATHEANNA, SPAR-H, and THERP methods. However, we believe that these methods, to a large extent, capture information needed to perform an HRA regardless of what method is employed. Our aim is to create a structure that can capture "generic" information (in terms of human events and associated performance shaping factors) needed to perform an HRA. However, the richness of the information captured in HERA is driven by the richness of information provided in the data sources. 2) HERA is populated with information obtained from licensee event reports. That is, HERA is not populated with human error probability (HEP) estimates derived for previous analyses. The objective of HERA is to make event information available to analysts so that HEP estimates can be derived or updated. A companion activity with developing HERA is the development of quantification tools specific to HRA applications on the basis of the Bayesian framework. These tools will help the analysts to use information such as that captured in HERA to derive HEPs instead of using readily available estimates and/or expert opinion. 3) The HERA data collection approach is under NRC staff review and will be published as a NUREG/CR by the end of 2005. Currently HERA is populated with recent LERs; however, because HERA structure is going through internal review and updates, the main focus is to finalize the HERA structure rather than to populate it with events. 4) Since HERA is under internal review process it has not become available yet for use; however, a HERA beta version will become available to NRC staff for trial applications soon.
114	Japan	10	NRC and industry representatives have cooperated in a number of activities and pilot programs to develop and apply risk-informed methodologies for specific regulatory applications. Q/What kinds of reliability data (i.e., the plant specific data or the U.S. generic data) are generally utilized in the PSA, which supports the licensee's application based on the Reg. Guide 1.174, etc? Especially, was the plant specific data utilized in the pilot programs for 10 CFR 50.69 and the Reg. Guide 1.200?	Most licensees use a combination of U.S. generic data and plant-specific data. The collection, derivation, and application of generic and plant-specific data are addressed in Regulatory Guide 1.200. The expectation for licensees that implement 10 CFR 50.69 is that they will collect plant-specific data and feed that data back into the risk analyses on a regular basis to ensure the validity of their application.
115	Japan	10	In December 2003, the NRC published Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," for trial use. Q/Before the issurance of Regulatory Guide 1.200, what sorts of the review processes of PRS quality had the NRC been using, in order to confirm the technical adequacy of the PRA quality, in the various risk- informed applications?	PRA technical adequacy (also referred to as PRA quality) is a topic that must be (and has been) addressed in risk-informed applications. The development of industry standards and Regulatory Guide 1.200 provides a more structured and consistent approach to addressing PRA technical adequacy for risk-informed applications. PRA technical adequacy reviews as part of risk-informed license applications has evolved as NRC staff have gained experience with these types of applications. Prior to the development of the industry standards and Regulatory Guide 1.200, the technical adequacy of licensee PRAs was considered by the staff, as documented in each safety evaluation, but this NRC review relied more on the individual NRC staff knowledge and experience with PRA methods and the industry peer reviews. Where the NRC staff questioned the adequacy of the licensee's analysis, this was pursued in further detail, including the potential for an actual audit of the licensee's PRA and supporting documentation.
118	Japan	10	Over the past several years, the agency has used these subsidiary objectives in developing new regulations. For example, it developed new regulations on anticipated transients without scram, station blackout, and pressurized thermal shock, in part, using the estimated changes to the collective core damage frequency provided by the rules, and by applying the subsidiary objectives.	For the most part, the identified examples of regulations (e.g., station blackout, anticipated transient without scram) were developed prior to the establishment of the subsidiary objectives and before many plant-specific PRAs were developed; these are not new regulations. For these regulations, generic-type risk studies were utilized in developing the rules. Regulatory effectiveness evaluations of these regulations were performed during the last couple of years by the NRC Office of Nuclear Regulatory Research and are documented in NUREG-1780 and NUREG-1776.

			Q/What sorts of PSA results were utilized in order to develop the new regulation such as the station blackout rule? - the generic plant PSA or the envelop of the individual plant PSAs - the PSA based on the generic reliability data or on the plant specific reliability data.	
119	Japan	10	The significance of cooperation to improve regulatory priority to safety is exemplified by theefforts of NRC and stakeholders to establish a database concerning equipment reliability andavailability to support the Maintenance Rule and other performance-based regulation. Q/The NRC has developed the reliability and availability database (i.e., RADS), incorporating the EPIX data and the INPO's SPI data, in order to apply for the risk-informed regulation. What is the current status of the database? Are the data of the RADS already used in the review process of the risk-informed applications? What sorts of parameters are estimated in the RADS (e.g., the component failure rate, the mean time to repair, the unavailability due to the maintenance, etc.)?	The RADS database is updated quarterly. Though the RADS database is not used in the review process of licensee risk-informed applications, it is used in the NRC SPAR models. The database contains failure rate, failure probability, and initiating event frequency data. It does not currently include mean time to repair or maintenance unavailabilities.
120	Japan	10	The agency has also approved two industry methodologies, one developed by Westinghouse Owners Group and the other by EPRI, to develop alternatives to the ASME XI Inservice Inspection Program. Q/In the risk-informed ISI, especially in the WOG methodology, the baseline PSA model may be used in order to estimate the core damage frequency induced by the failure of the piping segments. What sorts of the reliability data (i.e., the plant specific data or the U.S. generic data) are utilized in the baseline PSA? What sorts of databases does the NRC utilize to review the risk-informed application submitted by the utilities? Does the NRC have any issues or concerns on the current databases? Are the current databases in the U.S. technically adequate and appropriate for the risk-informed applications? The PRA will be utilized in the safety design of future NPPs. What sorts of database should be applied with future NPPs? How does the NRC review and confirm the technical adequacy of the plant specific database developed by the utilities? There are various types of databases, such as the plant specific database, the generic database, and the database gathered among the similar types of NPPs. How does the NRC define the role of these sorts of databases, and utilize each of these databases?	Most licensees use a combination of U.S. generic data and plant-specific data. The collection, derivation, and application of generic and plant-specific data is addressed in Regulatory Guide 1.200. The NRC Office of Nuclear Regulatory Research is currently reviewing the results of an expert elicitation on pipe break frequency. When finalized, these results will be incorporated into future risk-informed activities. The PRA used to support risk-informed inservice inspection (RI-ISI) applications is the latest version of the PRA at each plant. Generally, all current PRAs use a component failure parameter database that it is based on generic data updated with plant specific data. Each licensee should have a plant specific database so a licensee's database is not normally compared to any specific database or set of databases. Excessive deviations from the failure parameters used in the NRC plant models (i.e., SPAR models) and in various NRC documents (e.g., NUREGs) may be investigated during a NRC staff review. Observations regarding the (limited) extent of plant-specific data use, the update process, and the selection of an appropriate generic database have all been made by the industry peer review groups. Insofar as different concerns are identified at different plants, the concerns are addressed on a plant-specific basis during the NRC review of the individual licensee submittals. In RI-ISI applications, the quantitative results of the PRA model are used as order of magnitude estimates to support the assignment of piping welds into broad consequence categories. Inaccuracies in the models or in assumptions large enough to invalidate the broad categorizations developed to support the RI-ISI application should have been identified during the NRC staff's review of the licensee's individual plant examination (IPE) and by the licensee's model update control program that included a review of the PRA model by a peer review team. The resolution of significant observations made during the peer reviews are evaluated to ensure that there is sufficient confidence that the results are adequate to support the proposed modification of the in-service inspection program. The RI-ISI implementation program has not yet addressed how to best use PRAs for future plants. The staff does not normally review the PRA models (including the component failure parameter database) to assess the accuracy of the quantitative estimates. Evaluation of the component failure parameter database has been, and is, part of the peer review process. Review of the RI-ISI submittals includes evaluating the resolution of all important observations made by the peer reviews about the consistency of the plant's PRA with guidelines in standardized guidance documents. Occasionally, the staff will audit a PRA used to support a RI-ISI application. An audit includes an audit of the plant-specific failure parameter database as appropriate. Plant specific failure parameter databases are based upon appropriate generic data updated to the extent possible with plant-specific data (i.e., observed operation and failure data).
123	Mexico	10	In the National Report, Section 10.3.6 "Activities that Apply Risk Assessment to Plant-Specific Changes to the	Yes, deterministic approaches are still the dominant approach for assessing nuclear safety. Risk information is being used to "inform" the deterministic approaches, but does not replace the deterministic approaches. The risk-informed approach will

			Licensing Basis" the following is established: "the use of PRA technology should be increased in all regulatory matters ... in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy". However most what is described in Article 10 relates to PRA, and little is mentioned on deterministic assessment. Is deterministic still the dominant approach for assessing nuclear safety? Will this change in the future?	continue to be expanded into areas that have previously been solely deterministic, but there are no plans to become risk-based and replace the deterministic approaches.
124	Mexico	10	The National Report, Section 10.4.2 "Licensee Safety Culture – NRC's Response to Davis-Besse" describes that the NRC's staff's Lessons-Learned Task Force concluded that: (1) NRC failed to adequately review, assess, and followup on relevant operating experience. How is relevant operating experience from foreign nuclear power reactors included?	The NRC established an operating experience staff to perform gathering, screening, and communication functions (see Sec 19.7 of the National Report and Sec 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession Number ML033350063)). The operating experience staff reviews foreign experience as well as United States experience. For those issues deemed generic, such as for foreign events involving nuclear power plant designs used in the United States, the staff performs a number of actions, including communications to internal stakeholders, issuing generic communications to external stakeholders, and identifying needs for specific inspections. Reports of foreign operating experience received by NRC (mainly IRS and INES reports) are screened and communicated to NRC internal and external stakeholders just as with US operating experience. In recent years, the NRC issued several information notices (INs) dealing with foreign experience (available at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/): IN 2004-11, "Cracking in Pressurizer Safety and Relief Nozzles and in Surge Line Nozzle (Tsuruga Power Plant Unit 2, Japan)," IN 2004-04, "Fuel Damage During Cleaning at a Foreign Pressurized Water Reactor," and IN 2002-15, "Hydrogen Combustion Events in Foreign BWR Piping."
125	Mexico	10	Regarding the National Report, Article 10. The following questions are arisen: Why the USNRC with the industry develops programs pilots programs in PSA applications? What is the relation, if any, between the 10 CFR50.65 "Requirements for monitoring the effectiveness of maintenance at nuclear power plants" and the 10CFR 50.69 "Risk-Informed Categorization and Treatment of Structures, Systems and Components"? New designs for NPP are requested to prepare procedures of severe accidents. How are these procedures validated? What regulatory and/ or enforcement actions, if any, are you taking in those plants with CDF in the range of 1E-04/ Rx year? How many nuclear power plants have implemented the Regulatory Guide 1.200?	The NRC supports the activities of the industry to develop standards for determining the technical adequacy of PRAs when used in licensing activities. The pilot programs provide an opportunity to try a risk-informed approach/application and provide lessons learned from the application that can be fed back into improving the risk-informed approach. The only relation between 10 CFR 50.69 and 10 CFR 50.65 is that some aspects of a licensee's program to implement 10 CFR 50.65 (e.g., preventable failure data) may be useful in ensuring the implementation of 10 CFR 50.69 are maintained within its supporting analyses. Current operating plants have implemented severe accident management guidelines (SAMG) through a voluntary industry program. The advanced reactor designs have committed to develop applicable SAMG. The established risk-informed guidelines are used in evaluating licensee requests, but are not used for enforcement actions in the sense implied by the question. Plants that have a core damage frequency in the range of 10-4/reactor-year are considered safe and consistent with the Commission's safety goals. Regulatory Guide 1.200 is in a trial implementation phase and five plant sites have been part of this pilot program. All plants have conducted portions of Regulatory Guide 1.200 (e.g., subjection of plant-specific PRA to industry peer review).
126	Pakistan	10	It has been stated that the NRC has developed extensive guidance regarding the role of PRA in regulatory programs in the United States and has extensively applied information gained from PRA to complement other engineering analyses in improving issue-specific safety regulation, and in changing the current licensing bases for individual plants. This statement implies the use of PSA by NRC in developing risk informed/based regulations. USA may like to elaborate what are the current requirements of NRC for the licensee regarding PSA submissions with license renewal applications. Is low power and shutdown PSA a regulatory requirement?	For currently licensed plants, there is no general regulation that requires plant-specific PRAs. However, some specific risk-informed regulations (e.g., 10 CFR 50.69) do have PRA requirements if a licensee implements these regulations. Specific to license renewal, there are two aspects considered by the NRC: safety and environmental. The safety aspect of license renewal does not rely on PRA information. The environmental aspects must address severe accident mitigation alternatives, which relies heavily on PRA information. Licensees also have the option of utilizing their PRA information in partial support of changes to their licensing basis and technical specifications. As such, risk-informed applications should appropriately consider low power and shutdown risk contributions, which is often done, if necessary through qualitative risk assessments. A future risk standard is being developed in the area of shutdown risk by the American Nuclear Society. Risk assessment is considered during a portion of the environmental review for license renewals, rather than as part of the safety review.
127	Romania	10	NRC applies PRA technology to resolve severe accident issues, evaluate new and existing requirements and programs, implement risk-informed regulation, and	The NRC can run standardized plant analysis risk (SPAR) PRA models of the licensed plants using the SAPHIRE software. The NRC also has the capability of running software programs typically used by the industry (e.g., NUPRA, CAFTA). In addition, as described in Regulatory Guide 1.200 and the industry standards, there is guidance on maintaining up-to-date PRAs.

			improve data and methods of risk analysis. Could NRC provide additional information related to the necessary computer tools and PSA models that must be available in regulatory body and eventually agreements between NPPs and regulatory body, in order to keep up-to date the PSA model?	Within the application of PRAs for specific risk-informed regulations (e.g., 10 CFR 50.69), the requirements for maintaining the licensee's PRA up-to-date are explicitly stated within the regulation.
128	Russian Federation	10	Section 10.1 of the Report says that based on the results of risk assessments NRC has made changes to 10 CFR Parts 50 and 52 concerning combustible gas control in power reactors. These amendments eliminate the need for hydrogen reburn systems and "mitigate" requirements to hydrogen and oxygen monitoring systems commensurable with their risk significance. The Reports treats this action as a major achievement in the area of regulation. Nevertheless, on the one hand there are cases (e.g. event at Hamaoka-1 BWR plant in November 2001) when uncontrolled hydrogen leaks resulted in explosions in the piping connected to the primary circuit, and on the other hand installation of recombiners is viewed as one of the actions to cope with severe accidents. Which specifically hydrogen removal systems are covered by this change, and how can one, based on the results of probabilistic assessments, mitigate safety requirements if the process of water radiolysis and hydrogen generation cannot be excluded from the light water reactor technology on deterministic basis?	The rule change was supported by an improved understanding of combustible gas behavior during severe accidents and confirmation that the hydrogen release postulated from a design-basis accident loss-of-coolant accident was not risk-significant because it was not large enough to lead to early containment failure, and that the risk associated with hydrogen combustion was from beyond design-basis accidents where its generation rate would exceed the effectiveness of the recombiners. Additional detail is provided in the Federal Register (Volume 68, Number 179) dated September 16, 2003.
129	Russian Federation	10	As an example of incorporating risk information in the existing regulations and procedures Section 10.1 states that changes have been made to 10 CFR 50.69 "Risk-informed Categorization and Treatment of Structures, Systems and Components". What kinds of components are covered by the risk-informed categorization?	Risk-informed categorization in 10 CFR 50.69 is not limited to any specific components and is expected to be primarily used for categorizing safety-related systems that can be demonstrated as being non-safety significant.
130	Russian Federation	10	Section 10.3.2 of the Report indicates the "reference" value of 1x10-4 for core damage frequency and 1x10-5 for large early release probability as well as conditional probability of confinement failure of 0.1 for evolutionary light water rector designs. These values are used for risk-informed regulatory decision making. Could you give examples of specific regulatory decisions taken in cases when these criteria had not been met?	In the context of risk-informed licensing actions, the NRC has not received an application in which the Regulatory Guide 1.174 guidelines were significantly exceeded. There have been a few cases in which licensee total base risk slightly exceeded these guidelines, but justified the application due to conservatisms in their analyses (typically conservative analysis of external events - fires and seismic). This is consistent with the guidance provided in Regulatory Guide 1.174.
131	Russian Federation	10	NRC performs research to support and justify regulatory decisions on new technologies, on aging facilities and equipment as well as on a number of other safety issues. Section 10.3.4 of the Report says that NRC research activities consist of various programs aimed at resolving specific issues. Areas are mentioned, where certain progress has been made. 1) Can reactor designers and operators use the results of safety justification research efforts completed by NRC? 2) Is there a legal basis for NRC to recommend the use of the obtained research results to designers and operators to justify reactor installation safety?	1) The results of NRC research are available to the public and may be used by parties in their representation to the Commission. The burden is on the party (licensee, manufacturer, public) to demonstrate the applicability and adequacy of the technical work to support the desired decision. Three practical examples follow: A. RES is conducting an extensive high burn up fuel clad testing program with industry cooperation. All parties will receive the test results and data. The analysis of the data and the conclusions that may derive from the analysis will be independently done by each party. B. RES has developed computer simulations, especially in the area of thermal-hydraulics. A designer may adopt such computer codes. However, the designer would need to independently assess the codes for the intended application and justify use of the codes and input assumptions. Modifications would receive even greater scrutiny.

				C. RES may perform prototypical hardware testing. An operator or designer would have access to the test results, but would likely need to repeat the tests using their specific components and conduct tests in conformance with their quality assurance programs. 2) While the NRC makes available the results of it's research, it does not require it's adoption or use. Licensees or applicants need to present there own safety justification including their analyses and if applicable their own research and data.
132	Russian Federation	10	Subsection 10.3.5.4 of the Report mentions that the Nuclear Energy Institute has issued NEI-00-02 "PRA Peer Review Process Guidelines" to assist licensees in their assessments. 1) Has this document been reviewed by NRC and has it been adopted as a guide for PRA expert examination? 2) Is this document authorized for use in the industry? 3) How do the provisions of this document agree with the changes made to NUREG-0800 "Standard Review Plan"?	NEI 00-02 has been reviewed and endorsed for use by licensees with appropriate clarifications and qualifications in Appendix B of Regulatory Guide 1.200. In addition, a new section, 19.1, was added to the Standard Review Plan (NUREG-800) in conjunction with the development of Regulatory Guide 1.200. This guide is currently being tested through pilot applications and will be revised based on the resulting lessons learned.
133	Slovakia	10	What impact could be expected from your regulation on Risk-Informed Categorization and Treatment of Structures, Systems, and Components?	10 CFR 50.69 requires the licensee to calculate the impact on risk due to the implementation of the rule. This impact must be maintained "small" throughout the implementation of the rule. The definition of a "small" risk increase is further defined within the statement of considerations associated with the rule. In this context, the Commission regards "small" changes for plants with total baseline CDF of 10-4 per year or less, to be CDF increases of up to 10-5 per year, and for plants with total baseline CDF greater than 10-4 per year, to be CDF increases of up to 10-6 per year. Likewise, the Commission regards "small" changes for plants with total baseline LERF of 10-5 per year or less, to be LERF increases of up to 10-6 per year, and for plants with total baseline LERF greater than 10-5 per year, to be LERF increases of up to 10-7 per year. However, if there is an indication that the total baseline CDF may be considerably higher than 10-4 per year or the total baseline LERF may be considerably higher than 10-5 per year, the focus of the licensee should be on finding ways to decrease rather than increase CDF and the licensee may be required to present arguments as to why steps should not be taken to reduce CDF or LERF in order for the reduction in special treatment requirements to be considered. This approach is consistent with the acceptance guidelines established in Section 2.2.4 of Regulatory Guide 1.174.
134	Slovenia	10	In the NRC's response to Davis-Besse it is stated that the NRC staff's Lessons-learned task force concluded that: (1) NRC failed to adequately review, assess, and follow-up on relevant operating experience, and (2) NRC failed to integrate known or available information into its assessments of Davis-Besse's safety performance. Before Davis-Besse event the US and foreign operational experience have indicated stress corrosion cracking of reactor vessel head CRDM penetrations. How to explain the fact that in spite of this operational experience the missing material in reactor vessel head was discovered so late, almost before the rupture of the reactor vessel head?	The cavity was not found because Davis-Besse did not completely clean accumulated boric acid off of its reactor pressure vessel head. Therefore, the cavity was obscured from view. Additionally, indications of carbon steel boric acid corrosion were not well known. Before the circumferential crack was found at the Oconee plant in 2001, the only cracks that had been seen in the CRDM penetration nozzles were axial cracks. Following the discovery of the circumferential crack, the NRC informed the most susceptible plants to perform a special inspection of their CRDM penetration nozzles. In February 2002, Davis-Besse performed that inspection and found CRDM penetration nozzle cracks generally in accord with other plants. The cavity was found during repair activity. As the question states, there was in fact, significant operational experience in both the U.S. and abroad with stress corrosion cracking in reactor vessel head penetrations (VHPs). In fact the first observation of the phenomena was at Bugey in France. Information on this and subsequent occurences was widely disseminated. Concern over this issue led the NRC to issue Generic Letter 97-01 that requested PWR licensees to inform the NRC of their plans to monitor and manage cracking in VHP nozzles and their intentions, if any, to perform non-visual, volumetric examinations of their VHP nozzles. It was such inspection efforts that subsequently led to the discovery of VHP circumferential cracking at Oconee in 2001 and cracking of the VHPs at Davis-Besse. A major missed opportunity for NRC and the industry relative to the Davis Besse event, was in not making the connection between the VHP cracking and the potential for accelerated corrosive attack of the carbon steel head adjacent to the VHPs. This is what was meant, at least in part, by the statement,"NRC failed to integrate known or available information into its assessments of Davis-Besse's safety performance."
135	South Africa	10	As described in section 10.3.5 NRC actively participates in development of PSA/risk informed application together with industry, cooperates in number of activities and pilot programmes to develop the methodologies for specific applications. The NRC also participates in developing standards (ACME Code cases or ASME PSA standard) for those applications. From these remarks it seems that the independence between the nuclear regulatory authority and the industry/utilities could be compromised	The U.S. Nuclear Regulatory Commission (NRC) and industry staff have cooperated in a number of activities and pilot programs to develop risk-informed methodologies for specific regulatory applications, including the development of standards on determining the technical adequacy of probabilistic risk assessment (PRA) results for risk-informed activities. However, independence between the NRC's regulatory authority and the industry/utilities is not compromised by these cooperative efforts. When licensees apply the risk-informed methods in specific plant applications, the NRC reviews the application against the NRC's regulatory guidance (e.g., Regulatory Guides 1.174, 1.175, and 1.177) in determining its acceptability. Likewise, though a few NRC staff members with PRA expertise worked with the industry in developing a standard for PRAs, the PRA consensus standard is not binding upon the NRC until endorsed. The endorsement of the American Society of Mechanical Engineers PRA standard via Regulatory Guide 1.200 included a broad NRC review, which resulted in additional clarifications

			(NRC Reg Guid 1.2000 endorsed industry PSA standard developed by the NRC). Your views on that would be appreciated.	and qualifications on the use of the standard for risk-informed license applications. Regulatory Guide 1.200 provides guidance on: (1) a minimal set of functional requirements of a technically acceptable PRA; (2) the NRC position on the PRA consensus standards and industry PRA program documents; (3) an acceptable approach for determining that the PRA, in toto or in parts, used to support a licensee's risk-informed regulatory application is technically adequate; and (4) documentation to support a regulatory submittal.
136	South Africa	10	Good Practice: NRC policy on PRA and risk-informed initiatives In terms of the oversight programme, in all but few instances a quantitative PRA is not called for in the grading of inspection / audit findings. PRA methodology in its present form does not reflect explicitly relevant factors such as licensee processes, QA, organisational aspects and certain matters. In terms of the scope of PRA, should this not be expanded to include not only core damage frequency but also risk due to other sources such as spent fuel pools (particularly in the light of high density pools), waste treatment etc. and to operator risk as well? These factors should play an important role in decision-making. A further comment is that although the risk-informed approach contributes significantly to improving nuclear safety on a broad basis, in the US regulatory framework it is nevertheless only introduced as a voluntary add-on to the requirements of 10CFR.Although from a philosophical standpoint safety can in principle be quantified using a risk assessment, it is acknowledged that in practice this is achievable only with limited success. Problem areas include:Justification of realistic, credible data (including uncertainties) taking into account experience feedback, linkage to engineering standards and codes and general operating rules of the plant (eg. Maintenance programme) to extent that the impact on changes (or waivers) can be assessed quantitatively,difficulties in incorporating qualitative judgements into a quantitative process – in some cases the impractically of performing a quantitative assessment. What can be concluded is that the applicability of generic data to a specific plant is subject to compliance with the standards and practices of the plants from which the generic data is derived. Assessment of changes to (or departure from) these standards and practices on a risk basis is however generally nor credible without prior experience feedback (or appropriate expert opinion), unless the risk significance of the affected components is so low that the impact can be judged insignificant. Could you please provide your views the comments indicated above?	The current NRC guidance related to decisionmaking based on PRA results are derived from the Commission's safety goals, which are related to risks to the public. Within this context, decisions are not risk-based, but rather are risk-informed; meaning other factors (e.g., defense-in-depth and safety margins) are included in the decisionmaking processes. In specific cases, the NRC has used PRA techniques in providing preliminary insights for assessing other types of events (e.g., NUREG-1738, "Technical Study of Spent Fuel Pool Accident Risk at Decommissioning Nuclear Power Plants).
137	Sweden	10	Regarding safety goals, it is mentioned that NRC has established a subsidiary objective of a core damage frequency of 1x10-4 per reactor-year and a conditional containment failure probability of 0.1. Does this mean that if a reactor design meets these objectives, no additional requirements can be posed? Are there any	No, meeting the subsidiary objective does not mean that additional requirements cannot be posed in some specific situations if required to bring a licensee back into compliance with its license or for other deterministic factors (e.g., adequate defense-in-depth). The NRC has a regulation, 10 CFR 50.109 (Backfit Rule), where significant safety improvements can be imposed if certain risk-benefit regulatory analysis is satisfied. This could in some cases apply to a plant that met the subsidiary objectives. However, the NRC's safety goal is generally recognized as the level of safety that is safe enough. As stated in Regulatory Guide 1.174: "When the calculated increase in CDF is very small, which is taken as being less than 10-6 per reactor year, the

			circumstances which allow a plant modification to result in a CDF greater than 1x10-4 ?	change will be considered regardless of whether there is a calculation of the total CDF. While there is no requirement to calculate the total CDF, if there is an indication that the CDF may be considerably higher than 10-4 per reactor year, the focus should be on finding ways to decrease rather than increase it." Thus, it is conceivable that a plant modification could be allowed in which the total plant baseline CDF would be calculated as being slightly greater than 10-4, though the increase in CDF would have to be shown to be very small. These situations would also involve more regulatory attention.
146	Switzerland	10	What are the qualification requirements for inspectors in order to perform inspections and evaluations in the field of organisational and human factors? Do they have competences in the area of social sciences?	Currently, there are no formal qualification requirements for inspectors in the field of organizational and human factors. Most field inspectors, based either in a NRC regional office or onsite at a plant, who perform routine inspections do not usually have any formal training in organizational or human factors or social sciences. However, during some special or supplemental inspections, staff from NRC headquarters with experience in those areas have participated on the inspection teams to inspect or evaluate these areas.
148	United Kingdom	10	The reference to a "questioning attitude" in the third paragraph under this sub-heading is welcomed, but the paragraphs which follow are dominated by references to problems, issues and deficiencies. Are these not all lagging indicators, and would it not be better to supplement these with possibly less tangible measures which could be used as leading indicators?	The NRC acknowledges the importance of licensees having a healthy Safety Culture and has identified the need to enhance its guidance on identifying Safety Culture issues. The NRC staff prepared SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which provided the NRC Commissioners options for enhancing oversight of Safety Culture. The Commission responded with a Staff Requirement Memorandum (SRM), dated August 30, 2004, which directed the staff to undertake a number of activities related to Safety Culture, including: - To enhance the Reactor Oversight Process (ROP) treatment of cross-cutting issues to more fully address Safety Culture, including training for inspectors - To develop a process for determining the need for a specific evaluation of the licensee's Safety Culture and to develop a process for conducting an evaluation of the licensee's Safety Culture (for those plants in the degraded cornerstone columns, referred to as Column Three of the ROP Action Matrix) - To continue to monitor developments by foreign regulators The SRM directed staff to develop tools for inspectors to rely on more objective findings; to develop an enhanced training program; and to follow established processes for revising the ROP, in particular the process for involving stakeholders.
150	United Kingdom	11	Despite the statement in the opening section (11.1, first paragraph) that "there is some evidence that financial pressures have limited the resources that are devoted to corrective actions, plant improvements, upgrades, and other safety-related expenditures", the NRC does "not systematically review the financial qualifications of power reactor licensees once it has issued an operating license". Given that the financial position of a licensee could change markedly over a 40 year period, and the fact that "many States have initiated or completed action to economically deregulate their nuclear power plants", why should NRC not be empowered to conduct such reviews?	While the NRC does not conduct financial reviews of power plant licensees on a routine basis (e.g., annual reviews), the NRC is authorized to conduct reviews of licensee financial qualifications during a plant's operating life and also into its decommissioning period, pursuant to NRC regulations in 10 CFR 50.33(f)(4): "The Commission may request an established entity or newly-formed entity to submit additional or more detailed information respecting its financial arrangements and status of funds if the Commission considers this information appropriate. This may include information regarding a licensee's ability to continue the conduct of the activities authorized by the license and to decommission the facility." When the Commission has needed such financial information, especially from licensees experiencing significant financial stress, the Commission has requested and reviewed the information and has conducted ongoing financial monitoring of a licensee as long as the Commission deemed it to be necessary.
151	Belgium	11.2	§ 11.2.2 Experience and examples - last paragraph. Engineering expertise on shift: what is the present tendency of the licensees regarding employing staff with a Bachelor of Science (or equivalent) degree for the position of shift supervisor versus having a Shift technical Advisor on shift? (Earlier discussions in the USA indicated that some licensees were concerned about employing BS because of their presumed tendency to leave their position of shift supervisor after a few years to seek promotion. These licensees were afraid to lose these BS too soon and to have a too high turnover of Shift Supervisors).	The last Shift Technical Advisor (STA) staffing study conducted by the NRC (5/91) indicated that 79 facilities used dedicated (BS degree, non-licensed) STAs on shift (option 2 of the Commission Policy Statement on Engineering Expertise on Shift). The remaining 25 facilities used dual-role (BS degree, SRO licensed) STAs (Option 1 of the Policy Statement). The NRC does not compile licensed operator staffing and qualification data and thus has no more recent information relative to this SAT staffing question.
152	Mexico	11.2	The National Report in its section 11.2 "Regulatory Requirements for Qualifying, Training, and Retraining Personnel" indicates that the U.S. nuclear industry facing a shortage of human resources on skilled workers on the	The NRC does not monitor licensee's workforce to ensure meeting or maintenance of position qualification requirements. However, as required and necessary during implementation of the reactor oversight program, the NRC will evaluate the training and qualification of licensee personnel.

			nuclear due to different causes such retirement of personnel because of aging, or fewer university degrees granted in majors such as nuclear engineering, or nuclear sciences? If so, how is the industry dealing with this issue?	
153	United Kingdom	11.2	This section is clear on the qualification and training requirements for staff, but does not appear to address the requirement of Article 11.2 in relation to "sufficient numbers" of such staff. Given that the Indian Point 2 example identifies as a root cause that "the station had not maintained a core of career-orientated, plant knowledgeable instructors and operators", are there any plans to instigate inspection programmes to check on the adequacy of the numbers of appropriately trained staff?	At the present time the NRC does not have any formal plans to generically conduct staffing studies of licensee facilities to determine the adequacy of the numbers of appropriately trained staff. However, when required by the reactor oversight program, the NRC will evaluate the adequacy of licensee staffing.
154	Belgium	12	The chapter related to article 12 of the USA report explains the NRC's program on human performance, but does not provide information on the licensee programs in place related to human factors and human performance. What are the regulatory requirements and/or regulatory guidance related to licensee-ran human factors/ human performance programs? Which initiatives have been taken by the nuclear industry in this area, in response to such requirements or by free will?	The regulatory requirements for human factors have their origin in TMI Action Items that were provided to the US nuclear industry through means such as orders issued to plants, NUREG-0660, "NRC Action Plan Developed as a Result of the TMI-2 Accident," and Generic Letter 82-33, "Requirements for Emergency Response Capability," (Supplement 1 to NUREG-0737). Principal sources of NRC guidance that relate to human factors engineering include Chapter 18.0, "Human Factors Engineering," of NUREG-0800, "Standard Review Plan," NUREG-0711, "Human Factors Engineering Program Review Model," and NUREG-0700, "Human-System Interface Design Review Guidelines." Over the years since the TMI event, the industry has engaged in various initiatives in the areas of human factors/human performance programs. For example, in the years directly following TMI, the Electric Power Research Institute (EPRI) prepared a guidance document for the industry to use in completing design changes to their control rooms. This document, "Human Factors Guide for Nuclear Power Plant Control Room Development" (1984), was very similar in scope and content to the NRC's NUREG-0700, "Guidelines for Control Room Design Reviews (1981). During this time period and continuing today, the Institute of Nuclear Power Operations (INPO) supports the nuclear industry through preparing programs and guidance in the field of human factors covering a variety of human factors topics. Most recently, a joint program sponsored by EPRI and the industry has developed a guidance document for licensees to use in efforts to upgrade their analog control room instrumentation to digital instrumentation.
155	Belgium	12	Section 12.1.2 mentions the development of a supplemental inspection procedure related to the human performance crosscutting element of the Reactor Oversight Process. What are the specific human factor aspects covered by this newly developed procedure? To what extent are issues, such as sufficiency of staffing levels and safety culture, covered by this or other inspection procedures?	The "Human Performance" supplemental inspection procedure was developed in 2000. The objectives of the inspection procedure are (1) to assess the adequacy of the licensee's root cause evaluation and corrective actions with respect to human performance and (2) to independently assess the extent of condition associated with the identified human performance root causes. The topic areas covered by the procedure include mainly: human-system interface, environment, communication, coordination of work/supervision, work practices, and procedure use. The procedure was not intended to focus on staffing levels or Safety Culture. With specific regard to Safety Culture, the Commission recently considered options to revise its policies. The NRC staff had prepared SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which provided the NRC Commissioners with options for enhancing oversight of Safety Culture. The Commission responded with a Staff Requirement Memorandum (SRM), dated August 30, 2004, which directed the staff to undertake a number of activities related to Safety Conscious Work Environment (SCWE) and Safety Culture. Specifically, the SRM directed NRC staff to enhance the Reactor Oversight Process (ROP) treatment of cross-cutting issues to more fully address Safety Culture, including training for inspectors. In addition, the SRM called for developing a process for determining the need for a specific evaluation of the licensee's Safety Culture and a process for conducting an evaluation of the licensee's Safety Culture (for those plants in the degraded cornerstone columns referred to as Column Three of the ROP Action Matrix). The SRM also directed the staff to develop tools for inspectors to rely on more objective findings as well as create an enhanced training program. To ensure that the staff's actions are responsive to the SRM, that the public's confidence in the Safety Culture of nuclear power plants is enhanced, and that NRC and stakeholder resources are effectively and efficiently utilized, a Safety Culture Response Plan is being developed and will be placed on NRC's website in the future. Regarding staff, paragraph (m) of 10 CFR 50.54, "Conditions of Licenses," specifies the minimum number of licensed operators that are required for nuclear power reactor sites. In addition NRC has other requirements with staffing implications. These include the personnel requirements for fire brigades and emergency response personnel contained in Appendix R, "Fire Protection Programs for Nuclear Power Facilities Operating Prior to January 1, 1979," and Appendix E, "Emergency Planning and Preparedness for Protection and Utilization Facilities," to 10 CFR Part 50, respectively. In the September 2002, NRC began work on a process to evaluate exemption requests from 10 CFR 50.54(m) due

				to the changing demands and new technologies proposed by advanced reactor control room designs and significant light water reactor control room upgrades. At present, the process for submitting an exemption request is included in a draft guidance document that will be published for public comment in the near future. The justification for the recommended process is explained in NUREG/CR-6838, "Technical Basis for Assessing Exemptions from Nuclear Power Plant Licensed Operator Staffing Requirements 10CFR 50.54(m)."
156	Belgium	12	How does the USNRC program on human performance control human factor related issues related to the use of contractors? More specifically, how is appropriate training and qualification of contractor personnel assured and evaluated through the provisions of this regulatory program?	The NRC does not control the industry's use of contractors employed to perform human factors engineering activities. NUREG-0711, "Human Factors Engineering Program Review Model," provides guidance to the staff for evaluating the qualifications of a human factors engineering team used by a licensee to perform human factors engineering activities. For applicants submitting a request for design certification under 10 CFR Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," the applicant is expected to satisfy the staff's criteria for a human factors engineering team as identified in NUREG-0800, "Standard Review Plan," Chapter 18.0, "Human Factors Engineering," and associated guidance (e.g., NUREG-0711). The training and qualification of contractor personnel is the responsibility of the licensee. Training programs accredited by the National Academy for Nuclear Training contain contractor training requirements. The NRC does not normally evaluate accredited training and qualification programs. However, during implementation of the reactor oversight program, the NRC will evaluate licensee training and qualification programs and, as necessary, contractor training requirements within those programs.
157	Canada	12	The report indicates that "NRC reviews licensees' requests that involve aspects of human factors engineering." Please provide examples of experience with industry requests to transfer operating licenses and power uprates; particularly, specific safety-relevant issues that were unexpected. Please elaborate on how the US NRC adequately prepares/plans for such requests.	Power Uprates: Since 2002, steam dryer cracking and flow-induced vibration damage on components and supports for the main steam and feedwater lines have been observed at the Dresden and Quad Cities nuclear power plants, both of which use boiling water reactors, following implementation of extended power uprates. NRC staff have determined these issues do not pose an immediate safety concern, given the plants' current operating conditions. However, steam dryers and other internal main steam and feedwater components must maintain structural integrity to avoid generating loose parts that could impact safety system or reactor plant operation. The NRC has corresponded with and met with nuclear industry groups concerning these issues since the first occurrences, and continues to examine its regulatory options based on industry actions and the information available. More information on the power uprate program is at http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/power-uprates.html License Transfer: Pursuant to 10 CFR 50.80(b), "Transfer of Licenses", the NRC staff must consider many criteria when evaluating license transfer applications, such as the information described in Sections 50.33 and 50.34 with respect to as much of those parts dealing with the identity and with the technical and financial qualifications of the proposed transferee "as would be required by those sections if the application were for an initial license . . . ." Also, the Commission may require additional information from the applicant as needed. Various staff groups within the Office of Nuclear Reactor Regulation (NRR) evaluate different portions of license transfer applications, such as: (1) a Human Performance section for review of human factors related to a transfer that could potentially change operating performance and technical safety aspects of the reactor being transferred, such as changes in the reactor staff and management organizational structure; and (2) a Financial and Regulatory Analysis section for review of a variety of factors that could impact safety, such as: financial qualifications of the proposed transferee to operate the reactor, assurance of adequate decommissioning funding for the reactor associated with the transfer, adequacy of reactor liability and property insurance to be provided by the transferee, and whether there is a significant amount of foreign ownership or control of the proposed transferee. These staff groups prepare a detailed Safety Evaluation Report (SER) with the results of their analysis. This report is then evaluated by NRR's Division of Licensing Project Management (DLPM), which incorporates the SER and other information into an Order for approval or disapproval of the application. Then DLPM coordinates with NRC's Office of the General Counsel (OGC) for legal review of the Order. Ultimately, the Director of NRR must approve any Order allowing a license transfer. The NRC has received many operating license transfer requests during the past ten years, many of which have been wholly or in part related to the deregulation of the electric utility industry in the United States. Specific examples include: the purchase of TMI-1 by AmerGen Energy Company, LLC; the purchase of Pilgrim by Entergy Corporation; and the purchase of Millstone Units 1, 2, and 3 by Dominion Energy Holdings Inc.
158	France	12	The report expands on regulatory activities about human performance but is quite concise about actual actions performed by operators. Several plant modifications and improvements are implemented or planned. Could the United States of America explain how human factors are	Licensees, under 10 CFR 50, "Appendix B to Part 50 - Quality Assurance Criteria For Nuclear Power Plants And Fuel Reprocessing Plants," are responsible for assuring that changes to their facilities continue to meet applicable regulatory requirements and their design basis. For plant modifications, the licensee may make changes to its plant design, including human factors engineering changes

			taken into account by the licensees in case of plant modifications: - Before the modification (design stage of the modification)? - During the modification (ergonomics, radiation protection…)? - After the modification (plant operation, Man Machine Interface, procedures, maintenance, testing…)? This question applies to design or to operation modifications (for example a change of EOPs from event-oriented to symptom-oriented approach).	without review and approval from the NRC if the changes are in accordance with applicable criteria of 10 CFR 50.59, "Changes, Tests, and Experiments." If certain criteria of 10 CFR 50.59 are not satisfied, the NRC may become involved in reviewing the acceptability of the human factors engineering-related changes made by the licensee. Guidance for implementing 10 CFR 50.59 is contained in NRC Regulatory Guide 1.187, "Guidance for the Implementation of 10 CFR 50.59, Changes, Tests and Experiments" (2000).
159	Japan	12	The objective of the policy is to ensure, to the extent practicable, that personnel are not assigned to shift duties while in a fatigued condition that can significantly reduce their mental alertness or decisionmaking ability. The policy also allows deviations from the guidelines "for very unusual circumstances"... (2) it would be "highly unlikely" that such deviations would cause significant reductions in the effectiveness of operating personnel. Q/- Please explain the regulation for the working hours of nuclear reactor operators in the United States, in short, medium and long term. -Please explain the decision criteria for "highly unlikely that such deviations would cause significant reductions in the effectiveness of operating personnel for very unusual circumstances."	In 1982, the NRC issued its "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" which established guidelines for controlling the work hours of personnel performing safety-related functions. The policy guidelines were subsequently incorporated in plant technical specifications and administrative procedures. The NRC's policy addresses the long term control of work hours by establishing an objective of normal 40-hour week while the plant is operating. The policy also establishes guidelines to be used on a temporary basis, for periods requiring heavy use of overtime, such as plant refueling outages. For these periods the policy states: An individual should not be permitted to work more than 16 hours straight (excluding shift turnover time). An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any seven day period (all excluding shift turnover time). A break of at least eight hours should be allowed between work periods (including shift turnover time). Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on shift. Although the above guidelines are to be used "on a temporary basis," the NRC has never established more specific guidelines with respect to the acceptable duration for scheduling personnel at these limits. Similarly, the policy guidance provides for plant managers, and their designees, to authorize deviations from the guidelines for "very unusual circumstances." The NRC has not further defined "very unusual circumstance" or the duration for which individuals may be authorized to exceed the guidelines. With regard to criteria for determining if a deviation authorization would likely result in significant reductions in the effectiveness of operating personnel, the NRC has not issued guidance concerning the method or criteria for this determination. In practice, this determination is based upon a subjective assessment by the licensee. In Commission paper SECY-01-0113, Fatigue of Workers at Nuclear Power Plants, the NRC acknowledged that the lack of definitions for key policy terms has contributed to inconsistent interpretation and implementation of the policy and recommended development of clear and enforceable requirements for the control of working hours of plant staff performing safety-related functions. In response, in staff requirements memorandum SRM-SECY-01-0113 the Commission authorized the staff to develop a proposed rule for the management of worker fatigue. Information concerning the proposed rulemaking, including draft proposed rule language can be accessed online at: http://ruleforum.llnl.gov/cgi-bin/rulemake?source=Part26_risk&st=risk
160	Korea, Republic of	12	12 elements such as Procedure, Staffing, Issues Tracking System were suggested as Human Factors Engineering Program Review Model in NUREG-0711 Rev.2(2004.2). Your national report, however, describes only "Emergency Operating and Plant Procedure" and "Working Hours and Shift Staff". Why is it?	Section 12.1.3, "Significant Regulatory Activities," does not describe all the program elements of NUREG-0711; the purpose of this section of the Report is to describe, as indicated in the report, "....significant regulatory activities in the following seven areas to address human performance under the Human Factors Program." The report, though referring to the "human factors program," was not meant to discuss each element of NUREG-0711. The report discusses those elements/aspects of the human factors engineering program that were considered to be "significant regulatory activities." Working Hours and Shift Staffing were included in the national report due to significant recent NRC initiatives to address these issues.
161	Korea, Republic of	12	NUREG-0711 Rev.2 and NUREG_0800 Chap.18 require the "Issues Tracking System" of Human Factors. Your national report, however, described "Human Factors Information System". 1. What is the difference between the "Issues Tracking System" of Human Factors and "Human Factors Information System"?	The "HFE Issues Tracking" system is a licensee applicant system that should be available to address human factors issues that are: (1) known to the industry and (2) identified throughout the life cycle of the HFE aspects of design, development, and evaluation. The issues in the system need to be addressed at some point in the process, and thus need to be tracked to ensure that they are not overlooked. The "Human Factors Information System" is an NRC database that stores information about human performance issues. NRC collects data from its own inspection reports, licensed operator examination reports, and Licensee Event Reports (LERs), which are submitted by licensees, as their name implies. NRC uses this information to assist in its programmatic oversight. The information in the HFIS database is not considered to be all-inclusive but rather indicative of overall performance at an

			2. Among 12 elements described in NUREG-0711 Rev.2, what element(s) does the "Human Factors Information System" correspond to ?	individual plant. The information is intended to provide a general overview of the types and approximate numbers of performance issues documented in these reports. The categories in the "Human Factors Information System" do not correspond to any one of the 12 elements described in NUREG-0711, Rev. 2. NUREG-0711 is guidance to be used by the staff to review Chapter 18 of NUREG-0800 for applicants for construction permits, operating licenses, standard design certifications, combined operating licenses, and for license amendments.
162	Mexico	12	Regarding the National Report in its Section 12.1.3.6 "Support to Event Investigations and For-Cause Inspections and Training" Does the NRC have any specific methodology for event investigation and root cause analysis? What is the most used methodology at the nuclear power plants?	With regard to event investigation, the NRC's inspection program allows for investigation at three varying levels, the most significant being an Incident Investigation Team (IIT). The IIT is an in-depth team inspection that includes independent root cause analysis; however, this process has not been used in the last ten years. The next level of inspection is an augmented inspection team (Inspection Procedure 93800), which contains some elements of independence, but does not typically include independent root cause analysis. The lowest level of event investigation is a special inspection (Inspection Procedure 93801), which is primarily an overview of licensee actions to respond to the event. While the NRC does not typically perform independent root cause analyses, the NRC's reactor oversight process assumes that licensee's will conduct root cause analyses for risk significant issues and events. These licensee generated analyses are then reviewed by NRC inspectors using the guidance contained in specific NRC inspection procedures. The applicable inspection procedures (Inspection Procedure 95001 and Inspection Procedure 95002) include the specific attributes that need to be addressed by the licensee's root cause analysis before the issue can be considered "closed" by the NRC. The procedures do not favor any one specific root cause methodology, but rather stress matching an appropriate methodology to the issue being assessed. Our experience has shown us that there is not any one methodology that is most prevalent at US nuclear plants and that the implementation of the methodology chosen is often more important then the specific type of methodology itself.
163	Russian Federation	12	As is known from various sources, up to 40% of emergencies at NPPs are caused by NPP personnel errors. The importance of resolving this problem is stressed in the regulatory documents of IAEA and IEC. Therefore it is essential to have experience with good practices aimed at reducing the number of personnel errors. What methods of reducing human-induced failures out of those recommended by IAEA and IEC have proved in the USA to be most effective (examples are welcome from the operating experience and quantitative assessments of results)?	Methods for reducing human-induced failures recommended by the IAEA and IEC that have proved to be most effective in the USA is a question that is, perhaps, better answered by representatives from the industry rather than the NRC. Licensees are responsible for choosing the methods they believe are most effective for addressing situations that produce human-induced failures specific to their facilities.
164	Russian Federation	12	Section 12.2 of the Report notes that NRC conducts research in the area of human performance. This research has resulted in the publication of NUREG-1764 "Guidance for the Review of Changes to Human Actions". 1) Are there NRC requirements on the use of the results of human performance assessments and of the trends in human-induced NPP operational event numbers in the current risk analyses? 2) Does NRC use this information, and if so, then how it is used in NRC's risk assessments?	Part 1: there are no NRC requirements (regulations) for licensees of currently operating nuclear power plants (NPPs) to maintain a probabilistic risk assessment (PRA). Therefore, there are no requirements for licensees to conduct human performance assessments or trend analyses for the purposes of updating their PRAs. In Generic Letter 88-20 (issued November 23, 1988), the NRC requested all licensees to conduct an Individual Plant Examination to identify potential vulnerabilities to severe accidents using PRA; all licensees have complied with this request. There is a requirement to conduct a design-specific PRA as part of the standard design certification process for new NPPs. Motivated by the NRC's PRA Policy Statement (issued August 16, 1995), licensees have maintained their PRAs and routinely use their risk insights to help assess human performance. Part 2: the NRC routinely reviews operational events using risk-informed methods to determine their safety significance and detect worsening performance trends. As a part of these reviews, human performance issues are considered. The NRC's Office of Regulatory Research maintains the Standardized Plant Analysis Risk (SPAR) Model Development Program, which consists of NRC-developed PRAs of all currently licensed NPPs. These PRAs are used to support a variety of operational experience review programs such as the Reactor Oversight Process (ROP) and the Accident Sequence Precursor (ASP) Program. The NRC's Office of Regulatory Research also conducts research into human reliability analysis (HRA) methods that consider, in part, operational experience with human performance issues. Note: The purpose of NUREG-1764, "Guidance for the Review of Changes to Human Actions," is to provide guidance to the NRC staff during the review of changes in operator actions that are credited in NPP safety analyses. Changes in credited actions may result from a variety of NPP activities such as plant modifications, procedure changes, equipment failures, justifications for continued operations, and identified discrepancies in equipment performance or safety analyses. This guidance is based on a graded risk-informed process. Risk insights are used to determine the level of regulatory review that the NRC should perform, that is, human actions that are considered more risk significant receive a detailed review while those less risk significant receive a less detailed review. NUREG-1764 is not used to conduct human performance assessments or trend analyses of human

				induced NPP operational events.
165	Slovenia	12	This section states the objective of the policy is to ensure that personnel are not assigned to shift duties while in a fatigued condition that can significantly reduce their mental alertness or decision-making ability. Is compliance with the NRC guidance on working hours controlled in NPPs and enforced by NRC inspectors ? In case of a worker's complaint of deviations from the guidance, how NRC deals with such cases, what is the action against the operator (licensee)?	NRC policy statements are not enforceable requirements. However, licensees for U.S. nuclear power plants have incorporated the guidelines of NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Power Plants" in their plant technical specifications (TS), and these TS are enforceable requirements. The NRC does not routinely inspect for compliance with these TS as part of the current reactor oversight process. However, the NRC has on occasion issued violations for licensee failures to maintain compliance with these TS, such as failure to ensure that individuals do not exceed the TS work hour limits without written advance authorization. The NRC has recognized that due to the lack of definition of key items in the TS, the NRC cannot readily enforce certain provisions. The NRC has developed a draft proposed rule which, if approved as a final rule, would establish requirements that would be clearer and could be more readily enforced. The draft proposed rule language and other information concerning this rulemaking can be accessed online at: http://ruleforum.llnl.gov/cgi-bin/rulemake?source=Part26_risk&st=risk Regarding deviations from a plant's work hour limits, plant technical specifications for the administrative control of work hours for personnel performing safety-related functions provide plant managers, or their designee, the authority to approve deviations from the specific work hour limits of the plant technical specifications. This deviation approval authority is consistent with NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors." However, as noted in the policy, the paramount consideration in such authorization shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely. Accordingly, the NRC would encourage workers to communicate to their management any concern they may have regarding their ability to safely and competently perform their duties that may arise from an authorization to deviate from the work hour guidelines. It is the policy of the NRC to encourage workers at regulated nuclear facilities to take safety concerns to their own management first. However, workers can bring safety concerns directly to the NRC at any time. NRC's response to concerns regarding licensee control of work hours has been dependent on the specific circumstances and ranged from the issuance of generic communications and the imposition of Orders for generic concerns, and the issuance of notices of violations for site-specific concerns. For example, on May 10, 2002, the NRC issued NRC Regulatory Issue Summary (RIS) 2002-007: Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-for-Duty. The RIS summarizes several instances of worker concerns regarding self-declarations of fitness-for-duty related to fatigue and clarifies the applicable regulatory requirements, including the applicability of NRC's fitness-for-duty requirements (10 CFR 26, Fitness for Duty Programs) to worker fatigue, and 10 CFR 50.7, "Employee protection." Although security personnel were not subject to the plant technical specification limits on work hours, the NRC received concerns regarding fatigue of security personnel at nuclear power plants following the terrorist attacks of September 11, 2001. Increased security measures resulted in an increase in working hours for security personnel, causing some individuals to express concern regarding their ability to perform their duties. Review of the work hours for security personnel indicated many individuals had been working as much as 60 hours per week for an extended period of time. On April 29, 2003 the Commission issued Order EA-03-038, requiring compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work hour limits.
166	South Africa	12	Good practice: Recognition and consideration of human performance as a "cross-cutting factor" to the cornerstones of safety, and the working hour 'Policy on factors causing fatigue of NPP operating staff' are considered good practices. Comment (12.1.3.3): With respect to excessive fatigue prevention it is known workers become more susceptible to shift-work induced fatigue with age. By reducing the maximum age level for active shift-work duties the objective of the working hours policy could be partially achieved, though may not be feasible for a variety of reasons, for instance, in the case of staff shortages. 12.1.2: What are the current Human Reliability Analysis (HRA) techniques used in PRA applications, in particular severe accident sequences? 12.1.3.3: What is the maximum age level for active shift-work duties? Safety Culture is not specifically mentioned. What level	Part 1: Various methods, including combinations of methods, are used in risk-informed license applications. Section 5.3 of NUREG-1560 provides a brief discussion of the variability of human error probabilities and the influences of different human reliability analysis methods. Part 2: The NRC currently has no age limit for active shift work duties. Part 3: Information on policies, programs, and practices that apply to licensee Safety Culture can be found in section 10.4.2. The NRC does not currently conduct Safety Culture assessments. Recently, the Commission considered options to revise its policies on Safety Culture. The NRC staff had prepared SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which provided the NRC Commissioners with options for enhancing oversight of Safety Culture. The Commission responded with a Staff Requirement Memorandum (SRM), dated August 30, 2004, which directed the staff to undertake a number of activities related to Safety Conscious Work Environment (SCWE) and Safety Culture. These activities include: Enhance the Reactor Oversight Process (ROP) treatment of cross-cutting issues to more fully address Safety Culture, including training for inspectors, Develop a process for determining the need for a specific evaluation of the licensee's Safety Culture and develop a process for conducting an evaluation of the licensee's Safety Culture (for those plants in the degraded cornerstone columns, referred to as Column Three of the ROP Action Matrix), Continue to monitor industry efforts to assess Safety Culture, and

			of importance is ascribed to Safety Culture assessment. How and how often are safety culture influences measured? What procedural guidance is available to the operator in the event of an earthquake?	Continue to monitor developments by foreign regulators. The SRM further directed staff to develop tools for inspectors to rely on more objective findings as well as create an enhanced training program. In carrying out these activities, the staff were directed to follow established processes for revising the ROP, in particular the process for involving stakeholders. To ensure that the staff's actions are responsive to the SRM, that the public's confidence in the Safety Culture of nuclear power plants is enhanced, and that NRC and stakeholder resources are effectively and efficiently utilized, a Safety Culture Response Plan is being developed and will be placed on NRC's website in the future. In specific regard to Safety Culture assessments and measurements of influences, these areas will be examined as part of these activities. Part 4: Regulatory Guide 1.166 provides NRC guidance on pre-earthquake planning and immediate nuclear power plant operator post-earthquake actions.
167	United Kingdom	12	Under the sub-heading "Shift Staffing", the National Report states that 10 CFR 50.54 "specifies the minimum numbers of licensed operators that are required for nuclear power sites," and also the minimum numbers for various emergency response functions. Are there any requirements for minimum numbers of other types of staff, for example technical support staff, maintenance personnel, etc?	There are regulatory requirements only for minimum numbers of licensed staff.
168	France	13	Could the United States of America explain if the lists of safety-related structures, systems and components developed by the licensee's engineering organisations are analysed by the NRC and duly approved by the Regulator.	Safety-related SSCs are included in the licensee's final safety analsis report (FSAR) and are thus reviewed and approved by the appropriate NRC technical/engineering staff.
169	Germany	13	Is there a special QA program in case of life extension to monitor the ageing of components?	No, the licensee's existing QA programs, as committed to in the updated or FSAR, typically is utilized for plant life extension activities.
170	Korea, Republic of	13	Does the USNRC have plan for preparing detailed regulatory guideline or developing supplemental quality requirements so that the licensees may use ISO 9001 certified suppliers in procurement of safety related components?	No, the NRC staff articulated its position on the use of ISO-9000 2000 in NRC SECY-03 -0117, " Approaches for Adopting More widely Accepted International Quality Standards," dated July 9, 2003. ADAMS Accession Nos. ML031490421 & ML031490463
171	Slovenia	13	It is stated that changes that do reduce commitments related to the QA Program must receive NRC approval before implementation. In what case the reduction of commitments to the QA program can be justified?	Ultimately, all reductions in commitments to the licensee's existing QA program still must be in compliance with the QA requirements of Appendix B to 10 CFR Part 50. See 10 CFR 50.54 (a)(3) for regulatory guidance on reductions in commitments.
172	United Kingdom	13	Nuclear quality assurance criteria are said to apply to "all activities that affect the safety-related functions of structures, systems, and components that prevent of mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public." The public is mentioned at various other points in this section, but there is no mention of the workers at the plant. Does NRC have quality assurance requirements for structures, systems or components whose malfunction could affect only the health and safety of the workers at the plant?	No, there are no separate QA regulations that specifically focus on systems, structures, or components whose malfunction could only affect the health and safety of workers at the plant. NRC and licensees do not categorize systems in that manner. Other regulations seek to ensure worker safety, and the QA regulations designed to protect public health and safety will also protect workers' health and safety.
173	China	14	For the plants designed many years ago, how do they use risk-informed methodology to improve their operation safety in order to meet the changed design standard requirements?	Previously licensed plants are not required to meet changed design standard requirements, unless specifically required and supported by application of the Backfit Rule (10 CFR 50.109). In performing the backfit analysis, generic or plant-specific PRA information may be used. However, all U.S. nuclear power plants performed individual plant examinations to search for facility vulnerabilities, for which a number of plants voluntarily made improvements.
174	Korea, Republic of	14	Paragraph 14.1.2 refers to 'License Renewal'. What's the difference between environmental reports for license renewal and for the initial operating license of a nuclear power plant?, (Especially with regard to contents, scope	Background: Requirements for the content of environmental reports for initial licensing of nuclear facilities are outlined in 10 CFR Part 51, the NRC's rules on environmental protection (see 10 CFR 51.45, 51.50, and 51.53(b)). Since nuclear power plants are generally baseload facilities, the license renewal requirements recognize that the power from the facility is needed and does not need to be justified (see 10 CFR 51.53(c)).

			and depth of reports.)	Response: There are differences in the scope and level of detail in the Environmental Report (ER) that must be submitted by the applicant for an Operating License (OL) and the ER for License Renewal (LR). The OL ER is to focus on (1) the differences from the environmental inquiry performed in conjunction with the issuance of a Construction Permit (CP) and (2) any new information that had not been considered previously. The CP ER and the NRC's environmental impact statement (EIS) already considered the impacts of construction and the impacts of operation for a 40-year period of time. For LR, the NRC performed a significant environmental inquiry to assess (1) the environmental impacts of operation for a period 20 years beyond the expiration of operating licenses for nuclear power plants still under construction and those already operating and (2) the environmental impacts associated with major refurbishment activities that could be required for operation during the 20-year renewal period. The results of this inquiry were published in NUREG-1437, which was a Generic EIS (GEIS), and the findings from the inquiry were codified in the NRC's rules. Consequently, those issues that were generically resolved in the GEIS (these are called Category 1 issues) for all plants need not be addressed by the applicant in its LR ER. Therefore, the LR ER is to focus on (1) the site-specific environmental issues (these are called Category 2 issues) of extending the period of operation for up to 20 years and the site-specific issues associated with any refurbishment activity, and (2) any new and significant information of which the applicant may be aware.
175	Pakistan	14	Section 14.1.2.1 states that the NRC regulations limits commercial power reactor licenses to 40 years. As per policy, NRC grants license renewals to ensure safe plant operation up to an additional 20 years of plant life. The decision to seek license renewals rests entirely with nuclear power plant owners. As of April, 2004, NRC renewed licenses for 25 reactors at 14 sites following the first renewed licenses issued in 2000. USA has 104 NPP, however, some of these plants have remained shutdown for many years. USA may like to elaborate that: • Had all these plants been shutdown by NRC due to outstanding regulatory issues or was it voluntary due to economic considerations? • Had there been a major change in licensing basis of the plants which has led to some operators applying for renewals before the end of 40 year plant life?	- Some of the current 104 plants had shut down because of performance deficiencies identified by events, licensee reviews, and USNRC oversight programs. With the exception of Browns Ferry Unit 1, these plants have restarted and are currently operating such as Browns Ferry Units 2 and 3, Millstone Units 2 and 3, D. C. Cook Units 1 and 2, and Davis Besse. - Section 54.17 of Title 10, Code of Federal Regulations, states that "An application for a renewed license may not be submitted to the Commission earlier than 20 years before the expiration of the operating license currently in effect." Most of the plants have opted to submit their applications well before the expiration of their operating licenses which is allowed by the regulations. Major changes in licensing bases of plants are not the determining factor as to when licensees apply for license renewal. The decision whether to seek license renewal rests entirely with nuclear power plant licensees, and typically is based on the plant's economic situation and whether NRC requirements can continue to be met. Because license renewal is voluntary, each licensee's timing for submitting a license renewal depends on its own circumstances. The license renewal rule (10 CFR Part 54) states that an application for renewal may not be submitted earlier than 20 years before expiration of the current operating license. The majority of license renewal applicants to date have chosen to submit early in the 20 year period rather than wait until the end of the current 40 year operating license. Updating the status of license renewals in the U.S., the NRC has as of February 2005 issued renewed licenses for 30 reactors at 17 sites.
176	Pakistan	14	With reference to clause (ii) of the Article, please elaborate the scope of different type of analyses (such as deterministic, probabilistic, mechanical etc.,) performed by NRC or its support organizations for verification/audit of the analysis contained in licensees submissions, for developing of regulatory documents and for the assessment of any safety issue arising from regulator's perspective.	The intent of Article 14 is to provide at a summary level the type of information requested, with references to documents containing more detail. Additionally, Regulatory Guide 1.174 provides guidance for considering both deterministic and probabilistic information
177	Pakistan	14	With reference to section 14.1.1.2, it is mentioned in the report that after resolving management and regulatory issues that caused all three units of Brown Ferry to shutdown in 1985, the utility TVA successfully restarted unit-2 and 3 in 1990's. In May, 2002, TVA decided to initiate a restart effort for unit-1, planned for completion in 2007. Restarting unit-1 differs from restarting unit2 and 3 in that TVA is applying for license renewal and an extended power uprate in parallel. US may like to elaborate as to what major modifications in design/procedural change/hardware are being undertaken by TVA with regards to present day NRC safety requirements with special reference to strengthening of	TVA is performing modifications to Browns Ferry Unit 1 so that the unit is in compliance with regulatory requirements, codes and standards at the time the unit is restarted. TVA is replacing and refurbishing major portions of the facility, based on lessons learned from the recovery of Units 2 and 3 and from operating experience on Units 2 and 3. TVA is also making modifications to Unit 1 to support operation at the uprated power level. Similar modifications to support operation at the uprated power level will be made for Units 2 and 3 in the future. TVA has stated that their goal is to have the design and licensing basis for Browns Ferry Units 1, 2, and 3 to be essentially the same.

			level-4 and level-5 of defense in depth philosophy.	
178	Slovenia	14	Section 14.1.3 presents a detailed historical overview of NRC activities in assessing the NPPs' safety and their compliance with regulations and standards. This is US approach and is quite effective in assuring safe operation of NPPs. However, from what is presented, only IPA for the license renewal process could somehow be compared to a PSR but IPA is done only once in a plant's lifetime. From the data on individual NPPs it can be observed, that IPA was performed much sooner than the lifetime of the NPP would expire. How can the safety of an NPP be evaluated up to 60 years of operation, when NPP is subject to ageing of staff (knowledge), materials and technology, when the IPA is performed at 30 years of its operation? Is it intended to perform another IPA after certain period? Please, explain.	The Integrated Plant Assessment (IPA) associated with the license renewal process is not a stand alone substitute for a periodic safety review. Over the lifetime of a commercial nuclear power plant the IPA is one element of the US comprehensive regulatory process, as discussed in Section 14.1.3, that helps ensure continued safe operation on US nuclear power installations. An IPA would be performed again if a US licensee, once granted a renewed license, would seek to extend the license beyond 60 years.
179	Switzerland	14	The report claims that "NRC is actively increasing the use of risk insights and information in its regulatory decision making." Furthermore, the report refers to a risk-informed activity that deals with "improved standardized plant analysis risk models". a) What is the scope of the risk analyses in terms of PSA levels as well as the scope of initiating events and operational modes? b) How frequently are the risk analyses updated? c) What kind of activity is it that deals with "improved standardized plant analysis risk models", and how do the "improved standardized plant analysis risk models" look like with respect to the Questions a) and b) posed above?	All licensees have at least a Level I and simplified Level II (i.e., focused on large early releases) PRA addressing the range of initiating events for full power operating condition. Licensees establish their own update requirements for their PRAs, but with the issuance of Regulatory Guide 1.200 and industry standards that provide guidance in this area, the approach to maintaining up-to date PRAs has become more standardized. The NRC's SPAR models are also Level I, addressing the range of initiating events for full power operating condition, and an effort is under way to create the simplified Level II models. These models have been benchmarked against the licensee PRAs.
180	United Kingdom	14	The quotation from the Convention in (ii) uses the word "assurance". The official text uses the word "accordance", which makes much better sense. The last two paragraphs on this page contain the phrases "maintain the licensing basis" and "conform to the licensing basis". Does NRC have requirements for licensees to search proactively for, and to inform NRC of, those changes to plant or procedures which could improve as well as maintain safety?	The Atomic Energy Act establishes that the NRC may establish requirements deemed necessary to promote the common defense and security and to provide adequate protection to the health and safety of the public. As discussed in section 14.1 of the report, the NRC's regulatory approach is first to determine, before granting a license, that a facility satisfies NRC requirements and then to conduct a variety of regulatory activities to provide ongoing assurance that the facility continues to have an acceptable level of safety. This includes inspections to verify that requirements are met and programs to establish additional requirements if new information finds this to be necessary (as discussed in section 14.1.3, new requirements beyond those necessary to meet the statutory mandates are subjected to backfit analysis, including cost-benefit considerations). The report also noted activities that licensees perform that are not specifically required by regulation. For instance, the Institute of Nuclear Power Operations conducts various reviews and audits of licensee operations, including consideration of "good practices", to help licensees improve their operations. The NRC does not require licensees to search proactively for improvements to safety or to inform NRC of any such changes. NRC has a variety of reporting requirements, either with respect to changes a licensee decides to make without NRC review (see discussion in section 14.1.1.1), or if a licensee identifies "an unanalyzed condition that significantly degraded plant safety" [§ 50.73(a)(2)(ii)(B)].
181	United Kingdom	14	The requirement for an applicant seeking license renewal to "provide NRC with an evaluation that addresses the technical aspects of plan aging and describes the ways those effects will be managed" is laudable, but why wait for 40 years, a period "which was selected on the basis of economic and antitrust considerations, not on technical limitations"? How can NRC be sure that its "activities have continually ensured that the licensing basis will continue to provide an acceptable level of safety"? Has NRC any plans to place a duty on its licensees to continually search for ways of improving safety rather than in effect doing it itself?	The NRC does not explicitly require licensees to continually search for ways of improving safety. However, the NRC relies on its regulatory process to provide continuous oversight of nuclear power plants and upgrading of requirements as they are determined necessary. When the original operating license was issued, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied the NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety for 40 years. However, the licensing basis of a plant does not remain fixed for the term of the operating license. The licensing basis evolves throughout the term of the operating license because of the continuing regulatory activities of the NRC, as well as the activities of the licensees. The NRC engages in a large number of regulatory activities which, when considered together, constitute a regulatory process that provides ongoing assurance that the licensing basis of nuclear power plants provide an acceptable level of safety. This process includes research, inspections (both periodic regional inspections as well as daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. The NRC's activities may result in changes to the licensing basis for nuclear power plants through promulgation of new or revised regulations, acceptance of licensee commitments for the modification to nuclear power plant designs and procedures, and the

				issuance of orders or confirmatory action letters. Operating experience, research, or the results of new analyses are also issued by the NRC through documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change the plant's licensing basis. In this way, the NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provide an acceptable level of safety. This process continues for plants that receive a renewed license. In addition to NRC required changes in the licensing basis, a licensee may also seek changes to the current licensing basis for its plant. However, these changes are subject to the NRC's formal regulatory controls with respect to the changes (such as 10 CFR 50.54, 50.59, 50.90, and 50.92). These regulatory controls ensure that a documented basis for licensee-initiated changes to the licensing basis for a plant exists and that NRC review and approval is obtained prior to implementation if changes to the licensing basis raise safety questions. The plant's final safety analysis report is periodically updated to reflect changes to the licensing basis. Often safety enhancements are self-imposed initiatives above regulation, motivated by the US industry's self-described pursuit of excellence and by the recognition that, in a free-market competitive energy industry, safety and economics are directly linked. Licensees have, for example, voluntarily replaced analog instrumentation and control systems with digital instrumentation and control systems, upgraded their plants to increase production of electricity, and managed their plants to performance levels above the NRC's performance indicator thresholds.
182	United Kingdom	14	Why is the responsibility of carrying out the cost/benefit analysis that of NRC rather than the licensee?	NRC is required to conduct a regulatory analyses (which contain cost-benefit analyses) for rulemakings which propose to ease burden for licensees, not just impose new requirements. NRC considers proposed actions for their impacts on society and the ultimate objective of this regulatory process is to ensure that all regulatory burdens are needed, are justified, and will achieve intended regulatory objectives with minimal impacts. If a proposed safety improvement measure is required to comply with regulations or is needed for adequate protection of public health and safety, the NRC can impose the safety improvement regardless of the results of the cost benefit analysis. Otherwise, the NRC cannot impose new requirements on civil nuclear power plants unless the proposed safety enhancement will provide a substantial increase in overall protection of the public health and safety and that the costs for the facility are justified in view of the increased protection. For safety improvements or other changes that are not imposed by the NRC, the licensee makes those decisions independently. NRC may be involved in reviewing and approving certain proposed changes to the nuclear power facility. However, since the licensee has already determined that the change is justified, NRC's review is focused on the safety aspects of the proposed change and not on the cost/benefit.
183	United Kingdom	14	Page 14-9 says that the "issues material to the renewal of a nuclear power plant license are to be limited to those issues that the Commission determines are uniquely relevant to protecting the public". Is worker protection also considered?	The question only partially stated the context of the basis for the license renewal rule (10 CFR Part 54). The Commission concluded that "issues material to the renewal of a nuclear power plant operating license are to be limited to those issues that the Commission determines are uniquely relevant to protecting the public health and safety and preserving common defense and security during the period of extended operation." Programs that have been implemented to address the day-to-day operating reactor issues will remain in effect during the period of extended operation; among these programs are worker protection, emergency preparedness, and security. These are very important programs that are expected to remain in effect during the period of extended operation. The license renewal rule distinguishes between those programs that are in effect already and those that would need to be enhanced or implemented should the licensee be permitted to renew its license into the period of extended operation; for example, an aging management program.
184	United Kingdom	14	The example given on Page 14-10 of licensees who have "voluntarily" improved their plants seem to be limited to examples which offer the licensees clear economic advantage. Are there examples of licensees making voluntary changes to their plants to improve safety where there has been an economic disadvantage by doing so?	Background: NUREG-1650, Rev. 1, "The United States of America Third National Report for the Convention on Nuclear Safety," September 2004. 14.1.3 The United States and Periodic Safety Reviews Licensee Responsibilities for Safety: Regulations and Initiatives Above Regulations As in many countries, U.S. nuclear power plant licensees are responsible for the safety of their facilities. This responsibility is embedded in their license and in NRC's regulatory infrastructure. Under the regulatory umbrella, licensees routinely assess new technologies, off-normal conditions, operating experience, and industry trends to make informed decisions about safety enhancements to their facilities. Some of these reviews are not specifically mandated by NRC regulations. Rather, they are self-imposed initiatives over and above regulations, motivated by their self-described pursuit of excellence and by the recognition that, in the U.S. free-market

				competitive energy industry, safety and economics are directly linked. Licensees have, for example, voluntarily replaced analog instrumentation and control systems with digital instrumentation and control systems, upgraded their plants to increase production of electricity, and managed their plants to performance levels above NRC's performance indicator thresholds. Response: Licensee compliance with regulatory requirements or regulatory commitments is naturally connected with safety first. There may also be cases where safety improvements are undertaken voluntarily, but licensees usually make expensive changes only if there is some economic advantage; i.e., a resulting cost, efficiency or capacity benefit to justify costs. Nuclear plant site Vice Presidents and Plant Managers continually keep their corporate business plans and the "bottom line" in mind whenever plant improvements are considered. However, the following examples might be considered applicable examples of voluntary safety improvements made at an economic disadvantage: 1. One licensee has replaced older equipment with state of the art devices for improvement in operations, maintenance, etc. For example, the licensee upgraded Leak Detection systems with improved digital modules. None of these are mandated by the NRC, but the licensee decided to make the changes for their own reasons. Another example is the new suction strainers installed at the plant. This was a huge design change made solely to increase safety with no economic benefit of any kind, although it is possible the NRC could eventually have taken some enforcement action if they had not done it. 2. During a February 2004 refueling outage, another licensee performed a chemical decontamination on portions of the reactor recirculation piping, installed a permanent shielding modification on the recirculation pump riser piping, replaced all of the low pressure turbine buckets, and cleaned some fuel assemblies. These efforts resulted in significantly reducing the drywell dose rates. The licensee has also identified a large reduction in the amount of elemental cobalt concentrations measured in the condenser hotwell. Although the incentive to do this did have some economic aspects, another motivator appeared to be safety performance related.
185	United Kingdom	14	Does NRC consider that the Davis-Besse event represented a breach of the ASME Code for the periodic inspection of nuclear components? If not, is that Code adequate to ensure the safety of such components?	NRC requirements are adequate for ensuring the safety of nuclear components. The inspections were guided by NRC bulletins and Orders. Following discovery of the corrosion, the NRC issued two bulletins, Bulletin 2002-01, "Reactor Pressure Vessel Head Degradation and Reactor Coolant Pressure Boundary Integrity" and Bulletin 2002-02, "Reactor Pressure Vessel Head and Vessel Head Penetration Nozzle Inspection Programs." Additionally in 2003, the NRC issued an Order modifying licenses establishing inspection requirements for reactor pressure vessel heads at pressurized water reactors. A revised Order was issued in 2004 and superceded the original Order. An ASME Code case is being developed concerning reactor pressure vessel head inspection requirements.
186	Belgium	14.1	In Section 14.1.3 a description is given on how the USNRC regulatory approach provides a continuum of safety assessment and review. In the past, global safety evaluation programs such as SEP (around 1977) and ISAP (around 1984) were conducted. We understand that these programs allowed to have a global picture of the safety at a specific plant. The present approach seems to be much more program-oriented, as illustrated in the time-line diagram on page 14-13. It is not clear whether presently actions are still foreseen to make periodically a global evaluation of the safety at a particular plant (which is the typically the objective of a Periodic Safety Review). Can this be clarified?	The view that the US approach for ensuring safety is program- and process-oriented is correct. NRC's approach for continuing to ensure plant safety differs from the historically deterministic focus of PSRs. The transition to a more risk-informed regulatory framework, the Reactor Oversight Process, and other safety-focused aspects of the US regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, or process improvements and provides confidence that the US civil nuclear power plants can continue to be operated safely. Currently, there are no plans to periodically and comprehensively evaluate the safety of individual plants in a method similar to the periodic safety review process. However, the continuum of safety assessment, review, and oversight as discussed above and in Section14.1.3, provides a comprehensive evaluation of safety. This process allows for a more broad reaching and more comprehensive focused evaluation of safety at individual plants when warranted. The regulatory process will identify that need for broader and more comprehensive reviews in the future.
187	Sweden	14	Please explain the typical procedure used by US licensees for internal safety review, of plant modifications, Tech Spec changes etc, before the cases are submitted to NRC for approval.	Plant modifications are governed by engineering procedures that ensure 10 CFR 50.59 is addressed. Licensees must address a number of questions related to the effect the modification may have on the design bases of the plant. Depending on the results of this screening process, a Technical Specification change may be required. A Technical Specification change is allowed by 10 CFR 50.90. Licensees typically have a licensing organization procedure that outlines the process. A licensing engineer would be assigned the task of developing the license amendment request. Typically, a plant's onsite safety review committee would review the license amendment request for adequacy. The staff would subsequently review this document, when submitted.
188	Sweden	14.1	The procedure for licence renewal is explained. Please	1) When the Commission established the scope of the review for license renewal, it determined that resolution of generic issues

			clarify whether generic issues, such as the ECCS strainer clogging issue, other open issues and an assessment against relevant modern safety standards and practices are required to be resolved as conditions for re-licensing. The same question applies on licensing of power uprates (described in 6.2.1.1). Is there a requirement to solve other open safety issues, not directly associated with the uprate, as a condition for a power uprate?	that are under current investigation is not necessary for the issuance of a renewed license. Generic issues that are not related to the license renewal aging management review or time-limited aging evaluation are not a subject of review or finding for license renewal. However, designation of an issue as a generic issue does not exclude the issue from the scope of the aging management review or time-limited aging evaluation. For an issue that is both within the scope of the aging managment review or time-limited aging evaluation and within the scope of a generic issue, there are several approaches which can be used to satisfy the finding required by the license renewal rule (10 CFR 54.29). If an applicable generic resolution has been achieved before issuance of a renewed license, implementation of that resolution could be incorporated within the renewal application. An applicant may choose to submit a technical rationale which demonstrates that the current licensing basis (CLB) will be maintained until some later point in time in the period of extended operation, at which point one or more reasonable options (e.g., replacement, analytical evaluation, or a surveillance/maintenance program) would be available to adequately mange the effects of aging. An applicant would have to describe its basis for concluding that the CLB is maintained, in the license renewal application, and briefly describe options that are technically feasible during the period of extended operation to manage the effects of aging, but would not have to preselect which option would be used. Other approaches could be for an applicant to develop an aging management program which, for that plant, incorporates a resolution to the aging effects issue, or to propose (outside of license renewal) to amending the CLB such, if approved, would revise the CLB such that the intended function is not longer within the CLB. 2) The NRC reviews power uprate applications against a licensee's current design and licensing bases. The NRC does not intend to impose new criteria or requirements in the review of power uprate applications on plants whose design and licensing bases do not include the criteria or requirements contained in NRC review guidance. No backfitting is intended or approved in connection with the issuance of power uprate license amendments. The NRC will evaluate the licensee's proposed changes to the power plant in the power uprate application against the current NRC rules and regulations. When these generic safety issues are resolved and if the NRC determines there is a substantial increase in the overall protection of the public health and safety or the common defense and security, the NRC will impose these new requirements on operating reactors. The regulation used to control new requirements is Title 10 CFR 50.109. The regulation ensures that backfitting of a nuclear power reactor is appropriately justified and documented.
189	Sweden	14.1	It is mentioned that the objectives associated with Periodic Safety Review (PSR) are substantively accomplished in the US on an ongoing basis. An important part of a PSR is, as mentioned, to determine the extent to which the plant meets current safety standards and practices and in a transparent way on that basis identify reasonable safety improvement measures. Please explain how this part of the PSR is implemented in the US system.	The NRC inspection and oversight process helps ensure that plants meet current safety standards and practices consistent with NRC rules and regulations. NRC's reactor oversight process is highly transparent and poor performing plants or plants that are not in compliance with NRC's regulations are identified and compelled to improve performance through a variety of enforcement tools. The oversight, assessment and enforcement are, in general, conducted under the full view of the public. The transition to a more risk-informed regulatory framework and the revised oversight process further support the objectives of the PSR by providing an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, or process improvements and providing confidence that the plant can continue to be operated safely. NRC and US industry resources are most effectively and efficiently utilized by seeking to further focus on those issues of most safety importance. With respect to the comment regarding identifying "reasonable" safety improvement measures, it should be understood that the NRC can only require reactor licensee to make upgrades or changes to their plant that meet the requirements of 10 CFR 50.109, commonly referred to as "the backfit test". NRC's backfit rule establishes the standard for determining when new safety improvements are appropriate to impose on US licensees. Simply stated, if the proposed safety improvement measure 1) is required to comply with regulations, 2) is needed for adequate protection of public health and safety, or 3) will provide a substantial increase in overall protection of the public health and safety and that the costs for the facility are justified in view of the increased protection, then the NRC can impose the requirement on its power reactor licensees. It is of critical importance to understand that safety improvements imposed by NRC are a subset of safety improvements that are implemented at US nuclear power plants. Each US nuclear power plant licensee makes its own decisions about what is a reasonable safety improvement. Many safety improvements at US plants are not initiated or imposed by the NRC. Licensees are principally responsible for the safe operation of their facilities (emphasis added) and licensees routinely assess new technologies, off-normal conditions, operating experience, and industry trends to make informed decisions regarding safety enhancements to their facilities. Often safety enhancements are self-imposed initiatives above regulation, motivated by the US industry's self-described pursuit of excellence and by the recognition that, in a free-market competitive energy industry, safety and economics are directly linked. Licensees have, for example, voluntarily replaced analog instrumentation and control systems with digital

				instrumentation and control systems, upgraded their plants to increase production of electricity, and managed their plants to performance levels above the NRC's performance indicator thresholds.
190	France	14.2	The report contains additional paragraphs (§14.1.3 p 14-6, 14-7, 14-8) explaining the US approach for periodic safety reviews that is shown as a continuous Backfitting process fed either by input from the licensees or by the regulator and the proposals being reviewed by an ad hoc committee. This initiative has to be positively underlined. Nevertheless, even though this process allows enhancing safety beyond the level reached at the commissioning stage for the license, the US Periodic Safety Review doesn't appear as a thorough in-depth safety review. This seems to be achieved only through the license renewal process performed with the aim of life extension. Is it possible for the US regulator to illustrate the advantages of the Backfitting process by showing examples of significant improvements gained by the application of this Backfitting process? Furthermore, it is explained that, while no periodic safety reviews are implemented, some substitutes exist, such as the ISAP pilot program or the newly proposed IPE process. Could the USA provide some additional details about those two programs? The text refers to section 10.3 for the IPE process, but no relevant mention was found in this section.	The question can be divided into 3 parts. The first part deals with the relationship between the US license renewal process and the periodic safety review process. The second part concerns the backfitting process and the third part seeks additional information on the ISAP and IPE programs. First, although the license renewal process provides an opportunity for a more focused and comprehensive assessment of plant safety, it is not equivalent to the generally understood periodic safety review process. NRC's approach for continuing to ensure plant safety differs from the historically deterministic focus of PSRs. The transition to a more risk-informed regulatory framework, the Reactor Oversight Process, and other safety-focused aspects of the US regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, or process improvements and provides confidence that the US civil nuclear power plants can continue to be operated safely. While there have been some international efforts to establish common guidance and standards for periodic safety reviews, we understand that the periodic safety review process is implemented differently and for different purposes in many countries consistent with each country's regulatory structure. Consequently, we believe that the focus should be on the rigor and independence of the regulatory infrastructure as a whole and not just on an isolated element such a periodic safety reviews. Periodic safety reviews thoroughly and comprehensively implemented and considered in the context of a countries regulatory framework can be an effective, even a necessary, element in ensuring continued power plant safety. However, they are not the only way to ensure continued plant safety. Second, with regard to the NRC backfitting process, NRC has imposed requirements on US licensees such as the maintenance rule (10 Code of Federal Regulations (CFR) 50.65), the station blackout rule (10 CFR 50.63), the anticipated transient without scram rule (10 CFR 50.62) and the fitness for duty rule (10 CFR Part 26). In addition, for example, every 2 to 3 years, NRC amends 10 CFR 50.55a to incorporate by reference recent changes to the ASME Boiler and Pressure Vessel Code (BPV Code) and Code for Operation and Maintenance of Nuclear Power Plants (OM Code) for design, construction, and inservice inspection of pressure boundary components and testing of pumps and valves in nuclear power plants. Each of these requirements has resulted in significant safety improvement and several have resulted in design or modifications to the facility. Finally, with regard to the ISAP and IPE programs it is important to again emphasize that the ISAP program and the IPE program were not meant to be equivalent to the generally understood periodic safety review process. They are discrete elements of the continuum of safety assessment, review, and oversight associated with the US regulatory process as discussed in Section14.1.3. This process allows for a more broad reaching and more comprehensive focused evaluation of safety at individual plants when warranted and will identify that need for broader and more comprehensive reviews in the future. Section 10.3 does not provided detailed information on the IPE. We regret the error. The attached links contained additional information on the ISAP and IPE programs. http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1985/gl85007.html http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1988/gl88002.html http://www.nrc.gov/reactors/operating/ops-experience/fire-protection/plant-examination.html http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1996/secy1996-051/1996-051scy.htm
191	Germany	14.2	This chapter explains that "the US regulatory approach provides a continuum of assessment and review that ensure the public health and safety throughout the period of plant operation". This would mean that this procedure makes Periodic Safety Reviews (PSR) unnecessary. In a PSR, all aspects of plant safety are reviewed in an overall analysis at a given date. How is this comprehensive approach guaranteed in a continuous process?	While there have been some efforts to establish common guidance and standards for periodic safety reviews, we understand that the periodic safety review process is implemented differently and for different purposes in many countries consistent with each country's regulatory structure. Consequently, we believe that the focus should be on the rigor and independence of the regulatory infrastructure as a whole and not just on an isolated element such a periodic safety reviews. PSRs, by their very nature, are not continuous. They are typically snapshots taken at predefined intervals. Periodic safety reviews thoroughly and comprehensively implemented and considered in the context of a countries regulatory framework can be an effective, even a necessary element, in ensuring continued power plant safety. However, they are not the only way to ensure continued plant safety. NRC's approach for continuing to ensure plant safety differs from the historically deterministic focus of PSRs. The transition to

				a more risk-informed regulatory framework, the Reactor Oversight Process, and other safety-focused aspects of the US regulatory framework provide an ongoing approach and basis for implementing appropriate safety improvements, corrective actions, or process improvements and provides confidence that the US civil nuclear power plants can continue to be operated safely. The US regulatory process seeks to ensure that necessary safety improvements are imposed when needed, places the responsibility for the safety of nuclear power facilities unequivocally on the shoulders of the plant operators, and takes actions to ensures that adequate protection of public health and safety is provided every day throughout the operating life of a civil nuclear power plant. In the US, we currently believe that PSRs are not needed to ensure plant safety.
192	Japan	14.2	Before a nuclear facility is constructed, commissioned, and licensed, an applicant must perform comprehensive and systematic safety assessments, which are reviewed and approved by NRC. Q/The risk information from the PSA results is utilized to change the current licensing bases in the risk-informed regulation. The equipment aging, the modifications in the plant design and the operational procedures, etc may affect on the baseline PSA. Has the NRC developed the framework to regulate these changes in the baseline PSA, such as the periodic safety review in the other countries?	The NRC does not have a specific regulation that requires a periodic safety review by the NRC of the licensee's PRA or specifically regulates the licensee's baseline PRA. In the context of applying specific risk-informed regulations, such as 10 CFR 50.69, which may be voluntarily implemented by licensees as an alternative/enhancement to other regulations, there are specific requirements to ensure the licensee's PRA is maintained up-to-date and reflects the current plant design and operations. The implementation of these risk-informed regulations will typically require the submittal of a license application, which will include a review of the licensee's PRA, including the licensee's process for maintaining the PRA up-to-date. However note that aging effects are typically treated by aging management programs to ensure important structures, systems, and components are not susceptible to aging impacts. Thus, aging effects are not typically addressed in PRAs.
193	Japan	14.2	Research results have concluded that aging phenomena are readily manageable and do not pose technical issues that would preclude life extension for nuclear power plants. It was also found that many aging effects are dealt with adequately during the initial license period and credit should be given for these existing programs, particularly those under NRC's Maintenance Rule (10 CFR 50.65), which helps manage plant aging. Q/The NRC concluded the aging phenomena are readily manageable and do not pose technical issues that would preclude life extension. What is the basis of the conclusion, especially the technical basis of the 20 years life extension? How are the aging issues addressed in the framework of the maintenance rule (i.e., 10CFR50.65)?	The U.S. Atomic Energy Act (AEA) permits the Nuclear Regulatory Commission (NRC) to issue operating licenses with terms up to 40 years. Thus, the AEA limits the duration of operating licenses for nuclear power plants to a maximum of 40 years, but permits renewal of the licenses. It is important to note that the 40-year license term was selected on the basis of economic and antitrust considerations, not technical limitations. However, even though the 40-year license term was not based on technical limitations, the design of some plant structures, systems, and components was subsequently based on a 40-year operating life. In developing the license renewal rule, the Commission determined that the existing regulatory process is adequate to ensure that the licensing bases of all currently operating plants provides and maintains an acceptable level of safety. The rule credits existing licensee activities and Commission regulatory activities for continuing to ensure the safe operation of nuclear power plants and focuses the license renewal review on the effects of aging on the functionality of certain plant systems, structures, and components in the period of extended operation and possibly a few other issues related to safety during extended operation. The Commission believes that sufficient technical understanding of age-related degradation exists to enable licensees to develop activities for ensuring safe operation of their plants for the additional 20 years beyond expiration of their existing licenses and decided to limit the maximum period of extended operation under the renewed license to 20 years beyond the expiration of the existing (previous) operating license. This 20 year limit on extended operation would, in the Commission's judgment, provide a useful opportunity to validate and reassess, if necessary, the current understanding of age-related degradation effects. Licensees and the NRC also have the benefit of the operational experience from the nuclear industry, domestic and international, and are not limited to information developed solely by the licensee seeking license renewal. This experience increases each year and is considered in determining the adequacy of programs and activities credited for managing the effects of aging. When the Commission published the final license renewal rule, it also noted that it may revisit this issue in the future as experience with licensee performance in managing age-related degradation during the renewal term is gained. If the Commission has sufficient confidence in the adequacy of licensee programs to detect and resolve in a timely manner any unforeseen age-related degradation, it may revise the 20 year limit. However, the 40 year limit imposed by the AEA would remain. (The Commission can more readily change it's own regulations as appropriate, like the license renewal rule. However, a change to the AEA would require legislation by the United States Congress.) Maintenance Rule: Aging is not addressed explicitly by the maintenance rule, 10 CFR 50.65, but the rule does require monitoring performance or condition of systems, structures, and components (SSCs) in 50.65(a)(1) status. Condition monitoring could certainly be construed to take aging effects on condition into account. For SSCs in 50.65(a)(2) status, in order to keep them there, the licensee must demonstrate effective control of performance or condition through appropriate preventive maintenance. It would seem that appropriate preventive maintenance needed to control performance or condition effectively would necessarily take aging into account in that for those SSCs with identified age-related degradation susceptibilities, the affected attributes would need to be examined periodically and trended such that degrading items can be repaired, renewed or replaced before they fail, unless it is acceptable to replace them promptly upon failure when imminent failure is not readily detectable.

194	Japan	14.2	10 CFR Part 54, known as the "License Renewal Rule," establishes the technical and procedural requirements for renewing operating licenses. License renewal requirements for power reactors are based on two key principles: Q/In the licensing renewal, does NRC utilize the PSA in order to confirm the technical adequacy of the life extension?	In developing the current license renewal rule (10 CFR Part 54), the Commission determined that probabilistic safety analyses (PSA) would be of limited use for determining the scope of systems, structures, and components (SSCs) that would be subject to license renewal review. The current licensing basis (CLB) of operating plants in the U.S. is largely based on deterministic engineering criteria. Consequently, it was determined that it was appropriate to establish the license renewal scoping criteria recognizing the deterministic nature of a plant's original licensing basis, rather than one based on PSA. A PSA may be of use in license renewal on a plant-specific basis to help an applicant assess the relative importance of SSCs and assist in developing an approach for aging management. The use of PSA for license renewal could be revisited in the future as further risk-informed experience is gained.
195	Japan	14.2	The foundation of license renewal rests on the determination that currently operating plants continue to maintain an adequate level of safety. Over the plant's life, this level has been enhanced by maintaining the licensing basis, properly adjusted to incorporate new information that is derived from operating experience. It defines a backfit as any modification of or addition to plant systems, structures, components, procedures, organizations, design approvals, or manufacturing licenses that may result from the imposition of a new or amended rule or regulatory staff position. Q/The description of "properly adjusted to incorporate new information that is derived from operating experience" on P. 14-5 means implementation of the "back fitting process"?	The Nuclear Regulatory Commission (NRC) relies on its regulatory process to provide continuous oversight of nuclear power plants and upgrading of requirements as they are determined necessary. When the original operating license was issued, the NRC made a comprehensive determination that the design, construction, and proposed operation of the nuclear power plant satisfied the NRC's requirements and provided reasonable assurance of adequate protection to the public health and safety. However, the licensing basis of a plant does not remain fixed for the term of the operating license. The licensing basis evolves throughout the term of the operating license because of the continuing regulatory activities of the NRC, as well as the activities of the licensee. These various activities involve implementation of the backfit process as well as other regulatory processes. The NRC engages in a large number of regulatory activities which, when considered together, constitute a regulatory process that provides ongoing assurance that the licensing basis of nuclear power plants provide an acceptable level of safety. This process includes research, inspections (both periodic regional inspections as well as daily oversight by the resident inspector), audits, investigations, evaluations of operating experience, and regulatory actions to resolve identified issues. The NRC's activities may result in changes to the licensing basis for nuclear power plants through promulgation of new or revised regulations, acceptance of licensee commitments for the modification to nuclear power plant designs and procedures, and the issuance of orders or confirmatory action letters. Operating experience, research, or the results of new analyses are also issued by the NRC through documents such as bulletins, generic letters, regulatory information summaries, and information notices. Licensee commitments in response to these documents also change the plant's licensing basis. In this way, the NRC's consideration of new information provides ongoing assurance that the licensing basis for the design and operation of all nuclear power plants provide an acceptable level of safety, including consideration of operating experience. This process continues for plants that receive a renewed license.
196	Japan	14.2	As lessons are learned from the review of renewal applications or generic technical issues are resolved, improved guidance is issued in the interim for use by applicants until the guidance is incorporated into the next formal update of the guidance documents. Q/Regarding the regulatory implementation step of reflecting lessons learned from the review of renewal applications or resolved generic technical issues, your answer to the following questions would be appreciated. 1) How does NRC deal with lessons learned in regulatory process before issuance of interim improved guidance? 2) How does NRC deal with the interim guidance in regulatory process during the period between the issuance of improved interim guidance and the next formal update?	1) The license renewal program is a living program. The staff, industry, and other interested stakeholders gain experience and develop lessons learned with each renewed license. The lessons learned help the NRC's in maintaining safety, improving effectiveness and efficiency of the program, reducing regulatory burden, and increasing public confidence. The lessons learned are captured in interim staff guidance (ISG) for use by the staff and interested stakeholders until the license renewal guidance documents are revised. Because lessons learned are identified as part of the ongoing renewal application reviews, current applicants become aware of the lessons learned during interactions with the staff on their applications. Once identified, the NRC staff also communicates generically with the industry through the Nuclear Energy Institutes License Renewal Task Force using the ISG process. The ISG process captures lessons learned from license renewal application reviews and communicates them to all stakeholders. The process includes early interactions with stakeholders during the development of the ISG, including publishing of a Federal Register notice requesting comments. After resolution of any comments received, the approved ISG is issued. Before issuance of the approved ISG, license renewal applicants are encouraged to address the identified issue in their applications. If not addressed, the applicant will have to address it after the renewed license is issued. 2) Applicants for license renewal must address the position contained in an approved ISG, as applicable, in their license renewal application. Approved ISGs will be incorporated into the next update of the guidance documents. The NRC is currently updating the license renewal guidance documents to incorporate approved ISGs and other identified improvements with a scheduled issue date for the final documents of September 2005.
197	Germany	15	Which acceptance criteria have been used for the regulatory review of the radiological consequences of design basis accidents? Are these criteria related to releases or related to radiological exposures? If dose limits are applied, which are the parameters (e.g. exposure pathways, integration times, distances) considered for the calculation?	Regulatory Guide 1.195 and 1.183 provide the details of how the NRC performs design-basis accident analyses.
198	Japan	15	The program for occupational radiation control has succeeded in reducing doses. Q/More detail information would be appreciated regarding the program for occupational radiation control.	The "program for occupational radiation control" refers to the NRC's regulatory program to ensure adequate protection of worker health and safety from exposure to radiation from radioactive material during routine nuclear reactor operation. 10 CFR Part 20.1101 states that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Furthermore, it states that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound

			What kinds of factor do significantly contribute to this doses reduction?	radiation principles to achieve occupational doses and doses to members fo the public that are as low as is reasonably achievable (ALARA). The NRC's Regulatory Guide 8.8 provides information to licensees on suggested ways to maintain occupational radiation exposures ALARA. The NRC reviews the licensees' radiation protection programs and monitors how licensees are complying with the requirements of 10CFR Part 20 as part of their Regulatory Oversight Process (ROP). As part of the Occupational Radiation Safety cornerstone of the ROP, NRC inspectors perform routine inspections in the areas of access control, ALARA planning and controls, radiation monitoring instrumentation and protective equipment, and radiation worker performance. One of the metrics of the ROP is a plant's three-year rolling average collective dose. This metric, which can be used to determine the amount of inspection time allotted to a plant, has been steadily declining at US LWRs over the past 20 years. In the years immediately following the 1979 accident at TMI, doses at US reactors remained high as plants implemented numerous NRC mandated modifications. As plants completed these modifications, doses at US plants declined. Special maintenance jobs such as steam generator replacements and recirculation pipe replacements in the early 1980s also contributed to high plant doses. However, as plants gained experience in performing these jobs, these doses declined dramatically. Since a majority of a plant's dose is accrued during outages, the shortening of outages at US plants has led to lower annual collective doses. Other factors which have resulted in lower doses at US plants include improved water chemistry control programs, reduction in the source term (e.g., reduction in stellite containing components in contact with reactor coolant systems), increased use of mockups prior to high dose jobs, increased use of shielding and replacement of temporary shielding with permanent shielding, remote monitoring techniques, and the widespread adoption of the ALARA philosophy by plant personnel, from the corporate management down to the plant workers.
199	Japan	15	Thereafter, the doses increased as a result of the extensive modifications required of all nuclear power plants in response to new requirements. The average collective dose reached a peak of 7.91 person-Sv (791 person-rem) per reactor in 1980. Since then, doses have declined almost steadily to the current level of slightly above 1person-Sv (100 person-rem) per reactor, where they have remained for the past 5 years (1998-2002, the last year for which the data have been compiled). The 2001 average collective dose value of 1.07 person-Sv (107 person-rem) per reactor was the lowest average collective dose recorded since data collection began in 1969. Q/Does NRC believe that the present average collective dose level is sufficiently low ? Or the further reduction is needed?	The NRC has no regulatory criteria for setting collective dose levels. However, 10 CFR Part 20 states that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation principles to achieve occupational doses and doses to members fo the public that are as low as is reasonably achievable (ALARA). A low collective dose that may be considered ALARA at one plant may be unobtainable at another plant which may have a history of a high source term (due to such causes as high stellite levels, inadequate shielding, poor water chemistry, and cramped working conditions). As dose reduction practices improve, it is not unreasonable to expect that plant collective doses at US LWRs will continue to decline. Although the NRC does not set optimum plant collective dose levels, INPO has been setting more and more challenging 5-year collective dose goals for US PWRs and BWRs since 1986. The current collective dose goal for the year 2005 is a median collective dose of 65 person-rem for PWRs and 120 person-rem for BWRs.
201	Slovenia	15	In Chapter 15.4.2 the regulatory requirements for public are quoted. Could you provide some values on public exposure in the vicinity of nuclear installations to show the compliance with the requirements?	For nuclear power reactors, the data from licensee reports, shows that the annual dose to members of the public from radioactive gaseous effluents is below 5 mrem (0.05mSv) to the total body and 15 mrem (0.15mSv) to the skin. For radioactive liquid effluents, the annual dose is below 3 mrem (0.03 mSv) to the total body and 10 (0.10 mSv) mrem to any organ.
202	South Africa	15	An indication is given of how the occupational doses have evolved since 1969 to 2002. It would be useful if trends in average dose to the public due to effluent release for the period 1996 – 2002 could be indicated and explained. What methodology/measures taken ensured that the occupational doses were greatly reduced? What is the role of the NRC in independent verifications with regards to environmental monitoring?	a) For nuclear power reactors, the data from licensee reports, shows that the annual dose to members of the public from radioactive gaseous effluents is below 5 mrem (0.05mSv) to the total body and 15 mrem (0.15mSv) to the skin. For radioactive liquid effluents, the annual dose is below 3 mrem (0.03 mSv) to the total body and 10 (0.10 mSv) mrem to any organ. The NRC does not trend this data. The dose values given above are the NRC's ALARA numerical criteria from radioactive gaseous and liquid effluents. NRC inspects for compliance with these values. b) Although the NRC has no regulatory criteria for collective dose levels, 10 CFR Part 20 states that licensees shall use, to the extent practical, procedures and engineering controls based upon sound radiation principles to achieve occupational doses and doses to members fo the public that are as low as is reasonably achievable (ALARA). It is generally recognized in industry that there is a correlation between low collective dose rates and cost savings. Therefore, there has been a continuing effort in industry to develop dose reduction methodologies (e.g., improvements in plant water chemistry and water cleanup, components low in stellite content, remote monitoring techniques, crud control, robotics, and improved outage planning) that will result in lower collective doses. Dose reduction methodologies which are successful in reducing doses at one plant are shared with the industry so that other plants can benefit from these methodologies. A good example of this information sharing can be seen in the dramatic reduction in doses associated with steam generator replacement projects, which have dropped from approximately 2000 person-rem in 1980 to less than 200 person-rem today. c) The NRC periodically inspects each licensee's radiological environmental monitoring program, procedures, analyses, calculations, personnel qualifications, and reports to verify compliance with regulatory requirements. The NRC does not perform independent environmental monitoring around nuclear power plants.

204	Switzerland	15	What are the dose limits for a person of the general population? Are there source-related dose constraints for a person living near to nuclear installations?	The NRC specifies dose criteria in each nuclear power reactor license which requires the dose to members of the public living near the reactor from radioactive gaseous and liquid effluents to be ALARA. There are no "source-related" constrains. It is the licensee's responsibility to manage their radioactive effluents to be below the regulatory requirements. For nuclear power reactors, the regulatory dose requirements are: the annual dose to members of the public from radioactive gaseous effluents is below 5 mrem (0.05mSv) to the total body and 15 mrem (0.15mSv) to the skin. For radioactive liquid effluents, the annual dose is below 3 mrem (0.03 mSv) to the total body and 10 (0.10 mSv) mrem to any organ.
205	Switzerland	15	The 50 microSv-limit on page 15-2 does not fit to the defined ALARA criterias on Page 15-5 for the control of radiation exposure of members of the public: From the release of airborne effluents ALARA is fulfilled if the whole body is below 50 microSv (without all other exposure paths such as ingestion, inhalation and so on).	The ALARA criteria on page 15-2 is the dose in millirem to members of the public from radioactive gaseous effluents. The ALARA criteria on page 15-5 includes additional criteria for the "air dose" for beta and gamma radiation from radioactive gaseous effluents in millirads. The complete Appendix I to 10 CFR Part 50 ALARA criteria for radioactive gaseous and liquid effluents is: the annual dose to members of the public from radioactive gaseous effluents is below 5 mrem (0.05mSv) to the total body and 15 mrem (0.15mSv) to the skin. For radioactive liquid effluents the annual dose is below 3 mrem (0.03 mSv) to the total body and 10 (0.10 mSv) mrem to any organ. The annual air dose from gaseous effluents is below 10 millirads (0.01 cGy) for gamma radiation or 20 (0.02 cGy) millirads for beta radiation.
206	Switzerland	15	Small mistake: 2000\$/rem = 200000\$/Sv Please describe how the optimization is implemented in the procedures inside NPPs?	10 CFR Part 20 defines ALARA as making every reasonable effort to maintain exposures to radiation as far below the Part 20 dose limits as is practical, taking into account the state of technology, the economics of improvements in relation to benefits to the health and safety of the public and occupational workers, other societal and socioeconomic considerations, and the utilization of nuclear energy in the public interest. While licensees may use the \$2000/person-rem (\$200000/person-Sv) value to perform a quantitative cost/benefit analysis, this value should only serve as a dollar proxy for the health effects associated with a person-rem of dose. Current industry practice, particularly in the power reactor arena, is to value an averted person-rem at a higher dollar value owing to manpower constraints and other labor cost considerations that are integral to the licensees' cost-benefit tradeoffs. A study done in the year 2000 showed that the monetary value of a person-rem avoided at US utilities ranged from a low of \$5000 to a high of over \$30,000/person-rem (\$5E5 to \$30E5 person-rem/Sv). Licensees establish these values, in part, by the plant location, availability of replacement labor, and the cost of living. Licensees are encouraged to use such higher values for their own ALARA determinations. Since each plant establishes their own methodologies for performing quantitative cost/benefit analyses for ALARA determinations, the NRC does not have information on how each individual licensee implements their optimization methodologies.
207	Switzerland	15	Nothing is written about conditions concerning the release of inactive or low level radioactive material (clearance) and details of the environmental radiological surveillance (monitoring and reporting). Please give the missing information.	The NRC is currently developing a regulation which addresses the release of inactive or low level radioactive material (clearance). The details of this rulemaking are pre-decisional and cannot be discussed at this time. A radiological environmental program is required at every nuclear power reactor. The environmental assessment process begins several years before a nuclear plant is operated. The applicant conducts a pre-operational program at least 2 years prior to initial criticality of the reactor. The pre-operational program documents the background radiation levels and variations that exist in the environment around the proposed plant. The NRC staff reviews the applicant's pre-operational program for conformance to NRC criteria contained in the 1979 Branch Technical Position, "An Acceptable Radiological Environmental Monitoring Program." The criteria includes information on critical exposure pathways, types of samples (air, water, fish, vegetation, milk, and sediment), number of samples, analysis, sensitivity, frequency, location of indicator and control sample stations, based on physical and meteorological factors. Based on the pre-operational program, the applicant proposes an operational radiological environmental monitoring program for staff review and approval. The operational radiological environmental monitoring program is essentially a continuation of the pre-operational program. The operational radioactive environmental monitoring program is designed to verify the effectiveness of the licensee's radioactive effluent release program for controlling the release of radioactive materials and to verify that the levels of radioactive material in the environment do not exceed those originally anticipated in the Final Environmental Statement.
208	United Kingdom	15	There appears to be an error in the conversion of the "figure of merit". \$1000 per person-rem converts to \$100000 per person-Sv, not \$10 per person-Sv as stated. If one accepts the ICRP risk figure of about 5% risk of death per Sv, the latter figure would value a life at only \$200, whereas the corrected figure would value a life at \$2million.	That is correct. The conversion from \$ per person-rem to \$ per person-Sv was incorrect. The correct conversion should be \$1000 per person-rem is equivalent to \$1E5 per person-Sv.
210	Korea, Republic of	16	What is the rationale and the assumptions used for establishing "Plum exposure zone" and "Ingestion pathway zone" in the case of postulated accidents and accident consequence? And what extent of accident severity are included in postulated accident?	To facilitate a preplanned strategy for protective actions during an emergency, there are two emergency planning zones (EPZs) around each nuclear power plant. The exact size and shape of each EPZ is a result of detailed planning which includes consideration of the specific conditions at each site, unique geographical features of the area, and demographic information. The plume exposure pathway EPZ has an approximate radius of about 10 miles from the reactor. Predetermined protective action plans are in place for this EPZ and are designed to avoid or reduce dose from potential exposure to radioactive materials. These actions include sheltering, evacuation, and the use of potassium iodide where appropriate. The ingestion exposure pathway zone (IPZ) has a radius of about 50 miles from the reactor. Predetermined protective action plans are in place for this EPZ and are designed to avoid or reduce dose from potential exposure to radioactive materials through ingestion pathways such as food and water. The size of the plume exposure EPZ was based primarily on the considerations that projected doses from most accident

				sequences would not exceed Protective Action Guide levels outside the zone; for the worst accidents, immediate life threatening doses would generally not occur outside the zone; and detailed planning within 10 miles would provide a substantial base for expansion of response efforts in the event that this proved necessary. Rationale to the 50 mile IPZ includes the assumptions that detailed planning of control for food, water, livestock, and people within this area would provide a reasonable assurance that exposure to the public can be reduced or avoided. EPA protective action guides (EPA-400) provide the actions to be taken in both EPZs for protection of the public. The emergency preparedness planning basis was developed based on a number of accident descriptions, thus the planning basis is independent of specific accident sequences. No single accident sequence is isolated as the one for which to plan.
211	Korea, Republic of	16	Regarding the public protective measures, which emergency response organization among central government, local government and licensee has the responsibility for "evacuation time estimates" within emergency planning zone?	Licensees have the responsibility for evacuation time estimates. To help plan evacuations, licensees develop evacuation time estimates for each nuclear power plant site. These estimates assist government authorities to determine the best exit routes and traffic control points. For example, evacuating may take so long that authorities decide to recommend evacuation for a small part of the emergency planning zone and sheltering for other areas in the zone. Authorities would instruct those not evacuated to shelter in order to minimize the radiation dose and to listen for additional information and instructions, if needed. The time estimates are used to identify potential traffic congestion and to assist in the development of plans for traffic management and use of traffic control personnel during an evacuation. The NRC recently published NUREG/CR-6863, "Development of Evacuation Time Estimate Studies for Nuclear Power Plants" which integrates new technologies in traffic management, computer modeling, and communication systems to identify additional tools useful in the development of new, or updates to existing evacuation time estimates. An additional resource is NUREG/CR-6864, "Identification and Analysis of Factors Affecting Emergency Evacuations".
212	Korea, Republic of	16	NRC generally dispatch s team to the site for all serious incidents to fulfill its mission as the lead Federal Agency. Is there any transportation measures for rapid dispatch of the team?	In general, the NRC does not use specific, 'rapid transportation' methods to report to a licensee incident. NRC resident inspectors, who work at the nuclear plant, respond with the licensee's emergency response organization, generally within one hour, and represent the NRC's 'first response' capability. NRC regional personnel make up the 'NRC Site Team' who would respond in a coordinated manner using the easiest mode of transportation available (typically air travel or vehicle). The exception to this statement is one of the NRC regions has a contract to charter a jet, if rapid transportation is necessary for a site distant from the regional office.
213	Mexico	16	Regarding the National Report in its Section 16.6 "Responding to an Emergency" What level of government (federal, state, local) is in charged of taking the decision for evacuation during an Emergency?	The State or local government is responsible for making the decision to evacuate during an emergency. In the event of an incident at a nuclear power plant, the licensee is responsible for making protective action recommendations which may include evacuation, sheltering, KI, or a combination thereof. The State or local government is then responsible for reviewing these recommendations and making a protective action decision, which is in the best interest of protecting the population from exposure to radioactive material. Other federal agencies will provide monitoring and assessment data for the State and the NRC, however the decision on how to best protect its citizens resides with the State or local government officials.
214	Slovenia	16	This section mentions that if an event were to occur, NRC would co-ordinate the resources of more than 18 Federal agencies as indicated in the previous section on NRC Response, to mitigate radiological consequences of a serious accident or successful attack. How frequently does NRC test the communications including communication means and lines? And, are there performance indicators developed for the NRC's response for communications or any other activity similar to those described in 16.5 Inspection Practices-ROP for Emergency Preparedness?	Though the NRC does perform a critique of its performance during emergency exercises, there are no performance indicators for communications or any other activity in place, similar to those in the ROP for Emergency Preparedness. The NRC has a robust program of emergency exercises which are conducted with licensees. During these exercises communication checks are performed with participating agencies, and in many cases, select agencies may be present in the NRC Operations Center during the exercise. NRC also participates in National Exercises coordinated by the Department of Homeland Security - Federal Emergency Management Agency, which includes the involvement of many other Federal agencies.
215	Switzerland	16	How are the emergency scenarios, like design-basis accident, with the emergency classification system connected?	Emergency exercises are required by 10 CFR 50.47(b)(14) which will evaluate major portions of emergency response capabilities and periodic drills will be conducted to develop and maintain key skills of personnel. The scenarios are connected to the emergency classification system because in order to simulate different aspects of a scenario, the licensee typically progresses through different emergency classifications. For example, per NUREG-0654, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants", the emergency preparedness exercise shall simulate an emergency that results in offsite radiological releases that would require response by offsite authorities. Design basis accidents typically are classified as a General Emergency, which is the highest classification level. Precursors to this type of event, such as loss of safety related equipment or indications of reactor coolant leakage, are classified as lower level events.
216	France	16.1	Could the United States of America explain whether the NRC has defined criteria to shelter the population in the vicinity of a plant after a severe accident?	10 CFR 50.47(b)(10) requires that licensees have a range of protective actions in their emergency plans, which includes the consideration of evacuation and sheltering. The NRC has provided guidance to assist licensees for incorporating sheltering into protective action recommendations. Regulatory Issue Summary 2004-13, "Clarification of NRC Guidance for Modifying Protective Actions" was issued to provide additional information when NRC discovered that some licensees had not incorporated sheltering into their protective action scheme. The overall objective of emergency response planning is to provide dose savings to the public for a spectrum of accidents that could produce offsite doses in excess of the protective action

				guidelines. There are two important components to dose savings: evacuation and sheltering. Evacuation removes the public from exposure to the plume, and under most conditions, evacuation is preferred. However, there are instances where sheltering may be the preferred protective action. Sheltering may provide protection that is equal to or greater than evacuation, taking into consideration such factors as weather, competing disasters, short term release, traffic considerations, or even terrorist actions. The NRC has recently contracted a study of sheltering in the event of a severe accident, which will investigate the benefits of sheltering vs evacuation under certain circumstances.
217	France	16.1	Could the USA elaborate further about iodine prophylaxis: what are the criteria for deciding KI tablets distribution? What are the main results of the report of the National Academy of Sciences on that topic? Is it intended to make just now a provisional distribution to the population living in the vicinity of the sites, or to distribute only in the event of a severe accident? And what about the States which chose not to use potassium iodide for protecting their population?	The decision to use KI and the method for distribution is left to the discretion of the States. In April 2001, the Commission published a rule change to the NRC emergency planning regulations to include the consideration of the use of potassium iodide (KI). The Food and Drug Administration has issued guidance on the dosage and effectiveness of potassium iodide for thyroid prophylaxis. The NRC has supplied potassium iodide tablets to States requesting it for the population within the 10-mile emergency planning zone (EPZ). To date, 20 states have participated in this program for a total of approximately 11,200,000 tablets. Potassium iodide is to be used to supplement evacuation or sheltering, not to take the place of these actions. The population closest to the nuclear power plant, that is within the 10 mile EPZ, are at greatest risk of exposure to radiation and radioactive materials. When the population is evacuated out of the area, and potentially contaminated foodstuffs are interdicted, the risk from further radioactive iodine exposure to the thyroid gland is essentially eliminated. The National Academy of Sciences report which was published in December 2003 responds to the congressional mandate of Public Law 107-188, Section 127. This report assesses strategies for the distribution and administration of KI in the event of a nuclear incident. A full report may be found at the NAS website, but the study did acknowledge that KI is important for the protection against thyroid-related health effects due to radioiodine exposure, the likelihood and extent of a release in the United States cannot be extrapolated from the Chernobyl accident. There are substantial safety features of US reactors which are different from those at Chernobyl, and the food interdiction policies in the United States would protect the public from ingestion of I-131 contaminated foods, which was the leading cause of thyroid cancers due to the Chernobyl accident. In addition the NAS determined that State/local authorities should make the decision regarding implementation and structure of a KI distribution program.
218	Germany	16.1	What are the emergency reference levels applied for countermeasures (sheltering, iodine tablets and evacuation) in case of an emergency?	The technical basis and guidance for determining protective actions (evacuation, sheltering, use of KI) in the United States for severe reactor accidents are given in NUREG-0654, "Criteria for Protective Action Recommendations for Severe Accidents," Supplement 3, July 1996, and EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Action Guides and Protective Actions for Nuclear Incidents" May 1992. NUREG-0654, Supplement 3 provides simplified guidance for making PARs based on severe core damage or loss of facility control, which are tied to the emergency classification levels. Generally countermeasures such as protective actions are not implemented until the General Emergency action level is reached and a protective action recommendation has been made by a licensee and implemented by a state or local authorizing official. Emergency planning efforts are based on the EPA recommended protective action dose guidelines of 1 rem to the whole body and 5 rem to the thyroid gland. These guidelines are not dose limits, rather they represent risk decision points, where the risk of implementation of protective actions is measured against the risk of exposure to radiation at doses in excess of 1 rem. These dose guidelines are set at thresholds well below the values in which health effects occur. Although radiation may cause cancer at high doses and high dose rates, public health data do not unequivocally establish the occurrence of cancer following exposure to low doses and dose rates -- below about 10 rem (100 mSv).
219	Germany	16.1	Please give more information on how the public actively participates in these exercises.	Typically, the public does not actively participate in emergency exercises at nuclear power plants. The NRC and FEMA do not require the public to participate in order to evaluate response capabilities. Public activity is usually simulated during exercises and occasionally State/local governments will exercise certain public evacuation activities, for example simulating the transportation of students via bus to an area outside the emergency planning zone. Emergency exercises are federally evaluated demonstrations of the licensee and supporting offsite response agencies capability to implement their emergency plans and involves the participation of the licensee, state and local emergency responders and decision makers, and in some cases, Federal agency responders. NRC and other emergency organizations work together to keep the public informed and residents within a radius of approximately 10 miles from a nuclear power plant receive emergency information materials annually.
220	Japan	16.2	NRC recognizes the nuclear power plant operator (licensee) and the State or local government as the two primary decision makers in a radiological emergency at a licensed power reactor. Q/The nuclear power plant operator (licensee) and the State or local government are also the two primary decision makers even in a radiological emergency caused by terrorist attacks and natural disasters?	In the event of an incident at a nuclear power plant, whether it is due to a system malfunction, a terrorist event, or a natural disaster, the licensee is responsible for making a recommendation for protective action to the state or local decision makers which may include evacuation, sheltering, KI, or a combination thereof. The State or local government is then responsible for reviewing these recommendations and making a protective action decision, which is in the best interest of protecting the population from exposure to radioactive material. Federal agencies will provide monitoring and assistance for the State, local governments, and the licensee, however the decision on how to best protect its citizens resides with the State or local government official authorized to make this decision.
221	Korea, Republic of	17	What are the regulatory procedures for survey and evaluation of capable fault or geological structure suspicious of a capable fault without evidences, found at or near the site area of nuclear facilities in operation or under licensing review process? If there are nuclear	General Design Criterion 2 in Appendix A to 10 CFR Part 50 requires that safety related structures and components be designed to withstand the effects of natural phenomena such as earthquakes without loss of capability to perform their safety functions. Regulatory Guide 1.165 (RG 1.165), "Identification and Characterization of Seismic Sources and Determination of Safe Shutdown Earthquake Ground Motion," provides guidance for assessing a fault. If a "capable" fault (as defined in RG 1.165) is found at or near a nuclear facility (operating or undergoing a license review), then further investigation would be necessary to

			facility sites that were (or are) engaged in this procedure, what were(are) the sites and how were(are) the issues resolved?	characterize the fault. Appendix D of RG 1.165 and Section 2.5.1, "Basic Geologic and Seismic Information," of NUREG 0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," describe the appropriate geological, seismological, and geophysical investigations necessary to characterize faults. The resulting assessment would be used in a probabilistic seismic hazard analysis of the site. In addition, the potential for surface faulting would need to be thoroughly investigated. Of the currently operating nuclear power plants, the Diablo Canyon in central California is located about 5 km from the offshore Hosgri fault. An operating license application for the plant was under review when the fault was discovered and determined to be capable. The fault was characterized, and the licensee reanalyzed and upgraded the plant to accommodate the new seismic hazards. In addition, a small fault was discovered at the North Anna nuclear power plant site in Virginia. This fault was thoroughly evaluated and determined to be non-capable.
222	Korea, Republic of	17	Were tsunamis, caused by various sources such as earthquakes, volcano eruptions, landslides, etc., taken into consideration in the design of nuclear power plants? If yes, what are the methods and procedures for considering tsunamis in the plant design for each source (the evaluation method of tsunamis, plant protection against tsunamis, etc.)? What plants were designed against tsunamis and what are the location and maximum magnitude of each source assumed in the design? If not considered, what are the reason and countermeasures for protecting the plants against potential tsunamis?	All U.S. nuclear power plants are designed to have adequate protection against natural phenomena, including tsunamis, as stipulated in NRC regulation 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 2, "Design bases for protection against natural phenomena." GDC-2 states, "Structures, systems, and components important to safety shall be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches without loss of capability to perform their safety functions. The design bases for these structures, systems, and components shall reflect: (1) Appropriate consideration of the most severe of the natural phenomena that have been historically reported for the site and surrounding area, with sufficient margin for the limited accuracy, quantity, and period of time in which the historical data have been accumulated, (2) appropriate combinations of the effects of normal and accident conditions with the effects of the natural phenomena, and (3) the importance of the safety functions to be performed." Consideration of the effects of natural phenomena is site specific and depends on many factors, such as, proximity to coast line, bathymetry of coastline, site elevation above the mean sea level, seismicity of site, and proximity to near and distant faults with potential for significant fault displacement. These factors can lead to differences in the approach for protection against tsunami even for locations with known tsunami hazards. The methods and procedures for quantifying tsunami hazards may include geological and geophysical site investigation, consideration of historic and geological records obtained from the site vicinity, hydrodynamic analyses, scaled model studies, and shore protection measures as appropriate. Protection against tsunami hazard ensures that adequate protection is achieved to meet the requirements of GDC 2. The NRC review guidance is provided in Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants," Section 2.4.6, and NUREG-0800 Section 2.4.6, "Probable Maximum Tsunami Flooding," and Section 2.4.10, "Flooding Protection Requirement." Several sites considered significant fault displacements from near and distant sources for ensuring protection against tsunamis. Tsunami hazards for the U.S. Pacific coast plants are greater than for other sites.
223	Korea, Republic of	17	(First paragraph of Section 17.2.1) What are the methods and procedures to draw out the boundary line of the 'population center' defined in the 10 CFR Part 100 (1997)?	We do not have a written guidance (methods and/or procedure) in determining the distance to the nearest boundary line of the "population center (containing more than about 25,000 residents)," as defined in 10 CFR Part 100.3. However, the USNRC reviewer typically uses the nearest boundary line used by U.S. Census Bureau for collecting population data for that city. Some related guidance is available in Section 2.1.3 of Review Standard RS-002 (ADAMS ML040700317) and Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations."
224	Pakistan	17	Mention is made in section 17.3.2.5 of Severe Accident Mitigation Design Alternatives (SAMA). The current NRC policy requires consideration of such alternatives in the environmental impact statement for operating license or for license renewal. Could you kindly identify the major design alternatives that have so far been implemented at operating NPPs in US?	Background: Applicants for License Renewal (LR) are required to consider alternatives to mitigate severe accidents if the NRC staff has not previously evaluated Severe Accident Mitigation Alternatives (SAMAs) for the plant in an earlier environmental inquiry. For three plants (Limerick, Comanche Peak, and Watts Bar), the staff considered severe accident mitigation design alternatives (SAMDAs) in the environmental impact statement (EIS) associated with the Operating License review. The purpose in considering SAMAs is to ensure that plant changes (i.e., hardware, procedures, and training) with the potential for improving severe accident safety performance are identified and evaluated, usually using probabilistic safety analysis tools. Response: Licensees have programs in place to assess risk and vulnerabilities and, over the years since obtaining operating licenses, have made changes to designs, modified procedures and conducted personnel training to further reduce risk. Consequently, the SAMA analyses for the completed LR applications to date have not identified major design improvements. The largest group of cost-beneficial SAMAs fall into the category of new or modified procedures and subsequent training for operators to deal with unusual circumstances during postulated accidents. More recently, SAMAs associated with providing an alternate power supply in the nature of other-than-safety-related portable generators appear cost-beneficial. All of the procedures, training and low-cost hardware changes that were identified have not been related to adequately managing the effects of aging, so such SAMAs would not be implemented as part of the LR action. In practice, the results of the SAMA analyses are being considered by licensees as part of their safety improvement programs and by the NRC staff within the backfit process.
225	Turkey	17.1	In the Review Standard RS-002, there is no any guidance for evaluation of an application that includes a "plant parameter envelope (PPE)".	The NRC issued Review Standard (RS)-002, "Processing Applications for Early Site Permits," on May 3, 2004. Paragraph (1) under Section 4.6 of this document provides general guidance for review of an early site permit (ESP) application that includes a plant parameter envelope (PPE). In addition, the various sections of Attachment 2 to RS-002 contain, where appropriate,

			What is the position and/or strategy of NRC to review the ESP application, when there is an ESP application with a PPE. Is it possible to give a foreseen time to issue a version of RS-002 that give also guidance to the NRC staff on review of an ESP application that includes a PPE provided?	guidance for the NRC staff regarding an applicant's use of a PPE in specific technical subject areas. In brief, the NRC reviews PPE values at the ESP stage only to verify they are reasonable. At the combined license stage, the applicant will need to show that its chosen design falls within its PPE, or must otherwise demonstrate that the NRC's regulations are met.
226	Japan	17.2	NRC has since gained experience in implementing the goals of the executive order during the conduct of its environmental reviews, for example, during the conduct of license renewal reviews under 10 CFR Part 54, discussed in Article 14. Q/Which specific experience or useful experience did NRC gain as lessons leared during the implementation of license renewal reviews ?	Background: Since publishing the third U.S. National Report for the Convention on Nuclear Safety, in August 2004, the Commission finalized its policy statement to provide the public with its views on how the NRC will treat environmental justice (EJ) matters in agency regulatory and licensing actions. The policy reflected recent EJ decisions by the Commission related to practices implementing the February 1994, Presidential Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations." In the policy statement, the NRC recognizes that the impact of the agency's regulatory or licensing actions on certain populations may be different from those on the general population due to a community's distinct cultural characteristics. The policy statement reflects the view that the disproportionately high and adverse impacts of a proposed action that fall heavily on a particular community call for close scrutiny under the National Environmental Policy Act (NEPA). Consequently, every environmental impact statement (EIS) for a power reactor licensing action, for example, license renewal, has considered EJ as part of its environmental inquiry. Response: For every license renewal action completed to date, for those factors that were considered in its EJ analysis, the staff has found that the impacts are generally small; in addition, there have not been such distinct community characteristics, for example, subsistence farming or fishing, such that impacts would be borne disproportionately by a particular community from that to the general population. The promulgation of the Commission's policy statement reflects the experience gained by the NRC and clarifies the NRC practice that the EJ analysis is (1) addressed in the context of the NRC NEPA review and (2) limited in scope to the region in the vicinity of the project.
227	South Africa	17.2	In the third paragraph the impression is given ("the licensee is expected to monitor ....."etc.) that the NRC has no strict requirement on licensees to evaluate the impact of population developments in the vicinity of the site on the viability of the emergency plan (and other safety requirements) during the operational phase of the plant. It is also not clear whether mechanisms are in place to review proposed urban developments in the vicinity of nuclear power plants, and whether there are criteria for such reviews.	Background: In the site evaluation phase of a nuclear power plant, a wide variety of issues involving environmental factors that affect the design of the plant are considered. These are "site safety" issues and include severe natural phenomena, such as earthquakes, and man-made hazards, such as airports or pipelines. Other siting issues involve "environmental protection" or how the plant would interact with the human environment, and "emergency planning" or how the public would still be protected in the event that plant design features do not function as designed. Demographics is one of the factors that cut across the three siting areas: site safety, environmental protection, and emergency planning. The staff recognizes that population distribution will change over time. The environmental protection review is performed to comply with the NRC's obligations under the National Environmental Policy Act. The site safety and the emergency planning reviews are safety issues addressed by the NRC to fulfill its obligations under the Atomic Energy Act (AEA). Response: Both the NRC and the license holder have certain obligations for maintaining awareness of changes in population characteristics during the operational phase of nuclear power plants. An important element in the licensing basis of the facility is the maintenance of its Final Safety Analysis Report (FSAR); the license holder has the responsibility to update the FSAR on a periodic basis to ensure that the FSAR contains the latest information developed (see 10 CFR 50.71(e)). This is readily achieved in the context of modifications that result from design changes at the facility, but is equally applied in the context of changes that occur in the vicinity of the facility that may be outside of the control of the operator. If the latest information indicates that it could have a bearing on the safe operation of the facility (for example, placement a natural gas pipeline in close proximity to the facility), then an update to safety analysis would need to be performed. The NRC has reviews the updated FSAR. The essential regulatory concern with the general population is whether protective measures remain effective in providing reasonable assurance that the public is adequately protected in the event of a radiological emergency. If the NRC cannot find that reasonable assurance exists, then the NRC will take an action regarding emergency preparedness. The Commission could determine whether a shutdown or other enforcement action is appropriate (see 10 CFR 50.54(s)). Population growth of itself beyond the projected demographics considered in the initial licensing of the reactor is not a basis for such an action. New urban development in the vicinity of nuclear facilities is generally a matter for local zoning or governmental bodies. Apart

				from meeting security requirements, the operator must demonstrate that it has the authority to determine all activities in an area around the facility. This area, the exclusion area (see 10 CFR 50.2), generally excludes residences. The exclusion area boundary distance is an important element in the evaluation of the consequences of postulated design basis accidents (see 10 50.34(a)). A second distance, this one for the evaluation of the duration (around one month) of postulated design basis accidents, is the low population zone (LPIZ) (see 10 CFR 50.2). The LPZ is a function of the population center distance, which is the nearest boundary of a population center containing 25,000 residents. Therefore, if urban sprawl extends the reach of the population center distance beyond that considered in the initial licensing of the facility, then the LPZ may decrease and should be reflected in the updated FSAR as described above. Current NRC regulations do not dictate the update of Evacuation Time Estimates (ETE) in licensee emergency plans, however NRC has encouraged licensees to develop updates to their ETEs as they become aware of changes in factors, such as population density around nuclear power plants, that may affect evacuation. The recently published NUREG/CR-6863, "Development of Evacuation Time Estimate Studies for Nuclear Power Plants" provides information regarding new technologies that may be considered in the development of an ETE. RIS 2001-16, "Update of Evacuation Time Estimates" provides background and summary information of the update of evacuation time estimates in licensee emergency plans. Updated census reports may show increases or decreases in population within the plume exposure pathway emergency planning zone around certain nuclear power facilities. Consequently, the estimated times for evacuation of the public could increase or decrease. Longer or shorter evacuation times in turn affect decisions about evacuating the public in the event of a radiological emergency. Therefore, decision makers may need updated estimates of how long it would take to evacuate the public. Nuclear power plant licensees are required to follow and maintain in effect emergency plans which meet the standards in Section 10 CFR 50.47(b) and the requirements of 10 CFR Part 50 Appendix E. Additionally, Section IV.G of Appendix E requires licensees to have provisions in these emergency plans to ensure that the emergency plan and its implementing procedures are kept up to date and that emergency equipment and supplies are properly maintained. Since the emergency plan is contained in the Final Safety Analysis Report in accordance with 10 CFR 50 Appendix E Section III, the updating requirements of 10 CFR 50.71(e) apply. Updating evacuation time estimates would not be considered a decrease in the effectiveness of the emergency plan under Section 10 CFR 50.54(q) and licensees may update the estimates without prior Commission approval.
228	France	17.3	National seismic hazards have been updated in 2003. Could the United States of America indicate if consequences of this updating on NPP's systems behaviour have been re-assessed? Have lessons been learnt from this re-assessment?	The NRC assumes that the question refers to the US Geological Survey (USGS) National Hazard Mapping project, a nation-wide hazard mapping that was updated in 2002 (not 2003). Because the NRC has not endorsed the hazard maps from the USGS, the results from the USGS national hazard mapping project are not directly used in the assessment of NPPs.
229	Russian Federation	17.3	Subsection 17.3.2.1 states that NRC has issued a review standard (RS-002) which incorporates environmental guidance contained in NUREG-1555 standard review plan. 1) With what agency did you agree the NUREG-1555 document? 2) Does NRC perform review of the whole spectrum of potential impacts of NPP on the environment or there exist other agencies, which conduct the so-called "ecological review"?	Background: The NRC publishes regulatory guidance in a number of forms. There are a series of Regulatory Guides (RGs) that are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. RGs are issued in 10 broad divisions, which include Division 1, Power Reactors, and Division 4, Environmental and Siting. In addition, there are Standard Review Plans (SRPs) that are issued to provide guidance to NRC staff in implementing its regulations to ensure conformance with regulatory and statutory obligations as the staff prepares its safety evaluation reports (see NUREG-0800, NUREG-1800) and environmental impact statements (see NUREG-1555). The safety and environmental SRPs evolve based on changes in statutory and regulatory frameworks and advances in technology and analytical methods. Finally, the NRC has recently issued Review Standards (RS) which serve the similar purposes of SRPs, but are intended to consolidate or enhance review guidance to address a particular initiative. In preparing RS-002, the staff determined that it was appropriate to enhance and refine the existing review guidance (i.e., NUREG-0800 and NUREG-1555) that was developed before interest existed in the new regulatory framework for early site permits. Response: For all regulatory guidance documents (i.e., Regulatory Guides, Standard Review Plans, and Review Standards), the NRC issues guidance for public comment. The NRC is an independent executive agency and, in most respects, does not require the agreement of sister agencies to fulfill its responsibilities; nevertheless there are numerous instances (for example, environmental permitting) where other agencies at the Federal, State, or Tribal level have separate authorities that must be fulfilled before the NRC take its regulatory action. For these guidance documents, the NRC's sister agencies are given the opportunity to share their views as part of the public comment process and, on occasion, are invited to participate with the NRC in formulating the guidance before it is issued for comment. In some circumstances, regulatory guidance is issued for interim use and comment. Sister agencies do not have an obligation to comment on regulatory guidance, but they often provide valuable insight in the context of their mission responsibilities.

				The environmental impact statement (EIS) prepared by the NRC staff reflects its environmental inquiry of the effects of a regulated action on all the science and technology areas, namely the radiological, physical, ecological, and social sciences, that make up the human environment. While data that may be used to perform the assessment of impacts may be collected, in part, by the applicant and reported in its environmental report (see 10 CFR 51.41), the NRC is ultimately responsible for the reliability of the information that it uses to make its independent assessment. The EIS is prepared by the NRC staff and the staff is often supported by contractors. A number of issues involve interactions with other agencies, such as the Fish and Wildlife Service, the Fisheries Service, and State or Tribal Historic Preservation Offices, where the NRC has consultation requirements from other statutes, such as the Endangered Species Act and the National Historic Preservation Act. However, the NRC has a full complement of science and technology specialists to manage and conduct the review, and to participate in any hearings on the review.
230	Canada	18	The statement "over-reliance on programmatic activities to compensate for weaknesses in plant design is avoided" suggests that some reliance on programmatic activities is allowable to compensate for design weakness. Please cite some practical examples and guiding principles for determining when reliance on programmatic activities would not adversely impact on defense-in-depth.	The consideration of the cited principle relies upon the knowledge, understanding, and expertise of the NRC staff. A simplistic example of reliance on programmatic activities is the establishment of a fire watch when a fire barrier is inoperative to support maintenance activities. However, if it were discovered that a type of fire barrier used throughout the plant was defective, it would not be appropriate to rely on continuous fire watches throughout the plant instead of fixing/replacing the defective fire barriers.
231	Pakistan	18	Section 18.1-1 states that "As guidance in writing a safety analysis report, the applicant may use R.G.1.70". What other options are acceptable to NRC? Furthermore, the NRC staff reviews safety analysis reports according to NUREG-0800 (Standard Review Plan). Since 1978, there has been no revision of R.G. 1.70 published to facilitate guidance to the applicant to include information on design according to present day requirements. In contrast, the SRP has continuously been revised (the latest in 2003) to include, in addition to others, concepts of human factors, PSA and severe accidents. USA may like to clarify that how would NRC facilitate license renewal applications and its review with regards to format and content of the Safety Analysis Reports (SAR)?	Regulatory Guide 1.70, Rev. 3 is currently the only approved guidance for preparation of a safety analysis report for nuclear power plants. The NRC recognizes that this guidance is out of date and updated guidance on addressing issues, such as severe accidents, is provided to prospective applicants during pre-application meetings. In addition, the NRC is working with nuclear industry representatives on the preparation of a guidance document for combined license applications. The license renewal rule requires that each application for license renewal must include a supplement to the plant's final safety analysis report (FSAR) [10 CFR 54.21(d)]. The FSAR supplement must contain a summary description of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses for the period of extended operation. Guidance on an acceptable format and content of a license renewal application, including the FSAR supplement, is provided in the Nuclear Energy Institute's NEI 95-10, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 – The License Renewal Rule." The NRC has reviewed and found NEI 95-10 to be an acceptable approach for complying with the license renewal rule and has endorsed NEI 95-10 in its Regulatory Guide 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses." Guidance for the NRC staff performing reviews is contained in the "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants," NUREG-1800, which incorporates by reference the "Generic Aging Lessons Learned (GALL) Report," NUREG-1801. These guidance documents can be viewed at the NRC's license renewal web page: http://www.nrc.gov/reactors/operating/licensing/renewal.html.
233	Mexico	18.2	National Report in its Section 18.2 "Technologies Proven by Experience or Qualified by Testing or Analysis" Regarding the use of "best estimate" neutronics or thermal hydraulics computer analysis codes for licensing purposes, what is or what will be the NRC's approach?	The NRC approach to the use of best estimate or realistic methods for neutronics or thermal hydraulics is guided by the content of NUREG/CR-5249, "Quantifying Reactor Safety Margins, Application of Code Scaling, Applicability, and Uncertainty Evaluation Methodology to a Large-Break, Loss-of-Coolant Accident," along with Regulatory Guide 1.157, "Best-Estimate Calculations of Emergency Core Cooling System Performance." Additional guidance is also contained in Draft Regulatory Guide DG-1120, "Transient and Accident Analysis Methods." Each of these documents describes the approach to acceptable realistic analysis methods for thermal hydraulic analysis of loss-of-coolant accidents as well as operational transients. A basis for the acceptability of the methods is assessment against a qualified data base which adequately represents the important parameters for each accident and transient being analyzed. Both Westinghouse and General Electric utilized experimental program data bases derived from a series of separate effects, component, and integral system tests covering a variety of hardware scales up to and including full scale for specific components to support the use of best estimate methods for the review of the AP1000 and ESBWR. The approach described in the above documents and the experience obtained in review of the above mentioned designs have proven successful and will continue to be followed by the NRC.
234	Canada	19	The report indicates that "a licensee may propose relocating the limiting conditions for operation (LCO) that do not meet any of the criteria in 10CFR 50.36, and their associated actions and surveillance requirements from technical specifications to licensee-controlled documents." Please explain whether the NRC approval would no longer be required if the licensee wishes to make changes to that LCO and its associated actions and surveillance requirements	Although relocation of an LCO and associated requirements is contingent upon a determination that the LCO satisfies none of the four criteria in 10 CFR 50.36(c)(2)(ii), it is the Commission's policy that relocated LCO, action, and surveillance requirements be placed in licensee-controlled documents for which changes are controlled by regulation. For example, the Final Safety Analysis Report (FSAR) may only be changed in accordance with 10 CFR 50.59. This regulation requires an evaluation of any change to the facility or procedures as described in the FSAR to determine whether prior NRC approval of the change is required. If a licensee proposes a change to a requirement that was relocated from the technical specifications to the FSAR, and determines that the change requires revising the technical specifications or satisfies one or more of the eight criteria in 10 CFR 50.59(c)(2), it must obtain an amendment to the facility's operating license in accordance with 10 CFR 50.90 before

				implementing the proposed change. A licensee may implement a proposed change to a relocated requirement without prior NRC approval provided the change does not require revising the technical specifications and does not satisfy any of the eight criteria. Information related to 10 CFR 50.36(c)(2)(ii), which lists the four criteria needed to satisfy the LCOs being included in the Technical Specifications can be found at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0036.html Information regarding 10 CFR 50.59(c)(2), which lists the eight criteria that need to be excluded in making changes without NRC approval can be found at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0059.html
235	Korea, Republic of	19	(19.7 Programs to collect and Analyze Operating Experience) In the section 19.7 of the report, it is stated that '... to recommend improvements that address the recommendations of the Davis-Besse Lessons Learned Task Force. Some of the recommendations are to establish a central clearinghouse for operating experience, ...' What is the current status or the plan for this recommendation?	The clearinghouse is the part of NRC OE staff that performs gathering, screening, and communication functions described in the referenced Sec 19.7 and in Sec 3.2 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession Number ML033350063). The clearinghouse began operating on January 1, 2005.
236	Russian Federation	19	The Report lacks information on the issues of spent nuclear fuel (SNF) management. 1) How is the long-term SNF storage organized at NPPs? 2) What is the duration of SNF storage in the nuclear plants' spent fuel pools? 3) Are there on-site repositories for long-term SNF storage? 4) Do they practice SNF shipments away from the site? (NOTE: OUT OF SCOPE OF CNS)	1) NRC considers spent fuel to be out of the scope of the CNS. It plans to include spent fuel issues at nuclear plants in its next National Report for the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. 2) The Commission's waste confidence decision found reasonable assurance that, if necessary, spent fuel generated in a reactor can be stored safely and without significant environmental impacts for at least 30 years beyond the licensed life for operations (which may include the term of a revised or renewed license) of that reactor at its spent fuel storage basin or at either onsite or offsite independent spent fuel storage installations.
237	South Africa	19	The report is very comprehensive. All the activities of the article are regulated or coded. The report could eleborate more on the responsibility of the licensee in terms of the OE process.	In the United States, licensee responsibility in the OE process includes (1) required reporting of events, use of corrective action programs, and review of OE, (2) support of NRC inspection activities, (3) communication of OE to industry and the public, performance of self-regulation, and performance of generic correction activities through various industry organizations, such INPO, owners groups, and EPRI. The Three Mile Island Action Plan, NUREG-0737, Item I.C.5 provided that "Each utility shall carry out an operating experience assessment function that will involve utility personnel having collective competence in all areas important to plant safety. In connection with this assessment function, it is important that procedures exist to assure that important information on operating experience originating both within and outside the organization is continually provided to operators and other personnel and that it is incorporated into plant operating procedures and training and retraining programs ."
238	Ukraine	19	The reliability of power systems was added to significant safety issues after the blackout of power systems in the United States and Canada in August 2003. How is solution to this issue associated with operation of the energy market? Are there statistics regarding the impact of power system reliability performances on operational safety of reactors?	Since deregulation, the grid is now being used in ways for which it was not designed (the loading and directional flow), and there has been a large increase in the number and complexity of transactions on the transmission system. Users and operators of the system who used to cooperate voluntarily on reliability matters are now competitors with little incentive to cooperate with each other or to comply with voluntary reliability rules of the North American Electric Reliability Council (NERC). In addition, after deregulation, most licensees of the nuclear power plants no longer own the transmission lines. The NRC only regulates the licensees of the nuclear power plants. NERC revised its reliability standards and they were approved by its Board of Trustees on February 8, 2005. The new reliability standards take effect on April 1, 2005. The final report of the U.S.-Canada Power System Outage Task Force found that the single most important thing Congress can do to ensure reliability is to pass legislation that would make NERC rules mandatory and enforceable. Recent studies had shown that LOOP frequencies during critical operation have decreased significantly in recent years, while LOOP durations have increased. Studies also indicate that the reliability of on-site power sources has improved. Overall, the studies show a decrease in risk of core damage caused by LOOP
239	Ukraine	19	Is there interrelation or impact of the reactor operating	The impact of reactor operating experience on existing energy markets may occur in several ways, including but not limited to

			experience on the existing energy market?	the following: • There is a direct positive correlation between the efficiency of nuclear power reactor operations and the supply of electric energy available to the existing market; • The greater the supply of electric energy from nuclear power reactors, which currently is one of the least expensive sources of electric power on a cost per kilowatt basis in U.S. markets, the greater the amount of price competition in energy markets and the lower the average costs and prices in those markets; and • The greater the success of nuclear power licensees in achieving safe and efficient operations, the greater the probability that licensees will continue to seek license renewals and power uprates of their existing units, thereby continuing to provide more nuclear generated power to energy markets.
240	Ukraine	19	Could more detailed information be obtained on the specificity of the combined licence, in particular, its special terms and granting procedure?	A more detailed explanation of the licensing processes in 10 CFR Part 52 can be found in NUREG/BR-0298, Rev. 2, "Nuclear Power Plant Licensing Process." The procedure for granting a combined license is very similar to the procedure for granting an operating license and license conditions, such as technical specifications, are also similar.
241	Ukraine	19	Could more detailed information be obtained on the integrated approach implemented for qualification of foreign-manufacture equipment?	The NRC staff does not differentiate between the qualification of domestic or foreign suppliers to US licensees and thus does not implement an integrated approach for qualification of foreign-manufactured equipment . Licensees, through the Nuclear Procurement Issues Committee (NUPIC) perform joint utility audits of domestic and foreign suppliers, as necessary, for the qualification of suppliers of parts and equipment, to the QA requirements of Appendix B to 10 CFR Part 50.
242	Ukraine	19	What US authority determines the need to close access to information related to physical protection of nuclear installations?	In keeping with the NRC goals of openness and effectiveness, the NRC has traditionally provided the public with a significant amount of information about the facilities and materials for which the NRC has regulatory responsibilities. This policy has been and remains a cornerstone of the NRC's regulatory philosophy. However, in the aftermath of September 11, 2001, the NRC has been challenged, as have other government and private institutions, to assess and revise controls on withholding from public disclosure information that might be useful to terrorists. The Nuclear Regulatory Commission makes a determination of the security of a document by conducting a Sensitive Information Screening Project (SISP) review, which is a security/sensitivity review to determine whether a document will be voluntarily withheld from the public.
243	Ukraine	19	Could more detailed information be obtained on procedures and regulations for extension of the reactor lifetime and licence renewal?	Current, detailed information is available on the U.S. license renewal process and license renewal applications at the USNRC website. The Fact Sheet on Reactor License Renewal, located at: http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/license-renewal.html, provides a general discussion of the license renewal process and status of past and current license renewal applications. More detailed information on the license renewal process, regulations, guidance documents, public involvement, and past and current license renewal applications is available at the license renewal web page: http://www.nrc.gov/reactors/operating/licensing/renewal.html.
244	Ukraine	19	What emergency scenarios are regarded as such that can jeopardise and/or terminate operation of the emergency core cooling system and containment sprinkler system in the sump recirculation mode?	There are many scenarios that can jeopardize and/or terminate recirculation operation of these systems. Most of these scenarios are addressed by design provisions. As examples, equipment is qualified to the design basis conditions for protection against environment conditions including possible radiation effects. Fluid leakage programs are required to ensure that termination of recirculation is not required due to external leakage of potentially radioactive fluid. There are provisions to protect against pipe whips and jet effects that could impair or preclude recirculation. Adequacy of pumping capacity during recirculation is examined to assure continued operation considering the effects of issues such as vortexing, providing sufficient suction pressure to the pumps, and prevention of damage to recirculation system components caused by debris in the fluid. The United States has an open Generic Safety Issue (GSI-191) which is reexamining some of the previous design provisions related to assuring recirculation sump performance. Principal scenarios being revisited include sump blockage due to generation and transport of more debris and finer debris to the screens than was previously considered. Additionally, the NRC is asking its licensees to reexamine potential downstream effects such as continued pump operation with debris laden fluid, bypass debris effects on the fuel, and potential chemical precipitation effects which had not previously been considered. Details on these issues can be found at the NRC PWR Sumps Web page http://www.nrc.gov/reactors/operating/ops-experience/pwr-sump-performance.html
245	Ukraine	19	Are there formalised requirements for the simulator-based training programme and criteria for admission of personnel to independent or supervised work?	The training setting for a particular topic is determined by the licensee using Systems Approach to Training (SAT) principles. SAT is the dominant formalized or structured process for training program development. Individual licensees determine the criteria for workers to work either under supervised condition or independently (without supervision). However, as required and necessary during implementation of the reactor oversight program, the NRC will evaluate the licensee's program related to the ability of workers to operate independently.
246	Ukraine	19	Do the amendments included to 10 CFR 50.75 determine restrictions on the licensing scheme in case of decisions on "site partial exemption from regulatory control" and "site partial transfer to another legal entity"?	The amount of financial assurance required under 10 CFR 50.75(c) relates only to the power rating of the reactor, updated annually using several escalation factors, so additions or subtractions of property or buildings are not relevant to the total financial assurance requirement. Historical records of the use and locations of radioactive materials must be retained for the life of the facility, so that they can

				be used for the historical site assessment at the time of decommissioning. See 10CFR50.75(g). 10CFR50.75(g)(4)(iii), Recordkeeping, refers to 10CFR50.83, which is Partial Site Release. 10CFR50.75(g)(4)(i) requires the licensee to keep records of property transfers into and out of the originally licensed site area. For example, in one case, a reactor donated an acre of its site to the local town for a water tower. In another case, a reactor wanted to sell several hundred acres of its site to another party. The purpose for keeping records of property released for unrestricted use before the plant is decommissioned is to assure that all radioactive material is accounted for when demonstrating compliance with the radiological criteria for license termination. N.B. – Transfers for restricted use are not allowed under 10CFR50.83, the partial site release provision. It is not a factor in determining the total amount of financial assurance that the licensee must maintain .- as stated above, the power rating determines the amount of financial assurance.
247	Ukraine	19	Is there need to revise the safety analysis report (SAR) regarding external impacts or a new hazard in case of partial transfer of the site to another legal entity?	There is no need to revise the SAR in the case of a partial transfer of a license unless the transfer application also specifically requests changes to the licensing basis of the plant in addition to requesting approval of the license transfer. Thus far, no transfer application has involved technical changes to the licensing basis.
248	South Africa	19.1	Good practice:The authorisation process is flexible and allows for site and /or design approvals in advance of construction.Each application is reviewed and approved by the NRC and each application to construct and operate a nuclear power plant is reviewed by an independent statutory committee.Input from the public is also required by law.	No response required.
249	Czech Republic	19.2	The majority of the US NPPs is using improved vendor-specific standard technical specifications as the basis for plant-specific technical specifications (TS). What advantages can gain these NPPs from their use in relation to the NRC? What is the basis for the TS of the other NPPs? Is the NRC approving process of TS or their changes in such cases different and what are its bases?	1) The foremost benefit is the reduction in the number of Limiting Conditions for Operation that will be retained in the plant-specific TS. Other benefits that licensees of NPPs gain through adopting improved TS based on the applicable STS (NUREG-1430 through NUREG-1434) are fewer TS interpretations, relief from TS operational restrictions, fewer license amendment requests, and faster approval of standard license amendments. The Nuclear Power Plants (NPP) who adopt the STS changes obtain approval of generic TS changes with less NRC review effort that non-STS NPPs. These advantages reduce a licensee's cost of interaction with NRC licensing and inspection staff. 2) The basis for the TS of all US NPPs includes 10 CFR 50.36, the current licensing basis, the information contained in the FSAR regarding plant design and operation, and the design basis accident and transient analyses, which include the associated analyses of radiological consequences, and insights from a probabilistic risk assessment. However, the differences of the NPPs who adopt the STS in place of their plant-specific TSs as opposed to those NPPs who continue to use the plant-specific TSs is based on when the plants were licensed. The early licensed NPPs developed and operated with plant-specific TSs approved by NRC. The NPPs that were licensed later began using STS as part of developing their plant-specific TSs, which includes a standard approach to surveillance requirements, actions, and completion times. 3) The process for approving a change to a NPP's TS, 10 CFR 50.90, is the same regardless of whether the NPP has adopted improved TS. The NRC must find that the change is consistent with the Commission's regulations and the NPP's licensing and design bases, and that the change involves no significant hazards consideration as defined in 10 CFR 50.92(c). More information on the license amendment process can be found on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0090.html
250	Czech Republic	19.2	NRC and the nuclear industry are developing risk-informed improvements to technical specifications (TS). What is the relation between deterministic and probabilistic approach in the new risk-informed improvements to TS?	The deterministic risk approach was used exclusively by the NRC in the past to evaluate Technical Specifications (TS), which used requirements from Defense-In-Depth and engineering judgement to apply to plant-specific TSs. However, the NRC has adopted a probabilistic risk approach, which includes quantitative bases and risk insights to inform Defense-In-Depth and engineering judgement when establishing or modifying TS requirements. The NRC's policy statement on probabilistic risk assessment (PRA) (USNRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Activities: Final Policy Statement, " Federal Register, Vol. 60 p. 42622 (60 FR 42622), August 16, 1995) encourages greater use of PRA techniques to improve safety decision making and improve regulatory efficiency. More information of this policy is found on the following link on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/commission/policy/60fr42622.pdf
251	France	19.2	Could the Unites States of America indicate if risk-informed decision-making has led, up to now, to restrictive changes in operational technical specifications? If any, could the USA provide some examples?	In using the risk-informed approach to improving current regulations for Technical Specifications (TS), most of the changes have been less restrictive changes. However, the Maintenance Rule in 10 CFR 50.65 requires licensees to assess and manage risk in all configurations, regardless of whether the structures, systems, and components are in TSs. A risk-informed approach could entail more restrictive changes, such as in decisions that involve an integrated plant configuration risk assessment. For

				example, technical specification allowed outage times have been created considering only that system of the specific TS inoperable. With multiple systems inoperable, a configuration based allowed outage time would be more restrictive than any of the individual allowed outage times prescribed in the technical specifications. Risk management TSs will rely on requirements in license programs for the maintenance rule. Information regarding 10 CFR 50.65 can be located on the following link on the NRC website: http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0065.html
252	South Africa	19.2	Good Practice:10CFR50.36 requires that the technical specifications must be derived from analyses and evaluation in the SAR. Changes to the specification are subject to NRC approval.Revision 3 of the improved vendor-specific standard technical specifications has been issued in June 2004. Comment:The NRC and industry are developing risk-informed improvements to technical specifications. Is risk insights used as the primary justification to change limits and conditions or must be complemented by deterministic methods/calculations and principles?	Risk-informed improvements to technical specifications relies on both risk and deterministic considerations, including defense-in-depth and safety margins. Both aspects must be satisfied to make risk-informed changes to the technical specifications.
253	Japan	19.3	The public hearing is conducted by a three-member Atomic Safety and Licensing Board, which consists of one lawyer who acts as chairperson, and two technically qualified persons. Q/What is the basic reason why the public hearing is conducted by the Atomic Safety and Licensing Board member, not by NRC staff ?	Public hearings most typically are held to resolve contested licensing decisions of the NRC staff. The Atomic Safety and Licensing Board is independent of the staff and thus can fairly hear and decide such disputes.
254	Japan	19.3	NRC encourages licensees to use the improved standard technical specifications as the basis for plant-specific technical specifications. Q/Which specific benefits are expected by using the improved standard technical specifications as the basis, other than improvement from operating experience? For example, that could produce reduction in reviewing works of plant-specific technical specifications by standardization.	The benefits of using improved TS include: (1) ease of understanding and interpretation by a NPP's operators, licensing and engineering staff, and management, and by the NRC staff; (2) reduction in regulatory burden by less need for TS interpretations and relief, and amendments to change TS, and removal of inappropriate TS requirements; and (3) facilitation of developing and implementing generic improvements to the TSs, e.g., risk-informed initiatives.
255	South Africa	19.3	Good Practice:Operations, maintenance and I&T are governed by the Code of Federal Regulations which requires that these activities be prescribed by documented instructions.The Maintenance Rule requires assessment and management of risk before maintenance activities.	No response required.
256	South Africa	19.4	Good Practice:The NRC requires the licensee to develop procedures for coping with certain plant transients and postulated as well as beyond design base accidents. Plant procedures are reviewed by the NRC in accordance with an approved process.	No response required.
257	South Africa	19.5	Good practice:Several inspection procedures focus on ensuring that adequate support programmes are maintained. Considering the age profile of the nuclear professionals and the recent plant life extentions, what programmes are in place to ensure that vacancies left by retired nuclear professionals are filled?	In the agency's Strategic Plan, the management of human capital is identified as a major element necessary to achieve excellence in Agency Management. The agency utilizes multiple programs and activities to ensure that vacancies are filled with high quality, diverse professionals. Additionally, each Office continually manages knowledge transfer activities and employee development to ensure the skills and knowledge needed to achieve our mission are maintained. Examples of the agency's efforts include: - Double encumber selected positions (i.e., filling a position for a designated length of time with two people to allow for knowledge transfer) - Utilize entry-level and mid-level technical development programs for succession planning - Offer recruitment and retention bonus incentives for specialists

				- Utilize senior level and mid-level executive leadership development programs for succession planning in leadership positions - Establish web-based information forums for knowledge transfer - Provide internal and external training opportunities to develop critical skills - Update the Standard Review Plan for technical guidance - Re-employ annuitants (i.e., recent retirees) for knowledge transfer
258	Germany	19.6	Section 19.6 answers the question about incidents reporting but it does not mention the requirements for the time available for reporting. What are the criteria and reporting time schedule for event reporting?	The criteria and reporting time schedule are specified in the U. S. Regulations at Title 10, Code of Federal Regulations, 50.72 and 50.73. (See http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0072.html). Guidance on event reporting is also available in "Event Reporting Guidelines 10 CFR 50.72 and 10 CFR 50.73 (NUREG-1022, Rev. 2). (See ADAMS Accession Number ML003762595 or http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1022/r2/sr1022r2.pdf). The required timing for Emergency Notification System (ENS) reporting is spelled out in §§ 50.72(a)(3), (b)(1), (b)(2), (b)(3), (c)(1), (c)(2), as "immediate" and "as soon as practical and in all cases within one (or four or eight) hour(s)" of the occurrence of an event (depending on its significance and the need for prompt NRC action). The intent is to require licensees to make and act on reportability decisions in a timely manner so that ENS notifications are made to the NRC as soon as practical, keeping in mind the safety of the plant.
259	Japan	19.6	Requirements for incident reporting are specified in 10CFR50.72, "Immediate Notification Requirements for Operating Nuclear Power Reactors," and in 10CFR50.73, "Licensee Event Report System." NRC modified these rules in 1992 and 2000 to delete reporting requirements for some events that were determined to be of little or no safety significance. Q/Please explain the reason, background and justification for revisions of 10CFR50.72 and 10CFR50.73 in 1992 and 2000.	The objectives of the final amendments were: (a) to better align the reporting requirements with the NRC's needs for information to carry out its safety mission, (b) to reduce unnecessary reporting burden, consistent with the NRC's needs, (c) to clarify the reporting requirements where needed, and (d) any changes should be consistent with NRC actions to improve integrated plant assessments. Additional information is provided in Federal Register Notice dated October, 25 2000 (65 FR 63786 and 65FR63787). Other Federal Register Notices related to 10 CFR 50.72 since 1992 are: 57 FR 41381, September 10, 1992; 58 FR 67661, December 22, 1993; 59 FR 14087, March 25, 1994. Other Federal Register Notices related to 10 CFR 50.73 since 1992 are: 57 FR 41381, September 10, 1992; 58 FR 67661, December 22, 1993; 59 FR 50689, October 5, 1994; 63 FR 50480, September 22, 1998; and 69 FR 18803, April 9, 2004.
260	South Africa	19.6	Good Practice:Regulations are in place requiring timely reporting of safety significant incidents to the regulator.	No response required.
261	Finland	19.7	Assessment of operational safety of NPPs is based on ROP. ROP is based on indicators and results of the baseline inspection program. The inspections are carried out on areas which are not covered by the indicators or they cover it only partly. The results of indicators have already shown very good performance of NPPs for long time. Referring to the results of indicators - have indicators and their thresholds been working as design? - how and how often NRC assesses the functionality of the indicators?	During the first two to three years, the PIs were working as designed. However, we have learned from past experience with PIs that, over time, their effectiveness decreases. This occurs for several reasons. Licensees will (1) find ways to improve performance to keep the PIs in the green band, or (2) find ways to avoid having an event that counts, or (3) attempt to find an argument to not count an event. At present, we are seeing an increasing number of issues that fall into category 3. This is not unexpected. We knew that we would need to revise the PI program periodically to maintain its effectiveness. Therefore we continuously reassess the functionality of the indicators. With the exception of the Unplanned Scrams per 7,000 Critical Hours, all of the PIs in the Initiating Events, Mitigating Systems, and Barrier Integrity cornerstones are under review for modification or replacement.
262	Japan	19.7	A group of NRC experts in event evaluation, risk assessment, and human factors reviews issues that have potentially generic implications. Typically, this group analyzes about 1,000 events per year, and follows up on 175 of those events. Q/-Please explain some specific case and corrective-measures, and check items of the problem review conducted by the NRC human factor specialist group. -Please explain specific case and corrective-measures, and check items of the follow-up review by the human factor specialist group.	A group of NRC experts in event evaluation, risk assessment, plant operations, and human factors reviews approximately 3000 operating experience items per year and follows up on approximately 150 of those items. Occasionally, the group reviews events at nuclear power plants dealing with human factors issues. If the NRC determines that these issues are important to safety and are generic to other licensees, the NRC can issue a generic communication. Several information notices (INs) have been issued to address human factors events. The following is a list of a few of the relevant INs along with a brief description of the issue. All generic communications are available on the NRC website at http://www.nrc.gov. IN 85-51, "Inadvertent Loss or Improper Actuation of Safety-Related Equipment" - At Susquehanna Unit 2 with the plant at approximately 20% of full power, electricians removed two dc-control power fuses for personnel protection during modifications involving the core spray isolation logic. The electricians believed that removing these fuses would provide the nearest local blocking-point protection needed while performing the modification. However, the fuses that were removed were considerably "upstream" of the local blocking point, and several unexpected consequences occurred from this improper action. IN 91-04, "Reactor Scram Following Control Rod Withdrawal Associated with Low Power Turbine Testing" - On October 27, 1990, Quad Cities, Unit 2, scrammed on a hi-hi intermediate range scram signal, when the operator withdrew rods to increase reactor pressure without recognizing the need to follow the normal procedures for re-establishing reactor criticality. The operator focused on controlling reactor pressure and did not adequately monitor reactivity.

				IN 94-13, "Unanticipated and Unintended Movement of Fuel Assemblies and Other Components Due to Improper Operating of Refueling Equipment" - The Vermont Yankee facility was in a refueling outage with fuel movement in progress when an irradiated fuel assembly became detached from the grapple after being lifted out of its position in the reactor core. The assembly fell approximately 2.4 m [8 ft] back into its original location in the reactor core. The licensee determined that the grapple had not properly engaged the lifting bail on the fuel assembly and that the personnel performing the fuel handling activities had failed to verify proper grapple engagement.
263	Japan	19.7	Recent activities include chartering an operating experience task force to evaluate and to recommend improvements that address the recommendations of the Davis-Besse Lessons Learned Task Force. Q/Which concerns or items in the Agency's reactor operating experience program are evaluated by the task force? Is an operating experience task force permanent one or terminable one?	The Reactor Operating Experience Task Force evaluated all items in the NRC operating experience program. This task force has discontinued operation but various groups of NRC staff are permanently assigned the task of implementing the operating experience program.
264	South Africa	19.7	Good Practice:OEF analysis performed by the regulator. Comment:No indication in the report that the licensees are required to have an OE programme and act on its conclusions thereby improving safety continuously.	In the United States, licensee responsibility in the OE process includes (1) required reporting of events, use of corrective action programs, and review of OE, (2) support of NRC inspection activities, (3) communication of OE to industry and the public, performance of self-regulation, and performance of generic correction activities through various industry organizations, such INPO, owners groups, and EPRI. The Three Mile Island Action Plan, NUREG-0737, Item I.C.5 provided that ....Each utility shall carry out an operating experience assessment function that will involve utility personnel having collective competence in all areas important to plant safety. In connection with this assessment function, it is important that procedures exist to assure that important information on operating experience originating both within and outside the organization is continually provided to operators and other personnel and that it is incorporated into plant operating procedures and training and retraining programs (Sec 5 of "Reactor Operating Experience Task Force Report," dated November 26, 2004 (ADAMS Accession Number ML033350063).
265	South Africa	19.8	Good Practice:Policy in place requiring licensees to reduce waste. Comment:The economics of waste disposal also driving down waste production. What is the NRC policy and requirements in terms of the minimisation of activity?	Per Article 19.8, there are provisions in the USNRC regulatory scheme promoting the minimization of contamination and the generation of radioactive waste: "Applicants for licenses, other than renewals, after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste." See 10 CFR 20.1406. Article 19viii refers to the minimization of waste, not minimization of concentration. If a waste material is minimized, often the unit concentration increases unless a partitioning of the waste streams takes place in the process. In most cases, the ultimate inventory of radioactivity must still be addressed. Transmutation of waste material provides the possibility of radioactive waste concentration minimization, but this is still in the research phase and not required in regulation.
266	France	Planned Activities	Combustible gas control - As stated in page xxii of the report, the regulator amended the parts 50 and 52, based on risk informed regulation results, to eliminate the requirements for hydrogen recombiners and hydrogen purge system and relax the requirements for hydrogen and oxygen monitoring equipment, in order to reduce regulatory burden. A few years former the French nuclear safety regulator considering the TMI accident scenario took the opposite position on a deterministic basis. We would like the US regulator explain what are the new elements or assumptions leading to relax the safety requirements relating to combustible gas control.	The rule change was supported by an improved understanding of combustible gas behavior during severe accidents and confirmation that the hydrogen release postulated from a design-basis accident loss-of-coolant accident was not risk-significant because it was not large enough to lead to early containment failure, and that the risk associated with hydrogen combustion was from beyond design-basis accidents. Additional detail is provided in the Federal Register (Volume 68, Number 179) dated September 16, 2003.

Seq No	Country	Article	Question	Response
22	Slovenia	General	The report presents an overview of various NRC activities for control of NPP operation and design changes as well of some programs that exist in NPPs. However, reviews of either NRC or the NPPs by an international mission were not mentioned neither their findings or recommendations. The approach of those missions may be different from NRC's and would give different insight into NPPs' safety and operation. Could you present a list of these missions and their recommendations.	The US strongly supports the operational safety program of the IAEA, of which the OSART program is a very important part. We see participation in this program as a further indication to the IAEA and member states that all countries can learn from independent safety reviews of their nuclear power plants. Similarly, the US believes that IRRT missions provide a valuable and useful independent review of regulatory authorities. The IAEA has conducted four OSART missions in the US: at Calvert Cliffs (1987), Byron (1989), Grand Gulf (1992) and North Anna (1999) nuclear power plants. Next month, May 2005, the IAEA will conduct an OSART mission to the Brunswick nuclear power plant in Southport, North Carolina. The US is seeking to schedule an OSART mission to a US nuclear power plant at least once every 3 years. The North Anna OSART Report, with its conclusions and recommendations, is available publically through the NRC's ADAMS document management system. The North Anna OSART's ADAMS accession number is ML010470115. Because the Calvert Cliffs, Byron and Grand Gulf OSART reports are over 12 years old, the reports pre-date the implementation of ADAMS and they are not readily available. The United States believes that IRRT missions provide a valuable and useful independent review of regulatory authorities, as evidenced by our participation in 11 IRRT missions. The NRC staff intends to perform an IRRT self-assessment and provide the results, along with recommendations, to the Commission within the next two years. The Commission will determine its next steps with regard to a potential IRRT mission after reviewing the results of the self-assessment.
55	South Africa	6	Does the NRC monitor organisational aspects independently of the utility and industry initiatives (eg WANO) such as:Human performance, Competencies, Organisational structure and processes, Financial capacity (eg for decommissioning). If so, what criteria do you apply?	The NRC reviews a new applicant's or license transfer applicant's operating organization (including organizational structure), as described in its safety analysis report (SAR), according to criteria provided in Section 13.1 of the "Standard Review Plan", NUREG-0800. The NRC reviews the financial qualifications and methods of providing decommissioning funding assurance according to criteria provided in NUREG-1577. Both the Reactor Oversight Process (ROP) baseline and supplemental inspection programs encourage inspectors to identify issues related to the three cross cutting areas, i.e., human performance, safety conscious work environment (SCWE), and problem identification and resolution (PI&R). The PI&R area has an inspection associated with it that evaluates licensee's corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semi-annual trend review, sampling issues during each inspectable area inspection, performing focused reviews of three to six samples per year, and performing a biennial focused PI&R team inspection.

				In addition, the objectives of the "Human Performance" supplemental inspection procedure are (1) to assess the adequacy of the licensee's root cause evaluation and corrective actions with respect to human performance and (2) to independently assess the extent of condition associated with the identified human performance root causes.
67	Hungary	8	The IAEA IRRT mission is a group of international experts to perform independent review of all authority areas of a national regulatory body. Due to its independence and the high level of expertise of the selected review team members, such mission is generally accepted as a useful tool for identifying areas for further improvement. What are the views of the NRC on accepting an IRRT mission?	The United States believes that IRRT missions provide a valuable and useful independent review of regulatory authorities, as evidenced by our participation in 11 IRRT missions. The NRC staff intends to perform an IRRT self-assessment and provide the results, along with recommendations, to the Commission within the next two years. The Commission will determine its next steps with regard to a potential IRRT mission after reviewing the results of the self-assessment."
96	Bulgaria	10	There are no doubts that in the USA as a country with a developed nuclear power generation a mature safety culture exists. The Regulatory body plays an important role in the safety culture application. What concrete criteria US NRC applies for intervention aimed at regulation of safety culture at operator organisations?	The NRC may conduct special inspections of a licensee's corrective actions related to safety culture. For example, in the case of the reactor vessel head degradation at Davis-Besse, weaknesses in the licensee's safety culture were identified as a key contributor to not identifying the problems in a more timely manner. Therefore, on the basis of Appendix B Criterion XVII of Part 10 CFR 50, the NRC performed special inspections to evaluate the processes used by Davis-Besse to assess their safety culture and their corrective action plans. The evaluation areas in the Davis-Besse inspections were: the safety culture internal and external self-assessments and monitoring tools, the status of the Employee Concern Program, the safety conscious work environment (SCWE) at the facility, and tools Davis-Besse planned to use to monitor safety culture in the future. In addition, both the Reactor Oversight Process (ROP) baseline and supplemental inspection programs encourage inspectors to identify issues related to the three cross cutting areas, i.e., human performance, SCWE, and problem identification and resolution (PI&R). The PI&R area has an associated inspection procedure that evaluates the licensee's corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semi-annual trend review, sampling issues during each inspectable area inspection, performing focused reviews of three to six samples per year, and performing a biennial focused PI&R team inspection. Additionally, the objectives of the "Human Performance" supplemental inspection procedure are (1) to assess the adequacy of the licensee's root cause evaluation and corrective actions with respect to human performance and (2) to independently assess the extent of

				condition associated with the identified human performance root causes. Furthermore, the Commission recently issued a Staff Requirement Memorandum (SRM), SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which directed the staff to undertake a number of activities related to safety culture. Specifically, the SRM directed NRC staff to enhance the ROP treatment of cross-cutting areas to more fully address safety culture. In addition, the SRM called for developing a process for determining the need for a specific evaluation of the licensee's safety culture and a process for conducting an evaluation of the licensee's safety culture (for those plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed the staff to develop tools for inspectors to rely on more objective findings as well as ensure that the inspectors are properly trained in the area of safety culture. Additionally, the SRM requested the staff to monitor industry efforts to assess safety culture and to ensure the Commission remains informed of such efforts, particularly the progress made by the Institute of Nuclear Power Operations (INPO) to address recent industry issues in this area.
106	France	10	Could the United States of America explain what is the meaning of safety « climate »? Are there specific criteria to categorize safety climate different from those used for safety culture?	A "NRC Safety Culture and Climate Survey" was administered to all employees and managers from May 13 through June 7, 2002. "Climate" was defined in the survey as ". . . the current work environment of the agency. Climate is like a snapshot in time and can, over time, affect culture." "Safety Culture" was defined in the survey as ". . . the complex sum (or whole) of the mission, characteristics, and policies of an organization, and the thoughts and actions of its individual members, which establish and support nuclear safety as an overriding priority." The questions in the survey covered both of these concepts.
107	France	10	The report expands about the safety culture requirements from the Regulatory Body. Could the United States of America indicate what specific activities have been actually carried out by the licensees to enhance safety culture at the plants level?	Licensees' safety culture activities vary from plant to plant. However, the licensees' corrective action programs and safety conscious work environment (SCWE) are aspects of their safety culture activities. In addition, the Institute of Nuclear Power Operations (INPO), a U.S. nuclear industry group, has developed a safety culture evaluation as part of their plant evaluation process.
116	Japan	10	For example, Appendix B to 10 CFR Part50 requires the licensees to establish a quality assurance program. Concerning a safety-conscious work environment, NRC has a regulation,	Safety conscious work environment (SCWE) and Quality Assurance can be viewed as attributes of safety culture. In addition, Quality Assurance and safety culture become related via Appendix B relative to the licensee's corrective action program (see section 10.4.2, "NRC's Response to Davis Besse," for an example). The Commission recently issued a Staff Requirement Memorandum (SRM),

			10CFR50.7,"Employee protection," that prohibits licensees from firing or taking adverse actions against employees who raise safety issues. NRC also evaluates allegations from plant workers regarding safety culture issues. Q/-Please explain a framework or method how to regulate safety culture. Are "Safety Conscious Work Environment", "Safety Culture" and "Quality Assurance Program" regulated independently, or interdependently? Or are all of the above regulated in the Quality Assurance Program?	SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which directed the staff to undertake a number of activities related to safety culture. Specifically, the SRM directed NRC staff to enhance the Reactor Oversight Process (ROP) treatment of cross-cutting areas to more fully address safety culture. In addition, the SRM called for developing a process for determining the need for a specific evaluation of the licensee's safety culture and a process for conducting an evaluation of the licensee's safety culture (for those plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed the staff to develop tools for inspectors to rely on more objective findings as well as ensure that the inspectors are properly trained in the area of safety culture. Additionally, the SRM requested the staff to monitor industry efforts to assess safety culture and to ensure the Commission remains informed of such efforts, particularly the progress made by the Institute of Nuclear Power Operations (INPO) to address recent industry issues in this area.
117	Japan	10	To ensure sustained performance, NRC, in addition to its approval for restart, required, by a confirmatory order, annual assessments of organizational safety culture, including the safety conscious work environment, for five years. Q/It is reported that "the safety culture of Davis-Besse will be evaluated for 5 years". Please explain specific evaluation items and method (including the reason for "5" years and the evaluation criteria of improvement, etc).	There are no specific evaluation items or methods addressed in the Confirmatory Order. The only restraints were the evaluations have to be performed by independent, external organizations, and the organizational safety culture piece had to include evaluation of the safety conscious work environment (SCWE) at the plant. The Order allowed the licensee to propose a method and submit it to the NRC for review. NRC will review the overall process to determine if it is reasonable and fits with internationally accepted processes. As stated in the restart letter and in the Order, the basis for the Order and the five years of Annual Independent Assessments is "to provide reasonable assurance that the long-term corrective actions remain effective for those conditions that resulted in risk-significant performance deficiencies" and "to ensure effective assessment and sustained safe performance." In addition to the organization safety culture area, the five years of assessments include operations performance, the corrective action program, and the engineering program.
121	Korea, Republic of	10	1. In para 10.4(p.10-9) it is described that NRC performed a survey on NRC's safety culture and climate in 18 categories. What's the relationship between the 18 categories and safety culture indicators in INSAG-4, ASCOT Guidelines? How are	A "NRC Safety Culture and Climate Survey" was administered to all employees and managers from May 13 through June 7, 2002. The authors of the survey grouped the questions into 18 categories to ease the organization of the questionnaire. Several questions were asked of NRC employees related to each of the 18 categories. The categories were specifically developed for the NRC and do not directly correlate with the safety culture indicators in INSAG-4 Guidelines. Similarly, they are not meant to be comparable with the three levels of safety culture from IAEA TECDOC 1329.

			they related to the three level of safety culture in IAEA TECDOC 1329? 2. Do you consider a regulatory intervention in the safety culture of licensees before degradation of safety culture cause decrease in safety performance and result in failures in NPPs?	With respect to the second part of the question regarding regulatory intervention, the NRC takes early and aggressive action where potential safety performance or safety culture issues are observed. For example, recent actions were taken to address safety culture issues at Salem and Hope Creek plants (see section 10.4.2, page 10-11). In addition, both the Reactor Oversight Process (ROP) baseline and supplemental inspection programs encourage inspectors to identify issues related to the three cross cutting areas, i.e., human performance, safety conscious work environment (SCWE), and problem identification and resolution (PI&R). The PI&R area has an associated inspection procedure that evaluates the licensee's corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semi-annual trend review, sampling issues during each inspectable area inspection, performing focused reviews of three to six samples per year, and performing a biennial focused PI&R team inspection. Additionally, the objectives of the "Human Performance" supplemental inspection procedure are (1) to assess the adequacy of the licensee's root cause evaluation and corrective actions with respect to human performance and (2) to independently assess the extent of condition associated with the identified human performance root causes. Furthermore, the Commission recently issued a Staff Requirement Memorandum (SRM), SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which directed the staff to undertake a number of activities related to safety culture. Specifically, the SRM directed NRC staff to enhance the ROP treatment of cross-cutting areas to more fully address safety culture. In addition, the SRM called for developing a process for determining the need for a specific evaluation of the licensee's safety culture and a process for conducting an evaluation of the licensee's safety culture (for those plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed the staff to develop tools for inspectors to rely on more objective findings as well as create an enhanced training program. Additionally, the SRM requested the staff to monitor industry efforts to assess safety culture and to ensure the Commission remains informed of such efforts, particularly the progress made by the Institute of Nuclear Power Operations (INPO) to address recent industry issues in this area.
122	Mexico	10	The National Report (10.4.1) indicates that survey questions were grouped into 18 categories representing the major topics of NRC's safety culture and	These categories were given in the weblink in the report: http://www.nrc.gov/reading-rm/doc-collections/insp-gen/2003/03a-03.pdf The categories are:

			climate. Please list the 18 categories	1. Clarity of Responsibilities: Assesses clarity of job responsibilities, duplication across work units, and task prioritization. 2. Workload and Support: Evaluates the amount of staff to handle the workload, the amount of stress employees experience on the job, the prioritization, resource allocation to improve efficiency of work (e.g., information dissemination, computer systems support). 3. Management Leadership: Probes employees' views of the various management levels within the NRC including management style, management direction, confidence in management decisions, and the amount of effort by management to implement "risk-informed methodologies". 4. Supervision: Examines employee perceptions of their immediate supervisor's technical competency, level of authority, availability, communication skills, people management and team building skills, and competency for understanding future needs. 5. Working Relationships: Measures the level of cooperation, respect, and teamwork among employees, work units, divisions, office/regions, and headquarters. 6. Empowerment: Assesses the amount of authority employees have to do their job, the trust they receive from management, openness to discuss differing opinions, ability to openly and confidently raise issues, and whether NRC's climate allows one to be innovative. 7. Communication: Evaluates the availability of information about matters affecting the agency, and information employees need to do their job. Also assesses the openness of speaking up in the NRC. Measures employees' understanding of the goals and objectives of their work unit, division, office/region, and NRC as a whole. In addition, employees' awareness of NRC's plans, performance, and mission are evaluated. 8. Training and Development: Assesses the availability and quality of training, knowledge of safety concepts, recruitment and retention of talented employees, the development of employees to their full potential, and perceptions of career progression within the NRC. 9. Performance Management: Explores NRC's recognition for quality of performance and leniency for poor performance. Additionally, the breadth, utility, and understanding of performance reviews are investigated.

				10. Future of NRC: Measures employee concerns over reductions-in-force, changes in management, technology, regulatory methodology, the federal government, the future of their work unit, the NRC, and the industry, as well as fear of their skills becoming obsolete. 11. Job Satisfaction: Examines employees' satisfaction with their job being worthwhile, important to the NRC, providing a sense of accomplishment, and allowing adequate use of their abilities. 12. Organizational Commitment: Probes employees' willingness to recommend the NRC as a good place to work, whether they feel they are a part of the agency, and their pride in working for the NRC. 13. NRC Mission: Assesses the clarity of NRC's mission and whether employees believe management decisions are consistent with the mission. Employees are also asked to rate NRC's success in putting the "principles of good regulation" into practice. 14. NRC Image: Examines employee perceptions of whether NRC is highly regarded by its various stakeholders, NRC's effectiveness in communicating to the general public, and whether all employees are held to the same standards of ethical behavior. 15. Organizational Change: Evaluates employees' views on how the NRC's regulation of its licensees has changed in the past year. Employees are also asked to rate how the following have changed from the past and will change in the future: The way people are managed day to day, communication, the quality of work produced, productivity, the public image of the agency, and NRC as a whole. 16. Continuous Improvement Commitment: Assesses employee views on NRC's commitment to public safety, and whether employees are encouraged to communicate ideas to improve safety/regulations/operations. 17. Quality Focus: Explores employee views on the quality of NRC's (divisions') work, the relative balance between quality of work versus quantity of work, perceived sacrifice of quality to meet budget, deadline or political constraints, as well as the time spent by the NRC responding to allegations. 18. Regulatory Effectiveness Process/Initiatives: Investigates the perceived linkage between increased focus on risk-based and performance-based regulation, and improvement of regulatory effectiveness. Employees are asked

				to report the relative importance of the risk-based and performance-based regulation initiatives, and how layers of management and supervisors perceive the importance of these initiatives as well. Opinions are also solicited regarding the differing professional opinion process and risk-informed, performance-based regulation.
138	Switzerland	10	What kind of activities does the NRC perform in the area of Safety Culture and Safety Management? Does the NRC possess guidelines or standards that provide assistance for the assessment of Safety Culture or Management of US NPPs?	The NRC prepares, on a case by case basis, guidance for inspections evaluating corrective actions related to safety culture. For example, in the case of the reactor vessel head degradation at Davis-Besse, as part of a special inspection, the NRC evaluated the processes used by Davis-Besse to assess their safety culture and their corrective action plans. The evaluation areas in the Davis-Besse inspections were: the safety culture internal and external self-assessments and monitoring tools, the status of the Employee Concern Program, the safety conscious work environment (SCWE) at the facility, and tools Davis-Besse planned to use to monitor safety culture in the future. In addition, both the Reactor Oversight Process (ROP) baseline and supplemental inspection programs encourage inspectors to identify issues related to the three cross cutting areas, i.e.,human performance, SCWE, and problem identification and resolution (PI&R). The PI&R area has an inspection associated with it that evaluates licensee's corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semi-annual trend review, sampling issues during each inspectable area inspection, performing focused reviews of three to six samples per year, and performing a biennial focused PI&R team inspection. Additionally, the objectives of the "Human Performance" supplemental inspection procedure are (1) to assess the adequacy of the licensee's root cause evaluation and corrective actions with respect to human performance and (2) to independently assess the extent of condition associated with the identified human performance root causes. Furthermore, the Commission recently issued a Staff Requirement Memorandum (SRM), SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which directed the staff to undertake a number of activities related to safety culture. Specifically, the SRM directed NRC staff to enhance the ROP treatment of cross-cutting areas to more fully address safety culture. In addition, the SRM called for developing a process for determining the need for a specific evaluation of the licensee's safety culture and a process for conducting an evaluation of the licensee's safety culture (for those plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed the staff to develop tools for inspectors to rely on more objective findings as well as ensure that the inspectors are properly trained in the area of safety culture.

				Additionally, the SRM requested the staff to monitor industry efforts to assess safety culture and to ensure the Commission remains informed of such efforts, particularly the progress made by the Institute of Nuclear Power Operations (INPO) to address recent industry issues in this area.
139	Switzerland	10	"Licensee Safety Culture" Governing Documents and Process, Paragraph 1 What does NRC use as a definition of Safety Culture?	The NRC uses the definition of safety culture stated in the January 24, 1989 policy statement entitled "Policy Statement on the Conduct of Nuclear Power Operations." In that document, safety culture is described as "the necessary full attention to safety matters" and "the personal dedication and accountability of all individuals engaged in any activity which has a bearing on the safety of nuclear power plants. "A strong safety culture is one that has a "safety-first focus." The NRC also adopts the definition of safety culture from the International Nuclear Safety Advisory Group (INSAG). INSAG describes safety culture as the "assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance."
140	Switzerland	10	Licensee Safety Culture Governing Documents and Process, Paragraph 2 What is the theoretical background for the Attributes to Safety Culture?	The theoretical background for the attributes of safety culture considered by the NRC are generally drawn from IAEA, INSAG, and some international experts in the field. INSAG-4, 13, and 15 provide further explanation of specific attributes.
141	Switzerland	10	Licensee Safety Culture Governing Documents and Process, Paragraph 3 What are the criteria/background that NRC-Inspectors use for inspections in the area of Safety Culture. How and by which means is training of inspectors performed in this area?	There is currently no formal training for inspectors specifically in the area of safety culture. However, staff from NRC headquarters with knowledge in safety culture have participated on special or supplemental inspection teams. The Commission has recently directed the staff to undertake a number of activities related to safety culture, including developing an enhanced training program to ensure inspectors are properly trained in the area of safety culture.
142	Switzerland	10	What in detail are the criteria applied to evaluate the [licensee's] safety culture monitoring tools? What is monitored: Safety Culture (refer to above question about the definition) or Safety Management?	The NRC does not have a specific set of detailed criteria for evaluating a licensee's safety culture monitoring tools. For the Davis-Besse inspection, the inspection team developed its own tools tailored to the situation at Davis-Besse. Since Davis-Besse has several different tools to assess their safety culture, the team inspection reviewed each of the tools to determine which attributes of safety culture they were attempting to assess to determine if those tools were a reasonable means of assessing those attributes. The team relied heavily on the safety culture attributes from INSAG 15 as the basis for their assessment. The inspection team also conducted an independent series of interviews and focus groups with target populations to determine if the responses they obtained were consistent with the findings of the various tools the licensee was using. Further, the team conducted behavioral observations

				and document reviews, again to determine level of consistency with the licensee's findings. Since all of the Davis-Besse assessments and the NRC's assessment obtained generally the same findings, the team concluded that the Davis-Besse tools were adequate for their purpose. An underlying assumption was the concept of convergent validity. Regarding the second question, Davis-Besse monitors its safety culture.
143	Switzerland	10	What are the methods used for safety culture assessment? What are the mentioned methods, concepts, and focus areas accepted by the international nuclear community?	The method used at Davis-Besse is referred to as the Organizational and Management Assessment Methodology. It includes the use of functional analysis, structured interview protocol, behavioral anchored rating scales, behavioral observations, and a survey. The characteristics or attributes assessed are similar to those addressed in INSAG-13 and INSAG-15 for the IAEA. The group that implemented the approach uses convergent validity to help draw findings from the information collected. A derivative of this method has also been used in Canada by CNSC and in Spain by CSN. Some of the original research that went into developing the method was performed for the NRC and has theoretical underpinnings from Mintzberg and Schein.
144	Switzerland	10	What is the difference between "organizational safety culture" and "safety culture"?	There is no difference between organizational safety culture and safety culture. It is referred to as "organizational safety culture" in the Davis-Besse Restart Order (3/8/04).
145	Switzerland	10	This paragraph gives the impression that NRC's view of Safety Culture is mainly based on the INSAG-4 document. How does NRC recognize the developments made in this area since 1991 (i.e. the IAEA programmes SCEPT, SCART, and especially TECDOC 1329)?	NRC's "Policy Statement on the Conduct of Nuclear Power Plant Operations," which discusses safety culture at facilities, was issued on January 24, 1989. As noted in response to question 138, the Commission has directed the staff to undertake a number of activities related to safety culture. One of the activities is to monitor developments by foreign regulators to assess safety culture. To accomplish this task, the staff will be examining international developments, including those programs noted in the question.
147	United Kingdom	10	This section of the report, particularly in the second paragraph under the sub-heading "Governing Documents and Processes", tends to conflate safety culture with quality assurance. In particular, the references to "Corrective Actions" are all reliant on things having gone wrong to trigger any improvement. Safety culture is surely about the avoidance of non-conformances, rather than merely having an effective system for monitoring the	In regard to the question if there is an over-reliance on tracking quantitative issues, rather than focusing on the qualitative aspects of safety culture which can be harder to measure, NRC's more qualitative assessments of safety culture include: -Direct, daily observations of licensee operation of facilities -Followup of individual allegations -Enforcement of employee protection regulations -Safety-conscious work environment (SCWE) assessments, as necessary -Regulatory action where potential safety performance or safety culture issues are observed (e.g. recent actions taken to address safety culture issues at Salem and Hope Creek plants) NRC is further enhancing safety culture efforts by: -Revising the Reactor Oversight Process (ROP) to more fully address safety

			resolution of corrective actions. Is there not an over-reliance on tracking those issues which can be quantified, rather than trying to address the real issues of safety culture, which tend to qualitative in nature?	culture, in accordance with Staff Requirement Memorandum (SRM), SECY-04-0111, "Recommended Staff Actions Regarding Agency Guidance in the Areas of Safety Conscious Work Environment and Safety Culture," which directed the staff to undertake a number of activities related to safety culture. Specifically, the SRM directed NRC staff to enhance the ROP treatment of cross-cutting areas to more fully address safety culture. In addition, the SRM called for developing a process for determining the need for a specific evaluation of the licensee's safety culture and a process for conducting an evaluation of the licensee's safety culture (for those plants in the degraded cornerstone columns of the ROP Action Matrix). The SRM also directed the staff to develop tools for inspectors to rely on more objective findings as well as ensure that the inspectors are properly trained in the area of safety culture. -Taking significant corrective actions, including Davis-Besse Lessons Learned Task Force recommendations -Developing enhanced guidance to licensees by identifying best practices to encourage a SCWE and promote NRC's expectations -Monitoring efforts by foreign regulators to measure and regulate safety culture
149	United Kingdom	10	Why has the Commission given the staff guidance not to " conduct direct evaluations or inspections of safety culture as a routine part of assessing licensee performance"? In the final paragraph under the sub-heading "NRC's Response to Davis-Besse, the Advisory Committee on Reactor Safety appears to put its faith in "mature programmes to monitor reliability of equipment and simulator testing of control room staff", and advises on keeping "safety culture in perspective". How is it believed that either of these programs could have improved the performance of staff to detect the boric acid leakage and its possible significance at a much earlier stage?	The NRC conducts a number of activities that adequately evaluate how effectively licensees are managing safety. These include an inspection procedure for assessing licensees' Employee Concerns Programs, the NRC allegation program, enforcement of employee protection regulations, and safety conscious work environment (SCWE) assessments during problem identification and resolution (PI&R) inspections. The NRC does not assess, nor does it plan to assess, licensee management competence, capability, or optimal organizational structure as part of safety culture. The Commission has directed the staff to undertake a number of activities related to safety culture.
200	Korea, Republic of	15	According to Section 15, one important constraint that ICRP recommendations are not fully incorporated in US regulations has been the desire to keep	1) The US has several large industries that utilize special nuclear byproduct and source materials such that the protection of their workers and the public from exposure to radiation is an integral part of their operations. Even a seemingly small change (i.e., redefining the operational quantity for dose from effective dose equivalent to effective dose) results in significant costs to these

			regulatory stability. 1. Specifically which parts in the ICRP 60 recommendations are considered to influence greatly on the regulatory stability and also to impose serious burden on the licensees by the Backfit rule (10 CFR 50.109)? 2. What would be the desirable direction for next ICRP recommendations?	industries. At a minimum, such changes require procedure revisions and associated training of workers. The NRC implemented our Backfit rule to ensure that the costs associated with any required change is compensated for in enhanced safety. 2) The NRC Commission has instructed the staff to work closely with the ICRP, and other National and International bodies, to ensure that the 2005 or 2006 revision to the ICRP recommendations clearly represents an increase in worker and Public safety, an can be implemented in the US.
203	Switzerland	15	It would be interesting to know the reasons why the requirements about occupational exposure are still not consistent with international recommendations. If the administrative dose limits of many licensees and agencies are similar or below 20 mSv, it is astonishing that the regulatory body does except 50 mSv for a few NRC licensees. Nothing is reported about special occupational dose limits for pregnant women and young persons.	The US radiation protection regulations are based on International Recommendations. However, in some cases, they were established under one set of recommendations (e.g., Publication 26, or even Publication 2) and there has been insufficient evidence that the current regulations do not provide adequate public, and worker, health and safety. The US regulations for occupational radiation exposure do provide separate, lower, dose limits for minors (10% of the adult worker limit) and the fetus of a declared pregnant woman (5 mSv during the entire pregnancy). After BEIR VII and ICRP 2006, the Commission will reevaluate the need to update occupational dose limits, but will do so in partnership with OSHA, EPA, DOE and other appropriate agencies.
209	United Kingdom	15	Given the length of time for which the ICRP principles of "limitation","justification" and "optimisation" have existed (well over 20 years), and the fact that most other countries seem to have no difficulties, why does the USA seem to have a problem with these principles? Given that most countries have few difficulties with dose estimation before undertaking work involving radiation, why is it argued that working with radiation is a "new activity" whose outcome	The US radiation protection regulatory framework is consistent with the ICRP principles of "limitation, justification, and optimization." Our regulations provide clear dose limits for both workers and members of the public. Radiation doses are optimized through the application of engineering and other controls to ensure that they are as low as is reasonably possible (ALARA). The term "new activity" refers to new applications of radiation, or radioactive materials, that may result in exposure to workers or members of the public. The point that is being addressed is that the "justification" can be difficult for activities where there is not much relevant experience to base decisions on, or there is uncertainty over the ultimate control of the radioactive material. In such cases, there needs to be clear, identifiable, benefits to justify the activity (such as the lives saved by the use of radioactive materials in household smoke detectors). In addition, as currently recognized by the ICRP, justification of an activity is often not a radiation protection or engineering issue. In many cases, other factors such as national policy, public opinion, or economic realities, dominate the decision.

			"can never be determined in advance"? Would the USA not agree that advance survey techniques, possibly involving remote measurement, couple with real-time monitoring of personnel doses, and the use of the appropriate personal protective equipment, generally provide an adequate means of controlling individual doses against predetermined limits? If the USA accepts that it is reasonably practicable to predict doses in advance, does it accept the current ICRP estimates of the harm caused by those doses?	
232	Japan	18.1	The levels of protection in defense-in-depth are (1) a conservative design, quality assurance, and safety culture;(2) control of abnormal operation and detection of failures; (3)safety and protection systems; (4)accident management, including containment protection; (5) emergency preparedness; and (6) security. Q/ It is reported that "The levels of protection in defense-in-depth are (1) a conservative design, quality assurance, and safety culture". What are the specific criteria or regulatory guides explaining "Safety Culture"?	The agency's "Policy Statement on the Conduct of Nuclear Power Plant Operations," issued on January 24, 1989, discusses safety culture at licensee facilities. The NRC may conduct special inspections of a licensee's corrective actions related to safety culture. For example, in the case of the reactor vessel head degradation at Davis-Besse, weaknesses in the licensee's safety culture were identified as a key contributor to not identifying the problems in a more timely manner. Therefore, on the basis of Appendix B Criterion XVII of Part 10 CFR 50, the NRC performed special inspections to evaluate the processes used by Davis-Besse to assess their safety culture and their corrective action plans. The evaluation areas in the Davis-Besse inspections were: the safety culture internal and external self-assessments and monitoring tools, the status of the Employee Concern Program, the safety conscious work environment (SCWE) at the facility, and tools Davis-Besse planned to use to monitor safety culture in the future. In addition, both the Reactor Oversight Process (ROP) baseline and supplemental inspection programs encourage inspectors to identify issues related to the three cross cutting areas, i.e., human performance, SCWE, and problem identification and resolution (PI&R). The PI&R area has an associated inspection procedure that evaluates licensee's corrective action programs in detecting and correcting problems. This inspection involves screening all corrective action program issues, performing a semi-annual trend review, sampling issues during each inspectable area inspection, performing focused reviews of three to six samples per year, and performing a biennial focused PI&R team inspection. Additionally, the objectives of the "Human Performance" supplemental inspection procedure are (1) to assess the

				adequacy of the licensee's root cause evaluation and corrective actions with respect to human performance and (2) to independently assess the extent of condition associated with the identified human performance root causes. The Commission has directed the staff to undertake a number of activities related to safety culture.